Human Fertilisation & Embryology Authority

Authority meeting - agenda

6 July 2016

Venue: Etc Venues Victoria, 1 Drummond Gate, London SW1V 2QW

	Agenda item	Time
1.	Welcome, apologies and declaration of interests	1:00pm
2.	Minutes of 11 May 2016 **HFEA (06/07/2016) 798**	1:05pm
3.	Chair's report (verbal)	1:10pm
4.	Chief Executive's report (verbal)	1:20pm
5.	Committee chairs' updates (verbal)	1:30pm
6.	Strategic performance report **HFEA (06/07/2016) 799** For Information	1:45pm
7.	Strategic risk register **HFEA (06/07/2016) 800** For Information	2:05pm
	Break	**2:25pm**
8.	Information for Quality **HFEA (06/07/2016) 801** For Information	2:35pm
9.	Inspection ratings **HFEA (06/07/2016) 802** For Decision	2:55pm
10.	Opening the register report **HFEA (11/05/2016) 803** For Information	3:15pm
11.	Multiple births progress **Presentation** For Information	3:35pm

12.	Publication and disclosure policy **HFEA (11/05/2016) 804** For Decision	3:45pm
13.	Any other business	4:05pm

Minutes of Authority meeting 11 May 2016

Strategic delivery:	☐ Setting standards	☐ Increasing and informing choice	☐ Demonstrating efficiency economy and value
Details:			
Meeting	Authority		
Agenda item	2		
Paper number	HFEA (06/07/2016) 798		
Meeting date	6 July 2016		
Author	Charlotte Keen, Information Access and Policy Manager		
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 the Authority meeting on 11 May 2016 held at 10 Spring Gardens, London, SW1A 2BU

Members present	Sally Cheshire (Chair) Professor David Archard Dr Andy Greenfield Bishop Lee Rayfield Kate Brian Rebekah Dundas	Yacoub Khalaf Margaret Gilmore Anita Bharucha Ruth Wilde Dr Anne Lampe Anthony Rutherford
Apologies	Full attendance of members	
Observers/Presenters	Steve Pugh (Department of Health)	Dr David McLernon (University of Aberdeen)
Staff in attendance	Peter Thompson Nick Jones Juliet Tizzard Catherine Drennan	Paula Robinson Joanne McAlpine Charlotte Keen

Members

There were 12 members at the meeting, 8 lay members and 4 professional members

1. Welcome, apologies and declarations of interest

1.1. The Chair opened the meeting by welcoming Authority members and members of the public to the third meeting of 2016 and the first to be held at the HFEA's new offices at Spring Gardens. As with previous meetings, it was being audio-recorded and the recording would be made available on the HFEA website to enable interested members of the public who were not able to attend the meeting to listen to the HFEA's deliberations. This was part of the HFEA's drive to increase transparency about how the Authority goes about its business.

1.2. Declarations of interest were made by:

- Kate Brian (Regional organiser for London and the South East for Infertility Network UK)
- Yacoub Khalaf (Person Responsible at a licensed centre)
- Anthony Rutherford (Consultant in Reproductive Medicine and Gynaecological Surgery at a licensed centre)
- Ruth Wilde (Senior Fertility Counsellor at a licensed centre).

2. Minutes of Authority meeting held on 9 March 2016

2.1. Members agreed the minutes of the meeting held on 9 March as a true record, for signature by the Chair.

3. Chair's report

3.1. The Chair provided members with a summary of events that she had attended with organisations in the IVF sector and the wider health and care system since the last Authority meeting.

3.2. On 15 March, all Department of Health arm's length bodies (ALBs) were invited to a Policy seminar and on 24 March the HFEA held its annual conference which was a great success. Over 200 representatives from clinics attended the event and the Chair expressed her thanks to all members who were present on the day, together with the many staff who helped organise it and to everyone across the sector who attended.

3.3. On 20 April, the Chair attended the ALBs' Ministerial round table discussion and on 4 May she chaired the Multiple Births Stakeholder Group meeting.

4. Chief Executive's report

4.1. The Chief Executive advised members that, on 15 March and 20 April, he attended two National Information Board (NIB) Leadership meetings. The NIB was an initiative led by the Department of Health involving all of the health sector ALBs to make significant changes to the way in which information was used within the health and care system. The HFEA's role was limited given its specialist remit although it was appropriate that it was involved.

4.2. On 11 April, the HFEA moved offices from Finsbury Tower to 10 Spring Gardens and, despite a few teething problems, the move went well. The Chief Executive expressed his thanks to all staff involved in the move.

4.3. On 26 April, the Chief Executive attended the third meeting of the Health and Social Care Leadership Scheme which brought together the Department of Health and all of the Chief Executives of the health sector ALBs to identify senior talent within the system. Members were aware that both the Director of Compliance and Information and the Director of Strategy and Corporate Affairs had been selected onto the programme.

4.4. Also on 26 April, the Chief Executive, together with the Director of Compliance and Information, met colleagues from the National Institute of Clinical Excellence (NICE) to better understand the international work that NICE had developed. The Chief Executive reminded members that the Executive had been in discussions with Healthcare UK about how best to promote UK healthcare overseas.

4.5. On 29 April, the Chief Executive, together with the Director of Compliance and Information, met the Chief Executive of the Private Healthcare Information Network (PHIN) to consider how best the new data reporting requirements that the Competition and Markets Authority (CMA) placed on private IVF clinics could be delivered without unnecessary duplication.

4.6. The Chief Executive reminded members that, at the last Authority meeting, he had advised them that the triennial review, which had looked at the functions of the organisation and whether those functions were carried out in the most efficient way possible, would have been signed off by the time of the May meeting. That had not been possible, which was not to indicate that there were problems with the HFEA's triennial review report, but rather that the Ministerial sign-off process was complex.

4.7. Further, the Chief Executive reminded members that Government Departments were required to publish innovation plans by spring 2016 and ALBs were now required to follow suit. The HFEA's draft plan had issued on 26 April and the consultation would close on 6 June. The Executive believed that the regulatory scheme in place managed to support innovation in a way which also assured public confidence; indeed it was evident that regulation in bio-sciences had actually fostered innovation rather than hindered it. It was important to note it was the UK, with its robust regulation, that had achieved world firsts like the use of mitochondrial donation in treatment and the recent decision to allow genome editing in research. The HFEA's innovation plan set out those achievements.

4.8. Press coverage: the Chief Executive summarised press coverage since the last Authority meeting, details of which had been circulated to members. It had been a quiet few weeks compared to the beginning of the year, although there were two issues in particular worth reporting.

4.9. Fertility Trends report: the Chief Executive advised members that the 2016 report was launched at the HFEA's annual conference, with the Chair of the HFEA talking through the key figures. There were good, strong messages in the report, not least around multiple births and, in particular, egg freezing data which had been published for the first time.

4.10. Thirteen day embryos: the Chief Executive advised members that there had been widespread coverage in the press about a licensed research project at the University of Cambridge which had developed a new technique that enabled embryos to develop in vitro beyond implantation stage, allowing for the first time analysis of key stages of human development up to 13 days. The HFEA had been contacted by journalists asking whether the law, requiring that embryos were not kept beyond 14 days, should be changed. The Chief Executive emphasised that any decision to change the law was a matter for Parliament and the HFEA had therefore declined to comment. The Department of Health had confirmed there were no plans to change the law.

5. Committee chairs' updates

5.1. The Chair of the Statutory Approvals Committee (SAC) reported that the committee had met on 31 March and 28 April. There had been four preimplantation genetic diagnosis (PGD) applications in March, all of which were approved. At the April meeting, the minutes of which had not yet been published, four PGD applications had been considered.

5.2. The Chair of the Licence Committee reported that the committee had met on 17 March and 5 May. At the March meeting, one treatment and storage renewal application had been considered and approved. In April, the minutes of which had not yet been published, there had been one research renewal application and an executive update.

5.3. The Chair of the Audit and Governance Committee (AGC) advised members that the committee had met on 16 March, and had received reports on:

- Finance and resources risks, from the Director of Finance and Resources
- Strategic risks, from the Head of Business Planning
- Legal risks, from the HFEA legal advisor
- An IfQ update on managing risks, from the Director of Compliance and Information

- Updates from the Internal and External Audit teams
- The AGC training programme.

5.4. The Chair of the Executive Licensing Panel (ELP) advised members that the panel had met five times since the last Authority meeting, on 11 and 21 March, 11 and 22 April and 6 May. The panel had considered 26 items in total, all of which were approved. There were nine renewal licence applications; five interim inspection reports; one application for a new centre and a number of variations to licences and Persons Responsible.

6. Strategic performance report

6.1. The Chair introduced this item, advising that the strategic performance report was a general summary of both the HFEA's performance measures, the progress towards implementation of the strategy, the HFEA's programmes and their status, and generally the wider performance of the Authority.

6.2. In the absence of the Director of Finance and Resources, the Chief Executive provided an overview of financial performance and a summary of the position coming towards the end of the financial year. A surplus of almost £500k was forecast for year-end which was partly due to a lower spend on salaries, legal costs and a late surge in treatment fees in February and March.

6.3. The Chief Executive reminded members that the finance team was in the process of preparing the end of year accounts which would be submitted to AGC when the committee next met on 15 June. On 16 June the accounts would then be circulated to the wider Authority and members would have a week to respond. The Chief Executive advised members that he would need to sign the accounts by 21 June with a view to them being laid before Parliament around 27 June.

6.4. The Director of Strategy and Corporate Affairs reported on the HFEA annual conference which had taken place on 24 March. There were 200 delegates (85% of whom had attended before) and 70% giving feedback were positive about the conference. The success of the conference was due to a mixed and engaging programme, including the panel discussion on 25 years of IVF regulation and the previews of the new clinic portal and the website. As mentioned earlier in the meeting the annual Fertility Trends report was launched at the conference and the Chair was able to draw out some of the key findings from the report in her opening speech.

6.5. The Director of Compliance and Information summarised activities within his Directorate. The majority of staff within the Directorate were heavily involved in the IfQ programme of work. In relation to inspection and compliance activities, members were advised that the 2015/16 inspection year had been a particularly busy one, with a 40% increase year on year and a continuing rise in PGD applications. The Director of Compliance and Information also welcomed the new Chief Inspector, who had recently joined the HFEA, to the team.

6.6. Following a discussion, members noted the latest strategic performance report.

7. Strategy 2017-2020

7.1. The Chair introduced this item, the aim of which was to encourage an early and open discussion about possible strategic priorities for 2017-20.

7.2. The Director of Strategy and Corporate affairs summarised the proposed timeline for the new strategy, commencing with early discussions with Authority members and staff, and ending with publication of a new three year strategy document next April. The timeline would incorporate some internal discussions and planning, engagement with stakeholders in the autumn and winter, development of the actual document, and launch at the annual conference.

7.3. The current HFEA strategy had a central vision: high quality care for everyone affected by assisted reproduction. The vision was simple and compelling, with HFEA staff identifying with it, stakeholders associating the HFEA with it, and patients agreeing it should be the main focus of the HFEA.

7.4. The Director of Strategy and Corporate Affairs reminded members that the strategy had been organised around three areas: information, quality and value. It had been acknowledged at the time that the HFEA not only had to respond to wider political issues like the Francis review, but also needed, as an organisation, to take a technological step forward. The services and systems in place were out of date, hampering the organisation's ability to act. The strategy therefore had a strong theme throughout of service innovation and change. IfQ, once delivered, would enable the HFEA to use those services to further improve the quality of care.

7.5. As the HFEA came into the final year of the current strategy, the organisation needed to think further ahead to the next phase of its strategy through to 2020 and consider what would shape its thinking over the coming months and years, taking into account the wide environment, including:

- The sector
- Patient experience in clinics
- The wider health system
- The surrounding politics and economics
- How the HFEA could use its systems and information to give a good quality service to the public, patients, the sector and the Government.

7.6. It was also important to note that the HFEA would have new quality factors and drivers in place by April 2017, including:

- A new Register and data dictionary
- Better quality Register information
- Better published information – including from patients – about clinic performance
- A wider range of information for patients and the public on a range of topics
- More interactive engagement channels, including the website and clinic portal
- Incentives for clinics via the transparency of 'inspector ratings' etc.
- More published measures and benchmarking.

7.7. The strategy needed to strike a balance between allowing both the environment and stakeholders to shape the HFEA's thinking, and recognising the organisation should lead with its own clear vision for change. Believing that high quality care for everyone affected by assisted reproduction should remain the HFEA's vision, consideration needed to be given to what that would mean for the next strategy.

7.8. The Head of Business Planning set out some early thoughts on what themes the next strategy might focus on. Members noted that this was not an extensive or exclusive list, but reflected recent discussions and developing trends, and the increased quality of the HFEA's information infrastructure and provision after IfQ.

