Audit and Governance Committee meeting - agenda

21 September 2016
HFEA, Conwy Meeting Room – 1st Floor

10 Spring Gardens, London SW1A 2BU

Agenda item		Time
1.	Welcome, apologies and declaration of interests	9:45am
2.	Minutes of 15 June 2016 **[AGC (21/09/2016) 505]**	
3.	Matters Arising **[AGC (21/09/2016) 506 MA]**	
4.	Strategy & Corporate Affairs management **[Presentation JT]**	
5.	Information for Quality (IfQ) Programme – Managing Risks **[AGC (21/09/2016) 507 NJ]**	
6.	Strategic Risks **[AGC (21/09/2016) 508 PR]**	
7.	Internal Audit a) Progress report **[AGC (21/09/2016) 509 DH Internal Audit]**	
8.	External Audit a) Update **[Oral NAO]**	
9.	Implementation of Recommendations – Progress Report **[Oral MA]**	

10.	Cyber Security a) Information Security & Testing **[Oral DM)**	
11.	Reserves Policy **[AGC (21/09/2016) 510 MA]**	
12.	AGC Forward Plan **[AGC (21/09/2016) 511 MA]**	
13.	Any other business	
14.	Close (Refreshments & Lunch provided)	12:45pm
15.	Session for members and auditors only	12:45pm
16.	Next Meeting 10am Wednesday, 7 December 2016, London	

Minutes of Audit and Governance Committee meeting 15 June 2016

Strategic delivery:	☐ Setting standards	☐ Increasing and informing choice	☐ Demonstrating efficiency economy and value
Details:			
Meeting	Audit and Governance Committee		
Agenda item	2		
Paper number	AGC (21/09/2016) 505		
Meeting date	21 September 2016		
Author	Dee Knoyle, Committee Secretary		
Output:			
For information or decision?	For decision		
Recommendation	Members are asked to confirm the minutes as a true and accurate record of the meeting		
Resource implications			
Implementation date			
Communication(s)			
Organisational risk	☐ Low	☐ Medium	☐ High
Annexes			

Minutes of Audit and Governance Committee meeting on 15 June 2016 held at HFEA, 10 Spring Gardens, London SW1A 2BU

Members present	Rebekah Dundas (Chair) Gill Laver Jerry Page Margaret Gilmore Anita Bharucha
Apologies	None
External advisers	Internal Audit: Paul Foreman, Price Waterhouse Coopers (PWC) National Audit Office (NAO): Sarah Edwards George Smiles
Observers	Kim Hayes (Department of Health)
Staff in attendance	Peter Thompson, Chief Executive Sue Gallone, Director of Finance & Resources Ian Brown, Head of Corporate Governance Dee Knoyle, Committee Secretary Morounke Akingbola, Head of Finance Wilhelmina Crown, Finance & Accounting Manager Paula Robinson, Head of Business Planning Helen Crutcher, Project Risk and Performance Manager Patrick Winters, Information for Quality (IfQ) Internal Systems Project Manager David Moysen, Head of IT Ian Peacock, Analyst Programmer Hocine Amrane, Programme Support Officer

1. Welcome, apologies and declarations of interests

1.1 The Chair welcomed attendees to the meeting, including Ian Brown who was attending for the first time in his new role as Head of Corporate Governance for the HFEA.

1.2 There were no apologies or declarations of interest.

2. Minutes of the meeting held on 16 March 2016

2.1 The minutes of the meeting held on 16 March 2016 were amended at paragraph 7.2 in advance of the meeting. The Chair agreed that the amended version was a true record of the meeting and approved the minutes for signature.

3. Matters arising

3.1 The committee noted the progress on actions from previous meetings. Some items were ongoing and others were dependent on availability or were planned for the future.

3.2 Action (3.2), one of the two new members had completed the online information governance training.

3.3 Action (f), this item was completed. Gill Laver and Jerry Page had both observed an inspection and this was reported at the last meeting.

3.4 Action (i), the Head of Corporate Governance will circulate the formal annual report to members before it is presented to the Authority in July 2016.

Action

3.5 Head of Corporate Governance to circulate the formal annual report to members before it is presented to the Authority in July 2016.

4. People Strategy & HR Risks

4.1 The Chief Executive provided the committee with a paper and briefing on the outcome of the staff survey and HR risks.

4.2 The annual staff survey was completed in October/November 2015. The responses could be compared to the Civil Service (CS) People Survey for the first time and the HFEA compares well with the Department of Health (DH) and CS. Staff were given the opportunity to discuss the results of the survey at the all staff conference in December 2015.

4.3 The committee noted that despite some disappointing results, staff turnover has decreased and staff are generally enthusiastic and interested in the work they are involved in. Staff also have a good understanding of their work and how it links to the HFEA strategy.

4.4 The committee agreed that action as a result of the all staff survey should continue and that workloads should be monitored. It is important to continue to feedback the Authority's views of good performance and engagement to all staff.

5. Information for Quality (IfQ)

5.1 The committee was provided with a paper, presentation and briefing by the Information for Quality (IfQ) Internal Systems Project Manager, Programme Support Officer, Analyst Programmer and Head of Business Planning.

5.2 **The Programme**

5.3 The committee noted that a comprehensive assessment was carried out on the new HFEA Website and Clinic Portal, conducted by the Department of Health (DH) and Government Digital Service (GDS), to ensure that they meet the required standards before they are released in the 'Public Beta' stage. The committee was pleased to hear that the Executive was successful in achieving the required standards. There were recommendations made by the assessors which have been categorised as urgent and non-urgent and the Executive are working on these. Some are dependent on user testing to determine what action to take.

5.4 The IfQ programme is progressing well and currently operating within budget. Risks have been at similar levels over the last three months. The internal systems team are preparing for the final conclusion of the programme which is estimated in October 2016. The committee noted that the timeline is flexible and that extra financial resource had been approved by SMT (£90k).

5.5 The committee acknowledged the rigorous process of approvals that the Executive had to go through to move forward to the public beta stage and congratulated the project teams on the positive result.

5.6 The Information for Quality (IfQ) Internal Systems Project Manager will circulate a list of the recommendations and planned actions to the committee after they have been reviewed by the Programme Board.

Action

5.7 Information for Quality (IfQ) Internal Systems Project Manager to circulate a list of recommendations and planned actions to the committee after review by Programme Board.

5.8 **Data Migration**

5.9 Data must be migrated from the existing Register to the new Register and before this process takes place a 'data cleansing' process will be completed to improve the quality of historical data being transferred.

5.10 The data migration strategy sets out five phases of activity, 'trial loads', each of which has key processes which are to be undertaken to ensure that an appropriate level of testing, quality control and assurance has been carried out. The committee was informed of the risks and issues associated with data migration.

5.11 The Executive is currently seeking to identify a supplier to provide assurance over data migration. There are funds set aside within the budget and a supplier should be easier to find as the strategy is already in place.

5.12 The committee discussed the security considerations around the systems being developed in IfQ and stressed the importance of bringing in resource to ensure these are adequate and that penetration testing takes place.

6. Internal Audit

a) Annual Assurance Statement – 2015/16

6.1 The committee was provided with the annual assurance report for 2015/16.

6.2 The committee noted that the three areas of risk management, governance and control were all graded moderate, which is positive. The committee discussed the meaning of the term "moderate" as not reflective of the organisation. The committee noted that internal audit make limited reviews at the HFEA but that in future the individual areas of risk management, governance and control will be assessed in each audit.

b) Annual Internal Audit Plan – 2016/17

6.3 The committee was provided with the draft plan for 2016/17. The 2016/17 audit is structured in order to meet tight deadlines.

6.4 The committee discussed board effectiveness and the need to take account of the Triennial Review to ensure there is no duplication.

6.5 The committee noted the importance of cyber security and linking this audit to the work the HFEA has in train to review IT systems. The timing of IfQ work may have an impact on when this particular audit takes place.

6.6 The committee agreed the plan.

7. Implementations of recommendations progress report

7.1 The Finance Manager provided the committee with an update.

7.2 The committee was very pleased to hear that all actions have now been completed.

8. Information Assurance & Security

8.1 The Director of Finance and Resources and the Head of IT provided the committee with a report.

8.2 The committee was informed that the organisation has not suffered any data loss. The culture of information security is good, however there are plans in place to formalise procedures, such as developing the information asset register and embedding further policies within the organisation. The SIRO needs to be more closely involved in the assurance process and the committee discussed who is best placed to take on this role, taking into account practicality and independence.

8.3 The committee queried whether new staff are vetted. Independent checks do not take place at present and proportionality needs to be considered.

8.4 The committee noted that penetration testing is planned every two years, although with the changes, this last took place in 2012 and vulnerability testing is carried out every two weeks. The committee was of the view that penetration testing should next take place as planned in October 2016, regardless of IfQ progress. The committee need assurance about the IT infrastructure.

Action

8.5 The Executive/HR to consider the need for possible security checks for new staff, such as DBS.

8.6 Head of IT to provide the committee with a further update on information security and testing at the next meeting in September 2016.

9. Strategic Risks

9.1 The Project Risk and Performance Manager presented the strategic risk register.

9.2 There has been little change to risks levels in the last two months. The Business Continuity Plan needs to be updated to reflect the IT and office changes.

9.3 The committee noted that re-licensing will probably not be necessary as a result of the EU Regulations impacting on the movement of gametes. If it is necessary, changes during renewal of licences using variations would be the least resource intensive way.

10. Annual Report and Accounts (including Annual Governance Statement) - Approval

10.1 The Head of Finance presented the annual report and the Finance and Accounting Manager highlighted significant areas in the accounts.

10.2 The committee noted the significant changes to the format of the report with an additional disclosure on whistleblowing within the Governance Statement. The committee suggested some small additions to the reports.

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

10.4 The committee noted the Executive's plan to sign off the annual report and accounts by 27 June 2016 and for the NAO to certify and lay by 30 June 2016.

10.5 The committee thanked staff in the finance team for their efforts.

11. External audit

11.1 The National Audit Office (NAO) presented the audit completion report for 2015/16.

11.2 The committee noted the audit completion report and that there were no unadjusted errors.

11.3 The treatment of Information for Quality (IfQ) was identified as an adjusted error.

11.4 There were no items found that raised issues in relation to regularity or propriety and NAO's opinion is unqualified.

11.5 The NAO made a recommendation in relation to following IAS 38 (intangible fixed assets), to stress the importance of ensuring expenditure capitalised is true development expenditure.

12. Forward plan

12.1 The committee was satisfied with the content of the Forward Plan of agenda items for the forthcoming meetings, with the addition of training on best practice from other audit committees to be delivered by the National Audit Office (NAO).

