Audit and Governance Committee Agenda

Wednesday, 10 June 2015
etc.venues, Tenter House, 45 Moorfields, London EC2Y 9AE

Meeting starts: 10:00 am

1. Welcome, Apologies and Declarations of Interest

2. Minutes of 18 March 2015
   [AGC (10/06/2015) 453]

3. Matters Arising
   [AGC (10/06/2015) 454 SG]

4. People Strategy & HR Risks
   [AGC (10/06/2015) Presentation PT]

5. Information for Quality (IfQ) Programme – Managing Risks
   [AGC (10/06/2015) 455 NJ]

6. Strategic Risks
   [AGC (10/06/2015) 456 PR]

7. Internal Audit

   a. 2015/16 plan and progress report
      [AGC (10/06/2015) 457 DH Internal Audit]

   b. Annual Assurance Statement - 2014/15
      [AGC (10/06/2015) 458 DH Internal Audit]

8. External Audit

   a. Audit Completion Report
      [AGC (10/06/2015) 459 NAO]

9. Information Assurance
   [AGC (10/06/2015) 460 SG]

10. Annual Report & Accounts (including Annual Governance Statement)
    [AGC (10/06/2015) 461 MA]

11. Implementation of Recommendations – Progress Report
    [AGC (10/06/2015) 462 MA]

12. AGC Forward Plan
    [AGC (10/06/2015) 463 SG]

13. Any Other Business

14. Session for members and auditors only

Close: 1:00 pm (Refreshments & Lunch provided)
Next meeting: 10:00 am Wednesday, 7 October 2015, London

Audit and Governance Committee Paper

Paper Title	**DRAFT Minutes of the meeting 18 March 2015**
Agenda Item	**2**
Paper Number	[AGC (10/06/2015) 453]
Meeting Date	Wednesday, 10 June 2015
Author	Dee Knoyle
For information or decision?	Decision
Recommendation	Members are asked to confirm the minutes as a true and accurate record of the meeting.

Members present
Rebekah Dundas (Chair)
Jane Dibblin
Gill Laver

External attendees
Catherine Hepburn – NAO
Sarah Edwards - NAO
Kim Hayes – DH
James Hennessey – PWC - DHIA

Staff in attendance
Peter Thompson – Chief Executive
Sue Gallone – Director of Finance and Resources
Morounke Akingbola – Head of Finance
Sam Hartley – Head of Governance and Licensing
Dee Knoyle – Committee Secretary

Apologies
Jerry Page

Attendance for specific items:
Nick Jones – Director of Compliance and Information
Paula Robinson – Head of Business Planning

1. Welcome, Apologies and Declarations of Interests

1.1 The Chair welcomed all attendees to the meeting.

1.2 Jerry Page had sent his apologies for the meeting due to ill health.

1.3 Jane Dibblin, Authority Member has reached the end of her term as a member of the Authority and that this would be her last Audit and Governance Committee (AGC) meeting. The Chair thanked Jane for her contributions.

1.4 A new AGC member will be confirmed for the June 2015 meeting.

2. Minutes of the Meeting held on 10 December 2014

2.1 The Minutes of the meeting held on 10 December 2014 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 matters arising in progress, in particular:

3.2 There are only five items outstanding: three are underway and two are planned for later dates.

3.3 Risk of sabotage of IT systems - policies are in place, changes are logged and back-ups are kept securely should the system need to be restored.

3.4 Online governance training - Existing Authority members had completed the training and the new members are due to complete it by June 2015.

3.5 Appraisals for external members – Gillian Laver will have her appraisal after this meeting and another will be planned for Jerry Page at a later date.

3.6 The Committee noted that the number of meetings to be held each year will be reviewed in June 2015.

4. Finance & Resources – Risks and Shared Finance Resources

4.1 The Director of Finance & Resources made a presentation to the Committee.

Finance risks

4.2 The organisation relies heavily on income from treatment fees. There has been a reduction in income from treatments due to the discount applied for elective single embryo transfer and this was expected. It can be difficult to forecast treatment fee income as it is demand led. The NHS provides around 40% of HFEA income and the other 60% comes from clinics that provide private treatment. Next year's forecast for treatment fee income is expected to be similar.

4.3 The Fees Group will meet again in April 2015. The group will review HFEA income and spend in 2014/15 and explore forecasting treatment fees.

4.4 The HFEA has exceeded its budget for legal expenses. It can be difficult to forecast this type of expenditure it is reactive, although the latest expectations are factored in.

4.5 The HFEA will have a deficit for 2014-15 and is using reserves to meet the shortfall. The balance of available reserves is earmarked for the Information for Quality (IfQ) programme.

4.6 There is a risk that financial information is not up to date due to staff outside of the finance department not prioritising actions to input and approve financial transactions. This can also affect prompt payments. The finance team have taken steps to make improvements through training and reminders.

4.7 The finance team was restructured in 2013 and this resulted in a reduction in staff. Steps have been taken to capture knowledge and produce standard operating procedures. Lack of resource is a current risk.

Shared resources

4.8 The Committee were informed that there were benefits to sharing Director and Head resource with the Human Tissue Authority such as spreading good practice and knowledge and attending meetings on behalf of both organisations. Also, having the same auditors for the two organisations had helped. There were also personal benefits for the staff involved, including the expansion of knowledge and learning.

4.9 The challenges were outlined, such as the time required to attend corporate meetings for two organisations, the volume of work to deal with, managing two separate teams and peaks in workload happening at the same times in both organisations. There is also potential for confusion when dealing with two separate organisations.

4.10 Overall, there has been good feedback on the shared arrangement which is working thanks to the determination of the staff involved. Both organisations and individuals within the finance teams have felt well supported. However, there have been constraints on discretionary work and areas for development.

4.11 To achieve all of the benefits envisaged it would be necessary to create one finance team and merge functions more widely. This has not been possible due to the different organisational needs and each organisation having different financial systems. However this may be considered in the future, possibly after the planned office move in 2016 when HFEA & HTA staff should be working in the same building. In the meantime, the financial savings have been small and there has been pressure on the shared staff. The situation will be reviewed again after year-end.

Other Resources risks

4.12 The organisation is preparing for an office move and there is no longer a dedicated facilities team. The HFEA is currently located at Finsbury Tower as a sub-tenant of the Care Quality Commission (CQC). Part of CQC will move out soon and the building will undergo a refurbishment which may cause some disruption to working arrangements for HFEA. The CQC are working closely with the landlord at Finsbury Tower to ease any inconvenience the refurbishment programme may cause.

4.13 Business continuity can be a risk but plans are in place.

4.14 The organisation has a good information governance culture, however policies need to be updated.

4.15 The Committee noted the risks associated with reduced staffing. The Chair thanked the finance team for managing their business well and making things work during challenging times.

ACTION:

4.16 Head of Business Planning to reflect the risk of working with a reduced workforce in the Strategic Risk Register.

5. Finance Policies (including Counter-fraud policy)

5.1 The Director of Finance & Resources provided the Committee with a paper and made a presentation.

Standing Financial Instructions

5.2 The Standing Financial Instructions (SFIs) comprise the Standing Orders, Department of Health (DH) Framework Agreement, Delegations from DH, Accounting

Policies and Finance policies. They are supported by financial procedures and WAP guidance. The policies have been updated, following a helpful internal audit.

5.3 The finance team plan to provide AGC with an annual update on their policies review and bring the following updated policies to AGC for approval:

- October – Reserves
- December - Whistleblowing
- March - Counter-fraud and Anti-theft

5.4 The Committee discussed the involvement of the Authority in the Reserves policy and noted that reserves are reported to the Authority as a key performance indicator.

5.5 The Committee agreed the format of the SFIs and the approach to updating policies.

Counter-fraud and Anti-theft policy

5.6 Minor changes had been made to update the policy.

5.7 The Committee approved the updated Counter-fraud and Anti-theft policy.

6. Information for Quality (IfQ) Programme – Managing Risks

6.1 The Director of Compliance and Information presented his paper.

6.2 The Committee were reminded that the HFEA submitted a business case for IfQ to DH in December 2014. There has been a delay in receiving a response from DH and HFEA are still awaiting government digital approval. The delay has led to increased programme costs of approximately £40k. The HFEA has spoken to senior officials at DH and had a positive response. This means that we can now move ahead and tender for the work to be done.

6.3 The Committee noted that the Authority have agreed a revised IfQ budget of a total of £1.85m. Precise spend will be better determined when the tenders are returned.

6.4 The Authority also approved the following at its meeting in January 2015:

- The HFEA Register – a data dictionary and standing group to maintain the integrity of the data the HFEA collects and holds
- Data submission – including a new portal for centres to submit data to the HFEA
- Website - designed to be more user friendly
- Choose a Fertility Clinic (CaFC) - simplifying data presentation and including more patient feedback about clinics

6.5 Data migration is anticipated to start in the 2015-16 business year. A healthcare data specialist has been commissioned to support the development of the migration strategy. Key risks to the proposed approach have been identified and will be reviewed by the IfQ Programme Board in March 2015.

6.6 A member of the internal audit team will observe the next meeting of the IfQ Programme Board on 16 March 2015 to help provide assurance over data migration and programme governance. The Committee welcomed clear advice from internal audit.

6.7 A Government Gateway Review has been commissioned and will take place between 25 – 27 March 2015. The Committee questioned whether the delay in tendering would affect the value of the Gateway review and were assured that the review would be helpful in establishing what the HFEA could do better in the programme as a whole.

6.8 The Committee noted that one contract has been awarded since the last meeting, to Avoca Systems Ltd for the development of a data migration strategy.

6.9 The Committee noted that pre-market engagement had taken place with potential suppliers and that this should alert the HFEA to any potential issues.

6.10 The external auditors advised the Committee that they had not yet reviewed IfQ spend and approvals and would be doing so during the interim audit.

7. Strategic Risks

Strategic Risk Register

7.1 The Head of Business Planning presented the paper to the Committee.

7.2 HFEA Corporate Management Team (CMG) reviewed the new Strategic Risk Register on 5 February 2015. There were 12 risks identified, five were above tolerance and these were discussed along with control measures.

7.3 The Committee were informed that CMG would like to re-define inherent risks in order to make it more meaningful to '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. Inherent risks are usually defined as 'the exposure arising from a specific risk before any action has been taken to manage it'.

7.4 Internal audit commented that this would be in line with the COSO approach. External audit advised that it is important to have a clear baseline and considering risk before any action can be clearer. Whatever the approach it is important to record the factors considered in reaching the opinion.

7.5 The Committee agreed that the Executive should ensure that systems are suitable for the people using them and noted the possibility of down-grading risks that are inherently high and the potential introduction of subjectivity. The executive will reflect on this advice before making a decision.

7.6 The Committee noted the developments to the strategic risk register and that this is a live document. In particular the following were noted:

Legal Challenges to Decision Making

- Legal challenges are unpredictable and when they happen resources are diverted. There is good communication with legal advisers throughout the process. Standard Operating Procedures and decision trees are in place.

Capability

- There has been a high turnover of staff recently and a good calibre of new staff recruited. Induction and training is planned for new staff, however during this process staff capability is low even though we have capacity. Tolerance levels are to be discussed at the next AGC meeting in June 2015.

7.7 The Committee agreed that the timing of the publication of the Strategic Risk Register should be in line with other AGC meeting papers (with any necessary redactions) and no longer held back for a period of 12 months.

ACTION:

7.8 Head of Business Planning to update AGC on capability tolerance levels at the next AGC meeting in June 2015.

Operational Risks

The Committee noted the risks to resources and that the IfQ programme needs focus at this point in time. They questioned whether we might work differently to reduce

pressure and whether all risks are identified. The work of the Executive on Service Delivery Plans helps.

Risk Assurance Mapping

The approach suggested builds on the operational risk structure and uses the CQC model.

7.9 The Committee welcomes the developments and that the Executive is learning incrementally from others. It was agreed that assurance mapping should be kept proportionate.

8. Internal Audit

DH Internal Audit presented their reports:

8a Progress Reports & Internal Audit Plan

8.1 The Committee noted the details in the progress report.

8.2 The Committee advised that the 12 pillar approach should be considered in a proportionate way when reviewing project management for IfQ.

8.3 The Committee agreed the audit plan for 2015/16. They would find it helpful to see a three year rolling plan.

ACTION:

Internal audit and executive to present a plan of audits carried out and planned over a three year period to June AGC meeting.

8b (i) Standing Financial Instructions

8.4 The Committee noted this advisory audit that the executive had acted on. External audit commented that the Standing Financial Instructions need to be proportionate and work for the HFEA. Documenting policies and procedures is helpful and more so at times of change. NAO may refer to the policies and procedures as context for their audit.

8b (ii) Internal Policies Review

8.5 It was agreed that this audit may have been more useful as an advisory audit. It is important to clarify expectations at terms of reference stage to ensure the audit adds value.

8.6 The Committee noted the opinion and response to the recommendations.

8.7 The Committee received a report of a separate issue identified during this audit when the internal auditor had been able to access other documents. The matter had been rectified straight away by the Executive.

8.8 It was agreed that this was a systems issue and there had not been a breach of the Human Fertilisation and Embryology Act or the Data Protection Act, so no further action was necessary.

9. External Audit – Interim Feedback

9.1 The NAO provided the Committee with an update on the work completed in February 2015 and future plans.

9.2 For the 9 months from April 2014 to December 2014 the NAO carried out payroll and income testing, a review of provisions and contingent liabilities and a review of the interim draft financial statements.

9.3 In March 2015 the NAO plan to carry out testing on other expenditure, journals, and a review of the status of the IfQ capital expenditure programme to date. The audit will be completed in May 2015.

9.4 The NAO have shared with the HFEA the EPN412, issued by the Cabinet Office, which provides enhanced guidance for receiving timely information necessary for the pension disclosures in the remuneration report. The Head of Finance is currently awaiting a response from officials. The NAO offered their assistance if that is not forthcoming as they have various avenues of communication.

10. Implementation of Recommendations – Progress Report

10.1 The Head of Finance provided a paper to update the Committee.

10.2 The Committee noted that there had been good progress and there were good explanations of slippage in completing some outstanding recommendations. The delays were mostly due to staff workload and changing priorities.

10.3 Recommendations from the Internal Policies review will be included next time.

11. Annual Report & Accounts (including Annual Governance Statement)

11.1 The Head of Finance provided the Committee with an oral briefing.

11.2 The Head of Finance has taken responsibility for the Annual Report and Accounts as a whole and is working towards an absolute deadline of 5 May 2015 for submission to NAO. Contributions have been requested from staff with deadlines for submission. The organisation has learned from last year's production of the Annual Report and Accounts and made changes to the process. Version control is under strict management and the NAO will lay the report this year which is very helpful.

11.3 The Head of Governance & Licensing is responsible for the Annual Governance Statement and has started work in this area.

11.4 The Annual Report & Accounts (including Annual Governance Statement) will be reviewed at the next AGC meeting in June 2015.

12. AGC Forward Plan

12.1 The Director of Finance and Resources provided the Committee with a paper.

12.2 The Committee noted the forward plan and the Chair reminded members that the number of meetings to be held each year will be reviewed in June 2015.

ACTION:

12.3 AGC members to review number of AGC meetings to be held each year at AGC meeting in June 2015.

13. Any Other Business

13.1 The Director of Finance & Resources confirmed that there were no incidents of suspected or actual fraud. The Committee had already noted the contract awarded.

13.2 Members and auditors retired for their confidential session.

13.3 The next meeting is on Wednesday 10 June at 10am.

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

Chair

Date

Audit and Governance Committee Paper

Paper Title:	**Matters arising from previous AGC meetings**
Paper Number:	[AGC (10/06/2015) 454 SG]
Meeting Date:	10 June 2015
Agenda Item:	**3**
Author:	Sue Gallone
For information or decision?	Information
Recommendation to the Committee:	To note and comment on the updates shown for each item.
Evaluation	To be updated and reviewed at each AGC.

Numerically:

- 4 items added from March 2015 meeting, all completed.
- 2 items carried over from earlier meetings and ongoing.
- 5 items ongoing from AGC self–assessment of performance.

Matters Arising from Audit and Governance Committee – actions from 11 June 2014 meeting			
ACTION	**RESPONSIBILITY**	**DUE DATE**	**PROGRESS TO DATE**
3.2 HFEA to monitor Authority members' completion of online information governance training	Executive Assistant to Chair and Chief Executive	20 September 2014	**Ongoing** - being monitored by Executive Assistant. All Members have completed the training except for the new Members. They are being asked to undertake the training alongside their induction and thus is expected to be completed during summer 2015.

Matters Arising from Audit and Governance Committee – actions from 1 October 2014 meeting			
ACTION	**RESPONSIBILITY**	**DUE DATE**	**PROGRESS TO DATE**
14.13 Implement annual appraisals for external members	Head of Governance and Licensing	June 2015	**Part completed** – one external member has been appraised; the second was delayed due to scheduling problems. To be conducted asap.

Matters Arising from Audit and Governance Committee review of performance December 2014			
ACTION	**RESPONSIBILITY**	**DUE DATE**	**PROGRESS TO DATE**
e) Arrange for external members to attend Authority meeting as observers	Head of Governance & Licensing	September 2015	**Ongoing** – members invited to meetings, suitable dates to be agreed.
f) Arrange for external members to observe an inspection	Head of Governance & Licensing	September 2015	**Ongoing** – Inspectorate's business support team in contact with external members and attempting to find suitable dates. Still to be arranged at time of writing, given recent pressures on external members' time (that should now ease somewhat), and priority given to inducting new inspectors recently taken on.
g) Arrange for members to have an annual appraisal with the Chair, adhering to the Authority member	Chair of AGC	June 2015	**Part completed** – see 14.13 above

Matters Arising from Audit and Governance Committee review of performance December 2014			
ACTION	**RESPONSIBILITY**	**DUE DATE**	**PROGRESS TO DATE**
appraisal timescales			
i) Institute formal annual report to Authority board	Head of Governance & Licensing	July 2015	**Ongoing** – plan to formally report to July Authority meeting each year. Draft report to be agreed by Chair remotely.
j) Give thought to improving communication from external appeals committees to AGC/Authority board, while maintaining independence of those committees.	Head of Governance & Licensing	October 2015	**Ongoing** – pending completion of current Appeals process and lessons learned from that – expected in July.

Matters Arising from Audit and Governance Committee – actions from 18 March 2015 meeting			
ACTION	**RESPONSIBILITY**	**DUE DATE**	**PROGRESS TO DATE**
4.16 Reflect risk of working with a reduced workforce in the strategic risk register	Head of Business Planning	June 2015	**Completed** – see item 6 on the agenda
7.8 Update AGC on capacity tolerance levels	Head of Business Planning	June 2015	**Completed** – see item 6 on the agenda
8.3 Present plan of audits carried out and planned over three year period	Internal audit	June 2015	**Completed** – see item 7 on the agenda
12.3 Review number of AGC meetings to be held each year	AGC members	June 2015	**Completed** – see item 12 on the agenda

Audit and Governance Committee paper

How this paper relates to our strategy	Setting standards	☑	Increasing and informing choice	☑	Demonstrating efficiency, economy and value	☑
Paper title	Information for Quality – managing risks					
Agenda item	**5**					
Paper number	[AGC (10/06/15) 455) NJ]					
Meeting date	10 June 2015					
Author	Nick Jones, SRO & Director of Compliance and Information					
For information or decision?	Information					
Recommendation	The Committee is asked to note this update					
Resource implications						
Implementation	In progress.					
Communication	Extensive stakeholder communication					
Organisational risk	Medium.					
Annexes	Annex 1 – Gateway Report Annex 2 – Gateway Report Action Plan					

1. Introduction

This report updates the Audit & Governance Committee (AGC) on the progress of the programme specifically in the areas covered by the AGC terms of reference.