7.9. There were areas of the current strategy that the HFEA would like to build on, including:

- Support for patients whose treatment has been unsuccessful
- Treatment 'add-ons' (treatments such as additional drug regimes that are claimed to increase the chances of a successful pregnancy)
- Clinics' lifelong role as information providers
- Commissioning of IVF services (while recognising the limits of the HFEA's remit)
- Making more use of the information held by the HFEA
- Making good use of improved communication channels.

7.10. Potential new areas of focus included:

- Treatment costs
- Further gains from IfQ and the resulting improvements in the HFEA's information systems
- Genetics/genomics (a growth area).

7.11. The Head of Business Planning asked members to think about their personal experiences and interactions such as going to clinics, talking to clinic staff and patients, and attending the conference and to consider where the HFEA should focus its efforts in 2017-20. In particular, members were asked for their initial views on:

- The vision
- The future landscape and operating environment
- The ideas for future focus
- The proposed process/timetable.

7.12. Members agreed that the proposed timetable and process were suitable, and that the overall vision should remain.

7.13. There was strong support for the HFEA to address treatment add-ons, given the lack of scientific evidence for many such treatments. It was also recognised, in relation to this and other issues, that public understanding of science was limited, and often not well served by the media. There could be an educative role for the HFEA in articulating difficult scientific concepts more clearly and without bias or sensationalism.

7.14. In relation to commissioning and the costs of treatment, members were concerned at the lack of consistency across the UK, and the pressures on NHS clinics. Access to treatment was an issue. It was also felt that this lack of consistency was a general theme, seen across a range of fronts: quality of care, access to treatment, the quality of the information people receive when they first realise they may be infertile, and costs. Although the HFEA did not have any direct economic regulatory powers, there may still be actions the HFEA could take that would help to improve the current situation.

7.15. Members were keen to do further work to improve the experiences of people whose treatment was unsuccessful, and felt that the support given by clinics should be more holistic and not focused solely on counselling provision.

7.16. Members discussed genetics and genomics, and the wider research context. Although genetics and genomics was a high profile issue, the majority of the developments at this stage were in the research field, rather than treatment. The public would naturally expect research to lead directly to the creation of new treatments, when the reality may not be so straightforward. This was also another area where the science could be difficult even for experts in the field to grasp, and so there could be a communication role for the HFEA. It was felt that both embryo research and data-based research should be central in the new strategy. It was also suggested that the HFEA should make best use of the most up to date and widely used communication channels, including social media, to reach its intended audiences more effectively – especially so as to communicate key messages to younger people.

7.17. The HFEA should continue to focus on patients' core quality concerns, which remain success rates, safety, cost and donation. These should form the heart of the future strategy. 'High quality care' in the next strategic period would mean safe, supportive, effective and consistent care, backed up by well-articulated scientific and research information.

8. Presentation from David McLernon – cumulative live birth rates after one or more complete cycles of IVF[1]

8.1. The Chair reminded members that since 2009, HFEA Register data had been available for researchers. Professor Alastair Sutcliffe, from University College Hospital in London, presented his research to Authority members in September 2013 and the Executive had been keen to invite more researchers to share their work with the Authority and the wider public. The Chair introduced Dr David McLernon, from the University of Aberdeen. Members noted that Dr McLernon had used HFEA data with two publications to date: the first on cumulative live birth rates over one or more complete cycles of IVF; the second on a clinical prediction model that could estimate the probability of a live birth rate over multiple cycles of IVF.

8.2. Dr McLernon advised members that globally, the estimated prevalence of infertility was around 9%, whilst in the UK, one in six couples experienced problems conceiving, with many going on to have IVF treatment. Worldwide, by the end of 2013, over five million people were estimated to have been born as a result of IVF, with the UK accounting for over 4% of this total.

8.3. Dr McLernon explained that IVF success was generally calculated and reported on the basis of live birth rates per treatment attempt, involving either an intended fresh or frozen-thawed embryo replacement. However, in order for patients and clinicians to understand the success of a live birth over an entire IVF programme, the most appropriate way of reporting this was to estimate the cumulative chances of success per woman after a number of completed cycles. Although cumulative live birth rates following IVF had been reported at an international level, no studies

[1] Cumulative live birth rates after one or more complete cycles of IVF: a population-based study of linked cycle data from 178,898 women: http://humrep.oxfordjournals.org/content/31/3/572.full

had reported such rates for the UK. It was also important to determine whether cumulative live birth rates had improved over time.

8.4. Dr McLernon advised members that the aims of his study were to report the cumulative rates of live birth during two different time periods in UK women, and to estimate the personalised probability of a treatment dependent live birth over multiple complete cycles of IVF, between the time of the initial consultation before IVF began until after the first fresh embryo transfer attempt.

8.5. The study was conducted using records extracted from the HFEA Register of 178,898 women who had embarked on IVF treatment in the UK between 1992 and 2007.

8.6. Dr McLernon explained that a total of 71,551 women commenced IVF treatment during 1992-1998 and an additional 107,347 during 1999-2007. After the third complete IVF cycle, the 'conservative' cumulative live birth rate for women who commenced IVF during 1992-1998 was 30.8%, increasing to 42.3% during 1999-2007. The optimal cumulative live birth rates were 44.6% and 57.1% respectively. After eight complete cycles the optimal cumulative live birth rate was 82.4% in the latter time period. The conservative rate for multiple pregnancy per pregnant woman fell from 31.9% during the earlier time period, to 26.2% during the latter.

8.7. Dr McLernon advised members the results demonstrated that, in the last two decades, there had been a rise in cumulative live birth rates accompanied by a decline in multiple birth rates. However, most UK couples who did not conceive after their first complete cycle did not receive a further two complete NHS funded IVF cycles as recommended by NICE. If there were no barriers to continuation of IVF treatment, around 83% of women receiving IVF would achieve a live birth by the eighth complete cycle, similar to the natural live birth rate in a non-contraception practising population. This data could be used to inform policy and counsel patients commencing IVF treatment in order to prepare them both emotionally and financially for their complete IVF journey.

8.8. Following a discussion, members noted the presentation and the Chair thanked Dr McLernon for taking the time to share his study with the Authority.

9. Information for Quality: update

9.1. The Director of Compliance and Information explained that the IfQ programme was a comprehensive review of the information that the HFEA held, the systems that governed the submission of data, the uses to which it was put and the ways in which the information was published. It included:

- The redesign of the HFEA's website and Choose a Fertility Clinic (CaFC) function
- The redesign of the 'Clinic Portal' used for interacting with clinics
- New data submission functionality
- A revised dataset and data dictionary which would be accredited
- A revised Register of treatments, which would include the migration of historical data contained within the existing Register
- The redesign of the HFEA's main internal systems that comprised the Authority's Register and supporting IT processes.

9.2. The Director of Compliance and Information advised members that the purpose of this presentation was to update members on:

- The forthcoming approvals processes to proceed to 'public beta' phase and later to 'live'
- Progress since the HFEA annual conference
- Data migration and cleansing
- Programme timelines and budget implications.

9.3. The approvals process to proceed to 'beta' phase: the Director of Compliance and Information reminded members that the externally facing part of the programme could not formally proceed beyond 'alpha' proof of concept stage until approvals in line with Government Digital Standards (GDS) had been granted by the Department of Health. The first, alpha, stage assessment, undertaken by the Department of Health Digital Projects team was passed to a high standard. The second stage assessment, undertaken by the GDS (essentially a check on the first stage departmental process) had now also been passed. On 11 and 12 May, both the website and clinic portal would again be assessed and, subject to the associated approvals from the Department of Health and GDS, both products would be released to 'public beta'.

9.4. Progress since the HFEA annual conference**:** the Director of Compliance and Information reminded members that the HFEA website and clinic portal had been demonstrated at the Annual Conference and were very well received. The recent focus had been towards user testing, which had taken place in late April, and this had been carried out successfully with both the website and CaFC receiving a good reception from all those who tested it. Although there were a number of issues raised, these were minor additions and adjustments involving refinements and enhancements rather than fundamental changes.

9.5. Data migration and data cleansing: members were reminded that there was a certain amount of data cleansing that clinics were required to carry out before the data could be migrated to the new Register. The Executive had been communicating with clinics in order to prepare them for the requirement to cleanse data, and it was hoped that the prospective benefits offered by the new system would act as an incentive. The first tranche of eight clinics identified to undertake a pilot of cleansing activity had now received notification and, given the Executive's communication had been proactive and the volume of work for each clinic was modest, there had been no negative feedback.

9.6. Whilst the recent emphasis had been on data cleansing, the Director of Compliance and Information advised members that the Executive was still progressing the paperwork needed to get the data dictionary accredited, with the submission to NHS Digital in June for a July assessment.

9.7. Timelines and budget implications**:** the Director of Compliance and Information reminded members that a revised IfQ programme plan had been finalised and signed off by the IfQ Programme Board in January 2016, in line with the overall £1.134m agreed by the Authority. Whilst the overall budget for IfQ remained unchanged, the revised timeline would extend work, originally expected to be completed in the current financial year, into the next. This would result in approximately £450,000 within the IfQ budget being carried over into the next financial year.

9.8. Authority members noted:

- The forthcoming approvals processes to proceed to 'public beta' phase and later to 'live'

- Progress since the HFEA annual conference
- Data migration and cleansing
- Programme timelines and budget implications.

10. Any other business

10.1. The Chair confirmed that the next meeting would be held on 6 July (venue to be confirmed). Members were asked to confirm their attendance to the Executive Assistant to the Chair and Chief Executive as soon as possible.

11. Chair's signature

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

Signature

Chair

Date

Audit and Governance committee annual report

Strategic delivery:	☒ Setting standards	☒ Increasing and informing choice	☒ Demonstrating efficiency economy and value
Details:			
Meeting	Audit and Governance Committee		
Agenda item			
Paper number			
Meeting date	6 July 2016		
Author	Ian Brown, Head of Corporate Governance		
Output:			
For information or decision?	For information		
Recommendation			
Resource implications	In budget		
Implementation date	July 2016		
Communication(s)	N/A		
Organisational risk	X Low	Medium	High
Annexes			

Background

1. Following on from the 2015 review of committee effectiveness, it was agreed that an annual report of the activities of the Audit and Governance Committee would be made to the Authority. This report summarises the Committee's work during 2015/16.

Membership

2. Membership of the Audit and Risk Assurance Committee throughout the year has been:
    - Rebekah Dundas (Chair)
    - Anita Bharucha
    - Margaret Gilmore
    - Gill Laver
    - Jerry Page

3. Anita Bharucha joined the AGC bringing the number of members to five, increasing resilience given that quoracy is three. Gill Laver was appointed for a further 15 months from 1 June 2016 to 31 September 2017.

4. There are regular attendees from the executive, PwC (the HFEA's internal auditors), the National Audit Office (external auditors) and the Department of Health. The Chair of the AGC (Rebekah Dundas) also attended all sessions. The Committee met in normal session four times in the year (June 2015, October 2015, December 2015, March 2016).

Role and function

5. The purpose of the Audit and Governance Committee is to oversee corporate governance, risk, audit arrangements and financial matters. This includes:

- the strategic processes for risk, control and governance and the Annual Governance Statement
- the accounting policies, the accounts, and the annual reports of the HFEA, levels of error identified, and management's letter of representation to external auditors
- the planned activity and results of both internal and external audit;
- adequacy of management response to issues identified by audit activity, including external audit's audit completion report
- assurance relating to corporate governance requirements for the HFEA
- policies on whistle-blowing and fraud prevention, including the arrangements therein for special investigations

6. There is an annual cycle of matters to consider, with regular business focussing on assurance and risk management processes, as well as matters arising from internal

and external audit work. At each meeting, the Executive present progress reports on all these areas. After each meeting a confidential session is held between members and auditors.

Review of Committee effectiveness

7. The Committee reviewed its effectiveness at the December 2015 meeting by using the self- assessment checklist from the National Audit Office. As a result, the Committee decided on several actions that would add value to its work for example training by the NAO prior to meetings.

Risk Management

8. Strategic risks are reviewed by the Corporate Management Group at a quarterly risk meeting and reported to the Audit and Governance Committee quarterly. The Committee reviews the risks identified, to satisfy themselves that the risks are the key ones and that they are being managed effectively. The Committee also supported the proportionate approach to assurance mapping to demonstrate that risks in key areas are being controlled.

9. The success of risk management continues to rely on staff at all levels ensuring there is effective identification and management of risks. This requires the ongoing commitment and support of Directors and managers in encouraging the further development of risk management culture.

Internal Audit

10. The HFEA has had a Service Level Agreement with DH, for internal audit services to be provided by PwC, throughout 2015/16. The Committee endorsed the Internal Audit strategy and plans for the year, and monitored work progress. In addition, the committee chair has met with management and senior Authority members about a range of issues where AGC have a locus on an ad hoc basis. During the year, the Head of Internal Audit for the HFEA, provided under the DH contract with PWC for audit services, and at the same time the audit manager, changed. This was unfortunate and has caused some disruption. AGC were involved fully in the decision about ongoing arrangements and are monitoring how these are progressing.