12.2 Members were invited to make other suggestions for training.

13. Any other business

13.1 There was nothing to report on whistleblowing or suspected fraud incidents and no contracts were awarded since the last meeting.

13.2 The Chair informed the committee that the Director of Finance and Resources will be retiring from her post in the next few months. The committee thanked her for her efforts of providing the committee with regular updates over the years.

13.3 Members and auditors retired for their confidential session.

13.4 The next meeting will be held on Wednesday, 21 September 2016 at 10am.

14. Chair's signature

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

Signature

Name

Rebekah Dundas

Date

21 September 2016

Audit and Governance Committee Paper

Paper Title:	**Matters arising from previous AGC meetings**
Paper Number:	**[AGC (21/09/2016) 506]**
Meeting Date:	21 September 2016
Agenda Item:	**3**
Author:	Morounke Akingbola, Head of Finance
For information or decision?	Information
Recommendation to the Committee:	To note and comment on the updates shown for each item.
Evaluation	To be updated and reviewed at each AGC.

Numerically:

- 4 items added from June 2016 meeting, 2 completed.
- 4 items carried over from earlier meetings, 1 completed.
- 2 items carried over from AGC self–assessment of performance, 1 completed.

Matters Arising from Audit and Governance Committee – actions from 11 June 2014 meeting			
ACTION	**RESPONSIBILITY**	**DUE DATE**	**PROGRESS TO DATE**
3.2 HFEA to monitor Authority members' completion of online information governance training	Executive Assistant to Chair and Chief Executive	20 September 2014	**Completed**
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.
i) Institute formal annual report to Authority board	Head of Governance & Licensing	July 2015	**Completed**
Matters Arising from Audit and Governance Committee – actions from 10 June 2015 meeting			
ACTION	**RESPONSIBILITY**	**DUE DATE**	**PROGRESS TO DATE**
9.6 Report progress on actions from the information governance group to AGC	Director of Finance and Resources	December 2016	**Ongoing**
Matters Arising from Audit and Governance Committee – actions from 9 December 2015 meeting			
ACTION	**RESPONSIBILITY**	**DUE DATE**	**PROGRESS TO DATE**
12.6 The Executive to add a review of the procedures for representations to the Business Plan for 2016/17 and report back to the Authority with recommendations, in due course.	Head of Business Planning	April 2016	**Ongoing** – added to business plan, work to start in October 2016

ACTION	RESPONSIBILITY	DUE DATE	PROGRESS TO DATE
14.5 The Triennial review report is to be sent to committee members.	Director of Finance	When published	**Ongoing** – Review report not yet published
Matters Arising from Audit and Governance Committee – actions from 15 June 2016 meeting			
ACTION	**RESPONSIBILITY**	**DUE DATE**	**PROGRESS TO DATE**
3.5 Circulate the formal annual report to members before it is presented to the Authority	Head of Corporate Governance	July 2016	**Completed**
5.7 Circulate a list of recommendations and planned actions (relating to public beta) to the committee after review by Programme Board.	Information for Quality (IfQ) Internal Systems Project Manager	January 2017	**Ongoing**
8.5 Consider the need for possible security checks for new staff, such as DBS	CEO/Head of HR	October 2016	**Ongoing – needs and most appropriate checks being considered**
8.6 Provide the committee with a further update on information security and testing	Head of IT	September 2016	**Completed – on September agenda**

Information for Quality (IfQ) Programme – Managing Risks

Strategic delivery:	☒ Setting standards	☒ Increasing and informing choice	☒ Demonstrating efficiency economy and value
Details:			
Meeting	AGC		
Agenda item	5		
Paper number	AGC (21/09/2016) 507 NJ		
Meeting date	21 September 2016		
Author	Nick Jones, Director of Compliance & Information		
Output:			
For information or decision?	For information		
Recommendation	The Committee is asked to note this report.		
Resource implications	As outlined		
Implementation date	Ongoing		
Communication(s)	Ongoing		
Organisational risk	☐ Low	☐ Medium	☒ High
Annexes			
Annex A –			

1. Introduction and summary

1.1. The purpose of this report is to provide the Committee with a progress report on the IfQ programme. The Programme is now running through its 'public beta' phase for both the new Website and Clinic Portal. The next phase 'Release two' has completed its planning phase and partially started its development.

1.2. Following the legal injunction brought by a clinic in July 2016 now lifted, a judicial review has been scheduled in December 2016 and therefore the delivery plan has been updated including the next GDS assessment.

1.3. The consequences of the updated timeline as well as the judicial review have been assessed and the risks are currently being mitigated at a programme and corporate level.

1.4. Annex A sets out the proposed updated timeline for the remaining IfQ Beta phase, leading both to 'live' and to the next DH/GDS assessment.

2. IfQ projects update

2.1. IfQ Beta phase/GDS update

- The Clinic Portal was released to public beta one week later on 12 July 2016. Further development and improvements will continue throughout beta including user testing as well as collecting feedback. The Government Digital Service (GDS) assessment of the Clinic Portal to enable progression to 'live' is scheduled for October 2016.
- We had planned to make the beta version of the website available to the public a few weeks after showing it to clinics. However, we were prevented from doing so due to an injunction granted by the High Court on 14 July following an application brought by a clinic. This injunction was lifted following our application and the website proceeded to full public beta on 12 August 2016. The judicial review proceedings will place on 19 and 20 December 2016.
- We have launched a significant period of user testing and the gathering of feedback about aspects of the website. Visitors to the website are asked to complete a survey, and to date there have been over 500 visits to the beta site.
- The feedback from public beta will be one element of the evidence that will inform the Authority's decision on the final shape of the new website. We will also be inviting the IfQ Advisory Group to meet again to help inform the set of recommendations that we will put to the Authority at its meeting in November 2016.
- With the Judicial Review pending the GDS assessment to enable the website to 'go live' has been pushed back to January 2017.
- There are several consequences that flow from this delay. Two operational issues worth highlighting here are:
    - The current HFEA website content management system is dated and is no longer supported by the original supplier, which can lead to instability from time to time. This has been managed to date but this risk remains as long as it remains as our official site.
    - There has been a concentration of resources in preparing the website for beta launch. This reallocation of resources has had an effect on planning assumptions, in particular relating to development work necessary for Release 2 – the data submission module.

2.2. IfQ release 2

- This relates to the treatment data submission system, much awaited by clinics. It is 'release 2' because it forms part of the Clinic Portal (Release 1). Substantial work is now progressing. such that development work and design work can progress at pace. However, the additional work set out in section 2.1 above has meant that our end October 2016 release expectations for EDI users (those clinics submitting directly to the HFEA) are unlikely to be met. A revised plan is now being developed and an update of the timeline is available in the Annex A.
- The revised plan has been agreed by SMT in September, subject to some additional considerations.
- That said we are engaging with EPRS providers (suppliers of patient reporting systems to around half of all clinics) and who have been notified of the development path to March 2017 (the latest acceptable implementation date) such that they are well prepared. They have access to the technical architecture that will underpin the system – which has met with general approval. We plan to maintain close levels of engagement to enable gradual adoption of the necessary ways to 'connect' to the Authority and maintain necessary security.
- The Standardisation Committee for Care Information (part of NHS Digital) accreditation process for the 'UK ART dataset' and its implementation is on-track. It is an intensive process requiring the submission of substantial documentation considered by several committees but is a good external test of the thoroughness by which we have gone about our work.

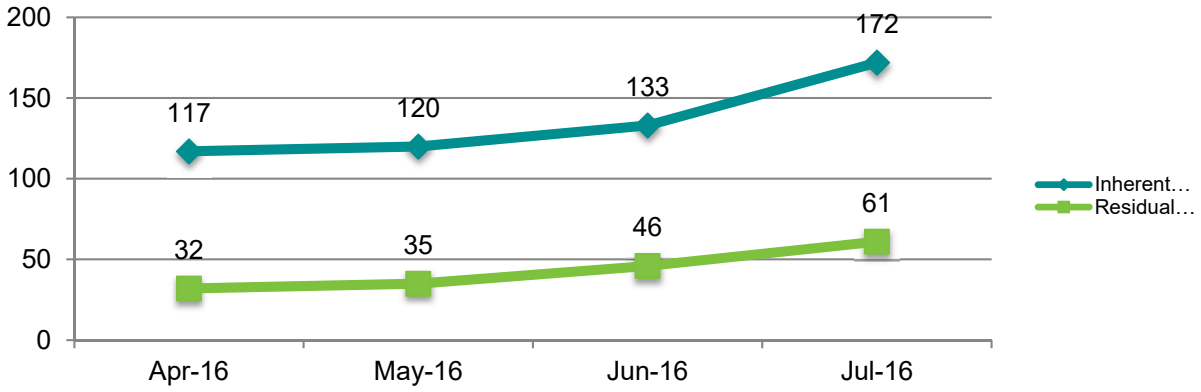
2.3. IfQ data cleansing/Migration

- Data Cleansing and Migration work is slightly behind schedule, also as a result of diversion of some resources. Data cleansing work remains primarily focused on dealing with 'severity 1' items (relating to treatment involving donor gametes), with all issues expected to be resolved this month.
- If necessary, the data migration of the existing (cleansed) database to a new structure can still occur by October 2016. However, this issue will be further addressed alongside broader discussions about overall timeframes for the Programme.
- Arrangements to provide assurance services for the data migration are now in place. We have commissioned an expert in data migration to provide a review of all steps we have taken and will take prior to transfer. This is intended to provide a further check and balance to the Senior Responsible Owner, and in turn the Audit and Governance Committee.
- Whilst most clinics have been cooperative in fixing errors (and we worked hard to minimise the quantum of tasks they had to undertake) there are issues with some centres in failing to deal swiftly with our requests and we continue to monitor progress closely, escalating our action as necessary.