By way of reminder, the IfQ programme encompasses:

- The redesign of our website and Choose a Fertility Clinic function

- The redesign of the ‘Clinic Portal’ (used for interacting with clinics) and combining it with data submission functionality that is currently provided in our separate EDI (Electronic Data Interchange) system (used by clinics to submit treatment data to the HFEA)
- A revised dataset and data dictionary which will be approved by the Standardisation Committee for Care Information (SCCI)
- A revised Register, which will include the migration of historical data contained within the existing Register
- The redesign of our main internal systems that comprise the Authority’s Register and supporting IT processes.

2. Progress

i. Since the last meeting the business case, along with associated digital expenditure controls, submitted to Department of Health (DH) on 18 December 2015, has been approved - on 28 April 2015.

ii. It should be noted that this approval is (in-part) conditional in nature - which introduces risk. The approval granted (partly expenditure limits, partly fit with government digital strategy) is made more complex due to the distinction made by government between ‘digital’ activity/expenditure and that associated with ‘infrastructure.’ The former is scrutinised by DH and Government Digital Service (GDS - part of the Cabinet Office), and the latter by DH alone. The basis of the approval to date is set out below.

iii. Broadly, there are three aspects of digital activity: the HFEA website; Choose a Fertility Clinic; and the clinic portal – by which clinics ‘transact’ with the HFEA. Approval in full has been granted by DH. Approval by GDS is conditional – with activity beyond c.30% of overall committed budget for this aspect of the programme subject to a further assessment by DH, with approval to proceed subject to GDS consideration in turn. This approach is informed by considerations relating to an ‘agile’ methodology for contemporary IT projects – that is developing to alpha stage (first draft) – then moving to beta stage (subject draft to testing by users) and then if all is well ‘go live.

iv. The delay has incurred additional programme management expenditure reducing the amount available this financial year – estimated at £40,000 in additional costs in 2016/17. Moreover, the potential for further delay introduces additional financial risk. Having mobilised contractors, any undue delay from moving to alpha to beta stage has consequences. We are seeking to mitigate this risk by

agreeing timescales and service standards - a reasonable set of expectations applicable to all. This will recognise that the HFEA holds the risks and consequences and there will be a point at which any delay beyond that agreed will not be tolerable.

v. More positively, unconditional approval has been granted for the infrastructure development element of the programme – redesigning our main internal systems that comprise the Authority's Register and supporting IT processes. This accounts for over 50% of budgeted programme costs.

vi. We are adopting a mixed procurement model - supplementing internal capacity with specific expertise further to a procurement exercise conducted on our behalf by the Crown Commercial Service. That procurement process by way of competitive tender has commenced and is progressing to timetable. The closing date for tenders was 6 May 2015 and the subsequent two to three weeks sees selection and contract agreement, with mobilisation of external and internal teams beginning in earnest in June 2015. An oral update will be provided at the meeting.

3. Governance

i. The IfQ programme board has continued to meet and has reported progress to the March, April and May 2015 meetings of the Corporate Management Group (CMG). An item regarding IfQ is presented at each meeting of the Authority, the latest on 13 May 2015.

ii. IFQ risks are integral to the HFEA strategic risk register, covered under a separate item at this meeting.

iii. At the last meeting we reported that a Government Gateway Review was to take place. A Gateway Review is a short, focused review of a programme or project, conducted on behalf of the project's Senior Responsible Owner. The Review's full report is at annex 1, and the summary conclusion was as follows:

- 'The Review Team (RT) consistently heard that the Programme is seen as the top priority within HFEA and there is clearly good stakeholder buy-in. The RT was impressed with the management and progress on the IT procurement and is confident that this will have a successful outcome. However, considering the Programme as a whole, there are a number of key issues which are not as well integrated into the Programme and require management attention. As the tender documentation has not yet been released to the market there should be sufficient time to address these without impacting on the delivery of

the overall Programme benefits. Therefore, the RT considers that the Delivery Confidence Assessment is Amber.'

iv. We view this as a fair assessment, and reflective of much of our focus to date. The 'key issues' that the Review Team alluded to relate to the impact of the programme on the organisation and the need to set out a future 'blueprint' against which decisions can be judged. We acknowledge that such work is necessary, though the detail will of necessity only emerge in time. We will be placing more emphasis on the change aspects of the programme over the next few months and beyond – in recognition of the ambition underpinning the programme. The action plan in place is shown at annex 2.

4. Internal Audit

i. As reported at the previous meeting, the IfQ internal audit programme is to observe deliberations as regards the data migration strategy and implementation. The first milestone - for a member of the internal audit team to observe a Programme Board meeting (focused on agreeing the strategy) took place on16 March 2015. The date where the next observation is to take place has yet to be determined – the key point being that this takes place at an appropriate milestone consistent with the data migration strategy.

5. Report from the our tender panel

In accordance with Standing Financial Instructions the Committee is asked to note that no contracts have been awarded since the last meeting.

Recommendation

The Committee is asked to note this report.

Nick Jones

Director of Compliance and Information

IfQ AGC 10/06/15 – Annex 1

Department of Health

NHS

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Health Gateway Review
Review 2: Delivery Strategy

Version number: v1.0

Date of issue to SRO: 1 April 2015

SRO: Nick Jones

Organisation: Human Fertilisation & Embryology Authority

Health Gateway Review dates: 25 – 27 March 2015

Health Gateway Review Team Leader:
Andrew Morgan

Health Gateway Review Team Members:
Scott Patterson
Roger Evans

Background

The aims of the programme:

The Information for Quality (IfQ) Programme is designed to transform the HFEA's approach to information, that is:

- The information which is collected
- How clinics submit data
- How information is published

The IfQ Programme also enables the Authority to meet national strategic priorities around information as well as its own recently redefined vision – high quality care for people affected by assisted reproduction.

The IfQ Programme will encompass:

- redesigning the website and the associated tool called Choose a Fertility Clinic (CaFC))
- redesigning the "Clinic Portal" (used for monitoring the performance and interacting with clinics) and combining it with data submission functionality that is currently provided in the separate EDI (Electronic Data Interchange) system and is used by clinics to submit treatment data to the HFEA
- redesigning the main internal systems that comprise the Authority's Register and supporting IT processes.

The driving force for the Programme:

The Programme addresses pressing and important issues with HFEA infrastructure and systems and websites that are no longer fit for purpose. There has been limited HFEA development activity on these for some years, partly because there were several years of uncertainty about the HFEA's future in the wake of the 2010 ALB Review.

The procurement/delivery status:

The Programme has delivered an Outline Business Case (OBC) to the Department of Health and the Government Digital Service to seek approval for digital spend. Approval has been granted to go out to tender. IfQ will be procured through the Digital Services Framework with the Crown Commercial Service, which has offered support and advice in the creation of the tender documents, which should be submitted in the next week.

Current position regarding Health Gateway Reviews:

This is the first time that the HFEA have undertaken a Gateway Review.

Purposes and conduct of the Health Gateway Review

Purposes of the Health Gateway Review

The primary purposes of a Health Gateway Review 2: Delivery strategy, is to confirm the Outline Business Case now that the project is fully defined and ensure that the delivery strategy and/or procurement is robust and appropriate.

Appendix A gives the full purposes statement for a Health Gateway Review 2

Conduct of the Health Gateway Review

This Health Gateway Review was carried out from 25 March to 27 March 2015 at Finsbury Tower, London. The team members are listed on the front cover.

The people interviewed are listed in Appendix B.

The review team would like to thank the IFQ Programme Team for their support and openness, which contributed to the review team's understanding of the programme and the outcome of this review.

The RT consistently heard that the Programme is seen as the top priority within HFEA and there is clearly good stakeholder buy-in. The RT was impressed with the management and progress on the IT procurement and is confident that this will have a successful outcome. However, considering the Programme as a whole, there are a number of key issues which are not as well integrated into the Programme and require management attention. As the tender documentation has not yet been released to the market there should be sufficient time to address these without impacting on the delivery of the overall Programme benefits. Therefore, the RT considers that the Delivery Confidence Assessment is **Amber**.

Colour	Criteria Description
A	Successful delivery appears feasible but issues require management attention. The issues appear resolvable at this stage of the programme/project if addressed promptly.

A summary of recommendations can be found in Appendix C.

The Programme Manager was praised by many interviewees for his sound management of the IT procurement programme. There was particularly positive feedback for the procurement processes being used, with significant value being seen from the Pre-Tender Market Engagement. In addition, the domain knowledge of the IT team was widely recognised, as was the importance of this to the success of the Programme.

The RT heard a mixture of views from the interviewees on the overall scope of the programme, and the expected timelines for the key activities. The key question was whether the scope was focused on IT procurement or also encompasses the business and cultural changes needed within HFEA operational delivery. This needs to be addressed urgently.

Although there were some good detailed project-level plans, the RT only saw a partial Programme-level plan which primarily covered the IT aspects. The RT did not see an overall detailed programme-level plan. This contributed to some uncertainty on roles, responsibilities and accountabilities, and due dates for deliverables. A historic track record of programme slippage led some interviewees to question the deliverability of the programme. A resourced plan should be put in place as soon as possible.

A detailed risk log was seen by the RT. However, there was not a consistent understanding of how risks were flagged up and added to the log, or how the mitigation actions would be taken forward.

The need to up skill staff to meet the challenges of the Agile methodology, and managing the delivery of service management through third party suppliers was recognised, and work is progressing to put this in place.

This is the first Gateway review within the HFEA.

1: Policy and business context

The IfQ Programme was initiated in October 2013 and is designed to transform the HFEA's approach to information. The importance of the Programme is recognized by key stakeholders inside and outside HFEA. It fits within the agreed strategy for HFEA and is overseen by the Audit Committee on behalf of the HFEA Board. The cornerstone of the Programme is the redesigning of its website, clinical portal, the Register and supporting IT services.

The HFEA is planning to outsource part of the design and development of the new IT system with the remainder staying in-house, and anticipate that this might also be the approach for the ongoing support services, although this decision has not yet been taken. The procurement strategy is to use the pre-approved Government Frameworks.

The Programme has already carried out pre-tender market engagement in anticipation of commencing formal procurement, and there is an encouraging level of market interest. A Programme Board has been set up, chaired by the SRO, with three Project Boards (Website, Clinic Portal, Internal Systems) reporting to it. An experienced Programme Manager has been appointed.

The RT heard differing perceptions as to the scope of the Programme, varying from an IT Procurement Programme to one which embraces the decommissioning of 30 IT systems and implementation of organisational and cultural changes. It will be important for the SRO and stakeholders to all hold a common view on the scope of the Programme. The RT understands that the SRO believed the Programme had a wider remit than just IT procurement.

Recommendation 1: It is recommended that the SRO clarify the scope of the Programme, and communicate this to all stakeholders. (Do Now)

2: Assessment of Delivery Approach

The RT was informed that the procurement and selection process was fit for purpose, and that, ultimately, the Programme Board would approve the recommended contract awards. Whilst acknowledging the presence of strong Programme Management for the IT procurement, the RT were concerned that there is uncertainty amongst some stakeholders on key issues which will ensure successful delivery of the overall programme benefits.

In particular, although there is a plan with timelines for the tendering process, the RT did not see a comprehensive, resourced plan for the overall Programme. Examples include: the RT was informed of several different dates for completion of the Website project; uncertainty with some stakeholders over their roles and responsibilities, and where decision making authority lies for several key components of the Programme.

Most importantly, not all of the interviewees were confident that the Programme would be completed by 31 March 2016, and several suggested that there would be some residual activities after this date. Issues such as the examples above would be more easily addressed if there was a comprehensive Programme Plan which includes timelines, resources and designated decision makers. This would also show the critical path and the overall impact of delays with components of the Programme, and increase the likelihood of timely delivery.

Recommendation 2: It is recommended that the SRO puts in place a comprehensive, resourced Programme Plan. (Do Now)

The RT heard that the historic delivery approach has been for the IT team to undertake the design and development work for the HFEA IT systems. The approach for the future will be for design and development work to be undertaken by third party suppliers, with the interfacing components built by the IT team. This will require a change in the focus of the IT team with an increased emphasis on supplier management.

It will be important to identify who the designated manager(s) of the contracts will be, and for those personnel to be fully involved in the tender selection process.

3: Business case and stakeholders

There is a clear appreciation and buy in from all members of staff interviewed by the review team on the importance of the Programme and its position as the key strategic driver for change within HFEA.

Extensive stakeholder engagement has been completed through the Discovery phase of the Programme. The OBC provides a clear picture of the Programme requirements. The OBC has received approval from the Department of Health but has yet to receive the required approval from the Government Digital Service.

Although the RT was provided with a benefits realisation plan for the Website project, similar evidence was not seen for the other two projects. There was some lack of clarity among interviewees on the overall benefits which would be realised from the Programme. This was mainly due to the uncertainty around timeframes and scope as a result of the absence of an overall plan. It was also unclear if decommissioning of legacy systems is within scope of the Programme. It was the opinion of a number of the interviewees that until decommissioning had been completed then full benefits realisation would not be achieved.

A key risk identified by the RT is the accountability for the integration of the deliverables from the different suppliers and the management of the contracts. It was found to be unclear as to where that responsibility would ultimately reside. This will be Business as Usual and will be key to the enduring success of the Programme. It would be beneficial if this was decided before the suppliers were selected.

The OBC states that the budget for this Programme consists of IT procurement funding and ongoing support over a 5 year contract period. The preferred option assumes this support to be with third party suppliers. However, the RT heard that the decision on the HFEA support strategy (in-house or outsourced) has not yet been made, and that this will be defined in the Blueprint. It would be beneficial to complete the Blueprint work as quickly as possible.

Recommendation 3: It is recommended that the HFEA Blueprint is put in place before the contracts are let. (Do By – July 2015)

4: Risk management

The RT saw a risk log which identified the majority of the risk owners to be either the SRO or the Programme Manager. Interviewees were consistently less clear about how the risks they could see for their elements of the work would be included, or escalated.

The RT team identified several potential risks, including the possibility of the HFEA having to move offices at some point during the next 12 months. This could impact on the resource available to support the programme. The RT heard that one of the key risks is that the bids submitted might exceed the budget, and if so, this may require the de-scoping of the Programme requirements.

The RT did not see evidence of a culture of all stakeholders identifying risks for inclusion in the log, and for the management of mitigation actions. A programme such as this would typically have a clear risk management procedure/strategy to supplement the top level Corporate Risk Strategy.

Recommendation 4: It is recommended that the SRO put in place an IfQ Programme Risk Strategy, and ensure that this is widely understood and used (Do By – May 2015)

The Data Migration project was seen as being high risk by senior and middle management due to the complexity and regulatory focus on data integrity. Whilst the risk log identifies the quality-related risk of not migrating data correctly, additional risks covering the time and cost dimensions relating to data migration should also be considered in the risk log. The RT heard that mitigation actions are underway to address this risk.

5: Review of current phase

The RT saw evidence of strong programme management of the IT procurement aspects. Other components of the Programme did not appear to yet have the same level of drive and focus.

There was widespread commendation for the depth and extent of the stakeholder engagement performed as part of the Programme Discovery Phase. However the length of time this took to complete combined with delays to the approval process has resulted in significant timeline slippage and an acceptance that this is to be expected. A greater focus on timely delivery will be needed during the remainder of the Programme.

The RT heard that, in general, the Programme Board operated effectively in providing leadership and direction. However, there was some feeling that the submissions to the Board could be more concise, provide less detail and more recommendations.

A recurring theme was the centrality of the IT function to the successful delivery of the Programme. There was recognition of the IT team's significant domain knowledge and ability to support the current complex bespoke systems during a period of change. The RT was informed that initially the relationship between the IT team and the business has not been that strong, which may have influenced the delivery programme. Whilst the establishment of the Project Boards is starting to move towards closer working, it is essential that there is a very positive working relationship between the business and the IT team which will necessitate changes to the ways of working for all parties.

The RT understands that the preferred methodology is "Agile", however a significant number of the interviewees did not seem to be familiar with this approach, and were not fully convinced of its value. For example, the role of the Product Owner was not well understood. Staff are expecting to receive Agile training, and this will be needed before the suppliers are on-board.

Recommendation 5: It is recommended that the SRO put in place formal training in the Agile methodology (Do By – May 2015)

The RT heard that there are significant risks with the website migration, and there was uncertainty as to where the responsibility lies for re-writing the content and how this would be accommodated alongside Business As Usual tasks. The RT understand that this task will be planned and finalised imminently. There appears to be a high degree of confidence in the Website project manager's capabilities and enthusiasm. The RT saw that backfill resource had been provided to cover for the Website project manager. This approach could be helpful for the other projects.

6: Readiness for the next phase: Delivery of outcomes

Although the overall plan did not cover the whole Programme scope, the RT saw a number of good detailed project plans, including the IT tender assessment process, and the Data Migration project. The RT did not see evidence that the Programme Critical Success Factors have been defined.

Recommendation 6: It is recommended that the SRO puts in place a formal set of Critical Success Factors are defined for the whole Programme. (Do By – April 2015)

The content of the tender documentation was understood to varying degrees by interviewees, and it would be of benefit to share this widely with the stakeholders before the tender responses are received to ease the assessment process.

It was recognised that there are several staff members who are key to the delivery of the project. For the Programme to be successful and for the continuity of Business as Usual, it is important for there to be stability in key roles within the HFEA, such as the Programme Management, and the IT team. However, there were a range of views on how these skills would be sustained for the future, and limited appreciation of how succession issues would be handled. The risk of staff turnover could be mitigated by putting in place a clear succession plan.

Recommendation 7: It is recommended that the SRO put in place a succession plan covering key programme roles. (Do by - June 2015)

This is a very important programme for HFEA and therefore it will be important for the lessons identified to be fed back into the planning for the remainder of the programme, as well as the broader HFEA business.

The next Health Gateway Review is expected once the tendering process has been completed and the selected suppliers have been on-boarded, so that the readiness for implementation can be assessed (Gate 4). This is anticipated to be during autumn 2015.