External Audit

11. NAO officials attend all Committee meetings and continue to make a valuable contribution to discussions.

Assurance processes

12. The Chief Executive meets Directors at least weekly individually to review the delivery of their responsibilities. Directors hold similar meetings with their staff and ensure that controls are in place on an ongoing basis. The Senior Management

Team of the Chief Executive and Directors meet weekly to provide updates on key work, discuss issues arising, identify and act on lessons learned. The Corporate Management Group meet monthly and approve new policies as well as managing risks on the risk register.

Governance Statement

13. The Governance Statement is a key part of the Annual Report and Accounts. It is signed by the Accounting Officer and explains how governance responsibilities have been discharged. We consider that there is sufficient evidence of effective governance processes to support the signing of the Governance Statement. The AGC were assured by the auditor's report that there are no material issues to be brought to the attention of the Accounting Officer.

Summary

14. The HFEA's governance systems are well established and include provision for continuous improvements. The Audit and Governance Committee are satisfied with the arrangements for risk management and the assurance processes.

Rebekah Dundas, Chair, Audit and Governance Committee.

June 2016

Strategic performance report

Strategic delivery:	☒ Setting standards	☒ Increasing and informing choice	☒ Demonstrating efficiency economy and value
Details:			
Meeting	Authority		
Agenda item	6		
Paper number	HFEA (06/07/2016) 799		
Meeting date	6 July 2016		
Author	Helen Crutcher, Project Risk and Performance Manager		
Output:			
For information or decision?	For information		
Recommendation	The Authority is asked to note and comment on the latest strategic performance report.		
Resource implications	In budget		
Implementation date	Ongoing – strategic period 2014-2017		
Communication(s)	CMG reviews performance in advance of each Authority meeting, and their comments are incorporated into this Authority paper. The Department of Health reviews our performance at each DH Update meeting (based on the CMG paper). The Authority receives this summary paper at each meeting, enhanced by additional reporting from Directors. Authority's views are fed back to the subsequent CMG performance meeting.		
Organisational risk	☐ Low	☒ Medium	☐ High
Annexes	Annex 1: Strategic performance report		

1. Introduction

1.1. The attached paper summarises the main performance indicators, following discussion by the Corporate Management Group (CMG) at its June performance meeting.

1.2. Most of the data relates to the position at the end of April 2016.

1.3. Overall performance is good, with three performance indicators in the red, and we are making good progress towards our strategic aims.

2. Recommendation

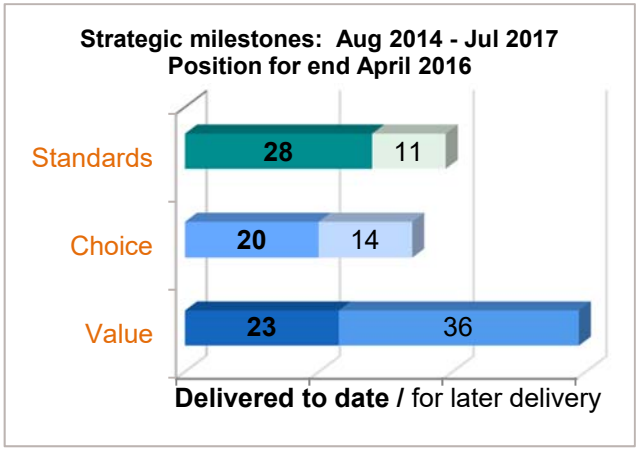
2.1. The Authority is asked to note the latest strategic performance report.

Annex A - HFEA strategic performance scorecard

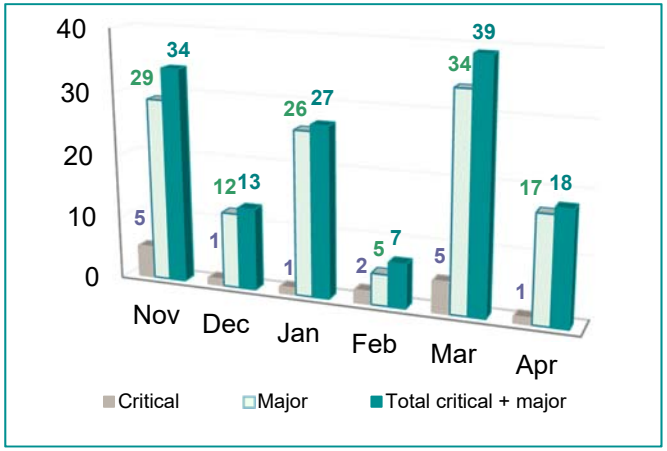
1. Summary section

Dashboard – April data

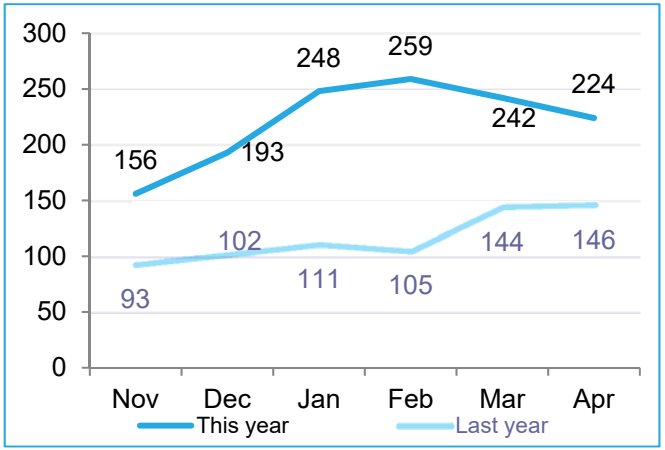
Strategic delivery totaliser
(see overleaf for more detail)



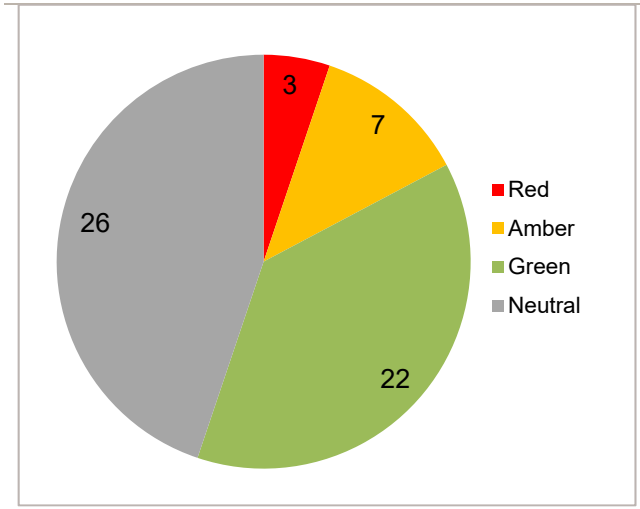
Setting standards:
critical and major recommendations on inspection



Increasing and informing choice:
public enquiries received (email)



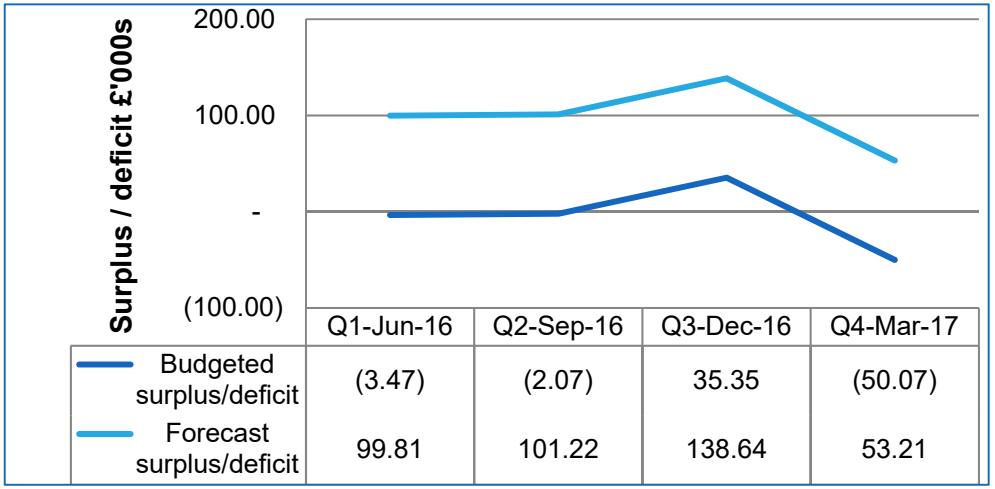
Overall performance - all indicators:



(See RAG status section for detail.)

Efficiency, economy and value: Budget status: cumulative surplus/(deficit)

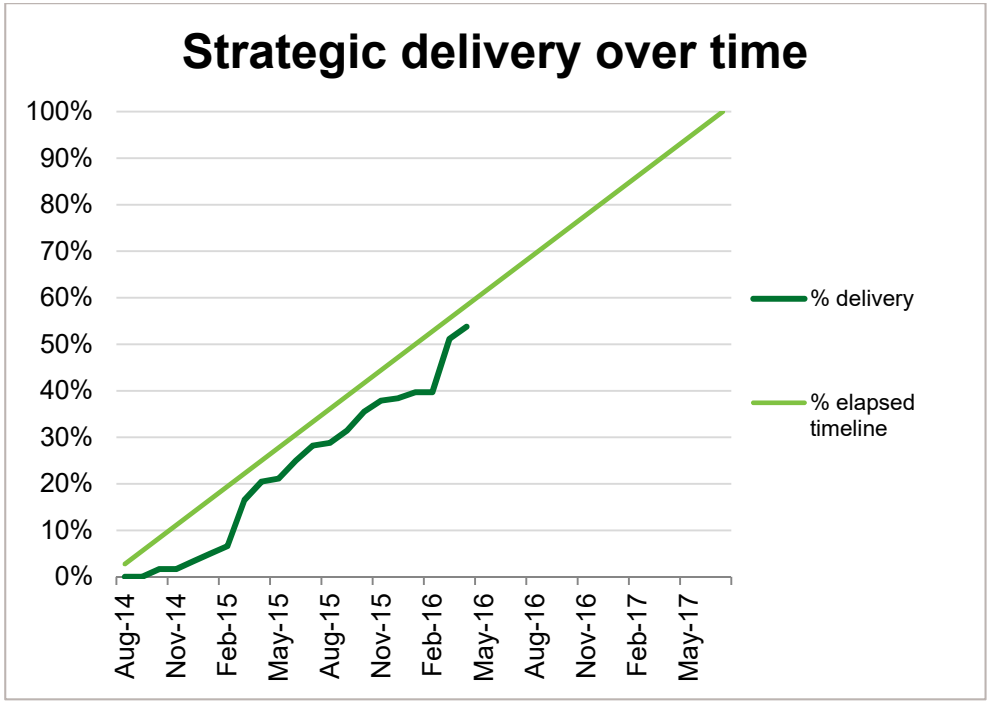
This graph details our net position as at 30 April 2016 (month one of the 2016/17 business year). The graph is intended to show how we perform against budget. The graph will become more meaningful from quarter 2 when we take a fresh look at our costs and income (re-forecast).

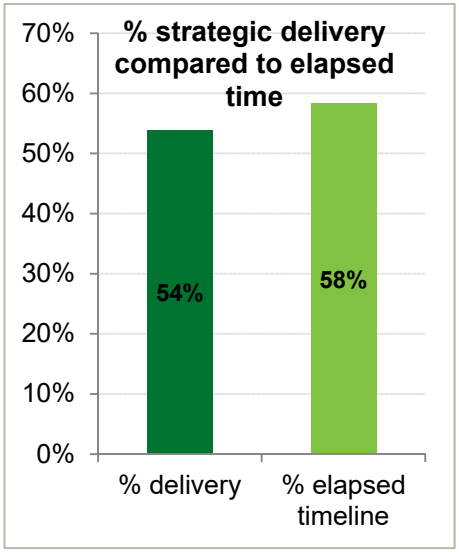


	Q1-Jun-16	Q2-Sep-16	Q3-Dec-16	Q4-Mar-17
Budgeted surplus/deficit	(3.47)	(2.07)	35.35	(50.07)
Forecast surplus/deficit	99.81	101.22	138.64	53.21

Dashboard - Commentary

Strategic delivery (to end of April) – summary:





It was previously necessary to re-cast the timeline for the beta phase of IfQ. We reached our next GDS gateway review point in mid-May, and passed the reviews for both the website and clinic portal (with a number of recommendations). This means that we can soon proceed to the public beta phase of work. In IfQ, much of April was spent preparing for these important gateway reviews.

Strategic delivery in April:

Setting standards

There were no delivery milestones due in this area in April.

Increasing and informing choice

Following the rescheduling of IfQ beta phase work, and the development of new content and templates for the website, we are now well positioned to ensure that patients will have access to high quality meaningful information in the new website. Preparations for the website GDS gateway review (done in May) were in full swing throughout April.