3. IfQ risks and issues

3.1. Overall update

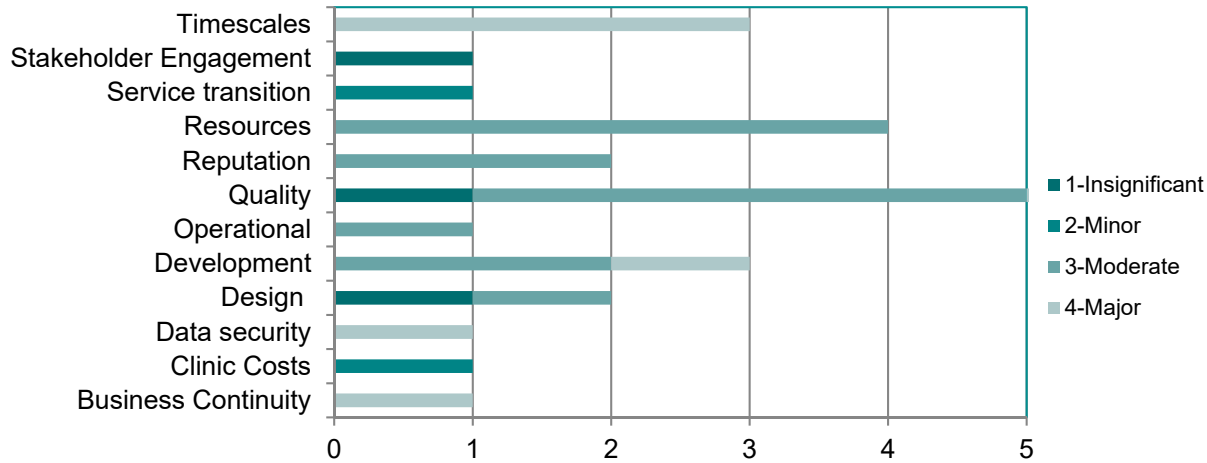
- The line graph below represents the overall IfQ risk score, which combines the perceived impact and likelihood of the current risks on hand each month. The overall risk score for the IfQ Programme has significantly increased this month. The main risk added rotates around EPRS providers and the impact on treatment fees and potential delay in R2.



- The major risks are associated with timescales, data security, development and business continuity.

3.2. Strategic Risk Update

- Three new inter-related strategic risk sources arising due to IfQ have been escalated to the corporate Risk register. These risks were the various impacts of Electronic Patient Record System (EPRS) providers not making the necessary changes to their systems to submit clinic treatment data to the new Register structure following IfQ release 2. (
- The risk areas affected are firstly RM1 (the risk of a loss of regulatory authority), because any gaps in data could impact effective regulatory monitoring. Secondly, IfQ1 (the risk to improved information access), since any data that had not been provided would then not be available to provide to patients through Choose a Fertility Clinic. And finally, FV1 (financial viability - risk of overspend) could be impacted if the HFEA were not able to bill clinics for treatments that they had undertaken but not reported to us.
- Work to develop further mitigation plans for these risks, alongside the finance and compliance departments is currently in progress.



4. IfQ budget

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

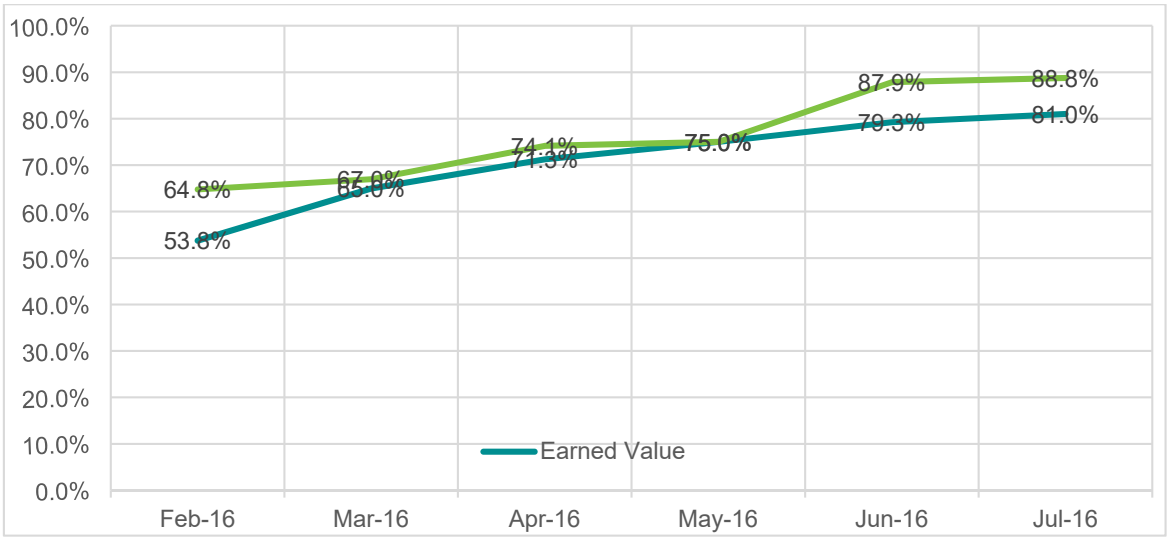
Total IfQ budget May 2016	Budget this F/Y	Planned spend	Actual to date	Monthly Variance
1,227,402	£619,025 (16/17)	£1054,946 (July 16)	£1036.530 (July 16)	£18,416 (The variance is due to the security, class consultants, IS contingency pot and data migration consultancy not being spent as forecasted.)

4.2. The delay to the programme will have financial consequences, with the effect being worked through at the time of writing.

5. Earned value

- The spend to date has raised slightly comparing to the earned value, this is mainly due to the delay caused by the injunction and the impact on Beta completion. Also note that the RR resources issues remain a blockage to complete Beta and has a noticeable impact on work completion and therefore the earned value.

Period	Feb-16	Mar-16	Apr-16	May-16	Jun-16	Jul-16
Earned Value	53.8%	65.5%	70.0%	75%	79%	81%
Spend to date	64.8%	67.0%	74.1%	75%	87%	88%



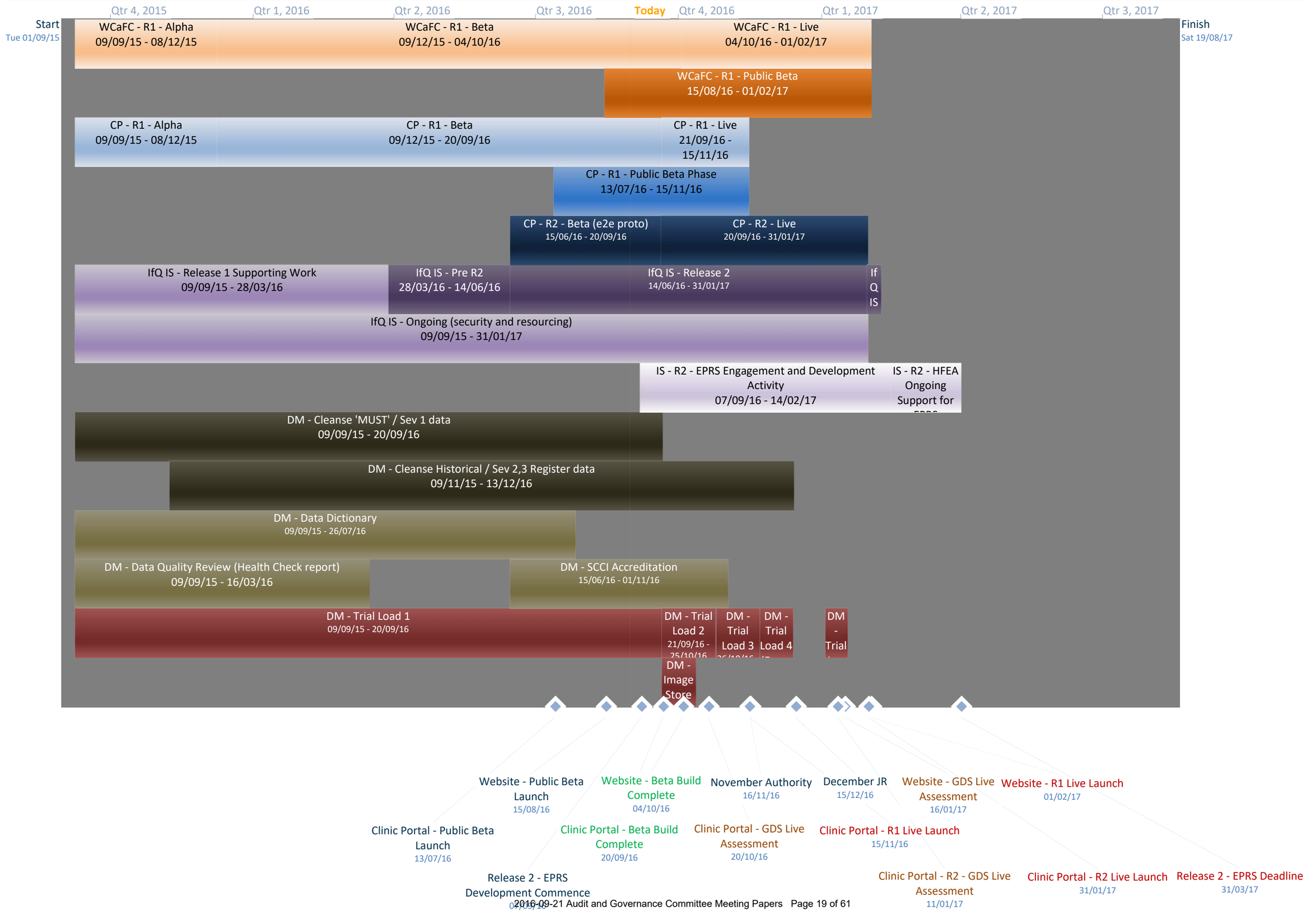
6. Recommendation:

6.1. The Audit and Governance Committee is asked to:

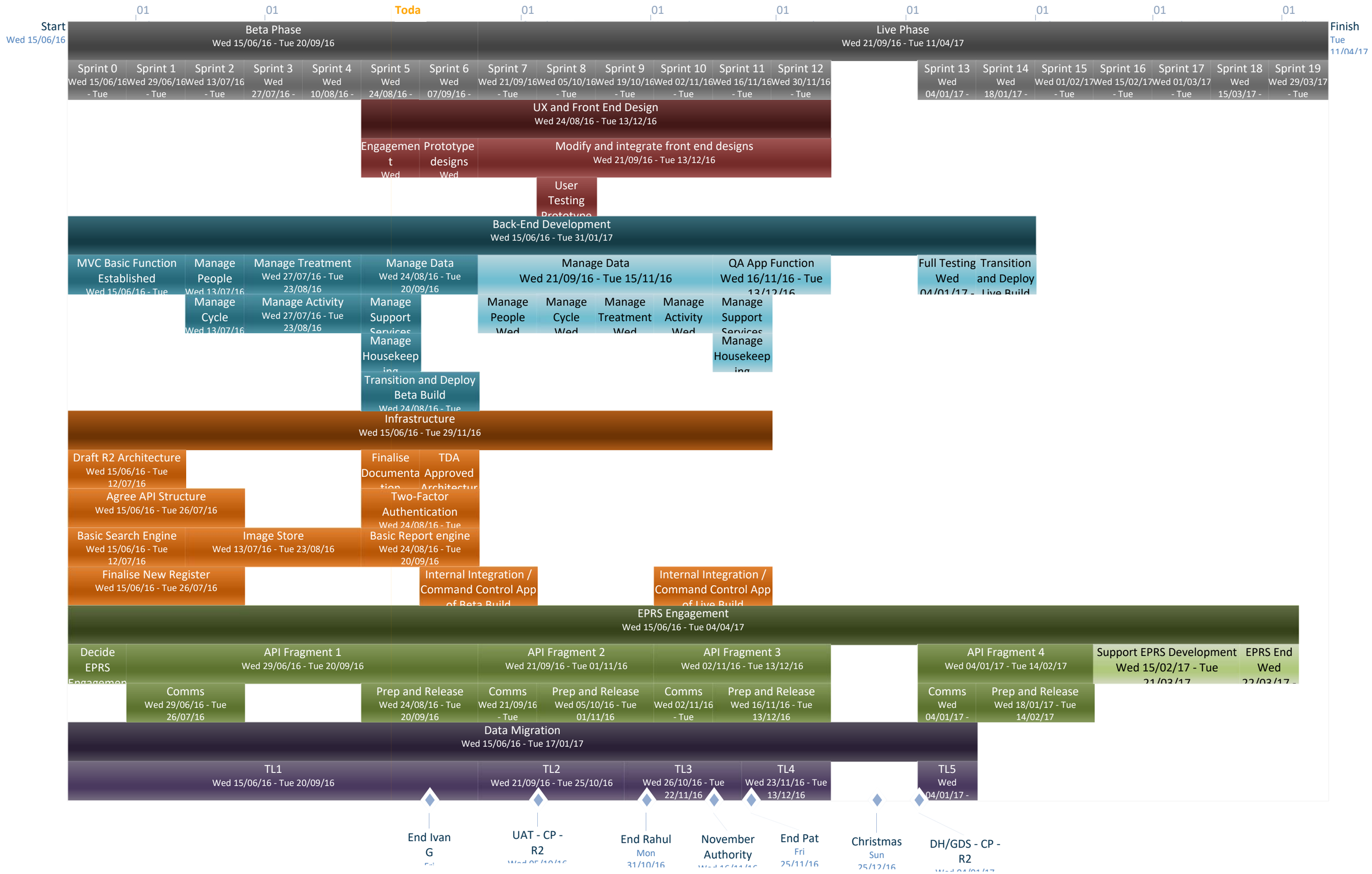
- Note progress, risks and the budget position on IfQ.
- Note in particular the update on the new risks.

7. Annexes:

- Annex A: Timeline for the remaining IfQ Beta phase


Qtr 4, 2015
Qtr 1, 2016
Qtr 2, 2016
Qtr 3, 2016
Today
Qtr 4, 2016
Qtr 1, 2017
Qtr 2, 2017
Qtr 3, 2017
Start
Tue 01/09/15
Finish
Sat 19/08/17
WCaFC - R1 - Alpha
09/09/15 - 08/12/15
WCaFC - R1 - Beta
09/12/15 - 04/10/16
WCaFC - R1 - Live
04/10/16 - 01/02/17
WCaFC - R1 - Public Beta
15/08/16 - 01/02/17
CP - R1 - Alpha
09/09/15 - 08/12/15
CP - R1 - Beta
09/12/15 - 20/09/16
CP - R1 - Live
21/09/16 - 15/11/16
CP - R1 - Public Beta Phase
13/07/16 - 15/11/16
CP - R2 - Beta (e2e proto)
15/06/16 - 20/09/16
CP - R2 - Live
20/09/16 - 31/01/17
IfQ IS - Release 1 Supporting Work
09/09/15 - 28/03/16
IfQ IS - Pre R2
28/03/16 - 14/06/16
IfQ IS - Release 2
14/06/16 - 31/01/17
If Q IS
IfQ IS - Ongoing (security and resourcing)
09/09/15 - 31/01/17
IS - R2 - EPRS Engagement and Development Activity
07/09/16 - 14/02/17
IS - R2 - HFEA Ongoing Support for
DM - Cleanse 'MUST' / Sev 1 data
09/09/15 - 20/09/16
DM - Cleanse Historical / Sev 2,3 Register data
09/11/15 - 13/12/16
DM - Data Dictionary
09/09/15 - 26/07/16
DM - Data Quality Review (Health Check report)
09/09/15 - 16/03/16
DM - SCCI Accreditation
15/06/16 - 01/11/16
DM - Trial Load 1
09/09/15 - 20/09/16
DM - Trial Load 2
21/09/16 -
DM - Trial Load 3
DM - Trial Load 4
DM - Trial
DM - Image Store
Website - Public Beta Launch
15/08/16
Website - Beta Build Complete
04/10/16
November Authority
16/11/16
December JR
15/12/16
Website - GDS Live Assessment
16/01/17
Website - R1 Live Launch
01/02/17
Clinic Portal - Public Beta Launch
13/07/16
Clinic Portal - Beta Build Complete
20/09/16
Clinic Portal - GDS Live Assessment
20/10/16
Clinic Portal - R1 Live Launch
15/11/16
Release 2 - EPRS Development Commence
Clinic Portal - R2 - GDS Live Assessment
11/01/17
Clinic Portal - R2 Live Launch
31/01/17
Release 2 - EPRS Deadline
31/03/17

Attachment – **Proposed** Release Plan for IfQ Release 2 Sprints



Strategic risks

Strategic delivery:	☒ Setting standards	☒ Increasing and informing choice	☒ Demonstrating efficiency economy and value
Details:			
Meeting	Audit and Governance Committee		
Agenda item	6		
Paper number	AGC (21/09/2016) 508		
Meeting date	21 September 2016		
Author	Helen Crutcher, Project Risk and Performance Manager		
Output:			
For information or decision?	Information and comment.		
Recommendation	AGC is asked to note the latest edition of the risk register, set out in the annex.		
Resource implications	In budget.		
Implementation date	Strategic risk register and operational risk monitoring: ongoing. CMG reviews risk quarterly in advance of each AGC meeting. AGC reviews the strategic risk register at every meeting. The Authority reviews the strategic risk register periodically.		
Organisational risk	☐ Low	☒ Medium	☐ High
Annexes	Annex 1: Strategic risk register		

1. Strategic risk register

Latest reviews

1.1. CMG reviewed the risk register on 7 September 2016. CMG discussed all risks, their controls, and scores. The Legal risk was reviewed in detail by risk owners at a separate meeting, to provide the current position. Three of the twelve risks are currently above tolerance.

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

1.3. The Authority reviewed the risk register at its meeting on 6 July 2016. No amendments were proposed to the risks or the scores.

2. Recommendation

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

Annex A

HFEA strategic risk register 2016/17

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	**12 – High**	At tolerance	⇩ ⇔⇔⇔
Information for Quality	IfQ1: Improved information access	Increasing and informing choice: information	**12 – High**	Above tolerance	⇔⇔⇔⇔
Data	D1: Data loss or breach	Efficiency, economy and value	**10 – Medium**	At tolerance	⇔⇔⇔⇔
Data	D2: Incorrect data released	Efficiency, economy and value	**9 – Medium**	Above tolerance	⇩⇔⇔⇔
Financial viability	FV1: Income and expenditure	Efficiency, economy and value	**9 – Medium**	At tolerance	⇔⇔⇔ ⇔
Donor conception	DC2: Support for OTR applicants	Setting standards: donor conception	**9 – Medium**	At tolerance	⇔⇔⇔⇔
Capability	C1: Knowledge and capability	Efficiency, economy and value	**9 – Medium**	Above tolerance	⇔⇔⇔⇔
Information for Quality	IfQ3: Delivery of promised efficiencies	Efficiency, economy and value	**8 – Medium**	Below tolerance	⇔ ⇔⇔⇩
Regulatory model	RM1: Quality and safety of care	Setting standards: quality and safety	**8 – Medium**	At tolerance	⇔⇔⇔⇔
Regulatory model	RM2: Loss of regulatory authority	Setting standards: quality and safety	**8 – Medium**	At tolerance	⇔⇔⇔⇔
Information for Quality	IfQ2: Register data	Increasing and informing choice: Register data	**8 – Medium**	At tolerance	⇔⇔⇔⇔
Donor conception	DC1: OTR inaccuracy	Setting standards: donor conception	**4 – Low**	At tolerance	⇔⇔⇔⇔

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

[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)

Recent review points are: CMG 18 May ⇨ AGC 15 June ⇨ Authority 6 July ⇨ CMG 7 September

CMG overview – summary from September risk meeting

CMG reviewed the risk register and risk scores at its meeting on 7 September. Detailed review of the legal (LC1) risk was undertaken offline with the risk owners.

CMG heard about the Department of Health risk audit recommendation that ALBs and the Department consider risk interdependencies across the health and care system, and heard that the HFEA would be seeking to embed this approach into future management of risk.

Three new inter-related strategic risk sources arising due to IfQ had been escalated to the register this month. These risks were the various impacts of Electronic Patient Record System (EPRS) providers not making the necessary changes to their systems to submit clinic treatment data to the new Register structure following IfQ release 2. The risk areas affected are firstly RM1 (the risk of a loss of regulatory authority), because any gaps in data could impact effective regulatory monitoring. Secondly, IfQ1 (the risk to improved information access), since any data that had not been provided would then not be available to provide to patients through Choose a Fertility Clinic. And finally, FV1 (financial viability - risk of overspend) could be impacted if the HFEA were not able to bill clinics for treatments that they had undertaken but not reported to us. CMG heard that this risk was not yet imminent since it would only apply following IfQ release 2, in 2017; however, the impact of the risk could potentially be wide-reaching if it were not managed effectively. CMG heard that the IfQ Programme Board had received proposals for a revised delivery plan and that this would positively affect the proximity of the risk. Work was also underway to develop further mitigation plans for these risks, alongside the finance and compliance departments where needed. CMG agreed that the HFEA was able to tolerate this situation at the current time, however, appropriate mitigation plans and risk monitoring would be essential.

Under item C1 (Knowledge and capability), CMG discussed the impact of the Head of Corporate Governance leaving the organisation in September. Although this would leave the HFEA with a Head level vacancy again, the residual risk level for this risk had previously been raised when there had been two Head vacancies at once, and had not been lowered since that point pending bedding in periods. Because of this, the risk would not increase as a result of having a vacancy again.