APPENDIX A

Purposes of the Health Gateway Review 2: Delivery strategy

- Confirm the Outline Business Case now the project is fully defined.
- Confirm, that the objectives and desired outputs of the project are still aligned with the programme to which it contributes.
- Ensure that the delivery strategy is robust and appropriate.
- Ensure that the project's plan through to completion is appropriately detailed and realistic, including any contract management strategy.
- Ensure that the project controls and organisation are defined, financial controls are in place and the resources are available.
- Confirm funding availability for the whole project.
- Confirm that the development and delivery approach and mechanisms are still appropriate and manageable.
- Check that where appropriate the supplier market capability and track record are fully understood (or existing supplier's capability and performance), and that there will be an adequate competitive response from the market to the requirement.
- Confirm that the project will facilitate good client/supplier relationships in accordance with government initiatives such as Achieving Excellence in Construction.
- For a procurement project, confirm that there is an appropriate procurement plan in place that will ensure compliance with legal requirements and all applicable EU rules, while meeting the project's objectives and keeping procurement timescales to a minimum.
- Confirm that appropriate project performance measures and tools are being used.
- Confirm that there are plans for risk management, issue management (business and technical) and that these plans will be shared with suppliers and/or delivery partners.
- Confirm that appropriate quality assurance procedures have been applied.
- For IT-enabled projects, confirm compliance with IT and information security requirements, and IT standards.
- For construction projects, confirm compliance with health and safety and sustainability.
- Confirm that internal organisational resources and capabilities will be available as required for future phases of the project.
- Confirm that the stakeholders support the project and are committed to its success.

Interviewees

Name	Role
Mike Arama	IfQ Programme manager
Nick Jones	Director of Compliance and Information (SRO / IfQIS Project Executive / BCM / IfQ Programme Board)
Dave Moysen	Head of IT (BCM/IfQ Programme Board/IfQIS Project Board)
Sue Gallone (telephone)	Shared Director of Finance and Resources (IfQ Programme Board)
Peter Thompson	HFEA CEO (N.B.: drop-in visit, not a formal interview)
Juliet Tizzard	Director of Strategy and Corporate Affairs (IfQW Project Executive/ BCM communications /IfQ Programme Board)
Paula Robinson	Head of Business Planning/ Chair of HFEA Programme Board (IfQ Programme Board member)
Jo Triggs	Head of Engagement (IfQ Communications and Stakeholder engagement lead / IfQW Senior User)
Ian Peacock	Analyst Programmer (Data Migration)
Nick Irvine (telephone)	IfQW Project Manager
Trisram Dawahoo	Communications Manager (Digital) (IfQW Product Owner/ Senior User)
Chris Hall	Information, Compliance and Audit Manager (IfQCP Project Manager/IfQCP and IfQIS Product Owner)
Cathy Hodgson	Register Information Team Leader (Data dictionary lead for IfQIS)
Debra Bloor (telephone)	Chief Inspector
Rachel Hopkins	Head of HR
Sam Hartley	Head of Governance and Licensing
Helen Crutcher	Outgoing IfQ Programme Support Officer

Summary of recommendations

The suggested timing for implementation of recommendations is as follows:-

Do Now – **To increase the likelihood of a successful outcome it is of the greatest importance that the programme/project should take action immediately.**

Do By – To increase the likelihood of a successful outcome the programme/project should take action by the date defined.

Ref. No.	Recommendation	Timing
1.	**The SRO to clarify the scope of the Programme, and communicate this to all stakeholders**	Do Now
2.	**The SRO to puts in place a comprehensive, resourced Programme Plan**	Do Now
3.	**The HFEA Blueprint is put in place before the contracts are let**	Do By July 2015
4.	**The SRO to put in place an IfQ Programme Risk Strategy, and ensure that this is widely understood and used**	Do By May 2015
5.	**The SRO to put in place formal training in the Agile methodology**	Do By May 2015
6.	**The SRO to put in place a formal set of Critical Success Factors are defined for the whole Programme**	Do By April 2015
7.	**The SRO to put in place a succession plan covering key programme roles**	Do by June 2015

Item	Finding & Recommendation	Comment / Action	Owner	Date
1	**Policy and business context**			
	The IfQ Programme was initiated in October 2013 and is designed to transform the HFEA's approach to information. The importance of the Programme is recognized by key stakeholders inside and outside HFEA. It fits within the agreed strategy for HFEA and is overseen by the Audit Committee on behalf of the HFEA Board. The cornerstone of the Programme is the redesigning of its website, clinical portal, the Register and supporting IT services. The HFEA is planning to outsource part of the design and development of the new IT system with the remainder staying in-house, and anticipate that this might also be the approach for the ongoing support services, although this decision has not yet been taken. The procurement strategy is to use the pre-approved Government Frameworks. The Programme has already carried out pre-tender market engagement in anticipation of commencing formal procurement, and there is an encouraging level of market interest. A Programme Board has been set up, chaired by the SRO, with three Project Boards (Website, Clinic Portal, Internal Systems) reporting to it. An experienced Programme Manager has been appointed. The RT heard differing perceptions as to the scope of the Programme, varying from an IT Procurement Programme to one which embraces the decommissioning of 30 IT systems and implementation of organisational and cultural changes. It will be important for the SRO and stakeholders to all hold a	We will define the business change & soft transformation projects as part of the blueprint and make sure there is a shared vision appropriately. Recommend having a separate decommissioning / mop up project as part of the overall programme plan.		

Item	Finding & Recommendation	Comment / Action	Owner	Date
	common view on the scope of the Programme. The RT understands that the SRO believed the Programme had a wider remit than just IT procurement.			
	Recommendation 1: It is recommended that the SRO clarify the scope of the Programme, and communicate this to all stakeholders. (Do Now)	Will be done as part of the Blueprint & programme definition	NJ	June-2015
2	**Assessment of Delivery Approach**			
	The RT was informed that the procurement and selection process was fit for purpose, and that, ultimately, the Programme Board would approve the recommended contract awards. Whilst acknowledging the presence of strong Programme Management for the IT procurement, the RT were concerned that there is uncertainty amongst some stakeholders on key issues which will ensure successful delivery of the overall programme benefits. In particular, although there is a plan with timelines for the tendering process, the RT did not see a comprehensive, resourced plan for the overall Programme. Examples include: the RT was informed of several different dates for completion of the Website project; uncertainty with some stakeholders over their roles and responsibilities, and where decision making authority lies for several key components of the Programme. Most importantly, not all of the interviewees were confident that the Programme would be completed by 31 March 2016, and several suggested that there would be some residual activities after this date. Issues such as the examples above would be more easily addressed if there was a comprehensive Programme Plan which includes timelines, resources and	We will share the high-level dates for the programme more effectively. Will investigate uncertainty about roles & responsibilities and issues with the website project. Agree that there are likely to be some residual activities which will be articulated once the tenders are received and the final scope is defined.	Jo Triggs	

Item	Finding & Recommendation	Comment / Action	Owner	Date
	designated decision makers. This would also show the critical path and the overall impact of delays with components of the Programme, and increase the likelihood of timely delivery.			
	Recommendation 2: It is recommended that the SRO puts in place a comprehensive, resourced Programme Plan. (Do Now)	Awaits tender responses	PMO	June 2015
	The RT heard that the historic delivery approach has been for the IT team to undertake the design and development work for the HFEA IT systems. The approach for the future will be for design and development work to be undertaken by third party suppliers, with the interfacing components built by the IT team. This will require a change in the focus of the IT team with an increased emphasis on supplier management. It will be important to identify who the designated manager(s) of the contracts will be, and for those personnel to be fully involved in the tender selection process.	Agree. Product Owners (Chris & Trisram) could be contract owners for Clinic Portal & Website with Dave Moysen for the IT parts (possibly after the main delivery bulge). Trisram & Chris are already involved in the tender process.		Completed May 2015
3	**Business case and stakeholders**			
	There is a clear appreciation and buy in from all members of staff interviewed by the review team on the importance of the Programme and its position as the key strategic driver for change within HFEA. Extensive stakeholder engagement has been completed through the Discovery phase of the Programme. The OBC provides a clear picture of the Programme requirements. The OBC has received approval from the Department of Health but has yet to receive the required approval from the Government Digital Service.		PMO	

Item	Finding & Recommendation	Comment / Action	Owner	Date
	Although the RT was provided with a benefits realisation plan for the Website project, similar evidence was not seen for the other two projects. There was some lack of clarity among interviewees on the overall benefits which would be realised from the Programme. This was mainly due to the uncertainty around timeframes and scope as a result of the absence of an overall plan. It was also unclear if decommissioning of legacy systems is within scope of the Programme. It was the opinion of a number of the interviewees that until decommissioning had been completed then full benefits realisation would not be achieved. A key risk identified by the RT is the accountability for the integration of the deliverables from the different suppliers and the management of the contracts. It was found to be unclear as to where that responsibility would ultimately reside. This will be Business as Usual and will be key to the enduring success of the Programme. It would be beneficial if this was decided before the suppliers were selected. The OBC states that the budget for this Programme consists of IT procurement funding and ongoing support over a 5 year contract period. The preferred option assumes this support to be with third party suppliers. However, the RT heard that the decision on the HFEA support strategy (in-house or outsourced) has not yet been made, and that this will be defined in the Blueprint. It would be beneficial to complete the Blueprint work as quickly as possible.	We will prepare the benefits realisation plans for IfQIS and IfQCP as part of the PID development process. Agree that full benefits will not be achieved until decommissioning complete. Integration sits with IfQIS. This is specified in the tender documents. We will communicate this more effectively.		
	Recommendation 3: It is recommended that the HFEA	Agree	NJ	June 2015

Item	Finding & Recommendation	Comment / Action	Owner	Date
	Blueprint is put in place before the contracts are let. (Do By – July 2015)			
4	**Risk management**			
	The RT saw a risk log which identified the majority of the risk owners to be either the SRO or the Programme Manager. Interviewees were consistently less clear about how the risks they could see for their elements of the work would be included, or escalated. The RT team identified several potential risks, including the possibility of the HFEA having to move offices at some point during the next 12 months. This could impact on the resource available to support the programme. The RT heard that one of the key risks is that the bids submitted might exceed the budget, and if so, this may require the de-scoping of the Programme requirements. The RT did not see evidence of a culture of all stakeholders identifying risks for inclusion in the log, and for the management of mitigation actions. A programme such as this would typically have a clear risk management procedure/strategy to supplement the top level Corporate Risk Strategy.	We will write up a single risk management document, articulating how team members can add risks and will communicate this more effectively to the programme.		Completed May 2015
	Recommendation 4: It is recommended that the SRO put in place an IfQ Programme Risk Strategy, and ensure that this is widely understood and used (Do By – May 2015)	Agreed	MA	Completed May 2015
	The Data Migration project was seen as being high risk by senior and middle management due to the complexity and regulatory focus on data integrity. However, the risk log identifies the time and cost impacts as being “Insignificant” and	In the particular risk, quality & reputational risk was identified as the main driver rather than cost.		

Item	Finding & Recommendation	Comment / Action	Owner	Date
	this does not appear to be consistent with senior management views. The RT heard that mitigation actions are underway to address this risk.	Additional risks relating to the cost and time elements will be added	MA	Completed May 2015
5	**Review of current phase**			
	The RT saw evidence of strong programme management of the IT procurement aspects. Other components of the Programme did not appear to yet have the same level of drive and focus. There was widespread commendation for the depth and extent of the stakeholder engagement performed as part of the Programme Discovery Phase. However the length of time this took to complete combined with delays to the approval process has resulted in significant timeline slippage and an acceptance that this is to be expected. A greater focus on timely delivery will be needed during the remainder of the Programme. The RT heard that, in general, the Programme Board operated effectively in providing leadership and direction. However, there was some feeling that the submissions to the Board could be more concise, provide less detail and more recommendations. A recurring theme was the centrality of the IT function to the successful delivery of the Programme. There was recognition of the IT team's significant domain knowledge and ability to support the current complex bespoke systems during a period of change. The RT was informed that initially the relationship between the IT team and the business has not been that strong, which may have influenced the delivery programme. Whilst the establishment of the Project Boards is starting to	Agree. We will work to this once the current tender phase is completed and the Projects pick up the momentum. Agree	PMO	

Item	Finding & Recommendation	Comment / Action	Owner	Date
	move towards closer working, it is essential that there is a very positive working relationship between the business and the IT team which will necessitate changes to the ways of working for all parties. The RT understands that the preferred methodology is "Agile", however a significant number of the interviewees did not seem to be familiar with this approach, and were not fully convinced of its value. For example, the role of the Product Owner was not well understood. Staff are expecting to receive Agile training, and this will be needed before the suppliers are on-board.	Agile Product Owner training is booked for 31st May Agile Scrum Developer training is for the IT team taking place 1-3 June 2015 inclusive.		
5	**Recommendation 5: It is recommended that the SRO put in place formal training in the Agile methodology (Do By – May 2015)**	**Agreed**	**MA**	**May 2015**
	The RT heard that there are significant risks with the website migration, and there was uncertainty as to where the responsibility lies for re-writing the content and how this would be accommodated alongside Business As Usual tasks. The RT understand that this task will be planned and finalised imminently. There appears to be a high degree of confidence in the Website project manager's capabilities and enthusiasm. The RT saw that backfill resource had been provided to cover for the Website project manager. This approach could be helpful for the other projects.	We have planned 1 WTE for 6 months for the website content migration. Responsibility sits with IfQW.		
6	**Readiness for the next phase: Delivery of outcomes**			
	Although the overall plan did not cover the whole Programme scope, the RT saw a number of good detailed project plans, including the IT tender assessment process, and the Data Migration project. The RT did not see evidence that the	Section 3.5 identifies the CSFs as 1. To develop & maintain a clear data dictionary that is consistent		

Item	Finding & Recommendation	Comment / Action	Owner	Date
	Programme Critical Success Factors have been defined.	with NHS national standards, understood by its users and reflects a balance that reduces the burden of submission whilst meeting the needs of researchers by 31/03/16 2. To enable clinic users that use the EDI system & Clinic Portal to reduce the end to end time spent submitting information, resolving data issues by 20% by 31/03/17 3. To reduce the number of current errors in submitted data from 600 per month to fewer than 200 per month by 31/03/17 4. To reduce the end to end cost of maintaining the Register by £100,000 per year (cash releasing at least £50,000 per year) by 31/03/17 5. To reduce the average time taken to produce internal information for analysis, FOI, PQQs & other information requests for data submitted from the new system to 3 days in 90% of cases by 31/03/17		

Item	Finding & Recommendation	Comment / Action	Owner	Date
		6. To ensure our information business systems are effective, efficient & economic in order to deliver our statutory functions and strategic objectives with 'fit for purpose' technologies supported by sound & resilient processes by 31/03/17 7. To make public information more accessible to users and to increase the satisfaction of users as defined by the net promoter score from 0 to 6 by 31/03/17 8. To ensure the CMS can support the Authority's website to publish new and expanded information (such as the publication of more data to drive up clinic performance), improved presentation of clinic information on CaFC, including user experience scores, and a range of new material for patients about treatment options and new scientific developments), by March 2016.		
	Recommendation 6: It is recommended that the SRO puts	We will revisit these as part of the	**NJ**	**June-2015**

Item	Finding & Recommendation	Comment / Action	Owner	Date
	in place a formal set of Critical Success Factors are defined for the whole Programme. (Do By – April 2015)	blueprint and programme definition & communicate it more effectively.		
	The content of the tender documentation was understood to varying degrees by interviewees, and it would be of benefit to share this widely with the stakeholders before the tender responses are received to ease the assessment process. It was recognised that there are several staff members who are key to the delivery of the project. For the Programme to be successful and for the continuity of Business as Usual, it is important for there to be stability in key roles within the HFEA, such as the Programme Management, and the IT team. However, there were a range of views on how these skills would be sustained for the future, and limited appreciation of how succession issues would be handled. The risk of staff turnover could be mitigated by putting in place a clear succession plan.	Agree, we will share the tender documents with the Programme Board and the tender assessors.		Completed
	Recommendation 7: It is recommended that the SRO put in place a succession plan covering key programme roles. (Do by - June 2015)	**Success plan will be articulated as part of the Blueprint planning.**	**NJ**	**June 2015**
	This is a very important programme for HFEA and therefore it will be important for the lessons identified to be fed back into the planning for the remainder of the programme, as well as the broader HFEA business.	We do have a lessons learned harvesting culture within the IFw programme that feeds back to the PMO		

Audit and Governance Committee paper

Strategic delivery	**Setting standards**	☐	**Increasing and informing choice**	☐	**Demonstrating efficiency, economy and value**	☑
Paper title	**Strategic Risk**					
Agenda item	**6**					
Paper number	AGC (10/06/2015) 456					
Meeting date	10 June 2015					
Author	Paula Robinson					
For information or decision?	Information and comment					
Recommendation	AGC is asked to note the latest edition of the risk register, and progress with agreeing our approach to risk assurance mapping, set out in the covering paper.					
Resource implications	In budget.					
Implementation	Strategic Risk Register and operational risk monitoring: ongoing. Risk assurance mapping: implementation approach agreed with CMG. Discussions to take place with DH Internal Audit so as to establish a viable programme of work over the next 2-3 years.					
Communication	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	Captured in document.					
Annexes	A: Strategic Risk Register					

HUMAN FERTILISATION & EMBRYOLOGY AUTHORITY

1. Strategic Risk Register

1.1. CMG review – May 2015

1.2. CMG reviewed the new Strategic Risk Register (SRR) on 20 May. Five of the twelve risks are currently above tolerance, and CMG discussed those risks, and their controls, in particular. Risk scores were also reviewed throughout. CMG's specific comments are contained in the attached SRR at Annex A, which also includes an overview of CMG's general discussions about the risk register.

2. Operational risk and risk assurance mapping

2.1. It is important that the existing operational risk system is revitalised, and that the system works hand in hand with the planned approach to risk assurance, as we develop it.

2.2. Following initial CMG consideration in February, the operational risk template used by teams was relaunched, with a view to reinvigorating teams' uptake of this process, and to using the same headings we will ultimately use in risk assurance mapping. This will serve the dual purpose of familiarising Heads and others with the broad headings, and of making our operational risk identification process more consistent between different teams. The revised template was relaunched to teams at the end of March, and the Head of Business Planning will now commence a period of working directly with other Heads and their teams to ensure that the new template is being adopted.

2.3. For the time being, we have agreed to use the following risk assurance areas:

- Planning
- Performance and risk management
- Quality management
- Financial management, systems and controls
- Information and evidence management
- People management
- Accountability
- Oversight and scrutiny

2.4. We consider that the latter will include our regulatory functions; if not, this could prospectively form an additional area of its own.

2.5. At the May CMG Risk meeting, we then considered how we could best adopt a proportionate risk assurance approach, given the lack of capacity to deliver this new function. The following was agreed as an outline methodology:

- Each of the listed risk assurance areas should be considered in turn.
- The relevant group to do this will be the CMG Plus group (CMG plus other team managers).
- In preparation for each of the meetings, we will draw on the following elements to identify the range of risks and controls to assure:
    - The HFEA strategy 2014-2017
    - Strategic Risk Register 2015/16
    - Team operational risk logs (transposed into the new template, to

assist read-across)
    - Business plan activities
    - Current projects / programmes and their associated risk logs
- We will also consider key questions to ask ourselves about risk assurance in each area.
- At each meeting we will then examine each risk, drawn out from the above, looking at the completeness and efficacy of the controls. We will:
    - Categorise the controls into the 'three lines of defence', where the first line of defence is operational management; the second line of defence would be CMG/AGC/Authority, the third line of defence would be internal audit, and the final (least-preferred) option would be external audit or another external agency.
    - Know how we can be sure each control is effective (ie, not just 'is it in place', but how is it monitored, and how often) – so that we can provide convincing assurance to AGC and the Authority, and to ourselves.
    - Identify improvements needed in our controls, including gaps.
    - Rate our controls for each risk area as 'inadequate', 'requires improvement', 'good', or 'outstanding' (against defined criteria for each area).