Owing to the earlier delays in the beta timeline, we have not yet reached the point where the six monthly CaFC update will appear in the new format, so this milestone will now be reached in October (the next six monthly CaFC update point).

Efficiency, economy and value

The successful focus on passing our two GDS gateways included website user testing, delayed from March. Earlier GDS approval delays (in 2015) continue to have a knock-on effect on the remainder of the IfQ timeline. So for instance the planned pre-private beta phase for release one of the clinic portal was not possible as originally planned in April. This will now occur once GDS recommendations from the recent gateway review have been addressed, over the next few sprints, as part of our continued preparations for full live beta.

Work has begun on developing the organisation's future 'blueprint'. However more work needs to follow on this, over the next six months, building in discussion and consultation with our staff as appropriate.

The other main milestone achieved in April was our office move to 10 Spring Gardens.

Red/amber/green status of performance indicators as at April 2016

The three red key performance indicators (KPI) shown in the 'overall status - performance indicators' pie chart on the dashboard are as follows:

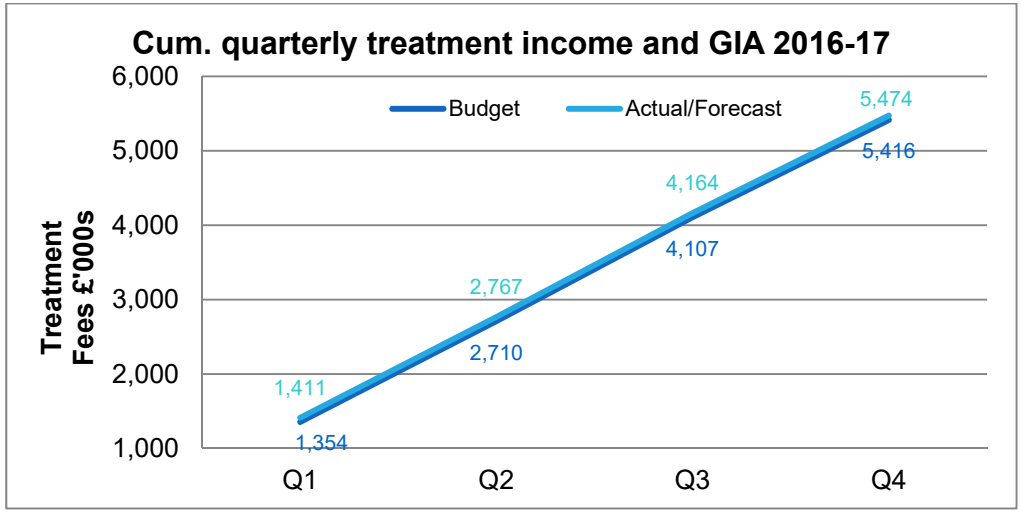
Number of working days to produce monthly management accounts. This took 14 working days compared to the <5 indicator target. This was due to the team delivering extra in-team training to increase resilience at the time, and to unforeseen leave.

Average number of working days between minutes being finalised and decision communicated to clinic (minutes forwarded and licence issued or letter sent explaining refusal of licence). This was due to IT issues causing an email containing a single decision not to send. When the issue emerged the decision was sent within 3 working days. For the same reasons, a second (related) indicator was also in the red.

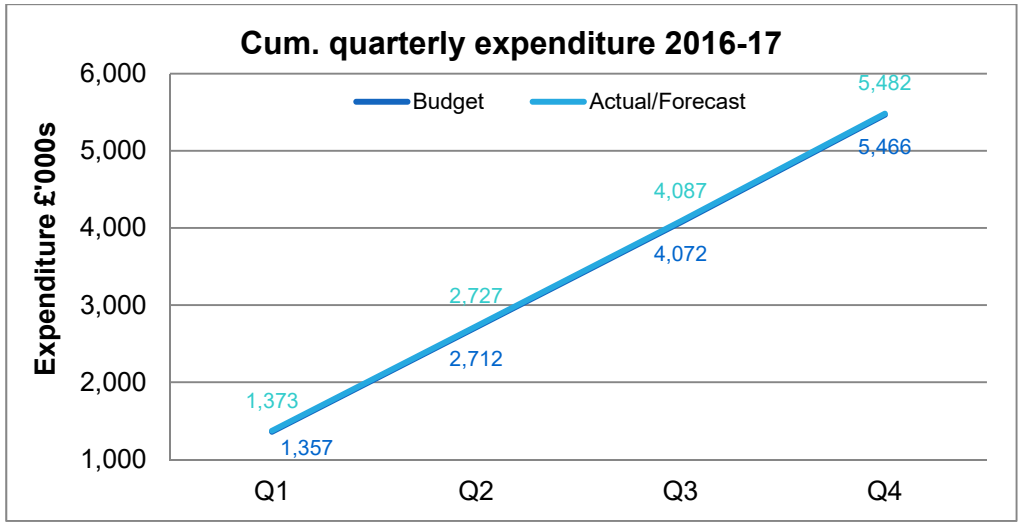
No projects were on a red risk rating in April.

Budget status – April data

The dashboard shows the overall surplus/deficit position. The graphs below show how the surplus or deficit has arisen. These figures are updated quarterly, approximately one month after the end of each quarter.



This graph shows our budgeted (planned) income including grant-in-aid (GIA) compared to what is actually happening. The remaining eleven months (3 quarters) are based on budget hence the closeness of the two lines.
As of month 1 (30 April 2016) we have exceeded our budget (a significant surplus of £436k).



This graph is the second component that makes up the surplus/deficit. This excludes costs relating to IfQ, since this is being funded from reserves and accounted for separately.

For the month of April we have a small surplus (£40k). The graph as the one above is showing our budget per quarter against our forecast. As we are at the start of the year the graph has little meaning. As we re-forecast (update our plans) the two lines will separate.

Quality and safety of care

As agreed previously, the following items are most meaningful when reported on an annual basis and will continue to be presented to the Authority each year in September:

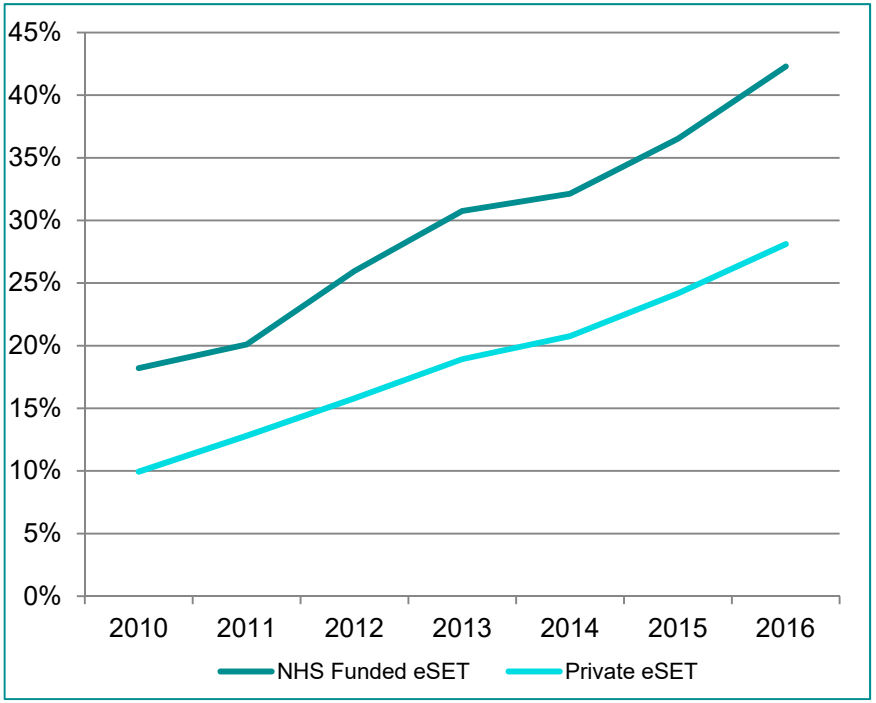
- number of risk tool alerts (and themes)
- common non-compliances (by type)
- incidents report (and themes).

The following figures and graphs were run on 2 June 2016.

ESET split by private/NHS:

Funding	Year						
	2010	2011	2012	2013	2014	2015	2016
NHS Funded:							
Recorded as eSET	4294	4903	6264	7868	8443	9742	4740
	7%	8%	10%	13%	13%	15%	17.5%
Not recorded as eSET	19284	19491	17869	17717	17830	16935	6469
	33%	32%	30%	29%	28%	26%	23.8%
Private:							
Recorded as eSET	3422	4630	5699	6858	7736	9334	4477
	6%	8%	9%	11%	12%	14%	16.5%
Not recorded as eSET	31022	31546	30398	29391	29536	29281	11453
	53%	52%	50%	48%	46%	45%	42.2%

Graph: eSET relative % trends NHS/private:



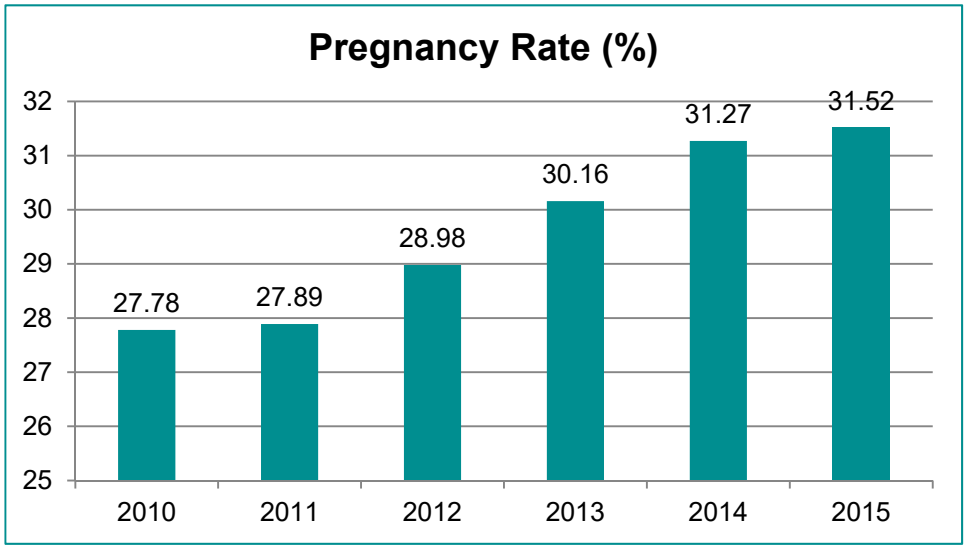
Explanatory text: Showing the total of all reported IVF treatment forms and counting those that the clinics recorded as eSET

As of February 2016 data, we updated this graph to display the relative percentages of eSET for NHS and privately funded cycles, rather than the percentage of all treatments as was previously shown. This relative approach gives a clearer picture, given that the number of overall cycles completed in the private sector is significantly higher than the number of NHS cycles. We have retained the raw figures in the table, so that the 'all treatment' numbers can still be seen as well.

Unfiltered success rates as % - pregnancies (rather than outcomes, since this provides a better real-time picture):

Years	All cycles	Pregnancies	Pregnancy rate %
2010	58022	16119	27.78
2011	60570	16896	27.89
2012	60230	17452	28.98
2013	61834	18649	30.16
2014	63545	19872	31.27
2015	65292	20580	31.52
2016	27140	6291	23.18

Graph showing the pregnancy rate over recent years:

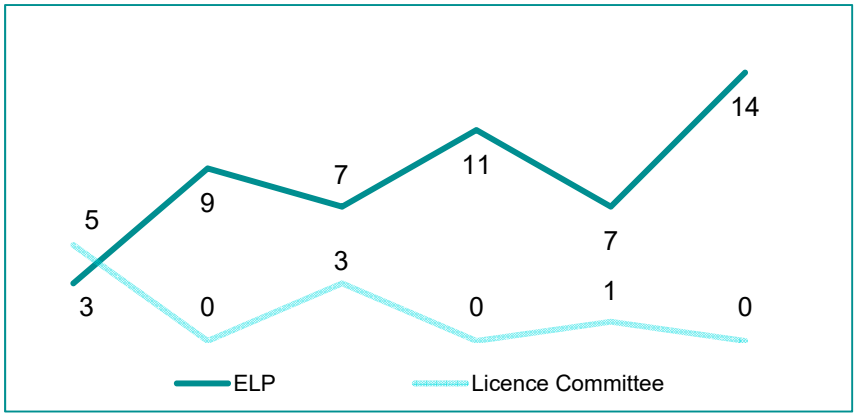
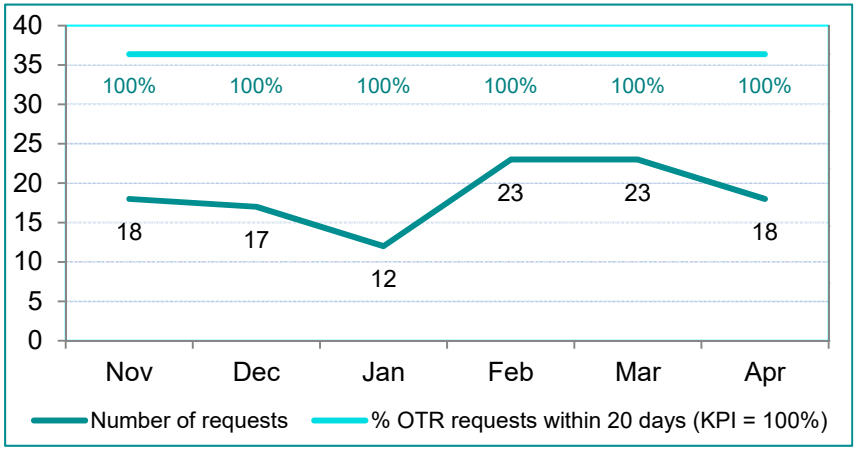


Explanatory text: Looking at all IVF treatment forms, and providing a count of pregnancies - as recorded on the early outcome form.