CMG reassessed the residual risk likelihood for IfQ3 (delivery of promised efficiencies), and agreed it should be reduced to a score of 2, since, with the mitigations currently in place it was unlikely that the HFEA would not be able to deliver these improvements. This brings this risk to within tolerance, with a score of 8.

All Finance related risks have been reassigned to the Head of Finance to reflect the interim period between the departure of the current Director of Finance and Resources and arrival of the new one at the beginning of November.

CMG also considered operational risks (under a different report) and noted that the main theme of each team's operational risks was resources. This has been the position for some time now and risks in this area were raised by all teams, though resource pressure was particularly being felt in the Legal team at the moment. Other teams have been made aware of these pressures on the Legal team and external support is being sought where useful.

An increase in the number of quality-related operational risks across teams was also noted. This was especially highlighted in a new business planning team risk, rated 'high', that 'unanticipated or uncontrolled risks could become live issues or cause internal incidents'. The importance of ongoing operational risk management with teams was highlighted to all Heads. The business planning team are also planning to implement further

measures to embed risk management in teams and upskill more junior team members, though this also requires the ongoing commitment of Heads.

A new finance risk was raised which was also the highest risk this month with a 'very high' rated residual risk of 20. This was the risk of non-payment of suppliers caused by technical issues with HFEA being migrated to Barclays internet banking, leaving the organisation with limited capability for paying suppliers. This had been escalated with the bank and meanwhile there is a workaround in place to use the existing system.

AGC feedback – June meeting (15/06/2016):

Some of the strategic risks were discussed in depth during the review of other agenda items, particularly IfQ risks. The committee was assured that the levels of risk were correctly recorded and that actions are being taken to mitigate the risks.

The committee discussed the data risk D2 – incorrect data being released – in particular detail and noted a recent upward trend in the number and complexity of Parliamentary Questions being raised, with challenging content and deadlines. The executive agreed to review the latest figures after the meeting, and consider the impact of this upon the risk level if it continued to be a trend. In summary, the committee noted they were encouraged by the consistency of risk levels and the management of the risks.

Criteria for inclusion of risks:

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

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

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

Risk scoring system
See last page.

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

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

System-wide risk interdependencies

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

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

Causes / sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Inspection/reporting failure.	Inspections are scheduled for the whole year, using licence information held on Epicentre, and items are also scheduled to committees well in advance.	In place – Sharon Fensome-Rimmer	At tolerance. The Head of Corporate Governance and Chief Inspector started in their posts (in March and May 2016 respectively). While they are bedding into the organisation it is likely that some degree of ownership of controls will sit with both the respective Directors as well as the Heads themselves until they are fully trained. The Head of Corporate Governance will now be leaving the HFEA in September 2016 which leaves a head vacancy again. There will continue to be a period of bedding in for the Chief Inspector. The need to manage the imminent Head vacancy, the continuing training period and also the action plan being
	Audit of Epicentre conducted to reveal data errors. Queries now routed through Licensing, who hold a definitive list of all licensing details.	Completed October 2015 – Ian Brown	
	Inspector training, competency-based recruitment, induction process, SOPs, QMS, and quality assurance all robust.	In place – Sharon Fensome-Rimmer	
Regulatory monitoring processes may be disrupted as a result of the temporary inability of Electronic Patient Record System (EPRS) providers to submit data to the new register structure until their software has been updated. This could impact performance information used in inspection notebooks and RBAT alerts	Proposals on an updated IfQ delivery plan were made to August IfQ Programme Board, these should help address this risk by extending the release date for the EDI replacement by 3 months (IfQ release 2). Mitigation plans for this risk are in the process of being prepared and agreed with SMT as at September.	Mitigation planning in progress in September - Nick Jones	
Monitoring failure.	Outstanding recommendations from inspection reports are tracked and followed up by the team.	In place – Sharon Fensome-Rimmer	
Unresponsiveness to or mishandling of non-compliances or grade A incidents.	Update of compliance and enforcement policy.	Completed following Authority approval of new policy March 2016 - Nick Jones	
	Staffing model provides resilience in the inspection	In place – Sharon Fensome-Rimmer	

	team for such events – dealing with high-impact cases, additional incident inspections, etc.		implemented in connection with legal parenthood consent issues, has raised the residual risk likelihood from 1 (very unlikely) to 2 (unlikely) – from November through to at least November 2016. On legal parenthood, a strong set of actions is in place and continues to be implemented. The inspection team continue to work with colleagues in licensed centres where there are anomalies. The focus is on ensuring all affected patients are informed and appropriately supported.
Insufficient inspectors or licensing staff	Inspection team up to complement. The new Chief Inspector joined the HFEA in early May 2016.	In place – Nick Jones	
	Licensing team up to complement following earlier recruitment. The new Head of Corporate Governance joined the HFEA in March 2016.	In place – Ian Brown	
Recruitment difficulties and/or high turnover/churn in various areas; resource gaps and resource diversion into recruitment and induction, with impacts felt across all teams.	So far recruitment rounds have yielded sufficient candidates, although this has required going beyond the initial ALB pool to external recruitment in some cases.	Managed as needed – Sharon Fensome-Rimmer	
	Additional temporary resources available during periods of vacancy and transition.	In place – Rachel Hopkins	
	Group induction sessions put in place where possible.	In place – Sharon Fensome-Rimmer	
Resource strain itself can lead to increased turnover, exacerbating the resource strain.	Operational performance, risk and resourcing oversight through CMG, with deprioritisation or rescheduling of work an option.	In place – Paula Robinson	
Unexpected fluctuations in workload (arising from eg, very high level of PGD applications received, including complex applications involving multiple types of a condition; high levels of non-compliances either generally or in relation to a particular issue).	Staffing model amended in May 2015, to release an extra inspector post out of the previous establishment. This increased general resilience, enabling more flex when there is an especially high inspection/report writing/application processing workload.	In place – Sharon Fensome-Rimmer	
	Greater sector insight into our PGD application handling processes and decision-making steps achieved in the past few years; coupled with our increased processing rate since efficiency improvements were made in 2013 (acknowledged by the sector).	In place – Sharon Fensome-Rimmer	
Some unanticipated event occurs that has a big diversionary impact on key resources, eg, legal parenthood consent issues, or several major Grade A	Resilient staffing model in place.	In place – Sharon Fensome-Rimmer	
	Update of compliance and enforcement policy and implementation of new policy and related procedures.	In place – revised policy agreed Spring 2016 – Nick Jones / Sharon Fensome-Rimmer	

incidents occur at once.			
	A detailed action plan in response to the legal parenthood judgment is in place. There has been correspondence with clinics, who have completed full audits. PRs are responsible for the robustness of the audit. The HFEA has required that clinics support affected patients – using Barts as a good example. In working with clinics, the HFEA has experienced good cooperation. All clinics engaged and have provided assurances about current practice. Through a detailed review of every clinic's responses, a summary list of all concerns is being produced. Management review meetings took place for all clinics at which there are handling concerns or anomalies. Plan of action in place to address all of the concerns identified, with direct follow up with centres who did not respond at all. Where there are engagement concerns, we will do short-notice inspections, focused on parenthood consent. The policy team will develop a range of tools to support licensed clinics in ensuring patients provide effective consent. Range of lessons learned identified.	In progress – Nick Jones/Sharon Fensome-Rimmer Policy team tools – development in 2017/18 business year – Joanne Anton	

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 – Ian Brown	At tolerance. Although two additional risk sources exist at present (website outages until the new beta website is live and the plan of work to address legal parenthood consent issues), these are being well managed and/or tolerated, and the overall risk score has not increased.
	Learning from past representations and Appeal Committee hearings incorporated into processes.	In place – Ian Brown	
	Appeals Committee membership maintained. Ongoing process in place for regular appointments whenever vacancies occur or terms of office end.	In place – Ian Brown	
	Staffing structure for sufficient committee support.	In place – Ian Brown	
	Decision trees; legal advisers familiar.	In place – Ian Brown	
	Proactive management of quoracy for meetings.	In place – Ian Brown	
	New (ie, first application) T&S licences delegated to ELP. Delegations were revisited during 2016 review of Standing Orders. Licensing Officer role to take certain decisions from ELP –the documentation for recording Licensing Officer decisions is complete as at September 2016 and this process is ready for implementation.	In place – Ian Brown Licensing Officer role – ready for implementation September 2016 – Ian Brown Delegations in SOs were put in place - Spring 2016	
Failing to demonstrate competence as a regulator	Update of compliance and enforcement policy and implementation of new policy and related procedures.	In place – revised policy agreed Spring 2016 – Nick Jones / Sharon Fensome-Rimmer	

	Inspector training, competency-based recruitment, induction process, SOPs, quality management system (QMS) and quality assurance all robust.	In place – Sharon Fensome-Rimmer
Effect of publicised grade A incidents.	Staffing model provide resilience in inspection team for such events – dealing with high-impact cases, additional incident inspections, etc.	In place – Sharon Fensome-Rimmer
	SOPs and protocols with Communications team.	In place – Sharon Fensome-Rimmer
	Fairness and transparency in licensing committee information.	In place – Sharon Fensome-Rimmer
	Dedicated section on website, so that the public can openly see our activities in the broader context.	In place – Sharon Fensome-Rimmer
Administrative or information security failure, eg, document management, risk and incident management, data security.	Staff have annual information security training (and on induction).	In place – Dave Moysen
	TRIM training and guidance/induction in records management in place pending new work on records management to be commenced in autumn 2016 (see below).	New work in development as at September 2016
	Further work planned on records management in parallel with IT strategy. This piece of work is currently being scoped.	Linked to IT strategy work – in progress – Ian Brown / David Moysen
	Guidance/induction in handling FOI requests, available to all staff.	In place – Ian Brown
	The IfQ website management project has reviewed the retention schedule.	Completed – August 2015 – Juliet Tizzard
Until the IfQ website project has been completed, there is a continued risk of HFEA website outages, as well as difficulties in uploading updates to web pages.	Alternative mechanisms are in place for clinics to get information about materials such as the Code of Practice (eg, direct communications with inspectors, Clinic Focus).	In place – Sharon Fensome-Rimmer
	The IfQ work on the new website will completely mitigate this risk (the new content management system will remove the current instability we are experiencing from using RedDot). This risk has informed our decisions about which content to move first to the beta version of the new site.	In progress – beta phase February 2016 – Juliet Tizzard