2.6. CMG agreed this outline approach, and concluded that in order to do this exercise successfully with our limited resources, it will be critical to adjust the way in which we use our DH internal audit capacity. It will also be important to define the parameters and rate of progress very carefully, to ensure that staff are able to participate fully and that the exercise is both worthwhile and proportionate.

2.7. The next step will be to work closely with DH internal audit to incorporate risk assurance workshops into our existing internal audit programme, so that the relevant arrangements can be put in place. The aim should be to focus on the most relevant areas first, and to draw up a timetable for delivery that fully addresses all the areas listed over (say) the next two to three years.

3. Recommendation

3.1. The Audit and Governance Committee is asked to note the above update on recent CMG discussions about strategic risk and risk assurance.

3.2. Comments are invited on the latest edition of the risk register, and on the other matters set out in this paper.

Annex A

HFEA Strategic Risk Register 2015/16

Risk summary: high to low residual risks

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

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

Recent review points:

CMG November 2014 (start - ⊙) ⇨ CMG February 2015 ⇨ AGC and Authority March 2015 ⇨ **CMG 20 May 2015 (latest review)**

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

CMG overview

20 May CMG risk meeting:

- CMG updated the controls and the scores throughout.
- Since March AGC approved our revised definition of inherent risk, CMG also reviewed the current inherent risk scores, but the review did not result in any changes.
- CMG noted AGC's discussion in March about the capability risk (C1) and its interaction with capacity (in the context of turnover and induction/probation periods for new staff members). CMG agreed that although the current period of high turnover seems to be coming to an end, this risk could recur, and should therefore be retained.
- AGC specifically requested that the tolerance level for this risk (set low, at 6) should be reviewed by CMG. The reduction in overall staffing numbers over the past few years has left us with little resilience, particularly in specialist and small functions, and so turnover could affect capability more in some instances, with possible impacts on strategic delivery. Therefore, CMG agreed that our tolerance for the capability risk needed to remain low, even though the risk level was now reducing. The tolerance level is therefore unchanged, and the risk is still currently above tolerance (although the residual risk has been reduced slightly), since the reduction in turnover is only just becoming apparent.
- CMG also agreed that there should be an SMT discussion in the near future about how best to instil and maintain good records management practices and learning in the organisation, given that this was not currently explicitly part of anyone's role. Having TRIM training and general guidance and induction in records management, was currently listed as a control under several risks. This was different from the technical issues relating to possibly replacing TRIM, or to previous discussions about implementing the retention schedule.

Criteria for Inclusion of Risks:

- Whether the risk results in a potentially serious impact on delivery of the HFEA's strategy or purpose.
- Whether it is possible for the HFEA to do anything to control the risk (so external risks such as weather events are not included).

Rank:

Risks are arranged above in rank order according to the severity of the current residual risk score.

Risk Trend:

The risk trend shows whether the threat has increased or decreased recently. The direction of arrow indicates whether the risk is: Stable ⇔ , Rising ⇧ or Reducing ⇩.

Risk Scoring System:

See last page.

Assessing Inherent Risk:

Inherent risk is usually defined as 'the exposure arising from a specific risk before any action has been taken to manage it'. This can be taken to mean 'if no controls at all are in place'. However, in reality the very existence of an organisational infrastructure and associated general functions, systems and processes does introduce some element of control, even if no other mitigating action were ever taken, and even with no particular risks in mind. Therefore, in order for our estimation of inherent risk to be meaningful, CMG 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.' (Agreed at March 2015 AGC.)

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

Causes/sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Inspection/reporting failure.	Inspections are scheduled for the whole year, using licence information held on Epicentre, and items are also scheduled to committees well in advance.	In place – Debra Bloor	Below tolerance for the time being, following recent recruitment and new staffing model.
	Audit of Epicentre to reveal any data errors.	Due for completion June 2015 – Sam Hartley	
	Inspector training, competency-based recruitment, induction process, SOPs, QMS, and quality assurance all robust.	In place – Debra Bloor	
Monitoring failure.	Outstanding recommendations from inspection reports are tracked and followed up by the team.	In place – Debra Bloor	
Unresponsiveness to or mishandling of non-compliances or grade A incidents.	Update planned to compliance and enforcement policy. Authority workshop took place in March 2015. More work to follow, including input from Committee Chairs and revised policy to September Authority alongside a set of other related Compliance team updates.	Partly complete – revision will go to September 2015 Authority – Debra Bloor	
	Staffing model changed to increase resilience in inspection team for such events – dealing with high-impact cases, additional incident inspections, etc..	Done – Debra Bloor – May 2015	
Insufficient inspectors or licensing staff	Recruitment completed for clinical and scientific inspectors.	In place – Debra Bloor	
	Recruitment completed for licensing team member.	In place – Sam Hartley	

Recruitment difficulties and/or high turnover/churn in various areas; resource gaps and resource diversion into recruitment and induction, with impacts felt across all teams.	So far recruitment rounds for inspectors have yielded sufficient candidates, although this has required going beyond the initial ALB pool to external recruitment in some cases.	Managed as the situation evolves – Debra Bloor	
	NHS Jobs account changed so that vacancies now appear under an HFEA identity rather than a CQC identity (with CQC continuing to administer), so as to address the cause of misunderstandings by many job candidates.	Done – May 2015 – Rachel Hopkins	
	Additional temporary resources available during periods of vacancy and transition.	In place – Rachel Hopkins	
	Group induction sessions put in place where possible.	In place – Debra Bloor	
Resource strain itself can lead to increased turnover, exacerbating the resource strain.	Operational performance, risk and resourcing oversight through CMG, with deprioritisation of work an option.	In place – Paula Robinson	
Unexpected fluctuations in workload (arising from eg, very high level of PGD applications received, including complex applications involving multiple types of a condition; high levels of non-compliances either generally or in relation to a particular issue).	New staffing model developed, to release an extra inspector post out of existing establishment. This has increased general resilience so as to enable more flex when there is an especially high inspection/report writing/application processing workload.	Done – Debra Bloor – May 2015	
	PGD workshop annually with the sector to increase their insight into our PGD application handling processes and decision-making steps; coupled with our increased processing times from efficiency improvements since 2013 (acknowledged by the sector).	In place and annual – Debra Bloor	
Some unanticipated event occurs that has a big diversionary impact on key resources, eg, several major Grade A incidents occur at once.	Addressed by new staffing model.	Done – Debra Bloor – May 2015	
	Compliance and enforcement policy review (see above) will improve handling processes for incidents and non-compliance.	Partly complete – revision will go to September 2015 Authority – Debra Bloor	

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

Causes/sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Failures or weaknesses in decision making processes.	Keeping up to date the standard operating procedures (SOPs) for licensing, representations and appeals.	In place – Sam Hartley	At tolerance.
	Learning from recent representations experience incorporated into processes.	In place – Sam Hartley	
	Appeals Committee membership maintained – vacancy filled.	In place – Sam Hartley	
	Staffing structure for sufficient committee support.	In place – Sam Hartley	
	Decision trees; legal advisers familiar.	In place – Sam Hartley	
	Proactive management of quoracy for meetings.	In place – Sam Hartley	
	New T&S licences delegated to ELP and now in place. Licensing Officer due to become live.	Delegation to be returned to in 2016 review of SOs. Licensing Officer role to take decisions from ELP due end June 2015.	
Failing to demonstrate competence as a regulator	Review of compliance and enforcement policy (in progress).	Partly complete – revision will go to September 2015 Authority – Debra Bloor	
	Inspector training, competency-based recruitment, induction process, SOPs, quality management system (QMS) and quality assurance all robust.	In place – Debra Bloor	

Effect of publicised grade A incidents.	Staffing model changed to build resilience in inspection team for such events – dealing with high-impact cases, additional incident inspections, etc.	Done – Debra Bloor – May 2015	
	SOPs and protocols with Communications team.	In place – Debra Bloor	
	Fairness and transparency in licensing committee information.	In place – Debra Bloor	
	Dedicated section on website, so that the public can openly see our activities in the broader context.	In place – Debra Bloor	
Administrative or information security failure, eg, document management, risk and incident management, data security.	Staff have annual information security training (and on induction).	In place – Dave Moysen (next round is due in Q1 of 2015/16)	
	TRIM training and guidance/induction in records management in place.	Internal ownership of this function will be decided by SMT in the near future – end June 2015	
	The IfQ website management project will be reviewing the retention schedule.	By December 2015 – Juliet Tizzard	
	Guidance/induction in handling FOI requests, available to all staff.	In place – Sam Hartley	
	Further work to be planned on records management in parallel with IT strategy	Syncs in with IT strategy work – Dave Moysen/Sam Hartley	
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 weaken cases that are otherwise sound.	Licensing SOPs, committee decision trees in place. Mitochondria tools in development.	Existing tools in place; mitochondria tools due by October 2015 – Sam Hartley.	
	Review of compliance and enforcement policy (in progress).	Partly complete – revision will go to September 2015 Authority – Debra Bloor	
	QMS and quality assurance in place in inspection team.	In place – Debra Bloor	

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

Causes/ sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Inability to extract reliable data from the Register.	Detailed planning and programme management in place to ensure this will be possible after migration. Migration strategy is in development. Decisions are being made about the degree of reliability required in each data field. For those fields where 100% reliability is needed, inaccurate or missing data will be addressed as part of delivery.	All aspects – detailed project planning in progress – Nick Jones (IfQ business case submitted Dec 2014; decision was delayed to April 2015 but then received)	Above tolerance. Managing these risks forms an intrinsic and essential part of the detailed project planning and tendering. Tendering is currently near completion. Following a lengthy delay, we received formal approval for both the data and digital elements of IfQ in late April 2015. The digital side of the programme has received only partial approval; full delivery will still require additional approvals after the first phase of work. There is a risk that this could lead to further long delays which would have a further negative impact. This would adversely affect the quality of the final product (rather than the existence of a final product).
Unable to work out how best to improve CaFC, and/or failure to find out what data/information patients really need.	Stakeholder engagement and user research is in place as intrinsic part of programme approach.	In place and ongoing – Dec 2014 onwards – Nick Jones	
Stakeholders not on board with the changes.	In-depth stakeholder engagement to inform the programme's intended outcomes, products and benefits – including user research consultation, expert groups and Advisory Board.	In place and ongoing – Juliet Tizzard / Nick Jones	
Cost of delivering better information becomes too prohibitive.	Costs taken into account as an important factor in consideration of contract tenders.	In place – Dec 2014 - May 2015 – Nick Jones	
Redeveloped website does not meet the needs and expectations of our various user types.	Programme approach and 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. Tendering and selection process includes clear articulation of needs and expectations.	In progress – delivery by end Mar 2016 – Juliet Tizzard	

Government and DH permissions structures are complex, lengthy, multi-stranded, and sometimes change mid-process.	Initial external business cases agreed and user research completed. Final business case for whole IfQ programme submitted.	In place (Nov 2014) – Juliet Tizzard In place (Dec 2014) – Nick Jones (decision received April 2015)	
Resource conflicts between delivery of website and business as usual (BAU).	Backfilling to free up the necessary staff time, eg, Websites and Publishing Project Manager post backfilled to free up core staff for IfQ work.	In place – Juliet Tizzard	
Delivery quality will be very supplier dependent. It is also likely to involve multiple different suppliers and 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 for other suppliers.	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 during the Sprint Zero start-up phase. Sound project management practices in place to monitor. Previous lessons learned and knowledge exist in the organisation from managing some previous projects where poor supplier delivery was an issue requiring significant hands-on management. Ability to consider deprioritising other work, through CMG, if necessary.	In place – Juliet Tizzard	
New CMS (content management software) is ineffective or unreliable.	CMS options being scrutinised as part of project.	In progress – Jan/Feb 2015 (depending on approval) – Juliet Tizzard	
Communications infrastructure incapable of supporting the planned changes.	Needs to be updated as part of IfQ in order to support the changes.	In place – set out in business case – Juliet Tizzard (Dec 2014)	

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

Causes/ sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Risks associated with data migration to new structure, together with records accuracy and data integrity issues.	IfQ programme groundwork focusing on current state of Register. Intensive planning in progress, including detailed research and migration strategy.	In place – Nick Jones/Dave Moysen	At tolerance. This risk is being intensively managed – a major focus of IfQ detailed planning work, particularly around data migration.
Historic data cleansing is needed prior to migration.	A detailed migration strategy is in place, and a data cleansing step forms part of this (the migration itself will occur much later).	In place – Nick Jones/Dave Moysen	
Increased reporting needs mean we later discover a problem, or that an unanticipated level of accuracy is required, with data or fields which we do not currently focus on or deem critical for accuracy.	IfQ planning work incorporates consideration of fields and reporting needs are agreed. Decisions about the required data quality for each field were 'future proofed' as much as possible through engagement with stakeholders to anticipate future needs and build these into the design.	In place – Nick Jones	
Reliability of existing infrastructure systems – (eg, Register, EDI, network, backups).	Maintenance of desktop, network, backups, etc. core part of IT business as usual delivery.	In place – Dave Moysen	
System interdependencies change / are not recognised	Strong interdependency mapping being done between IfQ and business as usual.	Done – Nick Jones – April 2015	

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

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

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

Causes/sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Complex and controversial area.	Panel of legal advisors from various firms at our disposal for advice, as well as in-house Head of Legal.	In place – Peter Thompson	Above tolerance. Two cases are awaiting judgments as at the end of May 2015. We expect a resolution on both shortly.
	Evidence-based policy decision-making and horizon scanning for new techniques.	In place – Hannah Verdin	
	Robust and transparent processes in place for seeking expert opinion – eg, external expert advisers, transparent process for gathering evidence, meetings minuted, papers available online.	In place – Hannah Verdin/Sam Hartley	
Lack of clarity in HFE Act and regulations, leading to the possibility of there being differing legal opinions from different legal advisers, that then have to be decided by a court.	Panel in place, as above, to get the best possible advice.	In place – Peter Thompson	
Decisions and actions of the HFEA and its committees may be contested.	Panel in place, as above.	In place – Peter Thompson	
	Maintaining, keeping up to date and publishing licensing SOPs, committee decision trees etc. Standard licensing pack completely refreshed and distributed to members/advisers April 2015.	In place – Sam Hartley	
	More work planned on enhancing committee tools to incorporate recent lessons learned.	In progress as at May 2015 – Catherine Drennan / Sam Hartley	

Subjectivity of judgments means the 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.	Scenario planning is undertaken at the initiation of likely action.	In place – Peter Thompson	
HFEA could face unexpected high legal costs or damages which it could not fund.	Discussion with the Department of Health would need to take place regarding possible cover for any extraordinary costs, since it is not possible for the HFEA to insure itself against such an eventuality, and not reasonable for the HFEA's small budget to include a large legal contingency.	In place – Peter Thompson	
Legal proceedings can be lengthy and resource draining.	Panel in place, as above, enabling us to outsource some elements of the work.	In place – Peter Thompson	
	Internal mechanisms (such as the Corporate Management Group, CMG) in place to reprioritise work should this become necessary.	In place – Peter Thompson	
Adverse judgments requiring us to alter or intensify our processes, sometimes more than once.	Licensing SOPs, committee decision trees in place.	In place – Sam Hartley.	
	Work planned to explore other relevant processes in light of lessons learned following a recent judicial review judgment.	In progress as at May 2015 – Catherine Drennan / Sam Hartley	

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

Causes/ sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Confidentiality breach of Register data.	Staff have annual compulsory security training to guard against accidental loss of data or breaches of confidentiality. Secure working arrangements for Register team, including when working at home.	In place – Dave Moysen	At tolerance.
Loss of Register or other data.	As above.	In place – Dave Moysen	
	Robust information security arrangements, in line with the Information Governance Toolkit, including a security policy for staff, secure and confidential storage of and limited access to Register information, and stringent data encryption standards.	In place – Dave Moysen	
Cyber-attack and similar external risks.	Secure system in place as above, with regular penetration testing.	In place – Dave Moysen	
Infrastructure turns out to be insecure, or we lose connection and cannot access our data.	IT strategy agreed, including a thorough investigation of the Cloud option, security, and reliability.	In place – Dave Moysen	
	Deliberate internal damage to infrastructure, or data, is controlled for through off-site back-ups and the fact that any malicious tampering would be a criminal act.	Done – March 2015 – Nick Jones	
Business continuity issue.	BCP in place and staff communication procedure tested. A period of embedding the policies is now in progress.	In place (Jan 2015) – Sue Gallone	

Register data becomes corrupted or lost somehow.	Back-ups and warehouse in place to ensure data cannot be lost.	In place – Nick Jones/Dave Moysen	
Other HFEA data (system or paper) is lost or corrupted.	As above. Staff have annual compulsory security training to guard against accidental loss of data or breaches of confidentiality.	In place – Dave Moysen	

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

Causes/ sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Poor record keeping	Refresher training and reminders about good records management practice.	Ownership of this function will be decided by SMT in the near future – end June 2015	Above tolerance. Although we have some good controls in place for dealing with PQs and other externally generated requests, it should be noted that we cannot control incoming volumes, which in January 2015 were among the highest we have ever experienced. It is not yet possible to tell if further high volumes will occur during the mitochondria project and the subsequent start-up of applications processing.
	TRIM review and retention policy implementation work – subsumed by IT strategy.	To sync in with IT strategy – Dave Moysen/Sam Hartley	
	Audit of Epicentre information	In progress – for completion June 2015 – Sam Hartley	
Excessive demand on systems and over-reliance on a few key expert individuals – request overload – leading to errors	PQs, FOIs and OTRs have dedicated expert staff/teams to deal with them. If more time is needed for a complex PQ, attempts are made to take the issue out of the very tightly timed PQ process and replace this with a more detailed and considered letter back to the enquirer so as to provide the necessary level of detail and accuracy in the answer. We also refer back to previous answers so as to give a check, and to ensure consistent presentation of similar data.	In place – Juliet Tizzard / Nick Jones	
	PQ SOP revised and log created, to be maintained by new Committee and Information Officer/Scientific Policy Manager	In place - Sam Hartley	

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. This, and ongoing issues with the very high volume being received at present, will be raised with DH when the framework agreement is next reviewed. HFEA's suggested answer and DH's final submission both to be captured in new PQ log.	In place – Sam Hartley / Peter Thompson Date of next review to be confirmed shortly – 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	

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

Causes/ sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Data accuracy in Register submissions.	Continuous work with clinics on data quality, including current verification processes, steps in the OTR process, regular audit alongside inspections, and continued emphasis on the importance of life-long support for donors, donor-conceived people and parents.	In place – Nick Jones	At tolerance (which is very low for this risk).
	Audit programme to check information provision and accuracy.	In place – Nick Jones	
	IfQ work will identify data accuracy requirements for different fields as part of the migration process, and will establish more efficient processes.	In progress – June 2015 – Nick Jones	
	If subsequent work or data submissions reveal an unpreventable earlier inaccuracy (or an error), we explain this transparently to the recipient of the information, so it is clear to them what the position is and why this differs from the earlier provided data.	In place – Nick Jones	
Issuing of wrong person's data.	OTR process has an SOP that includes specific steps to check the information given and that it relates to the right person.	In place – Nick Jones	
Process error or human error.	As above.	In place – Nick Jones	

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

Causes/ sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Lack of counselling availability for applicants.	Counselling service pilot being established with external contractor.	Set-up in progress – Nick Jones – Jun 2015	At tolerance. The pilot counselling service will be in place from June onwards, and we will make a further assessment shortly based on early uptake and the delivery experience.
Insufficient Register team resource to deal properly with OTR enquiries and associated conversations.	Additional member of staff dedicated to handling such enquiries.	In place – Nick Jones	
Risk of inadequate handling of a request.	Trained staff, SOPs and quality assurance in place.	In place – Nick Jones	
	SOPs being reviewed by Register staff, CMG and PAC-UK, as part of the pilot set-up. Contract signed with PAC-UK for pilot delivery.	Done (May 2015) – In June the management of the Pilot will transfer to Rosetta Wotton.	