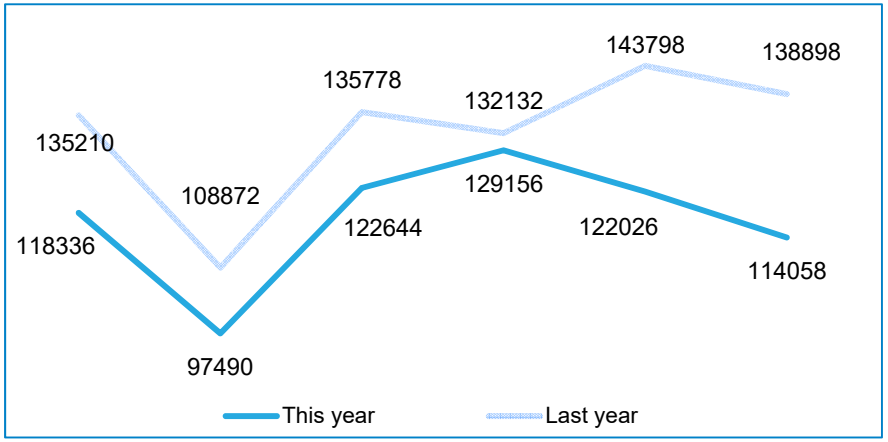
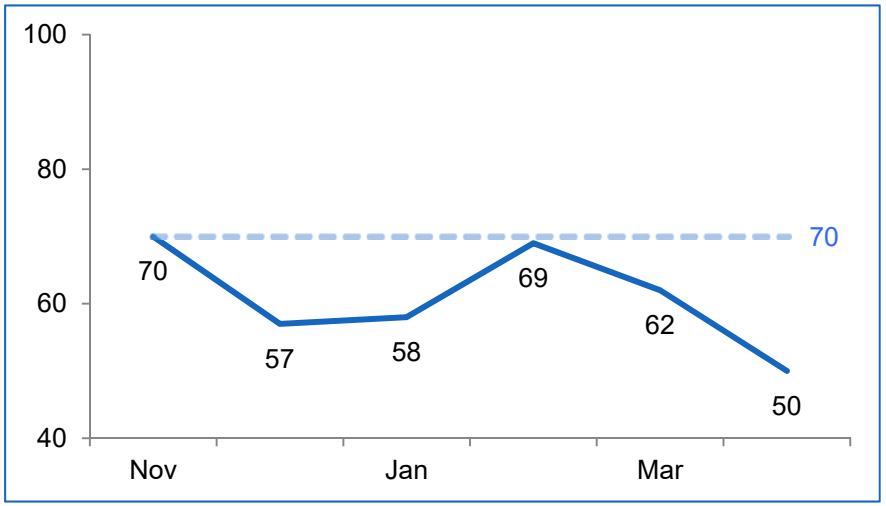
2016 figures are in grey since it is still quite early in the year, and there is always a lag in reporting pregnancies.

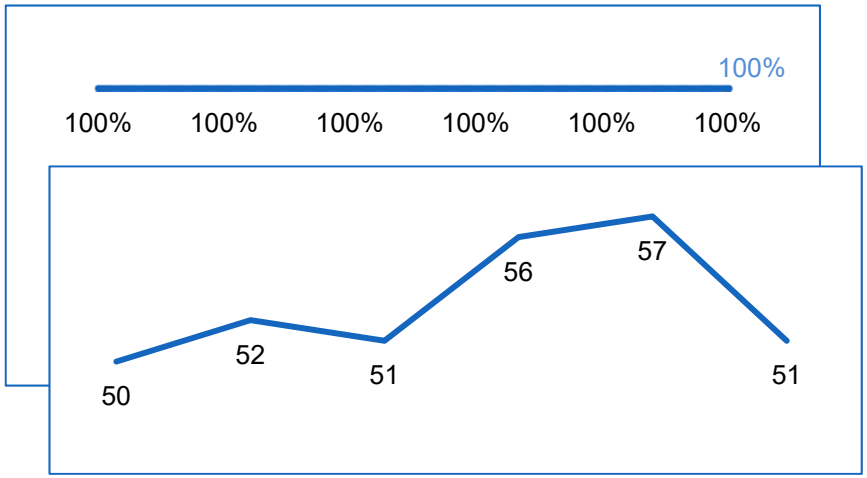
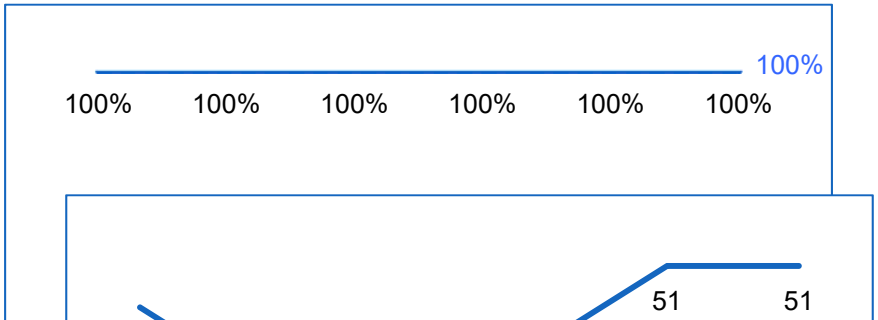
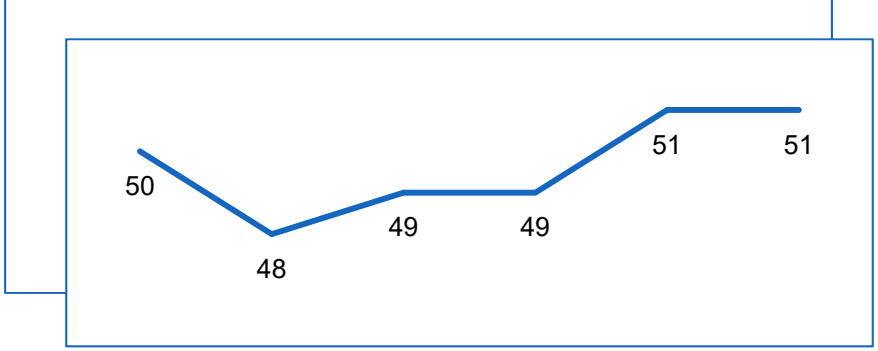
2. Indicator section

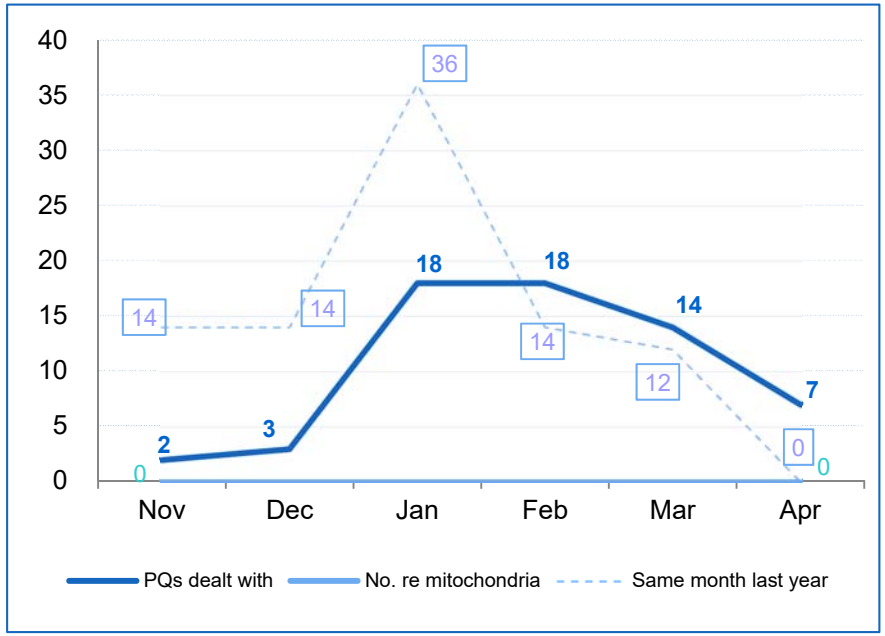
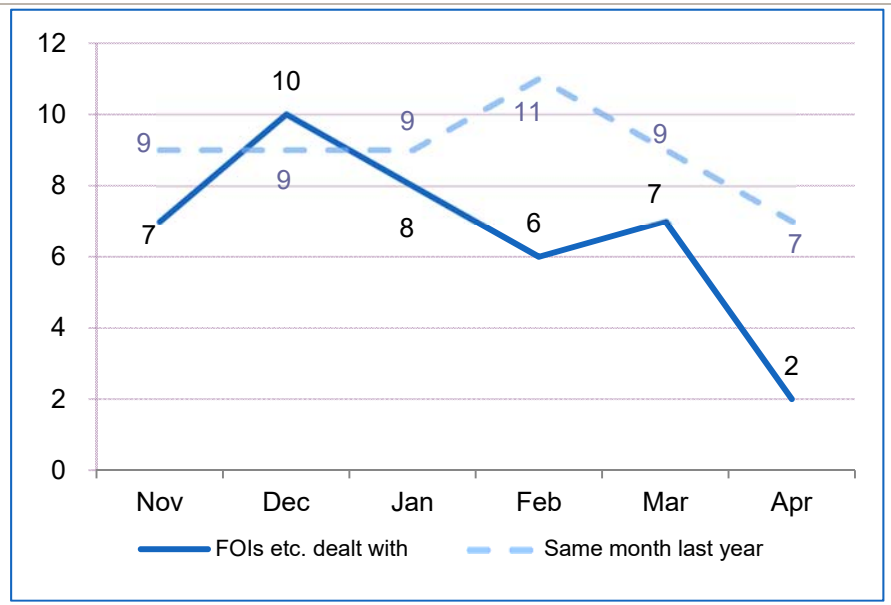
Key performance and volume indicators – February data:

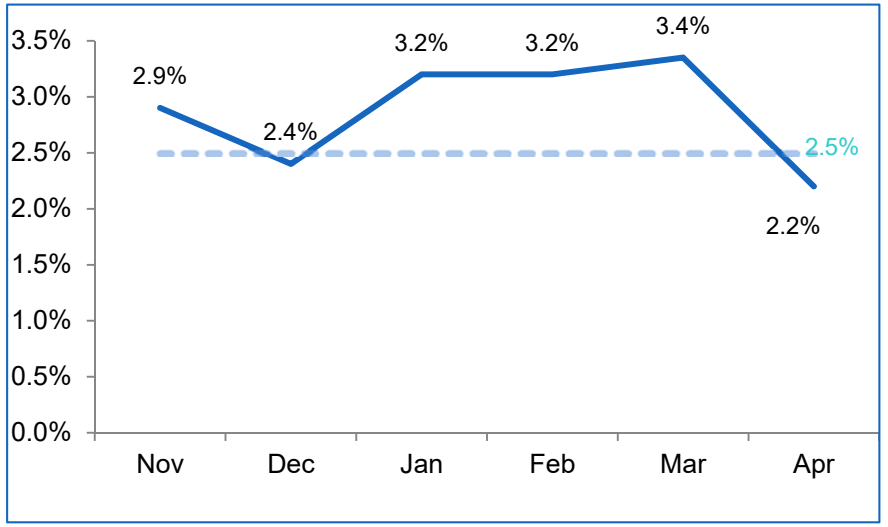
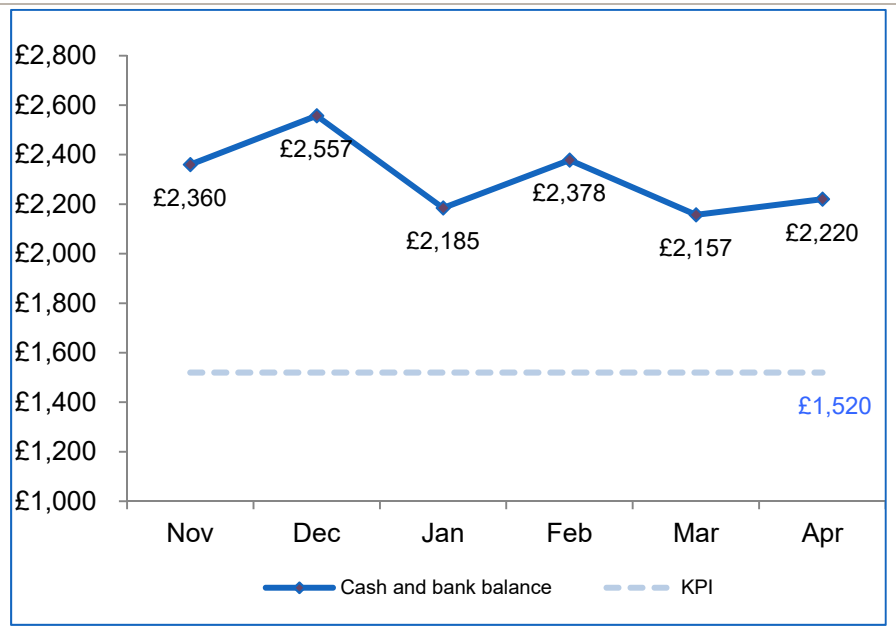
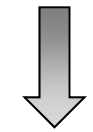
Indicator	Performance	RAG	Recent trend[1]	Aim[2]	Notes
Setting standards: improving the quality and safety of care through our regulatory activities.					
Licensing decisions made: - **By ELP** - **By Licence Committee**	14 0	⇧		No KPI – tracked for workload monitoring purposes	Volume indicator (no KPI target).
Setting standards: improving the lifelong experience for donors, donor-conceived people, patients using donor conception, and their wider families.					
Percentage of Opening the Register requests responded to within 20 working days	100% (18)	★		Maintain at 100% ↑	KPI: 100% of complete OTR requests to be responded to within 20 working days (excluding counselling time)