Negative media or criticism from the sector in connection with legally disputed issues or major adverse events at clinics.	HFEA approach is only to go into cases on the basis of clarifying legal principles or upholding the standards of care by challenging poor practice. This is more likely to be perceived as proportionate, rational and necessary (and impersonal), and is in keeping with our strategic vision.	In place - Peter Thompson	
HFEA process failings that create or contribute to legal challenges, or which weaken cases that are otherwise sound, or which generate additional regulatory sanctions activity (eg, legal parenthood consent).	Licensing SOPs, committee decision trees in place. Mitochondria donation application tools completed.	In place – Ian Brown	
	Update of compliance and enforcement policy and implementation of new policy and related procedures.	In place – revised policy agreed Spring 2016 – Nick Jones / Sharon Fensome-Rimmer	
	Seeking the most robust possible assurance from the sector with respect to legal parenthood consent issues, and detailed plan in operation to address identified cases and anomalies.	In progress – Nick Jones	
	QMS and quality assurance in place in inspection team.	In place – Sharon Fensome-Rimmer	

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

Causes / sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Inability to extract reliable data from the Register.	Detailed planning and programme management in place to ensure this will be possible after migration. Migration strategy developed, and significant work being done to identify and cleanse all of the data that will require correction before migration can be done. Decisions have been made about the degree of reliability required in each data field. For those fields where 100% reliability is needed, inaccurate or missing data is being addressed as part of project delivery.	All aspects – detailed project planning in place – Nick Jones	Above tolerance. The approval process has had to be tightly managed; a summary is set out below. The Department of Health gateway review took place in November 2015 and awarded a high score to the HFEA, but the formal decision on this was still not made by the Government Digital Service board until mid-January (a month later than expected). This meant that the beta (build) stage initially had to proceed at risk (subsequently resolved).
Reduced ability to provide for patient choice based on CaFC information as a result of EPRS inability to submit/correct data in the new register structure if they do not update their systems in time to comply. This could impact the publication of CaFC data.	Proposals on an updated IfQ delivery plan were made to August IfQ Programme Board, these should help address this risk. Mitigation plans for this risk are in the process of being prepared and agreed with SMT as at September.	In progress - Nick Jones	

Stakeholders dislike or fail to accept the new model for CaFC. Stakeholders not on board with the changes.	In-depth stakeholder engagement and extensive user research completed to inform the programme's intended outcomes, products and benefits. This included, consultation, expert groups and Advisory Board and this continues to be an intrinsic part of programme approach.	In place and ongoing – Juliet Tizzard /Nick Jones	Approval also carried a number of requirements and conditions which need to be added to the delivery. Owing to these delays, it was necessary to extend the timeline for the private beta phase from March to June 2016. The live beta gateway approval in May was much more efficient, with approvals received within days of the assessment taking place. However, there were a number of requirements to address before implementing live beta. The move to public (live) beta was delayed by an injunction brought by a licensed clinic. We successfully managed to have the injunction lifted, but it meant that we could not issue the new website to public beta testing until August 2016.
Cost of delivering better information becomes too prohibitive, either because the work needed is larger than anticipated, or as a result of the approval periods associated with required DH/GDS gateway reviews.	Costs were taken into account as an important factor in consideration of contract tenders and negotiations. Following earlier long timelines and unsuccessful attempts to discuss with GDS, our experience at the Beta gateway has been much improved and feedback was almost immediate. Watching brief being kept.	In place – Nick Jones In place – Nick Jones	
Redeveloped website does not meet the needs and expectations of our various user types.	Programme approach and some dedicated resources in place to manage the complexities of specifying web needs, clarifying design requirements and costs, managing changeable Government delegation and permissions structures, etc. User research done, to properly understand needs and reasons. Tendering and selection process included clear articulation of needs and expectations. GDS Beta assessment was passed on all 18 points.	In progress – delivery of next stage of user research by end Oct 2016 – Juliet Tizzard	
Government and DH permissions structures are complex, lengthy, multi-stranded, and sometimes change mid-process.	Initial external business cases agreed and user research completed. Final business case for whole IfQ programme was submitted and eventually accepted. All GDS approvals sought so far have been granted, albeit with some delays to the earlier ones. Additional sprints of work were incorporated in beta, in an attempt to allow sufficient time (and resources) for the remaining GDS gateway review processes	In place – Juliet Tizzard In place – Nick Jones (decision received April 2015) In place – Nick Jones	

	and subsequent formal approval mechanisms. The beta timeline was extended by 3 months to compensate for previous and anticipated future delays.	
Resource conflicts between delivery of website and business as usual (BAU).	Backfilling where possible/affordable to free up the necessary staff time, eg, Websites and Publishing Project Manager post backfilled to free up core staff for IfQ work.	In place – Juliet Tizzard
Delivery quality is very supplier dependent. Contractor management could become very resource-intensive for staff, or the work delivered by one or more suppliers could be poor quality and/or overrun, causing knock-on problems.	Programme management resources and quality assurance mechanisms in place for IfQ to manage (among other things) contractor delivery. Agile project approach includes a 'one team' ethos and requires close joint working and communication among all involved contractors. Sound project management practices in place to monitor delivery. Previous lessons learned and knowledge exist in the organisation from managing some previous projects where poor supplier delivery was an issue requiring significant hands-on management. Ability to consider deprioritising other work, through CMG, if necessary. Regular contract meetings in place. This remains a challenge.	In place – Juliet Tizzard
New CMS (content management software) is ineffective or unreliable.	CMS options were scrutinised carefully as part of project. Appropriate new CMS chosen, and all involved teams happy with the selection.	In progress – implemented in beta phase, July 2016 – Juliet Tizzard
Benefits not maximised and internalised into ways of working.	During IfQ delivery, product owners are in place, as is a communications plan. The aim is to ensure that changes are developed involving the right staff expertise (as well as contractors) and to ensure that the changes are culturally embraced and embedded into new ways of working. Knowledge handover with the contractors will take place.	In place – Nick Jones

Risk area	Description and impact	Strategic objective linkage	Risk scores			Recent trend	Risk owner
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 focused on current state of Register. Extensive planning in place, including detailed research and migration strategy.	In place – Nick Jones/Dave Moysen	At tolerance. This risk is being intensively managed – a major focus of IfQ detailed planning work, particularly around data migration.
The firm (Avoca) which was scheduled to provide assurance on data migration has gone out of business.	The HFEA has considered other sources of assurance and have now sourced a supplier and is currently going through procurement processes to appoint them.	Pending a successful appointment process, we would expect the new company to begin providing assurance in September/October– Nick Jones	
Historic data cleansing is needed prior to migration.	A detailed migration strategy is in place, and data cleansing is in progress.	In place – Nick Jones/Dave Moysen	
Increased reporting needs mean we later discover a barrier to achieving this, or that an unanticipated level of accuracy is required, with data or fields which we do not currently focus on or deem critical for accuracy.	IfQ planning work incorporated consideration of fields and reporting needs were agreed. Decisions about the required data quality for each field were 'future proofed' as much as possible through engagement with stakeholders to anticipate future needs and build these into the design.	In place – Nick Jones	
Reliability of existing infrastructure systems – (eg, Register, EDI, network, backups).	Maintenance of desktop, network, backups, etc. core part of IT business as usual delivery.	In place – Dave Moysen	
System interdependencies change / are not recognised	Strong interdependency mapping done between IfQ and business as usual.	Done – Nick Jones	
Benefits not maximised and internalised into ways of working.	During IfQ delivery, product owners are in place, as is a communications plan. The aim is to ensure that changes are developed involving the right staff expertise (as well as contractors) and to ensure that	In place – Nick Jones	

	the changes are culturally embraced and embedding into new ways of working. Knowledge handover with the contractors will take place.		

Risk area	Description and impact	Strategic objective linkage	Risk scores			Recent trend	Risk owner
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		
			2	**4**	8 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 phases of projects.	In place – Nick Jones/Juliet Tizzard	Below tolerance. September 2016 - Since, ultimately, we believe that the mitigations that are in place are working effectively and mean that we are on track to achieve the promised efficiencies, we have reduced the level of likelihood for this risk. This in turn brings the risk to below the tolerance threshold of 9. This risk is also affected by GDS approvals and associated requirements (see IfQ1).
Clinics not consulted/involved enough.	Working with stakeholders has been central to the development of IfQ, and will continue to be. Advisory Group and expert groups have ended, but a stakeholder group for the implementation phase is in place. Workshops were delivered with the sector regarding how information will be collected through the clinic portal. From beta live onwards we will receive feedback and iteratively develop the products.	In place – Nick Jones/Juliet Tizzard	
Scoping and specification are insufficient for realistic resourcing and on-time delivery of changes.	Scoping and specification were elaborated with stakeholder input, so as to inform the tender. Resourcing and timely delivery were a critical part of the decision in awarding the contract.	In place and contracts awarded (July 2015) – Nick Jones	
Efficiencies cannot, in the end, be delivered.	Detailed scoping phase included stakeholder input to identify clinic users' needs accurately. Specific focus in IfQ projects on efficiencies in data collected, submission and verification, etc.	In place – Nick Jones	
Cost of improvements becomes too prohibitive.	Contracts only awarded to bidders who made an affordable proposal. Detailed planning for release two (which includes the second iteration of the portal and the	In place (July 2015) – Nick Jones In progress (September 2016) – Nick Jones	

	introduction of the new EDI interface) is in progress and the HFEA will continue to work within agreed costs.	
Required GDS gateway approvals are delayed or approval is not given.	All GDS approvals sought so far have been granted, albeit with some delays to earlier gateways. Our detailed planning includes addressing the requirements laid down by GDS as conditions of alpha and beta phase approval. Additional sprints of work were incorporated into beta, in an attempt to allow sufficient time (and resources) for the remaining GDS gateway review processes and subsequent formal approval mechanisms. The beta timeline was extended by 3 months to compensate for previous and anticipated future delays.	In place – Nick Jones
Benefits not maximised and internalised into ways of working.	During IfQ delivery, product owners are in place, as is a communications plan. The aim is to ensure that changes are developed involving the right staff expertise (as well as contractors) and to ensure that the changes are culturally embraced and embedded into new ways of working. Knowledge handover with the contractors will take place.	In place (June 2015) – Nick Jones