Risk area	Description and impact	Strategic objective linkage	Risk scores			Recent trend	Risk owner
Financial viability FV 1: Income and expenditure	There is a risk that the HFEA could significantly overspend (where significantly = 5% of budget, £250k)	Efficiency, economy and value: ensuring the HFEA remains demonstrably good value for the public, the sector and Government.	Inherent risk level:			⊙ ⇔ ⇔ ⇔	Sue Gallone
			Likelihood	Impact	Inherent risk		
			4	4	16 High		
			Residual risk level:				
			Likelihood	Impact	Residual risk		
			4	**3**	**12 High**		
			Tolerance threshold:		9 Medium		

Causes/ sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Fee regime makes us dependent on sector activity levels.	Activity levels are tracked and change is discussed at CMG, who would consider what work to deprioritise and reduce expenditure.	Monthly (on-going) – Sue Gallone	Above tolerance, but 2014/15 overspend was able to be met from reserves.
	Fees Group created enabling dialogue with sector about fee levels.	In place. First meeting 29-10-14; Apr and Oct each year, ongoing – Sue Gallone	
GIA funding could be reduced due to changes in Government/policy	A good relationship with DH Sponsors, who are well informed about our work and our funding model.	Quarterly meetings in place – Sue Gallone	
	Annual budget agreed with DH Finance team alongside draft business plan submission.	December annually – Sue Gallone	
	Budget confirmation for 2015/16 obtained. Capital allocation is outstanding as at 27 May 2015.	In place – Sue Gallone Being actively sought from DH – Sue Gallone	
Budget setting process is poor due to lack of information from directorates	Quarterly meetings with directorates flags any short-fall or further funding requirements.	Quarterly meetings (on-going) – Morounke Akingbola	
Unforeseen increase in costs eg, legal, IfQ or extra in-year work required	Use of reserves, up to contingency level available. DH kept abreast of current situation and are a final source of additional funding if required. IfQ Programme Board regularly reviews budget / costs.	Monthly – Sue Gallone Monthly – IfQ Programme Board	
Upwards scope creep during projects, or emerging during early development of projects eg, IfQ.	Finance presence at Programme Board (PB) level. Periodic review of actual and budgeted spend by PB.	Ongoing – Wilhelmina Crown	
	Cash flow forecast updated.	Monthly (on-going) – Morounke Akingbola	

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

Causes/ sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
High turnover, sick leave etc. leading to temporary knowledge loss and capability gaps.	People strategy will partially mitigate. Mixed approach of retention, staff development, and effective management of vacancies and recruitment processes.	Done – May 2015 – Rachel Hopkins	Above tolerance. This risk and its controls currently focus on capability, rather than capacity. There are obviously linkages, since managing turnover and churn also means managing fluctuations in capability and ensuring knowledge and skills are successfully nurtured and/or handed over. Now that the period of highest turnover appears to be ending, CMG has reduced the likelihood of this risk, but still decided to retain it, since high turnover could recur. CMG also reviewed the tolerance level for this risk, and agreed it should remain at 6. Since the HFEA has become a much smaller organisation over the past few years, leaving less intrinsic resilience, it seems prudent to set a low tolerance threshold for this risk.
	A programme of development work is planned to ensure staff have the skills needed, so as to ensure they and the organisation are equipped under any future model, maximising our resilience and flexibility as much as possible. Staff can access civil service learning (CSL); organisational standard is five working days per year of learning and development for each member of staff.	In place – Rachel Hopkins	
	Organisational knowledge captured via records management (TRIM), case manager software, project records, handovers and induction notes, and manager engagement.	In place – Rachel Hopkins	
The new UK government may implement further cuts across all ALBs, resulting in further staffing reductions. This would lead to the HFEA having to reduce its workload in some way.	The HFEA has already been proactive in reducing its headcount and other costs to minimal levels over a number of years. We have also already been reviewed extensively (including the McCracken review). Although turnover is currently reducing to more normal levels, this risk will be retained on the risk register, and will continue to receive ongoing management attention.	In place – Peter Thompson	

Poor morale leading to decreased effectiveness and performance failures.	Engagement with the issue by managers. Ensuring managers have team meetings and one-to-one meetings to obtain feedback and identify actions to be taken.	In place – Peter Thompson	
	Staff survey and implementation of outcomes, following up on Oct 2014 all staff conference.	Survey done (Jan 2015) – Rachel Hopkins Follow-up communications and implementation in place (Staff Bulletin etc.) – Peter Thompson	
Differential impacts of IfQ-related change and other pressures for particular teams could lead to specific areas of knowledge loss and low performance.	Staff kept informed of likely developments and next steps, and when applicable of personal role impacts and choices.	In place – Nick Jones	
	Policies and processes to treat staff fairly and consistently, particularly if people are 'at risk'.	In place – Peter Thompson	
Additional avenues of work open up, or reactive diversions arise, and need to be accommodated alongside the major IfQ programme.	Careful planning and prioritisation of both business plan work and business flow through our Committees. Regular oversight by CMG.	In place – Paula Robinson	
	Early emphasis given to team-level service delivery planning for 2015, with active involvement of team members. Delivery (and resources) in Q1 to date were also considered at monthly CMG in May, and delivery is currently on track. CMG will continue to review this.	In place (Jan 2015) – 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 Civil Service Learning.	In place – Peter Thompson	
Regarding the current work on licensing mitochondrial replacement techniques, there is a possible future risk, beyond October 2015, that we will need to increase both capability and capacity in this area, depending on uptake (this is not yet certain).	Future needs (capability and capacity) relating to mitochondrial replacement techniques and licensing applications are starting to be considered now, but will not be known for sure until later. No controls can yet be put in place, but the potential issue is on our radar.	New issue for consideration – Juliet Tizzard	

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

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

RISK MANAGEMENT SCORING MATRIX

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

Risk Score = Impact x Likelihood

HFEA Internal Audit Plan 2015/16

This plan was finalised at the HFEA Audit and Governance Committee on 18th March 2015. It comprises an assessment of current risks, the audit plan itself, and a summary of review areas covered across the last three years.

Assessment of current risks:

The table below summarises the five risks in the latest HFEA Strategic Risk Register (January 2015) which have a residual risk of 'High' and a status of 'above tolerance.

Risk Area	Description and impact	Residual risk level	Status	Causes/sources
Legal Challenge	There is a risk that the HFEA is legally challenged in such a way that resources are diverted from strategic delivery.	**15 (High)**	Above tolerance	• Complex and controversial area; • Lack of clarity in Act and Regulations, leading to the possibility of there being differing legal opinions from different legal advisers, that then have to be decided by a court; • Decisions and actions of the HFEA and its Committees may be contested; • Subjectivity of judgments means the 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; • HFEA could face unexpected high legal costs or damages which it could not fund; • Legal proceedings can be lengthy and resource draining; and • Adverse judgments requiring us to alter or intensify our processes, sometimes more than once.
Information for Quality	If the information for Quality (IfQ) Programme does not enable us to provide better information and data, and improved engagement channels, patients will not be able to access the improved information they need to assist them in making important choices.	**12 (High)**	Above tolerance	• Inability to extract reliable data from the Register; • Unable to work out how best to improve CAFC, and/or failure to find out what data/information patients really need; • Stakeholders not on board with the changes; • Cost of delivering better information becomes too prohibitive; • Website redevelopment project fails to deliver or new website is inadequately designed; • Government and DH permissions structures are complex, multi-stranded, and sometimes change mid-project; • Resource conflicts between delivery of website and Business as Usual;

Risk Area	Description and impact	Residual risk level	Status	Causes/sources
				• New CMS (content management software) is ineffective or unreliable; • Communications infrastructure incapable of supporting the planned changes; and • Contractor failure – delivery is highly contractor dependent.
Data	There is a risk that incorrect data is released in response to a Parliamentary Question (PQ), or a Freedom of Information (FOI) or Data Protection request.	**12 (High)**	Above tolerance	• Poor record keeping; • Excessive demand on systems and over-reliance on a few key expert individuals – request overload – leading to errors; • DH altering careful drafting prior to submission, without always checking the response back with us; and • 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.
Income and Expenditure	There is a risk that the HFEA could significantly overspend (where significantly = 5% of budget, £250k).	**12 (High)**	Above tolerance	• Fee regime makes us dependent on sector activity levels; • GIA funding could be reduced due to changes in Government/policy • Budget setting process is poor due to lack of information from directorates; • Unforeseen increase in costs e.g. legal, or extra in-year work required; and • Upwards scope creep during projects, or emerging during early development of projects e.g. IfQ.
Capability	There is a risk that the HFEA experiences unforeseen knowledge and capability gaps, threatening delivery of the strategy.	**12 (High)**	Above tolerance	• High turnover, sick leave etc. leading to temporary knowledge loss and capability gaps; • Poor morale leading to decreased effectiveness and performance failures; • Differential impacts of IfQ-related change and other pressures for particular teams could lead to specific areas of knowledge loss and low performance; and • Additional avenues of work open up, or reactive diversions arise, and need to be accommodated alongside the major IfQ programme.

Internal Audit Plan 2015/16:

Based on the assessment of current risks above and discussions with HFEA senior management and the Audit Committee Chair, the table below sets out the reviews included in the final 2015/16 internal audit plan.

Suggested review	Rationale for inclusion	Scope	Estimated Audit days	Review date
Requests for Information	Links to the Data risk area	The HFEA may be required to release information as a result of: • Parliamentary Questions (PQs); • Freedom of Information (FOI) requests; and • Data Protection (DP) requests. We will examine current policies and procedures for the release of information under these circumstances and consider whether: • Current policies and procedures cover all relevant information held by the HFEA to which PQs, FOI and DP requests might relate; • Authorisation for the release of information is restricted to the appropriate committees and/or individuals; and • Risks in relation to the release of sensitive information have been identified, are regularly monitored, and are aligned to mitigating controls.	10	Mid August 2015
Incident Handling	Key regulatory activity	It is a requirement of licensed centres to report adverse incidents to the HFEA, where adverse incidents are described as 'any event, circumstance, activity or action which has caused, or has been identified as potentially causing harm, loss or damage to patients, their embryos and/or gametes, or to staff or a licensed centre.' NOTE: there are circa 500 incidents raised in each year in relation to circa 50,000 activities undertaken by the clinics. These incidents must be notified to the HFEA within 24 hours of their taking place. Once these reports are received, the HFEA must investigate and respond in line with its Compliance and Enforcement Policy. In addition, the HFEA has a responsibility to review and respond to complaints made against clinics. Circa 10 complaints are received each year. We will review current policies and procedures relating to incident and	12	September 2015

Suggested review	Rationale for inclusion	Scope	Estimated Audit days	Review date
		complaints reporting and responses and consider whether: • The HFEA's responses to reported incidents and complaints in the 12 months to the date of fieldwork have been conducted in line with agreed procedures; • The HFEA produces and retains sufficient documentation to support its response to incident and complaint reports; • Clear and sufficient information is available to all licensed centres to encourage the timely and appropriate reporting of adverse incidents and complaints; and • HFEA has appropriate performance reporting of all incidents and complaints in order to make appropriate management decisions on their relationships with the clinics.		
Data Migration – Register of Treatments	Links to the IfQ risk area	Building on the 2014/15 'Register of Treatments' review, we will: • Provide 'critical friend' input into the work performed by the HFEA to migrate data to the new Register of Treatments database; • Test a sample of data between the old and new Registers to verify the accuracy and completeness of data.	12	January 2016
Audit management		All aspects of audit management to include: • Attendance at liaison meetings and HFEA audit committees; • Drafting committee papers/progress reports; • Follow-up work; • Drafting 2016/17 audit plan; • Resourcing and risk management; and • Contingency.	6	-
		Total	**40**	

Internal Audit coverage 2013/14 - 15/16:

Review area	High-level scope	2013/14	2014/15	2015/16
Strategy/Compliance				
Francis and McCracken	Robust arrangements are in place to respond to the recommendations of the Francis and McCracken reports.	4		
Corporate Governance	An assessment of the efficacy of key HFEA committees	4		
Risk Management	Review and testing of the arrangements in place for managing risk at all levels across HFEA, including monitoring, filtering and escalation processes.	4		
Internal Policies	Review of the HFEA's arrangements to monitor, review and refresh key policies, procedures and terms of reference.		4	
Operational				
Requests for information	Review of policies and procedures in relation to Parliamentary Questions (PQs), Freedom of Information (FOI) requests and Data Protection (DP) requests.			4
Incident Handling	Review of current policies and procedures relating to incident and complaints reporting and responses			4
Financial				
Payroll and expenses	Accuracy and completeness of payments payroll and expense payments. Compliance with HMRC rules of payments for expenses and emoluments made to committee members	4		
Standing Financial Instructions	Assurance over current standing financial instructions, including a comparison with HFEA's existing arrangement versus good/best practice.		4	
Information Technology				
Information for Quality	Assurance over the IfQ programme using PwC's 'Twelve Elements Top Down Project Assurance Model'.		4	
Register of treatments	'Critical friend' input into key project meetings in relation to the migration of data to the new register of treatments.		4	
Data migration – Register of treatments	'Critical friend' input into the work performed by the HFEA to migrate data to the new Register of Treatments database. Testing a sample of data between the old and new Registers to verify the accuracy and completeness of data.			4

ANNUAL ASSURANCE REPORT 2014/2015

Human Fertilisation and Embryology Authority

Health Group Internal Audit Service

Background

In order to be able to provide an annual opinion for 2014/15 to the Human Fertilisation and Embryology Authority's Accounting Officer, it is necessary to consider the work undertaken by Internal Audit over the course of that year, the outcomes of that work and feedback from management on improvements to their areas of responsibility as a result of that work. This together with wider intelligence gathered from all sources of assurance (including the NAO and the Major Projects Authority) and performance reporting, inform the Head of Internal Audit's view of controls, governance and risk management. This report provides an overall summary of Internal Audit work delivered in 2014/15 as well as including the formal annual opinion of the Head of Internal Audit.

Executive Summary

Over the last few years, the Human Fertilisation and Embryology Authority has developed its regulatory model and its status within the NHS and beyond. To achieve its objectives, both executive and non-executive management have undertaken significant work to ensure that the organisation's governance structures including internal control and risk management arrangements are fit for purpose. Internal Audit has continuously provided assurance and advice where appropriate to support management's efforts.

Our opinion is based solely on our assessment of whether the controls in place support the achievement of management's objectives as set out in our 2014/15 Internal Audit Plan and Individual Assignment Reports.

We used the following levels of rating (in line with the agreed definitions across all government departments) when providing our internal audit report opinions:

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

2014/15 Performance Summary

Reviews carried over from 2013/14 plan	**0**
2014/2015 Agreed programme	**4**
Total reviews deferred to complete in 2015/16	**1**
Total reviews dropped in 2014/15	**0**
Total to deliver 2014/15 plus 2013/14 Carried over	**4**
Total reviews completed including carry over from 2013/14	**3**
Total remaining on plan to carry forward to complete in 2015/16	**1**
% of programme completed	**75%**
% of programme to carry forward to complete in 2015/16	**25%**

Total Number of Audits completed by rating (excludes follow up of recs)

Total no reviews completed (incl. agreed draft ratings) 2014/15	Substantial	Moderate	Limited	Unsatisfactory	Advisory	Total Rated Work	Advisory Work
3	0	1	1	0	1	**2**	**1**
						66%	**34%**

Internal Audit Plan Delivery 2014/15 - Assurance and Advisory Work Summary

#	Audit Title	Status	Outcome	Recommendations agreed by priority		
				High	Medium	Low
1	Information for Quality (IfQ)	Complete	Moderate	1	6	1
2	Internal Policies	Complete	Limited	2	0	0
3	Standing Financial Instructions	Complete	No rating – advisory review	N/A		
4	Register of Treatments	Partially complete	In process – Agreed with management to continue 'critical friend' input into 2015/16	N/A		
			Total	**3**	**6**	**1**

Compliance with Public Sector Internal Audit Standards and Quality Assurance

The audit work delivered during 2014/15 has been governed by the requirements of the UK Public Sector Internal Audit Standards. HGIAS have conducted a self-assessment against the requirements which indicates that the Internal Audit arrangements continue to comply with the standards and are generally satisfactory. We also continue to operate a system of cold reviewing audit documentation to ensure compliance for individual audit reports.

Head of Internal Audit Opinion 2014/15

"In accordance with the requirements of the UK Public Sector Internal Audit Standards, I am required to provide the Accounting Officer with my annual opinion of the overall adequacy and effectiveness of the organisation's risk management, control and governance processes.

My opinion is based on the outcomes of the work that Internal Audit has conducted throughout the course of the reporting year and on the follow up action from audits conducted in the previous reporting year. There have been no undue limitations on the scope of Internal Audit work and the appropriate level of resource has been in place to enable the function to satisfactorily complete the work planned.

For the three areas on which I must report, I have concluded the following:

- In the case of **risk management:** Substantial
- In the case of **governance:** Moderate
- In the case of **control:** Moderate

Therefore, in summary, my overall opinion is that I can give **MODERATE assurance** to the Accounting Officer that the Human Fertilisation and Embryology Authority has had adequate

and effective systems of control, governance and risk management in place for the reporting year 2014/15.

Lynn Yallop

Head of Internal Audit

National Audit Office

Human Fertilisation and Embryology Authority

Audit completion report on the 2014-15 financial statement audit

REPORT TO THOSE CHARGED WITH GOVERNANCE
June 2015

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

Contents

Introduction: status of our audit

Introduction	This report summarises the key matters from our audit of the 2014-15 HFEA financial statements which we must report to those charged with governance before we finalise our audit work and certify the accounts.
What work have we completed?	We have completed our audit of the 2014-15 financial statements in accordance with International Auditing Standards (UK and Ireland) issued by the Financial Reporting Council and with the audit planning report presented to the Audit Committee in October 2014. We have also read the content of the draft annual report and the governance statement to confirm: • their consistency with the financial statements and our understanding of the business; • that the audited part of the remuneration report has been properly prepared; and • that the governance statement has been prepared in accordance with HM Treasury guidance. The total audit fee charged for the year is £27,500.