[1] Blue dashed line in graphs = KPI target level. This line may be invisible when performance and target are identical (eg, 100%).
[2] Direction in which we are trying to drive performance. (Are we aiming to exceed, equal, or stay beneath this particular KPI target?)

Indicator	Performance	RAG	Recent trend[1]	Aim[2]	Notes
Increasing and informing choice: using the data in the Register of Treatments to improve outcomes and research.					
			See graphs focused on quality of outcomes – after dashboard page.		
Increasing and informing choice: ensuring that patients have access to high quality meaningful information.					
Number of visits to the HFEA website (compared with previous year) (trend arrow indicates movement since previous month)	114,058 (138,898)	⇩		No KPI – tracked for general monitoring purposes.	Volume indicator showing general website traffic compared to the same period in previous year. Measured on the basis of 'unique visitors'. This measure may vary significantly during public beta or when the new website becomes live.
Efficiency, economy and value: ensuring the HFEA remains demonstrably good value for the public, the sector and Government.					
Average number of working days taken for the whole licensing process, from the day of inspection to the decision being communicated to the centre.	50 working days	★		Maintain at 70wd or less	KPI: Less than or equal to 70 working days.

Indicator	Performance	RAG	Recent trend[1]	Aim[2]	Notes
Monthly percentage of PGD applications processed within three months (66 working days).	100%	★		Maintain 100%	KPI: 100% processed (i.e. considered by SAC) within three months (66 working days) of receipt of completed application.
Average number of working days taken.	51	★			
Annualised (rolling year) percentage of PGD applications processed within three months (66 working days)	100%	★		Maintain 100%	KPI: As above. (Annualised score). Performance has reached target, and the annualised figure is being maintained at 100%.
Average number of working days taken.	51	★			

Indicator	Performance	RAG	Recent trend[1]	Aim[2]	Notes
Number of requests for contributions to Parliamentary questions	Total = 7	⇔		No KPI – tracked for general monitoring purposes.	Volume indicator. Last year's numbers were notably high. Many of those PQs related to the work we were then doing on mitochondria. The recent approval of research using the CRISPR-Cas9 gene editing technique has led to multiple requests about this subject.
Number of Freedom of Information (FOI), Environmental Information Regulations (EIR) requests and Data Protection Act (DPA) requests	2	⇩		No KPI – tracked for general monitoring purposes.	Volume indicator. There does not appear to be any trend or predictability in the volume or focus of our FOI (and other) requests.

Indicator	Performance	RAG	Recent trend[1]	Aim[2]	Notes
Staff sickness absence rate (%) per month.	2.2%	★		 Maintain 2.5% or less	KPI: Absence rate of ≤ 2.5%. Public sector sickness absence rate average is eight days lost per person per year (3.0%).
	Commentary: The current absence rate has returned to below KPI following an earlier rise which was due mainly to long-term sick leave and seasonal illnesses. This was investigated and did not demonstrate a trend towards problematic sickness absence, though we will continue to monitor this.				
Cash and bank balance	£2,378k	⇧		 Reduce	KPI: To move closer to minimum £1,520k cash reserves (figure agreed with DH). **Commentary:** April's balance is approximately 3% above March's levels due to reduced suppliers' activities in April

Indicator	Performance	RAG	Recent trend[1]	Aim[2]	Notes

Management accounts:

April accounts:

Income & Expenditure Account

Accounting Period: Apr-2016

	Year to Date				Full Year		
	Actual YTD £	Budget YTD £	Variance YTD £	% Variance YTD %	Forecast £	Budget £	Variance £
Grant-in-aid	-	-	-	-	958	958	-
Licence Fees	458	400	(58)	(14)	4,472	4,472	-
Other Income	-	1	1	100	6	6	-
Total Income	458	401	(57)	(0)	5,436	5,436	-
Revenue Costs - Charged to Expenditure							
Salaries (excluding Authority)	216	295	79	(27)	2,662	2,679	(16)
Shared Services	14	14	-	-	81	81	-
Employer's NI Contributions	20	-	(20)	-	250	247	2
Employer's Pension Contribution	46	-	(46)	-	572	573	(1)
Authority salaries inc. NI Contributions	12	12	(0)	1	146	146	-
Temporary Staff costs	8	-	(8)	-	8	-	8
Other Staff Costs	23	19	(3)	18	265	265	-
Other Authority/Committee costs	18	25	7	(29)	301	301	-
Other Compliance Costs	(3)	2	5	(241)	28	28	-
Other Strategy Costs	3	7	3	(48)	142	142	-
Facilities Costs incl non-cash	58	55	(3)	5	488	488	-
IT costs Costs	14	8	(6)	76	93	93	-
Legal Costs	45	21	(24)	118	400	400	-
Professional Fees	6	6	(0)	1	67	67	-
Total Revenue Costs	479	463	(16)	4	5,500	5,507	(6)
Total Surplus/(Deficit) before Capital & Project costs	(21)	(62)	(41)	(66)	(64)	(70)	6
IFQ & Other Project Costs - Reserves funded	85	54	(31)	58	472	472	-
Other Capital Costs	1	-	(1)	-	100	100	-
TOTAL NET ACTIVITY	(108)	(116)	(8)		508	502	6

Indicator	Performance	RAG	Recent trend[1]	Aim[2]	Notes

Commentary:

Summarised management accounts for April

Income

April is the first month of the 2016/17 business year. We have seen a small increase in treatment fee income (£57k). We believe this may be due to clinics submitting treatment forms in April that relate to prior periods.

Expenditure

The accounts show that for the month of April, we have overspent by £16k or 3.5% before IfQ spend against budget. This is largely due to overspends on legal (£24k), IT (£6K) and £3k within Finance and Facilities. These are however, offset by underspends within both the Compliance and Strategy directorates (£15k). Within Finance we are accruing for rent and rates based upon CQC's charges as we have yet to receive an invoice from NICE, our new landlords.

IfQ and other project costs

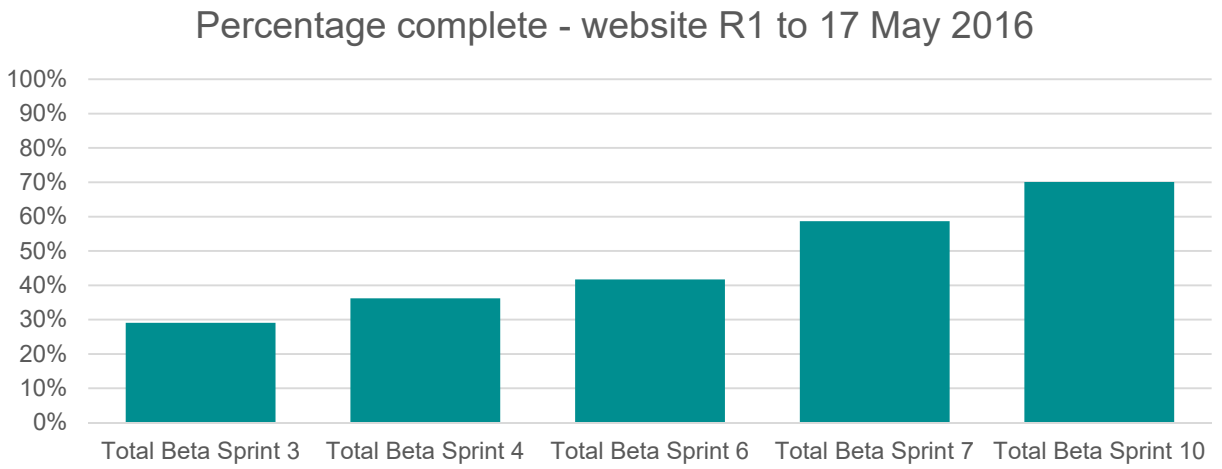
Last year we transferred over £600k of cost of IfQ to Assets under Construction which means we will fully capitalise these costs at the end of the calendar year. For the first month of 2016/17 we have overspent against plan by £31k or 58%. We are planning to spend in the region of £470k for the whole year. Therefore IfQ spends will be doubly monitored by both the PMO and Finance teams.

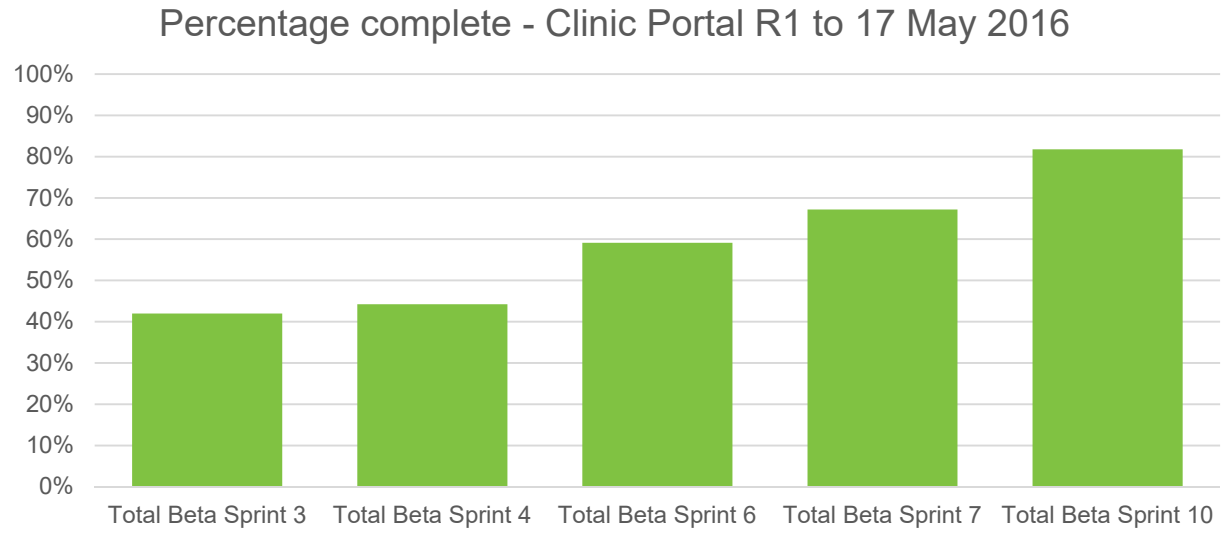
IfQ indicators: April update for Beta project phase

Frequency / trigger point	Metric	Purpose	Latest status:
At programme set-up / major reorganisation / new tranche	MSP health check overall score achieved / maximum score as a %	Is the programme set up to deliver?	**April update:** The MSP health check has been completed with the final report also completed. This should be circulated in June.
Monthly	Timescales: we changed the burndown chart showing remaining estimate of work to a chart showing percentage of works complete.	Is there scope creep/ over-run?	**April update:** The Programme continued to progress well through to end Beta Sprint 10. Both services passed their DH led GDS assessments to progress to public beta at the end of Beta Sprint 10, endorsing the completed work. Notwithstanding, work remains to finalise all remaining user stories in Beta, with the significant pieces remaining being the 'detailed statistics' pages for the Website, and the 'online applications' piece for the Clinic Portal. The below charts provides weighted data on the work completed for both website and CP. The data includes all the features completed on each project for front end, back end design and API related work. The weighting takes into consideration the level of complexity for each feature to calculate the percentage complete. It should be noted that each is completed by the product team for that product, so there isn't an objective measure of completion between the two for this measure.