Risk area	Description and impact	Strategic objective linkage	Risk scores			Recent trend	Risk owner
Legal 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	**4**	**12 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	At tolerance. **Current cases:** The judgment in 2015 and subsequent cases on consents for parenthood have administrative and policy consequences for the HFEA. Further cases are going through court, although there have been no cases arising from new incidents post the 2015 judgment. The HFEA is unlikely to participate in most of these legal proceedings directly, though the court has required us to provide information and clarification in relation to six legal parenthood cases. A judicial review hearing of one discrete element of the IfQ CaFC project has been set for December. Authority decisions in November may impact on the
	Evidence-based policy decision-making and horizon scanning for new techniques.	In place – Joanne Anton	
	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 – Joanne Anton/Juliet Tizzard	
HFE Act and regulations lead 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. Case by case decisions regarding what to argue in court cases, so as to clarify the position.	In place – Peter Thompson	
Decisions and actions of the HFEA and its committees may be contested. New guide to licensing and inspection rating (effective from go-live of new website) on CaFC may mean that more clinics make representations against	Panel in place, as above.	In place – Peter Thompson	
	Maintaining, keeping up to date and publishing licensing SOPs, committee decision trees etc. consistent decision making at licence committees supported by effective tools for committees Standard licensing pack completely refreshed and distributed to members/advisers (April 2015).	In place – Ian Brown	

licensing decisions.	Well-evidenced recommendations in inspection reports.	In place – Sharon Fensome-Rimmer	scope of the JR. We are advised that our case is strong; however, if it were lost then it may impact on aspects of the presentation of data. A patient has brought an application for a declaration seeking clarification about the continued storage of her embryos. The matter will be considered in court in September and we are hopeful that the agreed outcome can be reached.
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 any likely action.	In place – Peter Thompson	
HFEA could face unexpected high legal costs or damages which it could not fund.	If this risk was to become an issue then discussion with the Department of Health would need to take place regarding possible cover for any extraordinary costs, since it is not possible for the HFEA to insure itself against such an eventuality, and not reasonable for the HFEA's small budget to include a large legal contingency. This is therefore an accepted, rather than mitigated risk. It is also interdependent risk because DH would be involved in resolving it.	In place – Peter Thompson	
Legal proceedings can be lengthy and resource draining.	Panel in place, as above, enabling us to outsource some elements of the work.	In place – Peter Thompson	
	Internal mechanisms (such as the Corporate Management Group, CMG) in place to reprioritise work should this become necessary.	In place – Peter Thompson	
Adverse judgments requiring us to alter or intensify our processes, sometimes more than once.	Licensing SOPs, committee decision trees in place.	In place – Ian Brown	

Risk area	Description and impact	Strategic objective linkage	Risk scores			Recent trend
Data D 1: Data loss or breach	There is a risk that HFEA data is lost, becomes inaccessible, is inadvertently released or is inappropriately accessed.	Efficiency, economy and value: ensuring the HFEA remains demonstrably good value for the public, the sector and Government.	Inherent risk level:			⇔ ⇔ ⇔ ⇔
			Likelihood	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 through off-site back-ups and the fact that any malicious tampering would be a criminal act.	In place (March 2015) – Nick Jones	
Business continuity issue.	BCP in place and staff communication procedure tested. A new BCP is being produced by the Head of IT to reflect the changes to this following changes	In place – Morounke Akingbola Update being done by Dave Moysen – September 2016	

	to infrastructure and the office move.		
Register data becomes corrupted or lost somehow.	Back-ups and warehouse in place to ensure data cannot be lost.	In place – Nick Jones/Dave Moysen	
Other HFEA data (system or paper) is lost or corrupted.	As above. Staff have annual compulsory security training to guard against accidental loss of data or breaches of confidentiality.	In place – Dave Moysen	
Poor records management	TRIM training and guidance/induction in records management in place pending new work on records management to be commenced in autumn 2016 (see below). New work in development as at September 2016	New work in development as at September 2016	
	Further work planned on records management in parallel with IT strategy. This piece of work is currently being scoped. Linked to IT strategy work – in progress – Ian Brown / David Moysen	Linked to IT strategy work – in progress – Ian Brown / David Moysen	

Risk area	Description and impact	Strategic objective linkage	Risk scores	Recent trend	Risk owner
Data D 2: Incorrect data released	There is a risk that incorrect data is released in response to a Parliamentary question (PQ), or a Freedom of Information (FOI) or data protection request.	Efficiency, economy and value: ensuring the HFEA remains demonstrably good value for the public, the sector and Government.	Inherent risk level: Likelihood: 5 / Impact: 4 / Inherent risk: 20 Very high Residual risk level: Likelihood: **3** / Impact: **3** / Residual risk: **9 Medium** Tolerance threshold: 8 Medium	⇩ ⇔ ⇔ ⇔	Juliet Tizzard

Causes / sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Poor record keeping	Refresher training and reminders about good records management practice.	In place – SMT	Above tolerance. Although we have some good controls in place for dealing with PQs and other externally generated requests, it should be noted that we cannot control incoming volumes, complexity or deadlines. In September 2016 we have not yet registered an unusual spike in volumes following on from recess (during which time there were no PQs). However, with the current work on the mitochondria scientific review, due to be published in November, this situation is likely to change in future months. We continue to closely monitor volumes.
	TRIM review and retention policy implementation work – part of records management project	To sync in with IT strategy. RM project to start autumn 2016– Dave Moysen/Ian Brown	
	Audit of Epicentre to reveal any data errors. All queries being routed through Licensing, who have a definitive list of all licensing details.	Completed October 2015 – Ian Brown Implementation of actions following Epicentre audit planned and to be completed by November 2016– Ian Brown	
Excessive demand on systems and over-reliance on a few key expert individuals – request overload – leading to errors	PQs, FOIs and OTRs have dedicated expert staff/teams to deal with them. If more time is needed for a complex PQ, it is occasionally necessary to take the issue out of the very tightly timed PQ process and replace this with a more detailed and considered letter back to the enquirer so as to provide the necessary level of detail and accuracy in the answer. We also refer back to previous answers so as to give a check, and to ensure consistent presentation of similar data.	In place – Juliet Tizzard / Nick Jones	

	FOI requests are refused when there are grounds for this.	
	PQ SOP revised and log created, to be maintained by Committee and Information Officer/Scientific Policy Manager.	In place - Ian Brown
Answers in Hansard may not always reflect advice from HFEA.	The PQ team attempts to catch any changes to drafted wording that may unwittingly have changed the meaning. HFEA's suggested answer and DH's final submission both to be captured in new PQ log.	In place – Ian Brown / Peter Thompson
Insufficient understanding of underlying system abilities and limitations, and/or of the topic or question, leading to data being misinterpreted or wrong data being elicited.	As above – expert staff with the appropriate knowledge and understanding in place.	In place – Juliet Tizzard / Nick Jones
Servicing data requests for researchers - poor quality of consents obtained by clinics for disclosure of data to researchers.	There is a recognised risk of centres reporting research consents inaccurately. Work is ongoing to address consent reporting issues	Inspections now routinely sample check a clinic's performance comparing original consent form with the detail held on the Register, to ensure it has been transcribed effectively. Where the error rate is above tolerance the clinic must undertake a full audit and carry out corrections to the Register as necessary – Nick Jones

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

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

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

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

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

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) – Morounke Akingbola	At tolerance. 2015/16 achieved a small under-spend but risk of additional legal costs remains. The increase of per-cycle fees by £5 (to £80) and the end of the small 'eSET discount' for elective single embryo transfer has now been implemented following Treasury approval in February 2016. This should help secure sufficient funds going forward. It is too early for us to tell whether this reduces this risk further. The situation will be clearer following IfQ implementation. The potential impact of the IfQ risk here, related to EPRS suppliers and the impact on treatment fees, is not yet fully
	Fees Group created enabling dialogue with sector about fee levels. Fee increase was agreed and approved by Treasury. This was implemented and the eSET discount ended (April 2016).	In place. Fees Group meeting in October, ongoing – Morounke Akingbola	
EPRS suppliers may not make required changes to their systems in line with IfQ data submission mechanism (EDI, Register) changes. Clinics using these suppliers would be unable to provide treatment data leading to deferral of fee payment since we could not bill centres for treatments.	Proposals were made to August IfQ Programme Board for adjustments to the IfQ schedule which would impact when this risk is likely to be felt. Further discussions are needed with Finance to understand the scale of the potential impact of this risk and to plan for an effective mitigation to secure cash flow. These discussions will be ongoing while IfQ release 2 develops further.	Ongoing -Nick Jones	
GIA funding could be reduced due to changes in Government/policy	A good relationship with DH Sponsors, who are well informed about our work and our funding model.	Quarterly meetings (on-going) – Morounke Akingbola	
	Annual budget agreed with DH Finance team alongside draft business plan submission.	December annually – Morounke Akingbola	
	Detailed budgets for 2016/17 have been agreed with Directors. DH has previously agreed our resource envelope.	In place – Morounke Akingbola	

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

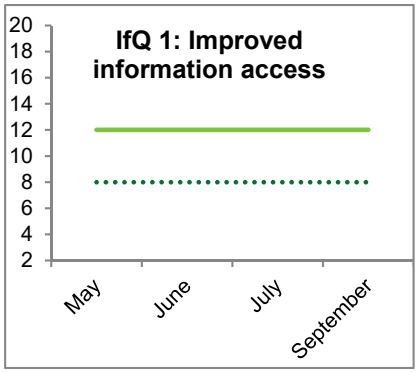
Risk area	Description and impact	Strategic objective linkage	Risk scores			Recent trend	Risk owner
Capability C 1: Knowledge and capability	There is a risk that the HFEA experiences unforeseen knowledge and capability gaps, threatening delivery of the strategy.	Efficiency, economy and value: ensuring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

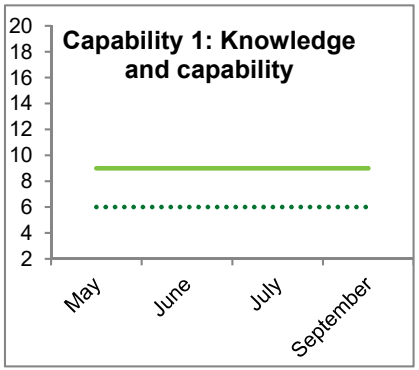
Causes / sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
High turnover, sick leave etc. leading to temporary knowledge loss and capability gaps.	People strategy will partially mitigate. Mixed approach of retention, staff development, and effective management of vacancies and recruitment processes.	Done – May 2015 – Rachel Hopkins	Above tolerance. This risk and the set of controls remains focused on capability, rather than capacity. There are obviously some linkages, since managing turnover and churn also means managing fluctuations in capability and ensuring knowledge and skills are successfully nurtured and/or handed over. Since the HFEA is a small organisation, with little intrinsic resilience, it seems prudent to have a low tolerance level for this risk. Both Head vacancies were filled (in March and May 2016 respectively). The Head of Corporate Governance is now leaving in September 2016 which leaves a head vacancy again. There will continue to be a period of bedding in for the
	Staff have access to civil service learning (CSL); organisational standard is five working days per year of learning and development for each member of staff.	In place – Rachel Hopkins	
	Organisational knowledge captured via records management (TRIM), case manager software, project records, handovers and induction notes, and manager engagement.	In place – Rachel Hopkins	
The new UK government may implement further cuts across all ALBs, resulting in further staffing reductions. This would lead to the HFEA having to reduce its workload in some way.	The HFEA was proactive in reducing its headcount and other costs to minimal levels over a number of years. We have also been reviewed extensively (including the McCracken review). Turnover is variable, and so this risk will be retained on the risk register, and will continue to receive ongoing management attention.	In place – Peter Thompson	
Poor morale leading to decreased effectiveness and performance failures.	Engagement with the issue by managers. Ensuring managers have team meetings and one-to-one meetings to obtain feedback and identify actions to be taken.	In place – Peter Thompson	