Actions for the Audit and Risk Committee

The Audit and Risk Committee should:

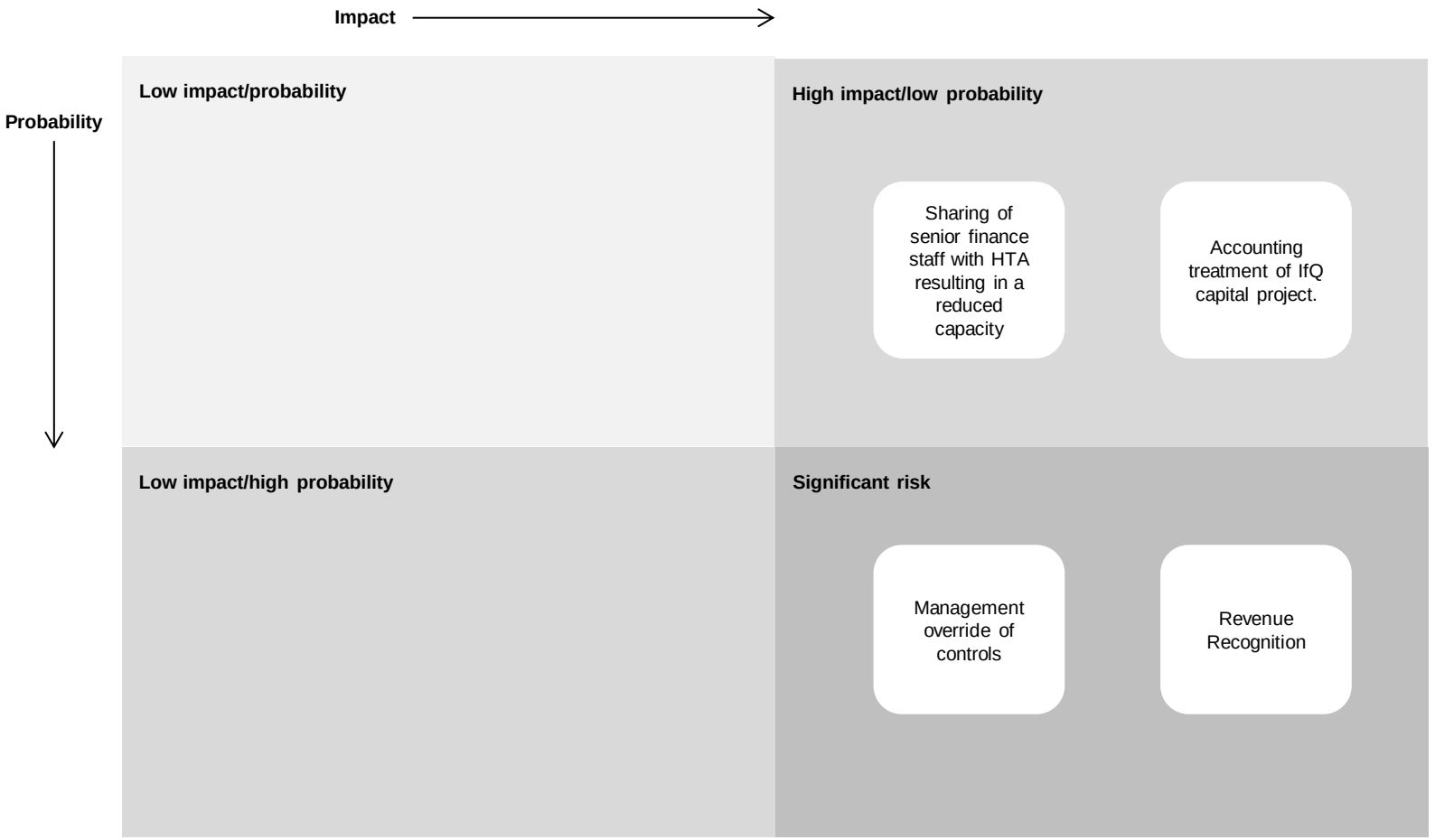
- Review the findings set out in this report, including the draft letters of representation and audit certificates at Appendix 1 and 2 respectively; and
- Consider whether the unadjusted misstatements, set out in the identified misstatements section (page 11) should be corrected. The Audit Committee minutes should provide written endorsement of management's reasons for not adjusting misstatements.

Introduction: status of our audit

What is the status of our audit? **Substantially complete**	At the time of writing this report, the audit is substantially complete. The following issues are outstanding: • Review of the final Annual Report and Accounts; • Director's final review of the audit work; • Review of Events After the Balance Sheet Date; and • Review of the final Consolidation Schedule The Accounting Officer will sign the annual report and accounts together with a letter of representation which is attached at Appendix 1.
What is our conclusion?	We anticipate recommending to the Comptroller and Auditor General (C&AG) that he should certify the 2014-15 financial statements with an unqualified audit opinion, without modification. The draft audit certificate is presented in Appendix 2 – Draft audit certificate.

Key audit findings:
Significant financial statement risks

We identified the risks below in our audit planning report presented to your Audit and Risk Committee on 1st October 2014. No additional risks have been determined in the course of our audit. Responses and findings against significant risks can be seen in the Key audit findings section of this report.



Key audit findings
Significant financial statement risks

ISA 240 Presumed Risks
Risk of Fraud through management override of controls and revenue recognition

Audit areas affected

- Pervasive

Key features

- The Auditing Standard ISA240 states that there is a risk in all entities that management override controls to perpetrate fraud. The standard required that auditors perform audit procedures to address this risk in the following areas;
  - Journal entries
  - Bias in accounting estimates
  - Significant unusual transactions
- There is also a presumed risk of fraud arising through revenue recognition

Audit Response

Controls & substantive work over

- Journal entries;
- Accounting estimates; and
- Significant unusual transactions
- Income

Findings

Observations and recommendations

- Controls were assessed to be robust and fully operational: no issues in relation to the above were identified through our audit work. Through our testing we are able to take assurance that there is no material misstatement due to management override of controls.
- We have carried out specific testing to address the risk of fraud through revenue recognition by reviewing the HFEA's audit compliance control and gaining assurance over accuracy and completeness of this revenue. We formed a prediction for licence fee revenue based on information derived from the CRM licence system and confirmed that the revenue recognised in the accounts was in line with this prediction.
- The audit procedures that we performed provided sufficient assurance that there is no material misstatement in the accounts in respect of income recognition.

The risks were addressed and sufficient assurance was obtained

Key audit findings - audit recommendations

Each issue has been given a priority rating to assist in assessing the level of potential risk associated with the finding. The levels are:

1	Major issues for the attention of senior management which may have the potential to result in a material weakness in internal control and/or impact on the ability of the CA&G to certify the accounts.
2	Important issues to be addressed by management in their areas of responsibility.
3	Problems of a more minor nature which provide scope for improvement.

Non-current assets *Review of the expected useful lives of assets*	Review of HFEA's Fixed Asset Register demonstrates that assets are often in use for longer than their estimated useful lives. This suggests lack of an appropriate assets replacement policy. In addition assets held beyond their useful lives may not be fit for purpose or may be costly to maintain. In addition there is a risk that asset valuation in the accounts could be misstated if the volume of nil net book value assets is high. Many of the assets on the Fixed Asset Register have been in use for twice as long as their useful lives Depreciating these assets over a longer period would have a significant impact on the net book value of the non-current assets and the depreciation charge in year. We are satisfied that at 31 March 2015 the impact of the nil net book value assets is not material to the accounts. There are however a significant number of assets that are likely to be used beyond this date which suggests the estimated useful lives currently used may not reflect the actual asset management policy and need revising.	2	We recommend that HFEA Finance performs ongoing review of the estimate of useful lives applied to assets to ensure they are an accurate reflection of their likely use. This will provide management with clear visibility of when assets need to be replaced and allow them to budget for it accordingly. We recommend that at the end of each financial year HFEA Finance assess the impact of the fully depreciated assets on the net book value of the non-current assets and the depreciation charge in year to ensure that balances disclosed are free from material misstatement.	Agreed. We are to conduct a detailed review of Useful Economic Lives (UEL) of all our fixed assets in conjunction with our IT team. This will commence in Q2 of 2015-16 business year.

Key audit findings - audit recommendations (continued)

Area	Issue	Priority	Recommendation	Management Response
Management Accounts Insufficient *documentation of challenge and review*	As part of the planned audit procedures we have evaluated the effectiveness of the high level controls. In doing so we have assessed the robustness of the budget setting process, the quality of the Monthly Management Accounts as well as the review and challenge process. We have found that although the budget setting process is robust and a review of variances and challenge are in place there was no formal documentation of challenge to the variances and directors' responses were not sufficient to enable us to place reliance. By improving the trail of management's review and challenge of the financial performance, HFEA would encourage greater transparency and robustness of the process. It would also give management better visibility of previous decisions and any emerging issues. Robust documentation of management's challenge would also increase the scope for reliance on the high level controls in performing our audit which in turn could lead to efficiencies.		HFEA Finance should maintain sufficient documentation to evidence the review and challenge of the Monthly Management Accounts by the Senior Management.	Agreed. We have email exchanges monthly about the management accounts and email summaries of the quarterly meetings, outlining issues by exception. Headlines are discussed at ST and with the Authority. We believe this is proportionate and efficient for our organisation. Advice on the documentation required for NAO's potential reliance on these controls would be welcome.

Key audit findings: other key findings

Identified misstatements	Misstatements that we have identified above our clearly trivial threshold of £1,500 and have not been adjusted are detailed in the identified misstatements section (page 10) . Uncorrected misstatements would decrease net assets by £11,721.60.
Financial statement disclosures	We have also made a number of other suggestions to improve narrative disclosures and to ensure completeness of the disclosures required under the FReM and other relevant guidance. The most significant of which are: • Disclosure of the redundancy package received by the previous Director of Finance and Facilities who left in 2014/15. • Show the split between Permanent Staff and Other staff in the staff costs note. • Amendment to the Related Party note to show clearly the split between expenditure relating to 13/14 and 14/15; accrued expenditure and invoiced expenditure.
Accounting policies and financial reporting	As part of our audit, we consider the quality and acceptability of HFEA's accounting policies and financial reporting: • The quality of financial reporting was good. The draft accounts presented for audit were of a good quality. • We considered the appropriateness of the accounting policies to the particular circumstances of the HFEA, judged against the objectives of relevance, reliability, comparability and understandability. We have no issues to raise on this matter. • In addition, the Annual Report was considered to be consistent with our understanding of the business, and was in line with the other information provided in the financial statements. • We will provide a verbal update on the audit of HFEA's consolidation schedule to the audit committee.
Regularity, propriety and losses	We found no items that raised issues in relation to regularity or propriety. There were no significant losses to report and account for.

Key audit findings: list of identified unadjusted misstatements

Unadjusted misstatements

Area	Issue	SoCNE Dr £	SoCNE Cr £	SoFP Dr £	SoFP Cr £
Other expenditure	Prior-period cut-off error which should have been accrued for; does not require adjustment.		11,721.60	11,721.60	

Follow up to key recommendations we made in the previous year

Area	What was the recommendation?	Response/Progress	Status
Provisions and contingent liabilities	We recommend that management review of the Accounts for next year is informed by the lessons learnt from this year so that sufficient time and resource can be built in to aid the Accounts production and review process. The completeness of disclosure of Provisions and Contingent Liabilities should be considered and new cases disclosed where there is the possibility of an outflow of resources as per IAS 37.	Accounts production and review took account of lessons learnt from the 2013/14 audit and there were no misstatements identified in the 2014/15 Provisions & Contingent Liabilities notes. Two contingent liabilities were promptly recognised and have been disclosed in the 2014/15 Contingencies note in the financial statements.	Implemented
Asset Valuations	HFEA should ensure their non-current asset register is reviewed on a periodic basis, given that their review in 2013-14 found assets no longer in use at an original cost of c.£200k.	A full review of the Fixed Asset Register was conducted in 2014/15 and a list of assets still in use with a nil net book value were identified. HFEA will need to review the useful economic life of different classes of assets to ensure that assets are not depreciated too quickly.	Keep in view
	However, in applying FREM 6.2.5 and IAS 16, reporting entities should ensure all tangible non-current assets shall be carried at valuation at the reporting period. This is not currently the case at HFEA, and while it is accepted that the impact may be immaterial on the accounts, HFEA need to ensure that this is considered.	HFEA have identified a significant number of assets on the Fixed Asset Register which are at nil net book value and still in use. We expect an exercise to be carried out in Quarter 2 of the 2015/16 financial year to identify the value of these assets in use.	Keep in view

Follow up to key recommendations we made in the previous year

Area	What was the recommendation?	Response/Progress	Status
Intra-Government balances	Finance should review categorisation of suppliers and customers to ensure that this corresponds with the information reported in the DH Consolidation return.	No issues were identified in this year's testing of Intra-government balances.	Implemented.
Cash & cash equivalents	HFEA should ensure that in-year bank reconciliations are performed for every month in 2014/15 and that reconciling items are followed up in subsequent months. Credit card balances should not be netted off from cash balances.	Controls around cash reconciliations in 2014/15 did not identify any weaknesses and the year-end cash reconciliation testing was carried out effectively. Credit card balances were correctly not netted off from cash balances in 2014/15.	Implemented.

Follow up to key recommendations we made in the previous year (continued)

Area	What was the recommendation?	Response/Progress	Status
Accruals	HFEA Finance should ensure accruals are supported by evidence that there is an obligation to pay at the end of the reporting period. Where this information is provided by other teams within the organisation, finance should obtain evidence to assure themselves that they are raising accruals for the correct amounts in the right years.	Finance have reviewed accruals raised by other teams in 2014/15 and no errors were found during our accruals testing.	Implemented
Annual Report	HFEA should consider the drafting of their 2014-15 Annual Report to ensure that the headings of Strategic Report and Directors' Report are included and that these sections of the report are fully compliant with Chapter 4A and 5 of Part 15 of the Companies Act 2006 and Schedule 7 of SI 2008 No 410 as required by the FReM.	HFEA implemented the required changes in the 2013/14 Annual Report and no major disclosure issues were identified in the 2014/15 Annual Report.	Implemented
Remuneration Report	As with the Annual Report, whilst the requirements of the Companies Act 2006 as interpreted by the FReM had broadly been addressed, there were a minor number of disclosures missing or that required amendment. Total employer pension contributions for HFEA as a whole were also inaccurate.	HFEA implemented the required changes in the 2013/14 Remuneration Report. No major disclosure issues were identified in the 2014/15 Remuneration Report.	Implemented

Implemented

Other matters for communication

Independence	We consider that we comply with Auditing Practices Board (APB) ethical standards and that, in our professional judgment, we are independent and our objectivity is not compromised. There are no relationships between us and HFEA that we consider to bear on our objectivity and independence.
International standards on Auditing (UK and Ireland)	We consider that there are no additional matters in respect of items requiring communication to you, per International Standards on Auditing, that have not been raised elsewhere in this report or our audit planning report. Items requiring communication cover: • Fraud • Going concern • HFEA's compliance with laws and regulations • Significant difficulties completing the audit • Disagreements or other significant matters discussed with management
Cooperation with other auditors	Internal Audit We reviewed the internal audit plan to gain an understanding of the work they performed during the year. This informed our planning and our consideration of the Governance statement.
Treatment of personal data	During the course of our audit we have had access to personal data to support our audit testing. We have established processes to hold this data securely within encrypted files and destroyed 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 on the NAO website: http://www.nao.org.uk/publications/0708/statement_personal_data.aspx

Appendix 1 – proposed letter of representation

[Client letterhead]

The Comptroller and Auditor General
National Audit Office
157-197 Buckingham Palace Road
Victoria
LONDON
SW1W 9SP

LETTER OF REPRESENTATION: HUMAN FERTILISATION & EMBRYOLOGY AUTHORITY 2014-15

I acknowledge as Accounting Officer of the Human Fertilisation & Embryology Authority my responsibility for preparing accounts that give a true and fair view of the state of affairs, net expenditure changes in tax payers equity and cash flows of the Human Fertilisation & Embryology Authority for the year ended 31 March 2015.

In preparing the accounts, I was required to:

• observe the accounts direction issued by the Secretary of State, including the relevant accounting and disclosure requirements and apply appropriate accounting policies on a consistent basis;
• make judgements and estimates on a reasonable basis;
• state whether applicable accounting standards have been followed and disclosed and explain any material departures in the accounts; and
• make an assessment that the Human Fertilisation & Embryology Authority is a going concern and will continue to be in operation throughout the next year; and ensure that this has been appropriately disclosed in the financial statements.

I confirm that for the financial year ended 31 March 2015:

• neither I nor my staff authorised a course of action, the financial impact of which is that transactions infringe the requirements of regularity as set out in Managing Public Money;
• having considered and enquired as to the Human Fertilisation & Embryology Authority's compliance with law and regulations, I am not aware of any actual or potential non-compliance that could have a material effect on the ability of the Human Fertilisation & Fertilisation Authority to conduct its business or on the results and financial position disclosed in the accounts;
• all accounting records have been provided to you for the purpose of your audit and all transactions undertaken by the Human Fertilisation & Embryology Authority have been properly reflected and recorded in the accounting records. All other records and related information, including minutes of all management meetings which you have requested have been supplied to you; and
• the information provided regarding the identification of related parties is complete; and the related party disclosures in the financial statements are adequate.

All material accounting policies as adopted are detailed in note 1 to the accounts.

INTERNAL CONTROL

I acknowledge as Accounting Officer my responsibility for the design and implementation of internal controls to prevent and detect error and I have disclosed to you the results of my assessment of the risk that the financial statements could be materially misstated.

I confirm that I have reviewed the effectiveness of the system of internal control and that the disclosures I have made are in accordance with HM Treasury guidance on the Governance Statement.

FRAUD

I acknowledge as Accounting Officer my responsibility for the design and implementation of internal controls to prevent and detect fraud and I have disclosed to you the results of my assessment of the risk that the financial statements could be materially misstated as a result of fraud.
I am not aware of any fraud or suspected fraud affecting the Human Fertilisation & Embryology Authority and no allegations of fraud or suspected fraud affecting the financial statements has been communicated to me by employees, former employees, analysts, regulators or others.

ASSETS

General
All assets included in the statement of financial position were in existence at the reporting date and owned by the Human Fertilisation & Embryology Authority, and free from any lien, encumbrance or charge, except as disclosed in the accounts. The statement of financial position includes all tangible assets owned by the Human Fertilisation & Embryology Authority.

Non-Current Assets
Only items, or groups of related items, costing £1,000 or more and with individual values over £250, are capitalised. They are valued at historic cost, as this is not materially different to fair value. Depreciation is calculated to reduce the net book amount of each asset to its estimated residual value by the end of its estimated useful life in the Human Fertilisation & Embryology Authority's operations.

Other Current Assets
On realisation in the ordinary course of the Human Fertilisation & Embryology Authority's operations the other current assets in the statement of financial position are expected to produce at least the amounts at which they are stated. Adequate provision has been made against all amounts owing to the Human Fertilisation & Embryology Authority which are known, or may be expected, to be irrecoverable.

LIABILITIES

General
All liabilities have been recorded in the statement of financial position. There were no significant losses in the year and no provisions for losses were required at the year-end.

Provisions
Provision is made in the financial statements for:
- Costs of early retirement.

Contingent Liabilities
Except as disclosed in the accounts, I am not aware of any pending litigation which may result in significant loss to the Human Fertilisation and Embryology Authority, and I am not aware of any action which is or may be brought against the Human Fertilisation and Embryology Authority under the Insolvency Act 1986.