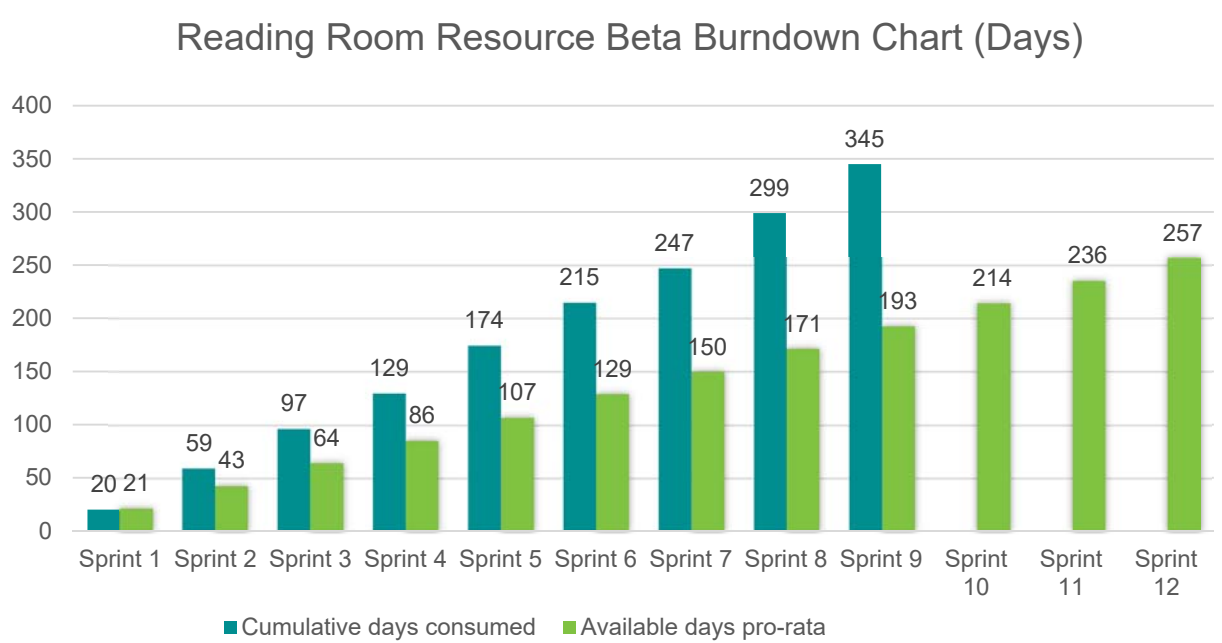
IfQ indicators: April update for Beta project phase

Frequency / trigger point	Metric	Purpose	Latest status:





IfQ indicators: April update for Beta project phase

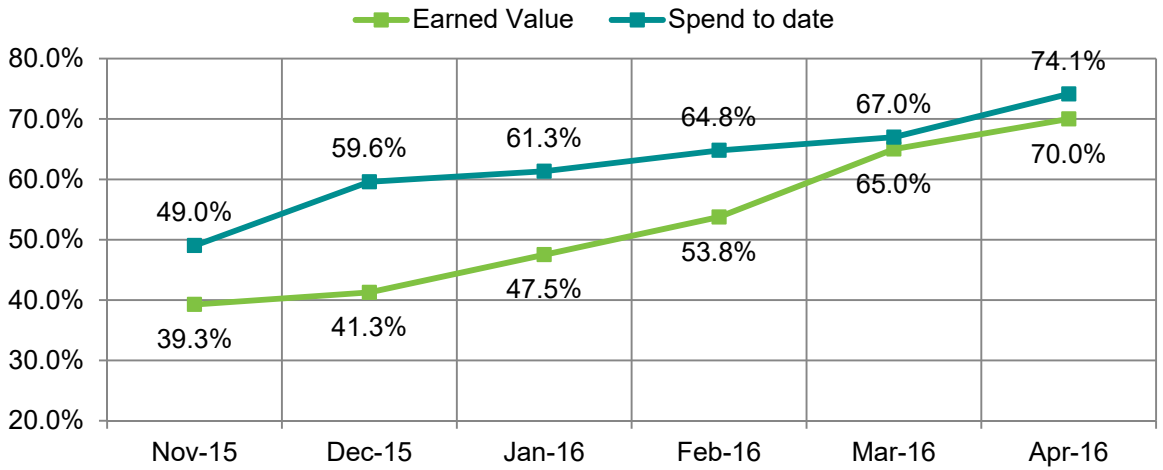
Frequency / trigger point	Metric	Purpose	Latest status:
Monthly	Resource usage: The total number of days Reading Room are contracted to provide, vs the number of days consumed to date.	To monitor the rate of resource usage.	**April update:** The below graph shows days consumed by sprint, against a pro-rata trend of those days divided equally by the number of sprints in Beta. We have exceeded the number of days allocated by the contractor for Beta. However, due to the nature of the capped time and resource contract with Reading Room, they are contractually obliged to continue building the Beta product at their own cost. 

IfQ indicators: March update for Beta project phase

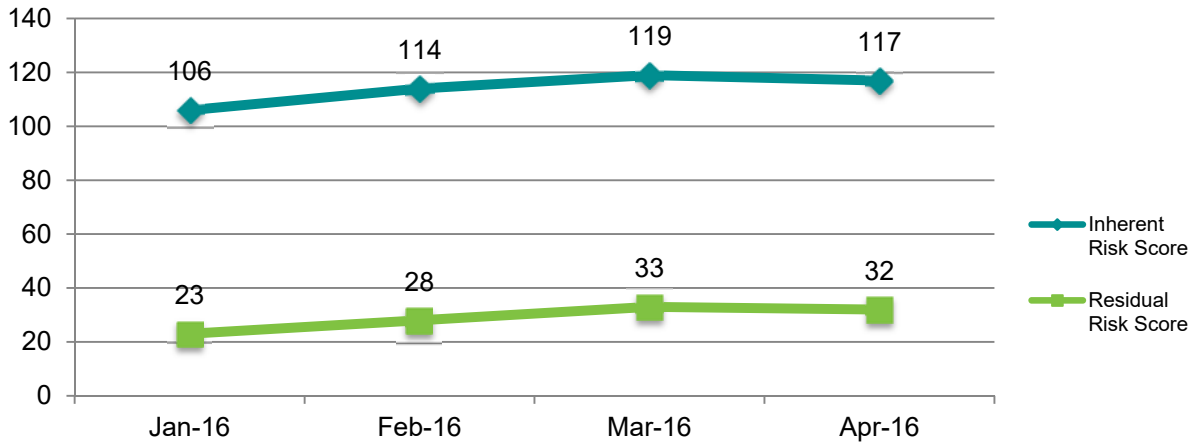
Frequency / trigger point	Metric	Purpose	Latest status:
Monthly	Cost: earned value (% complete * estimated spend at completion)	Is the spend in line with milestone delivery?	There are four things we can attribute value to: website and CaFC; Clinic Portal; the Register and internal systems; and the defined dataset, discovery, stakeholder engagement etc. 25% of the value of the 1.8M programme cost at completion has been attributed to each of these elements. **April update:** The earned value and spend to date are still joining up, with a slight difference compared to last month's figures. We are expecting the spending figures to increase in the upcoming month, mainly due to the Beta invoices and Internal Systems external contractors who have started the work on security/CLAS[3]. Also note that the percentage increase in the earned value measures the work underway for delivery of the project and not against the agile 'definition of done' assessment. For the April period the main focus was on ensuring existing work was ready for GDS assessment, through bug fixing and other similar activities. As a result, the proportionate level of new work underway was less than in previous months.

[3] CLAS stands for CESG Listed Adviser Scheme; CESG stands for the Communications-Electronics Security Group (a branch of GCHQ), the national technical authority for information assurance.

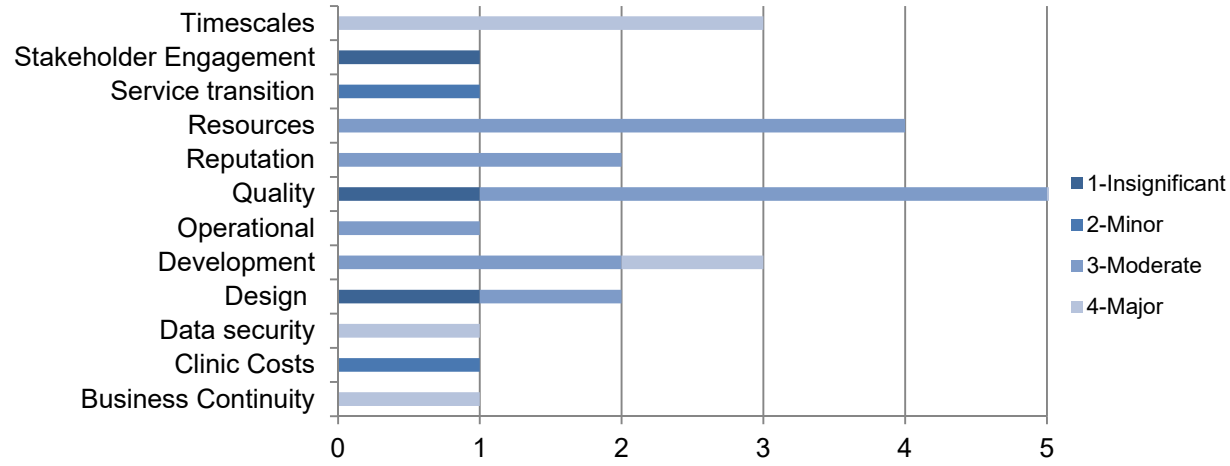
IfQ indicators: March update for Beta project phase

Frequency / trigger point	Metric	Purpose	Latest status:
			
Monthly	Stakeholder engagement: combined stakeholder engagement score (internal plus external stakeholder events or communi-cations)	Are we keeping stakeholders with us? Is it getting better or worse?	**March.** In March there was a lot of IfQ stakeholder activity as we held our annual conference and the IfQ stakeholder group meeting. The conference included presentations about the new website and CaFC and gave delegates the chance to ask questions about the new products. Total combined score = 4 **April.** In April the patient stakeholder group met, and the website product owner gave a presentation on the new website and CaFC search that was very well received. The group complimented him on the design of the new website. There was also a show and tell session for staff. Total combined score = 2
Monthly	Risks: sum of risk scores (L x I)	Is overall risk getting worse or better	**April update:** The below line graph represents the overall IfQ risk score, which combines the perceived impact and likelihood of the current risks on hand each month. The overall risk score for the IfQ

IfQ indicators: March update for Beta project phase

Frequency / trigger point	Metric	Purpose	Latest status:
		(could identify death by a thousand cuts)?	Programme has decreased during the last period.  The majority of the risks are associated with timescales, data security, development and business continuity. The Audit and Governance Committee received additional information about the controls and mitigations in place for these risks, at its June meeting.

IfQ indicators: March update for Beta project phase

Frequency / trigger point	Metric	Purpose	Latest status:
			
Quarterly	Benefits: value (£) of tangible benefits planned to be delivered by the programme	Is the value of the benefits increasing or decreasing – could trigger a review of the business case.	**April update:** The benefits realisation value should be reviewed periodically based on the business case; this will be looked at during the June IfQ Programme Board. No issues have been raised regarding benefits realisation to date.

Strategic risk register

Strategic delivery:	☒ Setting standards	☒ Increasing and informing choice	☒ Demonstrating efficiency economy and value
Details:			
Meeting	Authority		
Agenda item	7		
Paper number	HFEA (06/07/2016) 800		
Meeting date	6 July 2016		
Author	Helen Crutcher, Project Risk and Performance Manager		
Output:			
For information or decision?	For information		
Recommendation	The Authority is asked to note and comment on the latest edition of the strategic risk register.		
Resource implications	In budget		
Implementation date	Ongoing		
Communication(s)	The risk register is reviewed quarterly by the Corporate Management Group (CMG), and presented at every Audit and Governance Committee (AGC) meeting. AGC last reviewed the risk register at its meeting on 15 June.		
Organisational risk	☐ Low	☒ Medium	☐ High
Annexes	Annex 1: Strategic risk register		

1. Latest reviews

1.1. CMG reviewed the risk register at its meeting on 18 May. Four of the twelve risks are above tolerance. CMG reviewed all risks, controls and scores, although IfQ and legal risks were reviewed in more depth and updated at additional meetings, since these had changed since the previous review. CMG's specific comments are contained in the risk register at Annex A.

1.2. The risk register was last discussed at AGC on 15 June. AGC did not amend any of the risk scores. Comments from this meeting are also included in the register at Annex A.