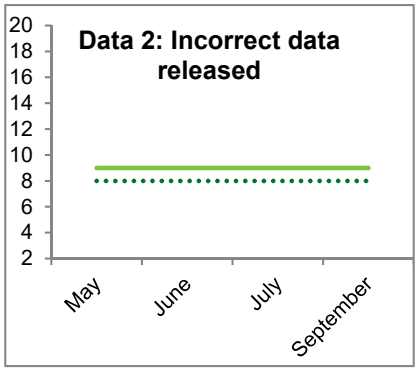
	Staff survey and implementation of outcomes, following up at December 2015 all staff conference.	Survey and staff conference done – Rachel Hopkins Follow-up communications in place (Staff Bulletin etc.) – Peter Thompson	Chief Inspector.
Differential impacts of IfQ-related change and other pressures for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

Tolerance vs Residual Risk:

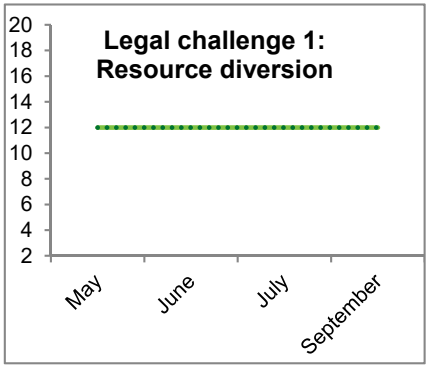
Risks above tolerance

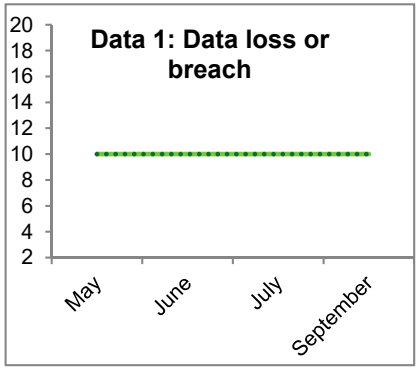


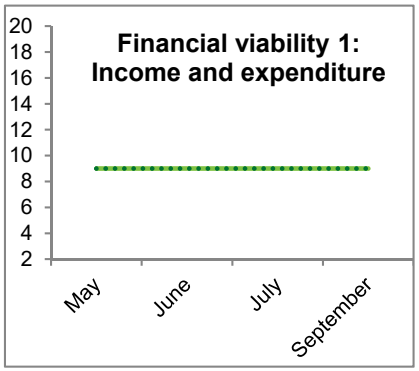


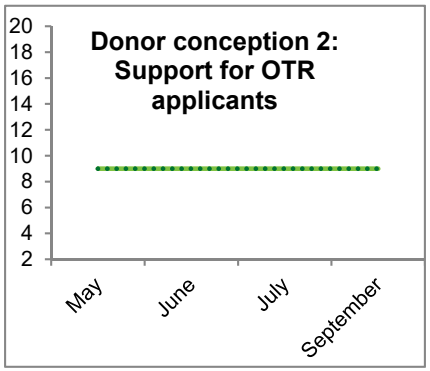


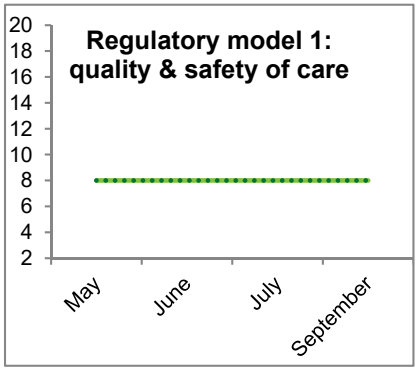
Risks at tolerance

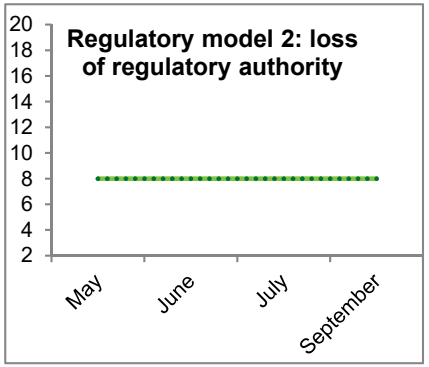


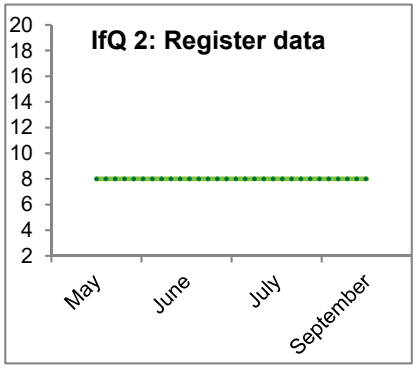


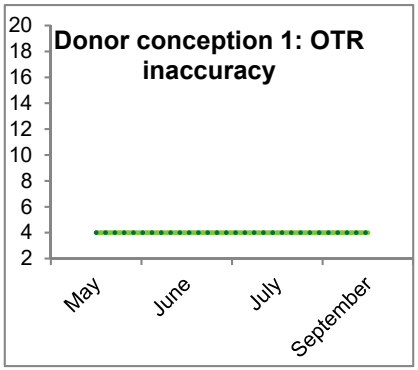




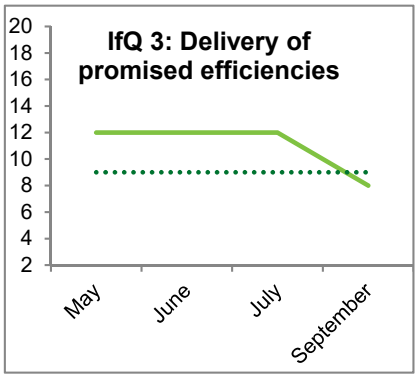








Risk below tolerance



Scoring system

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

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

Risk scoring matrix

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

Risk Score = Impact x Likelihood

Likelihood

Reserves Policy

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

Details:	
Meeting	Audit and Governance Committee
Agenda item	11
Paper number	AGC (21/09/2016) 510
Meeting date	21 September 2016
Author	Morounke Akingbola - Finance Manager
Output:	
For information or decision?	Decision
Recommendation	AGC is requested to consider, comment and approve the updated reserves policy. It will then be agreed with DH.
Resource implications	Implementing and monitoring the policy is part of the role of the Finance directorate
Implementation date	
Organisational risk	☐ Low ☐ Medium ☐ High
Annexes	

Reserves Policy

Introduction

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

Principles

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

Reserves Policy

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

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

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

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

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

Cashflow

4. To enable sufficient cover for day-to-day operations, a cash flow forecast is prepared at the start of the financial year which takes into account the timing of when receipts are expected and payments are to be made. Most receipts come from treatment fees -

invoices are raised monthly and on average take 60 days to be paid. Cash reserves are needed to ensure sufficient working capital is available to make payments when they become due throughout the year.

5. The HFEA experiences negative cashflow (more payments than receipts) in some months. £510k is needed to cover this cash shortage. Reserves should be maintained so that there is always a positive cash balance.

Unforeseen difficulty

6. The level of reserves required for unforeseen difficulty is based on two elements: salaries (including employer on-costs) and the cost of accommodation. These are deemed to be fixed costs that would have to be paid in times of unforeseen difficulty with all other of the HFEA's running costs being regarded as semi-variable or variable costs and thus excluded from this calculation. These two areas currently represent 77% of the HFEA's total annual budget.

7. The certainty and robustness of HFEA's key income streams and the predictability of fixed costs, as well as the relationship with the sponsor, the Department of Health, indicate that 2 months' salary and accommodation costs is a prudent, but sufficient, minimum level of reserves to hold.

8. Based on the HFEA's current revenue budget, the combined monthly cost of salaries and accommodation is around £336k. A prudent reserve of two months going forward would therefore be £672k.

Other potential commitments

9. The HFEA is also mindful of the financial risks it faces, in particular that it may be required to undertake additional activities not planned or make additional spend not included within budget or utilise its reserves for key pieces of work. While every effort would be made to cover costs within the budget allocated for the year, it may be necessary to use reserves to meet the cashflow needs arising from additional necessary spend.

10. A prudent reserve for other commitments would be £150k. If other exceptional spend was required, the HFEA would look to the Department of Health for support.

Minimum reserves

11. The HFEA's minimum level of reserves will be maintained at a level that enables positive cashflow (£510k), provides £672k for unforeseen difficulty and £150k for other potential commitments. The minimum level of cash reserves required is therefore £1.33m. These reserves will be in a readily realisable form at all times.

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

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

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

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

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

Document name	Reserves Policy
Release date	October 2014
Author	Head of Finance
Approved by	CMG
Next review date	September 2017
Total pages	3

Version/revision control

Version	Changes	Updated by	Approved by	Release date
1.0	Created			Feb 2015
2.0	Branded/amended	HoF		August 2016

Audit and Governance Committee Forward Plan

Strategic delivery:	☐ Setting standards	☐ Increasing and informing choice	☒ Demonstrating efficiency economy and value
Details:			
Meeting	Audit & Governance Committee Forward Plan		
Agenda item	12		
Paper number	AGC (21/09/2016) 511		
Meeting date	21 September 2016		
Author	Morounke Akingbola, Head of Finance		
Output:			
For information or decision?	Decision		
Recommendation	The Committee is asked to review and make any further suggestions and comments and agree the plan.		
Resource implications	None		
Implementation date	N/A		
Organisational risk	☒ Low	☐ Medium	☐ High
	Not to have a plan risks incomplete assurance, inadequate coverage or unavailability key officers or information		
Annexes	N/A		

Audit & Governance Committee Forward Plan

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

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