OTHER DISCLOSURES

Results
Except as disclosed in the accounts, the results for the year were not materially affected by transactions of a sort not usually undertaken by the Human Fertilisation & Embryology Authority, or circumstances of an exceptional or non-recurring nature.

Unadjusted errors
I confirm that I am aware of the unadjusted error that is included on the attached schedule. I do not wish to correct this error as I consider the effect of this unadjusted error to be immaterial to the financial statements as a whole.

Events after the Reporting Period
Except as disclosed in the accounts, there have been no material changes since the reporting date affecting liabilities and commitments, and no events or transactions have occurred which, though properly excluded from the accounts, are of such importance that they should have been brought to notice.

To the best of my knowledge, there are no announcements scheduled to be included in the Chancellor of the Exchequer's Budget, to be given on 8 July, that would impact on the financial statements and disclosures.

Management of Personal Data
Except as disclosed in the Governance Statement, there have been no personal data related incidents in 2014-15 which are required to be reported.

Consolidation Return
The consolidation return is accurate and consistent with the statutory accounts, and is complete in respect of disclosures and the information required by the Department.

Peter Thompson
Chief Executive and Accounting Officer
Human Fertilisation & Embryology Authority

Appendix 2 – Draft audit certificate

Proposed audit certificate

HUMAN FERTILISATION & EMBRYOLOGY AUTHORITY 2014-15 FINANCIAL STATEMENTS
AUDIT CERTIFICATE AND C&AG'S REPORT

THE CERTIFICATE AND REPORT OF THE COMPTROLLER AND AUDITOR GENERAL TO THE HOUSES OF PARLIAMENT

I certify that I have audited the financial statements of the Human Fertilisation & Embryology Authority ("the Authority") for the year ended 31 March 2015 under the Human Fertilisation & Embryology Act 1990 amended to the Human Fertilisation & Embryology Act 2008. The financial statements comprise: the Statement of Comprehensive Net Expenditure, the Statement of Financial Position, the Statement of Cash Flows, the Statement of Changes in Taxpayers' Equity; and the related notes. These financial statements have been prepared under the accounting policies set out within them. I have also audited the information in the Remuneration Report that is described in that report as having been audited.

Respective responsibilities of the Accounting Officer and auditor
As explained more fully in the Statement of the Authority and Accounting Officer's Responsibilities, the Accounting Officer is responsible for the preparation of the financial statements and for being satisfied that they give a true and fair view. My responsibility is to audit, certify and report on the financial statements in accordance with the Human Fertilisation & Embryology Act 1990 amended to the Human Fertilisation & Embryology Act 2008. I conduct**ed** my audit in accordance with International Standards on Auditing (UK and Ireland). Those standards require me and my staff to comply with the Auditing Practices Board's Ethical Standards for Auditors.

Scope of the audit of the financial statements
An audit involves obtaining evidence about the amounts and disclosures in the financial statements sufficient to give reasonable assurance that the financial statements are free from material misstatement, whether caused by fraud or error. This includes an assessment of: whether the accounting policies are appropriate to the Authority's circumstances and have been consistently applied and adequately disclosed; the reasonableness of significant accounting estimates made by the Authority; and the overall presentation of the financial statements. In addition I read all the financial and non-financial information in the Annual Report to identify material inconsistencies with the audited financial statements. If I become aware of any apparent material misstatements or inconsistencies I consider the implications for my certificate.

I am required to obtain evidence sufficient to give reasonable assurance that the expenditure and income recorded in the financial statements have been applied to the purposes intended by Parliament and the financial transactions recorded in the financial statements conform to the authorities which govern them.

Opinion on regularity
In my opinion, in all material respects the expenditure and income recorded in the financial statements have been applied to the purposes intended by Parliament and the financial transactions recorded in the financial statements conform to the authorities which govern them.

Opinion on financial statements
In my opinion:
• the financial statements give a true and fair view of the state of the Authority's affairs as at 31 March 2015 and of its net expenditure, changes in taxpayers' equity and cash flows for the year then ended; and
• the financial statements have been properly prepared in accordance with the Human Fertilisation & Embryology Act 1990 amended to the Human Fertilisation & Embryology Act 2008 and Secretary of State directions issued thereunder.

Opinion on other matters
In my opinion:
• the part of the Remuneration Report to be audited has been properly prepared in accordance with the Secretary of State's directions issued under the Human Fertilisation & Embryology Act 1990 amended to the Human Fertilisation & Embryology Act 2008
• the information given in the Accounting Offer's report, and the management commentary included within the Annual Report, for the financial year for which the financial statements are prepared is consistent with the financial statements.

Matters on which I report by exception
I have nothing to report in respect of the following matters which I report to you if, in my opinion:
• adequate accounting records have not been kept or returns adequate for my audit have not been received from branches not visited by my staff; or
• the financial statements and the part of the Remuneration Report to be audited are not in agreement with the accounting records and returns; or
• I have not received all of the information and explanations I require for my audit; or
• the Governance Statement does not reflect compliance with HM Treasury's guidance.

Report
I have no observations to make on these financial statements.

Sir Amyas C E Morse
Comptroller and Auditor General

Date

National Audit Office
157-197 Buckingham Palace Road
Victoria
London
SW1W 9SP

Audit and Governance Committee Paper

Paper Title:	**Information Assurance**
Paper Number:	[AGC (10/6/2015) 460]
Meeting Date:	10 June 2015
Agenda Item:	**9**
Author:	Sue Gallone
For information or decision?	Information
Resource Implications:	None
Implementation	N/A
Communication	N/A
Organisational Risk	Not to have an assessment would undermine the Annual Governance Statement and improvement required may not be identified and acted upon.
Recommendation to the Committee:	The Committee is asked to note the SIRO's assessment of information governance and discuss.
Evaluation	Annually, to inform the consideration of the annual report and accounts
Annexes	A: compliance with IGT requirements

Information Assurance

Background

1. It is a Cabinet Office (CO) requirement that boards receive assurance about information risk management. This provides for good governance in its own right, ensures that the board is involved in information assurance and informs the Audit and Governance Committee's consideration of the Annual Governance Statement (AGS). The Senior Information Risk Officer (SIRO) makes an annual report to the Accounting Officer to inform the AGS and this paper provides that report for the Committee's purposes too. The report is also reviewed by the Senior Management Team (SMT).

2. The Department of Health (DH) requires arms length bodies (ALBs) to make a similar report to them, to inform their departmental reporting to CO. A preliminary report was made to DH in February 2015, at their request, subject to review and agreement by SMT and AGC in June 2015.

3. My assessment, and the reports, are based on the requirements of the NHS Information Governance toolkit (IGT) and the Security Policy Framework (SPF) Security policy framework - Publications - GOV.UK. The HFEA holds patient data although we do not use the patient information in the same way as the NHS institutions at which the IGT is aimed. The HFEA has attempted to complete the IGT on-line, although we have found the level of detail not to be appropriate to a small, self-standing organisation such as the HFEA and somewhat prescriptive. Therefore I have completed my assessment by interpreting these requirements for the HFEA and also by considering the requirements set out in the SPF.

4. ALBs are also asked to assess themselves and report against the 10 Steps to Cyber Security, the guidance issued as part of the Government's cyber security strategy 10 Steps to Cyber Security. My assessment is included in this report.

Recommendation

5. Members are asked to note the assessment set out in this paper.

Report

6. Annex A of this paper records compliance with the requirements of the NHS IGT, as appropriate to the HFEA.

7. The key actions the HFEA needs to implement from the IGT toolkit are:

- Communicate our policies (information governance and information security) and ensure these are understood
- Monitor compliance with policies
- Develop our information for service users
- Document information processes (this is planned in our Information for Quality programme)
- Review network security events more formally
- Risk assess information assets more formally
- Develop oversight of records management

8. There is also a need for me as SIRO to gain greater assurance that other technical IT areas are well controlled and to review evidence in all areas to support information provided by the Head of IT.

9. My high level assessment of the 10 areas relating to cyber security is:

   i. Information risk management – action required to formally risk assess information assets (as above)

   ii. Secure configuration – considered satisfactory, based on assurances from IT team

   iii. Network security - considered satisfactory, based on assurances from IT team

   iv. Managing user privileges – satisfactory

   v. User education and awareness – policies need to be communicated and assurance sought that these are understood

   vi. Incident management – satisfactory

   vii. Malware prevention – considered satisfactory, based on assurances from IT team

   viii. Monitoring – considered satisfactory, based on assurances from IT team

   ix. Removable media controls - satisfactory

   x. Home and mobile working – satisfactory.

10. The HFEA has a sound culture of protecting information and staff have a good understanding of the need and protocols. There have been no incidents of data

loss in 2014/15 and there is a good track record of properly protecting information and systems. Satisfactory penetration testing last took place in March 2012 and the Head of IT performs monthly vulnerability assessments. Further external penetration testing is planned for 2015/16 after the next server upgrade. There are clear instructions to staff, policies have been updated recently and are being communicated to staff. There are other actions to take, as identified above, to ensure full compliance with requirements.

11. On the basis of the information and assurances received from the Head of IT, and my observations, information security is not at risk at the HFEA. Information risk is being managed but there are areas to work on to be fully compliant with requirements. An action plan is being developed.

Annex A – HFEA's compliance with IGT requirements

Audit and Governance Committee

Paper Title:		**Implementation of Audit Recommendations – Progress Report**
Paper Number :		**[AGC (10/06/2015) 462 MA]**
Agenda Item:		**11**
Meeting Date:		10 June 2015
Author:		Wilhelmina Crown
For information or decision?		Decision
Resource Implications:		As noted in the enclosed summary of outstanding audit recommendations
Communication		CMG
Organisational Risk		As noted in the enclosed summary
Recommendation to the Committee:		AGC is requested to review the enclosed progress update and to comment as appropriate.

Annexes		**Summary of Recommendations**		
Recommendation Source	Status / Actions	**2011/12 to 2013/14**	**2014/15**	**Total**
Internal – *DH Internal Audit*	*To complete*	*1*	*3*	***4***
	Complete	*3*	*5*	***8***
External Auditor – *NAO*	*To complete*	*1*	*-*	***1***
COUNT		***5***	***8***	***13***

1. Report

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

1.2. Two new recommendations agreed by this committee at the last meeting have been added.

1.3. Recent updates received from Action Managers are recorded in this document.

1.4. Recommendations are classified as high (H), medium (M), low (L) or N/A for advisory.

1.5. Eight recommendations are noted as completed and the remaining are in hand.

1.6. Of the five remaining outstanding, two recommendations are classified as high, two as medium and one as low

1.7. Progress with the implementation of the remaining outstanding audit recommendations will be provided to future meetings of this committee and to CMG on a quarterly basis.

2. Recommendation

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

2011 - 12	Title	Section	Grade	Findings	Risk / Implication	Recommendation	Management Response	Action Manager	Date
2011-12	Review of Supplier Maintenance	1	L	**Guidance for Supplier Maintenance:** Documentary guidance exists which sets out the financial authorities and responsibilities over procurement, purchasing and payment for goods and services. However, some of the detailed guidance needs to be updated. The HFEA Ordering and Payment Procedures are based on the Barclays Business Master system, which has been replaced by the Barclays Internet Banking system. The HFEA Financial Reporting Procedures do not reflect the current suite of management accounting reports.		HFEA Ordering and Payment Procedures should be updated to reflect the use of the Barclays Internet Banking system. HFEA Financial Reporting Procedures should be updated to reflect the current suite of management accounting reports.	Agreed. The Financial Procedures will be updated to reflect this and other recommendations arising from this audit, and also updates to the Authority's Fraud and Anti-Theft Policy. **June 2012 update:** The finance procedures have been revised in draft and presented to CMG. Recommendations from the meeting are due to be incorporated and finance training arranged for staff new to their financial responsibilities / who would like a refresher. **September 2012 update**: The Financial Procedures – the main document setting out procedures and processes for all staff – have been updated and are on the intranet. Revisions include reference to the Fraud and Anti-Theft Policy; changes in staffing; and enhancement of T&S information in line with DH policy. The detailed procedures in use by only the finance team have been substantially updated. The banking procedures refer to Barclays Internet banking. Some detailed procedures remain to be updated, it is anticipated this will be completed by end October. **November 2012 update:** The finance SOP on the HFEA's Ordering and Payment of goods and services has been updated to reflect the use of Barclays Internet Banking. The imminent delivery of the SAGE 200 project will radical transform the financial system and processes currently in place. It is therefore recommended that all other documents are reviewed after the new system is introduced. **March 2013 update:** The Sage 200 project is underway. The financial procedures and finance team SOPs will be subject to material revisions to reflect the forthcoming (1 April 2013) introduction of WAP (to facilitate online processing of purchase orders to payment). **June 2013 update:** Pending resolution of the technical problems with the new WAP system the revisions to the financial procedures were also delayed. The WAP system went live on 3rd June and revised summary financial procedures are to be presented to this meeting. Some of the individual detailed procedures will be completed subsequently. **Aug 2013 update**: Delayed due to finance team restructuring. In addition, an annual review of the existing suppliers database will be written into the standard operating finance documentations which is planned to be completed by November 2013 **Nov 2013 update** Now expected in Dec 2013 **Feb 2014 update** A review of time and availability resources has necessitated moing this piece of work back in Q1 of 2014-15. This rrecommendations relates to the updating of SOP's which are internal to finance staff only. **May 2014 update** Awaitng completion by Director of Finance and Facilities Internal audit planned in Q1 2014/15 to update this recommendation **September 2014 Update** Finance policies and SOPs to be updated. **November 2014 Update** As above. Financial controls audit is to look at existing policies to highlight "gaps" and any identifeid will be incorporated **February 2015 update** Policies for Procurement and Budgetary Control have been updated and agreed. The Financial Procedures Manual is the final document to be produced and will be drafted by the end of March. **May 2015 update:** Financial procedures now in place **Recommendation complete**	*Head of Finance*	**April-12** **July-12** **October-12** **May-13** **March / April 2013** **July-13** **November-13** **December-13** **April-14** **June-14** **December-14** **February-15** **March-15** **Complete**
	Data Confidentiality	4	L	**Information Asset Register** A number of policies are in place that relate to the management of information, including: · Information Classification and Retention; · Records Management; and · Information Access. These policies do not reference HFEA's Information Asset Register (IAR) which is used to apply a security classification to information assets. HFEA use different security classifications to define the controls which are to be applied to data sets.	Polices related to information management may be applied without consideration of the security classifications documented in the	Management should review the policies related to information management to consider whether those policies require linking to the IAR.	**1. This is a good suggestion which we will progress during 2012.** **November 2012 update** In progress, a meeting has been arranged to initiate changes. **March 2013 update**: The OGSIRO has recently issued documents relevant to risk appetite and security for information assets. This needs to be taken account of in the review, which has been delayed. **June 2013 update**: Work delayed **Nov 2013 update** Now expected in Dec 2013 **Feb 14 update -** due to workload pressures, this has been delayed again. It is now firmly scheduled to be completed end March 2014 **May 14 update** Policies to be updated after IfQ changes - discussion to take place by end June 2014 to see if interim update possible **September 2014 Update** These policies form part of the Information Governance toolkit and are currently being reviewed. It is anticipated that the reviews will be completed by November 2014. **November 2014 Update** - Work in progress **January 2015 Update** Policies to be reviewed. The new anticipated completion date end May 2015 **May 2015 update:** The policies have been completed and will be considered at the CMG meeting in May **Recommendation complete**	*Director of Finance / SIRO* *Head of IT*	**November-12** **December-12** **May-13** **September-13** **December-13** **April-14** **December-14** **November-14** **January-15** **May-15** **Complete**

2011 - 12	Title	Section	Grade	Findings	Risk / Implication	Recommendation	Management Response	Action Manager	Date
P W C	R I S K M A N A G E M E N T	2	M	**Risks are significantly summarised within the HLRR and the supporting Assurance Framework has yet to be prepared**					
				We noted that the risks within the HLRR are summarised to a significant degree with a large number of contributory factors. For example: • The risk around decision making quality has a number of causes including decision-making apparatus, representation and appeals processes, workload pressures, governance transition programme and business/admin processes, practices and behaviours. Business/admin processes, practices and behaviours itself then refers to document management, risk and incident management, data security and finance processes. • The statutory and operational systems and delivery risk relates to operational delivery and business continuity being hampered by unreliability in, or excessive demand on, key statutory and infrastructure systems. Causes are reliability of a range of IT and non-IT systems, excessive demand on various processes, data integrity, records accuracy and behaviours. Whilst we can see how the underlying factors draw together into the overall risk, at this summarised level it becomes more difficult to evidence the alignment of controls and assurances against the overall risk. Each risk has a series of controls identified, but they are not directly aligned to each underlying cause of the overall risk and if every control in the organisation relevant to possible factors impacting the risk were listed the HLRR would be unmanageable. In some organisations, many of these causes and underlying controls would appear as risks within a risk management system in their own right, and of course in HFEA a number will be within the operational risk registers. However, we believe that what this highlights is the need for development of an Assurance Framework, as management have identified, that would sit behind the risk register and provide a more detailed level of information on individual controls, risk mitigations and sources of assurance within the business.	The HLRR may not provide sufficient detail to ensure that controls to address the broad nature of identified risks are adequate and that there is sufficient assurance over the continued, satisfactory operation of those controls	As intended, an Assurance Framework should be developed showing the alignment of controls, mitigating actions and sources of assurance relating to the risk of breakdown in areas underlying the high level risks.	**Accepted in part. We will need to approach this finding in a proportionate and manageable way. Our proposed actions are:** 1. To review our operational risk system to ensure it is being used fully and consistently across the organisation – the aim being to ensure operational risk is managed in a coherent and comparable way between all teams. This will help our overall risk assurance. The Head of Business Planning to start on this following Corporate Strategy work. **January 2015 update:** Following some initial discussion at the CMG Risk meeting on 19 November 2014, a further paper was considered at the next CMG Risk meeting, which took place on 5 February. This set out overall proposals for a revised operational risk approach, and, in tandem, the gradual introduction of risk assurance mapping, with an outline suggested process. The process will now be designed in more detail in line with the discussion at CMG. Although the risk assurance element will take longer to achieve, since we have very limited capacity for extra activities, and staff are unfamiliar with this sort of process, the changes to the existing operational risk system are expected to be implemented in February and March, and will focus on increasing consistency between teams. This will be done in tandem with service delivery planning for 2015/16. **May 2015 update:** At February CMG, we agreed to relaunch the operational risk log template, amended to correspond to the suggested future broad risk assurance headings of Planning, Performance and Risk Management, Quality management, Financial management, systems and controls, Information and evidence management, People management, Accountability, Oversight and scrutiny. This framework should help us to identify operational risks more comprehensively and consistently, and will also serve to familliarise Heads (in particular) with the risk assurance headings we plan to bring into use next. The new operational risk template was launched in March. CMG discussed both operational risks and RAM again at its next meeting, on 20 May. An approach was agreed, and discussions will now be commenced with DH internal audit, to integrate this work into the HFEA's internal audit programme. Since full implementation will take some time, and will be reported on to AGC regularly, it is suggested that this item is now regarded as completed, for tracking purposes, and therefore removed from this listing. **2. Revise the High Level Risk Register template to make more apparent the linkages and lines of sight between causes/sources of risks and the corresponding controls.** **Head of Business Planning – part of AGC paper for 06/14** **September 2014 Update** Most of this work will form part of the post-Strategy review of the whole content and lay-out of the risk register, but efforts have already been made to make the lines of sight more obvious, as indicated above. **January 2015 update:** Presented at December AGC. A CMG workshop was held in January to review all risks in detail, and we now regard this recommendation as complete. CMG will continue to review the risk register on a quarterly basis, reporting to AGC at every meeting and to the Authority when agenda space permits. **3. Explanation of whole current risk system (all levels) to June AGC, for clarity (particularly for the newer members / attendees who will not be aware of all aspects of our risk management system). Head of Business Planning to work with CMG and members to consider this between 07/14 & 01/15** **January 2015 update:** This was addressed as above in June 2014. As soon as the work on risk assurance and operational risk has been completed, the risk policy will be reviewed and updated to reflect the newly agreed approach and procedures. At the same time, SOPs will be incorporated that reflect all procedures. We will also schedule regular annual reviews to ensure the policy always remains up to date and reflects current practice. **May 2015 update:** This work will be done in June, now that CMG has agreed a way forward on risk assurance. Maintenance of up to date procedures and policies will then become ongoing work. **4. Regarding the composite nature of our strategic risks, we will consider whether to break these down into smaller components when we review the high level risk register following the setting of our new strategy. (However, for the time being we are satisfied that the** **November 2014 Update** A revised version of the high level risk register will be brought to the December AGC meeting for comment. This has been redesigned to take in the audit recommendations, as well as the HFEA's strategy. **5. Risk Assurance Mapping – we will consider what other small organisations do, and review whether it would be worthwhile and feasible for the Authority to adopt a similar approach. Meanwhile, some of our other planned actions, listed in this report, will increase** **September 2014 Update** Via a useful DH Risk Assurance Network meeting in July (the first one of an ongoing series), we have made a useful contact at the CCQ, who are also considering how to introduce risk assurance in a manageable and proportionate way. It is likely that we will be able to adopt some of their methodology, which they are kindly sharing with us as they continue to develop it. This work will be considered following the more urgent work to align all of our planning, performance measurement	HoBP	**February-15** **End March 2015; and ongoing gradual implementation of RAM** **Operational risk template relaunch COMPLETED. Implementation of RAM will be planned next, as indicated previously.** **June-14** **Complete** **January-15** **June-15** **end June 15** **December-14** **Complete**

2011 - 12	Title	Section	Grade	Findings	Risk / Implication	Recommendation	Management Response	Action Manager	Date
							November 2014 Update Risk assurance mapping will be explored alongside the redevelopment of our operational risk system. The recent development of DH's risk and assurance network has already proved useful in this regard, and the CQC (also new to risk assurance as an activity) have kindly shared their process with us. It is likely that we will be able to adopt a very similar approach. Resource implications will remain an important factor in agreeing the detail of this, and this will be discussed in more detail at CMG (most likely in the new year). **January 2015 update:** As indicated above, Risk CMG considered a paper and recommendations about operational risk and risk assurance mapping on 5 Feb. Further work will follow. We expect full implementation to be gradual over several years. Development of this activity will require some coaching, training and various group meetings, since we are new to this as a concept and as an activity. We also need ot consider team resources, which are already at full stretch. We will ensure managers understand the difference between operational risk identification/management, and risk assurance. To some extent we can learn useful lessons and borrow processes from the recent introduction of RAM into the HTA, and the CQC, both of whom are in the same position of trying to accommodate this additional new activity in a proportionate and manageable way, such that the process yields useful assurance and is understood by those using it, but does not cause more risk than it manages. **May 2015 update:** A paper was considered by CMG at its risk meeting on 20 May. The approach described above was agreed and is now being implemented.		**March-15** **May 2015 for an approach and draft implementation plan over several years** **As above. COMPLETE**
	CORPORATE GOVERNANCE	2	M	**Some governance information on the website needs updating**					
				We noted that there are a number of governance items on the HFEA website that appear to require updating: • In the "About HFEA" section the link to provisions of the 1990 Act as amended by the 2008 Act (www.dh.gov.uk/en/Publicationsandstatistics/Legislation/Actsandbills/DH080211) does not work, that legislation page seemingly having been archived, and the About HFEA section also still refers to having 22 members; • The section on Equality and Diversity refers to new guidance to public bodies due to be issued in 2010 and goes on to say that the Authority intends to overhaul and update its approach to equality issues as part of its preparation for the commencement of the new public sector duty, and makes mention of having considered an initial preliminary assessment at the open public meeting in Cardiff on 8th December 2010; and • On the website the "Our Public Events" sub sections are for the 2008 and 2009 Annual Conferences.	Users of the website may be confused by out of date information. Reputation may be impaired as a result of the perception of lack of attention to the quality of information on the web. There may be a perception that the Authority has not paid sufficient attention to its equality and diversity objectives.	Review the website and update any information that is out of date. In particular, update the equality and diversity section. Implement a mechanism for regular testing for broken links to third party information.	**Equality policy being refreshed in summer 2014, with updated documentation to go on website. Other website changes being factored into IfQ programme.** **November 2014 Update** Delayed due to member of staff allocated to project being re-deployed on IFQ01 project. Policy refresh to be conducted Q4. **March 2015 update** Review of equalities initiated and expected to be considered by Authority at its meeting in May 2015. **May 2015 update:** Equalities review considered by Authority at May meeting. Item closed. **Website** **September 2014 Update** All sections apart from the Equality and Diversity section of the website have now been fixed. The Equality and Diversity section has been delayed due to IFQ **May 2015 update:** Equalities table uploaded to website. Item closed. **Recommendation complete**	**Equalities – HoGL** **IfQ Programme Manager transferred to Director of Strategy and Corporate Affairs**	**Equalities – by October 2014.** **Now expected March 2015** **Now expected May 2015** **On implementation of IfQ programme** **March-15** **Complete**
	NAO Annual Report & Accounts	6	L	**Intra-Government balances**					
				Significant discrepancies were identified in the categorisation of intra-government balances. The disclosures in the latest draft Accounts have now been corrected		Finance should review categorisation of suppliers and customers to ensure that this corresponds with the information reported in the DH Consolidation return	**September 2014 update** Comparison will take place when DH request future consolidations **November 2014 updated** This will take effect when Decembers' hard close commences in Jan-15 **January 2015 Update** As above, however it is at year end that this important point will be embedded. Note will be taken of progress from M9 audit, which will be completed by 20/03/15. **May 2015 update:** Work completed. To be agreed in the annual audit, by end June 2015	**HoF**	**March-15** **April-15** **end June 15**

Audit by:	Title	№	RATING / IMPORTANCE	FINDING/OBSERVATION	RISK / IMPLICATION	RECOMMENDATION	AGREED ACTION	ACTION MANAGER	IMPLEMENTATION DATE
DH's INTERNAL AUDIT	Information for Quality	1	M	**The IT strategy needs to be updated and finalised**					
				We acknowledge that an overall vision and some business objectives have been set. However, an IT Strategy, aligned with business strategy, has not yet been formally documented. Our review showed that the current IT strategy has not been adequately defined but will be updated based on the programme implementation as well as consideration around infrastructure requirements and the target operating model. The data security and end point security requirements are still being defined as well. We also noted that a clear view of the regulatory requirements for data security is also not in place.	Lack of alignment of the programme to the organisational and IT strategy may lead to directing resources in a manner that is not effective and efficient.	The IT strategy needs to be defined upfront and the programme and changes within the IT environment need to be aligned to the wider IT strategy in order for IT to effectively meet business and regulatory needs.	**The strategy and IfQ can be worked up in parallel. An IT strategy is in development to take into account wider infrastructure developments (e.g. cloud hosting), office relocation, and the IfQ programme. CMG and SMT have considered 'first principle' proposals and the strategy will be worked up fully in the new year.** **May 2015 update:** Completed and agreed at CMG May 2015 **Recommendation complete**	*Director of Compliance & Information*	**April - 2015** **Complete**
		2	M	**Delays in progress against original plan**					
				Under the original plan, a proof of concept (POC) was expected to be delivered at this time. However initial requirements gathered were not detailed sufficiently to progress with the POC to a level that could provide sufficient assurance to the programme board. Subsequently the programme approach, scope and timelines have since been revised to allow further work to be performed to capture detailed requirements. It is unclear at this stage whether a standalone POC will still take place or built into the implementation phase and whether the anticipated programme duration of up to 24 months for 2015 completion is still possible.	Lack of clearly defined plans will impact the progress of the programme against the original plan.	Develop detailed plans in conjunction with the key stakeholders for each phase of the programme, so that keys steps, dependencies and durations are captured earlier on and reduce the risk of scope creep and/or significant extension to timelines.	**Yes, this will be defined in the programme definition.** **May 2015 update:** Plans for the website project have been produced and remaining plans will be finalised once the current tender process is compelted and the exact scope of the programme is defined.	*Information for Quality Programme Manager*	**April - 2015** **End June 2015**
		4	M	**Management of risks**					
				The current risks that the programme faces such as data migration and data quality issues have been documented. We also noted that risks registers and issue logs are maintained and there is adequate reporting to the CMG. However, the risk register does not formally capture the residual risk or the assurance obtained over those mitigation actions.	Lack of a comprehensive risk management approach may mean the programme may not fully address the identification and mitigation as well as monitoring of programme risks.	We recommend that a risk mitigation process that includes contingency plans and residual risks be documented. The trend of increase / decrease in risk profile over time should also be understood and there should be ongoing independent assurance over the management of program risks.	**Yes, Gateway review booked for 26/03/15.** **March 2015 update** Gateway review to be undertaken March 2015 **May 2015 update:** The gateway review has been completed trend in risk profile is routinely reported. **Recommendation complete**	*Director of Compliance & Information*	**April - 2015** **Complete**
		5	M	**Data Migration**					
				Data migration is acknowledged as a key risk and a key requirement to informing the POC and implementation phase. Subsequently on 21st July, 2014 the programme board agreed for IT to commence research on migration of the register data. The data migration strategy will be critical to informing: ● Data quality standards; ● Ensuring the data directory from source to target is mapped in line with requirements and linked to the data dictionary that has been produced via a separate programme. The data migration strategy should also include approach, data mappings, reconciliations and User Acceptance Testing (UAT) at key stages of the programme for all 'in-scope' system environments (circa 30+ systems to be replaced). We understand that the initial data migration strategy will be developed in December 2014.	Lack of a data migration strategy and execution plan/cut over plans to may mean that the programme goes live with erroneous data which would severely impact the business operations and the reputation of the Authority.	A data migration and quality management plan which includes formal controls around data migration and quality needs to be put in place. Independent assurance need to be given over the data migration and reconciliation.	**Yes, a third party has been commissioned to produce a data migration strategy and formal controls for the migration and reconciliation.** **March 2015 update** The draft data migration strategy has been submitted for review by the internal team - revised date April 2015 **May 2015 update:** The data migratuion strategy has been approved and is now being implemented **Recommendation complete**	*Information for Quality Programme Manager*	**January - 2015** **April - 2015** **Complete**
		6	M	**Engagement with stakeholders**					
				We noted that advisory and expert groups are in place and that meetings were held where the needs and interests of different stakeholders' groups were taken into consideration. However engagement with key operating teams such as IT, who would be a key enabler for the programme, should be strengthened and engaged as soon as possible. Some stakeholders were unsure of their role post December 2014 as the programme looks to move into the next phase (implementation phase).	A lack of engagement by key internal stakeholders can lead to staff not buying into what is to be delivered and loss of their support.	Key internal stakeholders should be carefully managed and monitored throughout the lifecycle of the programme to encourage engagement and support.	**Yes, internal stakeholders will be part of the new Programme** **March 2015 update** A stakeholder engagement plan is in progress and should be compelted by the end of this month **May 2015 update:** The stakeholder engagement strategy has been approved and is now in implementation phase **Recommendation complete**	*Information for Quality Programme Manager*	**March - 2015** **April - 2015** **Complete**

Audit by:	Title	№	RATING / IMPORTANCE	FINDING/OBSERVATION	RISK / IMPLICATION	RECOMMENDATION	AGREED ACTION	ACTION MANAGER	IMPLEMENTATION DATE
	Standing Financial Instructions	3	N/A	**Additional Sections**					
				Our review of the SFIs for four other Arm's Length Bodies identified the following sections which are commonly included but which are not currently detailed in HFEA's existing SFIs: ● Income, fees and charges and security of cash, cheques, banking arrangements, cash limit control and petty cash; ● Capital expenditure including disposals; ● Non-pay expenditure; ● Payroll expenditure; and ● Stores and receipt of goods.	N/A	Consideration should be given for the inclusion of each of the areas set out to left in the HFEA's updated SFIs.	**March 2015 update** These areas will be described in the HFEA's financial procedures **May 2015 update:** **Financial procedures updated in March 2015 and include these areas.** **Recommendation complete**	*Head of Finance*	**March - 2015** **Complete**
	Internal Policies	1	H	**Key Policies The Register of Policies is not complete.**					
				The Register currently contains a mixture of 47 strategies, policies and procedures. These are split across various operational areas, including Human Resources, Health and Safety, Compliance, Information Management, and Communication and Finance. From our review of the register we have made the following observations: There are multiple documents that have not been included within the register such as the HFEA's Standing Financial Instructions and documents found within the Authority Standing Orders (for example, Guidance for Authority and Committee members on Handling Conflicts of Interest); There is a lack of consolidation across HR policies, with 24 of the total 46 documents on the Register relating to this area alone. As an example we have noted that there exists a Working from Home document, Homeworking policy and an Occasional Homeworking Policy; One policy ('Health and Safety in the Service') relates to another Government department (the Insolvency Service). We also note that there are no controls in place to action upcoming expiry dates for documents listed on the register. We have been informed that a single co-ordinator for the Register has been assigned from January 2015, who will inform individual document owners of expiry dates of documents and who will also ensure that the register is complete.	An incomplete register prevents HFEA from ensuring that all strategies, policies and procedures are being monitored and reviewed on a regular basis. This may lead to policies not being in line with the current updated working practices and legislation. This issue is compounded where the responsibility for ensuring policies are updated has not been assigned. The existence of a significant number of HR policies increases the risk of duplication or contradictions between them. Additionally this may reduce their usage of by staff and negatively impact on the implementation of controls that they are designed to aid.	A complete list should be made of all strategies, policies and procedures currently in existence across the HFEA. This would be facilitated through searching the organisation's document management system (TRIM) and liaison with individual department heads. All documents in the Register should clearly state, as a minimum, the following information to facilitate monitoring: ● Relevant department, document owner, and TRIM reference; ● Approval details, including date and details of approver; and ● Future dates of review. A set process should be introduced to ensure that document owners are contacted with sufficient time prior to expiry of the document for them to coordinate review prior to approval. Once a complete list of policies has been compiled, consideration should be made for the streamlining of policies (including consolidating a number into one policy or removal from the Register). Please see **Appendix A** for good practice guidance that can be used to inform the HFEA's response to this finding.	**Complete list to be compiled, to specification outlined in recommendation.** **Complete list to be in place by end April 2015** **May 2015 update:** List created - proposals on track for August 2015. **Proposals for priority of update/ streamlining of policies to be considered by SMT.** **Priorities/streamlining of policies to be considered by SMT by end August 2015**	*Head of Governance and Licensing*	**April - 2015** **August - 2015** **August - 2015**
		2	H	**Review and Approval: The majority of strategies, policies and procedures on the register evidenced are past their review date and are not subject to version control.**					
				We reviewed the 47 documents on the Register and found that only two were currently up to date - i.e. had been reviewed and appropriately approved with an expiry date past the date of fieldwork for this review (January 2015). Of the remaining 44 documents owned by HFEA (i.e. discounting the policy from the Insolvency Service identified in Finding 1 above) we noted that: ● 25 of these had projected dates for review to be performed prior to January 2015, of which: o One was due for review in 2010 o Nine were due for review in 2011; o 14 were due for review in 2012; o One was due for review in 2013. ● 19 documents did not specify a projected date for review. We also note in this context that there is no set guidance which specifies that version control should be applied to all HFEA strategies, policies and procedures.	Where documents are not updated regularly these may not reflect current working practices and may not be in line with applicable regulatory or legislative parameters. Additionally without a set policy for version control, including review and approval processes, the quality and consistency of strategies, policies and procedures may be poor and may not reflect organisational objectives and risks where no input is sought from those charged with governance.	The HFEA should develop a set process for the production, approval and version control of its policies which ensures consistency across operational areas in the HFEA. This process should include the requirement that documents are assessed for their alignment to the HFEA's three strategic objectives and how they align with other policies. We have shared examples of best practice for this process with the Head of Governance and Licensing and this is also included within the Appendix of this report. Please see **Appendix A** for good practice guidance that can be used to inform the HFEA's response to this finding.	**SMT to give consideration to process to be used to introduce/ revise/monitor policies, proportionate to size of HFEA and number of** **Set process for introduction/revision/monitoring of policies to be in place by end June 2015**	*Head of Governance and Licensing*	**June - 2015**

Audit and Governance Committee Paper

Paper Title:	**AGC Forward Plan**
Paper Number:	[AGC (10/06/2015) 463]
Meeting Date:	10 June 2015
Agenda Item:	**12**
Author:	Sue Gallone
For information or decision?	Decision
Resource Implications:	None
Implementation	N/A
Communication	N/A
Organisational Risk	Not to have a plan risks incomplete assurance, inadequate coverage or unavailability key officers or information
Recommendation to the Committee:	The Committee is asked to review and make any further suggestions and comments and agree the plan. The Committee is asked to consider the ongoing need for four meetings per year.
Evaluation	Annually, at the review of Committee effectiveness (but the forward plan is reviewed briefly by the Committee at each meeting)
Annexes	N/A

AGC Forward Plan

Item↓ Date:	**Mar 2016**	**June 2016**	**7 October 2015**	**9 December 2015**
Following Authority Date:	**May 2016**	**July 2016**	**11 November 2015**	**14 January 2015**
Meeting 'Theme/s'	**Finance and Resources**	**Annual Reports, Information Governance, People**	**Strategy & Corporate Affairs, AGC review**	**Register and Compliance, Business Continuity**
Reporting Officers	**Sue Gallone**	**Peter Thompson**	**Juliet Tizzard**	**Nick Jones**
High Level Risk Register	Yes	Yes	Yes	Yes
Information for Quality (IfQ) Programme	Yes	Yes	Yes	Yes
Annual Report & Accounts (inc Annual Governance Statement)	Plan & review any drafts	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	Early Results, approve draft plan	Results, annual opinion	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		
Strategy & Corporate Affairs management			Yes	
Regulatory &				Yes

Item↓ Date:	**Mar 2016**	**June 2016**	**7 October 2015**	**9 December 2015**
Register management				
Resilience & Business Continuity Management				Yes
Finance and Resources management	Yes			
Reserves policy			Yes	
Review of AGC activities & effectiveness, terms of reference				Yes
AGC Forward Plan	Yes	Yes	Yes	Yes
Session for Members and auditors	Yes	Yes	Yes	Yes
Other one-off items			Representations hearing – lessons learned	