2. Recommendation

2.1. The Authority is asked to note and comment on the latest edition of 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	⇔⇔⇔⇔
Information for Quality	IfQ3: Delivery of promised efficiencies	Efficiency, economy and value	**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	⇔⇔⇔⇔
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,⇧⇔⇩⇔).
Recent review points are: CMG 4 February ⇨ AGC 16 March ⇨ CMG 18 May ⇨ AGC 15 June.

[1] Strategic objectives 2014-2017:

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

Setting standards: improving the lifelong experience for donors, donor-conceived people, patients using donor conception, and their wider families. (Setting standards – donor conception)

Increasing and informing choice: using the data in the register of treatments to improve outcomes and research. (Increasing and informing choice – Register data)

Increasing and informing choice: ensuring that patients have access to high quality meaningful information. (Increasing and informing choice – information)

Efficiency, economy and value: ensuring the HFEA remains demonstrably good value for the public, the sector and Government. (Efficiency, economy and value)

CMG overview – summary from May risk meeting

CMG reviewed the risk register and risk scores at its meeting on 18 May. Detailed review and update of IfQ (IfQ1, IfQ2 and IfQ3) and Legal (LC1) risks was completed offline with the risk owners.

Since the two Head posts that had been vacant for a period have now been filled, this improves the position for several of the risks, in that the controls now have long term owners and are no longer being carried by the relevant Directors. It will take some time for the new appointees to bed in fully, however, so this does not in itself immediately reduce the risk scores.

When reviewing RM2 (the risk of a loss of regulatory authority), CMG discussed the records management mitigation which had originally been assigned to the Head of Corporate Projects, who had now left the organisation, meaning this mitigation was no longer in place. We agreed that, in the event, this part of the role had not been made a priority. CMG agreed the organisation's records management practices had not worsened, so the risk rating should remain the same. Work is now being planned on records management, probably to be managed as a project.

CMG noted that since the move, IfQ product owners were finding oversight and day-to-day communication with Reading Room more difficult since colocation is harder to achieve in the HFEA's smaller office, and opportunities for continued colocation at Reading Room's offices are limited. We have agreed that this should be rectified by ensuring 3-4 desks are available to accommodate the contractors when needed. We believe that desk occupancy is now settling down and that it should be possible to find the space needed.

CMG agreed to remove the office move risk (OM 1) from the strategic risk register since the move had been completed and any risks or issues were now operational rather than strategic. All causes had been reviewed and outstanding related actions have been incorporated into an ongoing post-move snagging list, which is being tracked by the Business Planning team.

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. The Finance team is under particular pressure at this time of year, owing to the usual year end peak and the fact that the Director and Head also unavoidably experience this for two organisations at once.

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 appropriate 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 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 arrow indicates whether the risk is: Stable ⇔ , Rising ⇧ or Reducing ⇩.

Risk scoring system
See last page.

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

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

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

Causes / sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Inspection/reporting failure.	Inspections are scheduled for the whole year, using licence information held on Epicentre, and items are also scheduled to committees well in advance.	In place – Sharon Fensome-Rimmer	At tolerance. The Head of Corporate Governance and Chief Inspector have now started in their posts. 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 need to manage this training period, together with the action plan being implemented in connection with legal parenthood consent issues, has raised the residual risk likelihood from 1 (very unlikely) to 2 (unlikely) – from November through to at least June 2016.
	Audit of Epicentre conducted to reveal data errors. Queries now routed through Licensing, who hold a definitive list of all licensing details.	Completed October 2015 – Ian Brown	
	Inspector training, competency-based recruitment, induction process, SOPs, QMS, and quality assurance all robust.	In place – Sharon Fensome-Rimmer	
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 team for such events – dealing with high-impact cases, additional incident inspections, etc.	In place – Sharon Fensome-Rimmer	
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 times 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 incidents occur at once.	Resilient staffing model in place.	In place – Sharon Fensome-Rimmer	On legal parenthood, a strong set of actions is in place and continues to be implemented. 10 cases have been determined and 10 cases await determination in the High Court, and in Scotland. The inspection team continue to work with colleagues in around
	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	
	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	In progress – Nick Jones/Sharon Fensome-Rimmer	

	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. Range of lessons learned identified.		20 licensed centres where there are anomalies. The focus is on ensuring all affected patients are informed and appropriately supported. The policy team is developing a range of tools to support licensed clinics in ensuring patients provide effective consent.

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 to be revisited during 2016 review of Standing Orders. Licensing Officer role to take certain decisions from ELP – work on this is continuing, with the preparation of suitable documentation for recording decisions.	To be put in place – Ian Brown Licensing Officer role – this was postponed pending recruitment of Head of Corporate Governance, work is now continuing – Ian Brown Delegations in SOs have been 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	In place – Sharon Fensome-Rimmer	

	system (QMS) and quality assurance all robust.	
Effect of publicised grade A incidents.	Staffing model provide resilience in inspection team for such events – dealing with high-impact cases, additional incident inspections, etc.	In place – 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 mid-2016 (see below).	New work in development as at May 2016 – SMT
	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 is informing our decisions about which content to move first to the beta version of the new site.	In progress – beta phase February 2016 – Juliet Tizzard

Negative media or criticism from the 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:			⇔ ⇔ ⇔ ⇔	Juliet Tizzard
			Likelihood	Impact	Inherent risk		
			4	4	16 High		
			Residual risk level:				
			Likelihood	Impact	Residual risk		
			3	**4**	**12 High**		
			Tolerance threshold:		8 Medium		

Causes / sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
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. Managing these risks has formed an intrinsic and essential part of the detailed project planning and tendering, throughout. Following a lengthy delay, we received formal approval for both the data and digital elements of IfQ in late April 2015. The digital side of the programme received only partial approval; full delivery still required an additional gateway approval (ie, prior to commencing beta). The Department of Health gateway review took place in November 2015 and awarded a
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	

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	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). 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 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 are a number of requirements to address before we can implement live beta.
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 by end July 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 and subsequent formal approval mechanisms. The beta timeline was extended by 3 months to compensate for previous and anticipated future delays.	In place – Juliet Tizzard In place – Nick Jones (decision received April 2015) In place – Nick Jones	
Resource conflicts between delivery of website and business as usual (BAU).	Backfilling where possible/affordable to free up the necessary staff time, eg, Websites and Publishing Project Manager post backfilled to free up core staff for IfQ work.	In place – Juliet Tizzard	

Delivery quality is very supplier dependent. Contractor management could become very resource-intensive for 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. 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	
Colocation in the HFEA's smaller office at Spring Gardens is harder to achieve with the risk that Product Owners have less oversight of contractor delivery.	Disruption during the move was minimised through careful planning. Since the move, some colocation has been possible at Reading Room and other options are being explored, including a resumption of colocation at Spring Gardens to the extent possible.	Considered and further action in progress – 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 is considering other sources of assurance, and will agree a new plan shortly.	To be resolved. Update to be provided to June AGC – 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 the changes are culturally embraced and embedding into new ways of working. Knowledge handover with the contractors will take place.	In place – Nick Jones	
Colocation in the HFEA's smaller office at Spring Gardens is harder to achieve with the risk that Product Owners have less oversight of contractor delivery.	Disruption during the move was minimised through careful planning. Since the move, some colocation has been possible at Reading Room and other options are being explored, including a resumption of colocation at Spring Gardens to the extent possible.	Considered and further action in progress – Nick Jones	

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

Causes / sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Poor user acceptance of changes, or expectations not managed.	Stakeholder involvement strategy in place and user testing being incorporated into implementation phases of projects.	In place – Nick Jones/Juliet Tizzard	Above tolerance. 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 introduction of the new EDI interface) is in progress and the HFEA will continue to work within agreed costs.	In place (July 2015) – Nick Jones In progress (May 2016) – Nick Jones	
Required GDS gateway approvals are delayed or approval is not given.	All GDS approvals sought so far have been granted, albeit with some delays to earlier gateways. Our detailed planning includes addressing the requirements laid down by GDS as conditions of alpha and beta phase approval. Additional sprints of work were incorporated into beta, in an attempt to allow sufficient time (and resources) for the remaining GDS gateway review processes and subsequent formal approval mechanisms. The beta timeline was extended by 3 months to compensate for previous and anticipated future delays.	In place – Nick Jones	
Benefits not maximised and internalised into ways of working.	During IfQ delivery, product owners are in place, as is a communications plan. The aim is to ensure that changes are developed involving the right staff expertise (as well as contractors) and to ensure that the changes are culturally embraced and embedded into new ways of working. Knowledge handover with the contractors will take place.	In place (June 2015) – Nick Jones	
Colocation in the HFEA's smaller office at Spring Gardens is harder to achieve with the risk that Product Owners have less oversight of contractor delivery.	Disruption during the move was minimised through careful planning. Since the move, some colocation has been possible at Reading Room and other options are being explored, including a resumption of colocation at Spring Gardens to the extent possible.	Considered and further action in progress – 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 on consents for parenthood has had administrative and policy consequences for the HFEA. Further court cases are coming to light now, and more are also likely, although the frequency of these cases is reducing. The HFEA is unlikely to participate in legal proceedings directly. There has been a pre-action protocol letter challenging one discrete element of the IfQ CaFC project. If the case were lost then this would impact on the presentation of data. There is also an outstanding pre-action protocol letter regarding a decision of the ELP.
	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 on CaFC may mean that more clinics make representations against licensing decisions.	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	

	Well-evidenced recommendations in inspection reports.	In place – Sharon Fensome-Rimmer	The matter has now been considered by the Licence Committee and this may mean that the pre-action is dropped. A patient has brought an application for a declaration seeking clarification about the continued storage of her embryos. We are hopeful that the matter can be resolved by way of agreement.
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.	Discussion with the Department of Health would need to take place regarding possible cover for any extraordinary costs, since it is not possible for the HFEA to insure itself against such an eventuality, and not reasonable for the HFEA's small budget to include a large legal contingency.	In place – Peter Thompson	
Legal proceedings can be lengthy and resource draining.	Panel in place, as above, enabling us to outsource some elements of the work.	In place – Peter Thompson	
	Internal mechanisms (such as the Corporate Management Group, CMG) in place to reprioritise work should this become necessary.	In place – Peter Thompson	
Adverse judgments requiring us to alter or intensify our processes, sometimes more than once.	Licensing SOPs, committee decision trees in place.	In place – Ian Brown	

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

Causes / sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Confidentiality breach of Register data.	Staff have annual compulsory security training to guard against accidental loss of data or breaches of confidentiality. Secure working arrangements for Register team, including when working at home.	In place – Dave Moysen	At tolerance.
Loss of Register or other data.	As above.	In place – Dave Moysen	
	Robust information security arrangements, in line with the Information Governance Toolkit, including a security policy for staff, secure and confidential storage of and limited access to Register information, and stringent data encryption standards.	In place – Dave Moysen	
Cyber-attack and similar external risks.	Secure system in place as above, with regular penetration testing.	In place – Dave Moysen	
Infrastructure turns out to be insecure, or we lose connection and cannot access our data.	IT strategy agreed, including a thorough investigation of the Cloud option, security, and reliability.	In place – Dave Moysen	
	Deliberate internal damage to infrastructure, or data, is controlled 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 period of embedding the policies is in progress. Awareness of the importance of maintaining business continuity was built into our office move planning	In place – Sue Gallone	
Register data becomes corrupted or lost somehow.	Back-ups and warehouse in place to ensure data cannot be lost.	In place – Nick Jones/Dave Moysen	
Other HFEA data (system or paper) is lost or corrupted.	As above. Staff have annual compulsory security training to guard against accidental loss of data or breaches of confidentiality.	In place – Dave Moysen	

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

Causes / sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Poor record keeping	Refresher training and reminders about good records management practice.	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. After a period of reduced volumes at the end of 2015, January and February 2016 saw an increase. This seems to be levelling off again as of May 2016, so in the light of this the residual risk level has been reduced somewhat.
	TRIM review and retention policy implementation work – subsumed by IT strategy.	To sync in with IT strategy – 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 in Q2 2016/17 – 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. FOI requests are refused when there are grounds for this.	In place – Juliet Tizzard / Nick Jones	

	PQ SOP revised and log created, to be maintained by 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 will be 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 on long term sick leave, and this together with work pressures from IfQ delivery means there is still some pressure on team capacity (being discussed by managers).	In place, with current team capacity issue under discussion – Nick Jones	
Risk of inadequate handling of a request.	Trained staff, SOPs and quality assurance in place.	In place – Nick Jones	
	SOPs reviewed by Register staff, CMG and PAC-UK, as part of the pilot set-up. Contract in place with PAC-UK for pilot delivery.	Done (May 2015) – ongoing management of the pilot by Rosetta Wotton.	

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

Causes / sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Fee regime makes us dependent on sector activity levels.	Activity levels are tracked and change is discussed at CMG, who would consider what work to deprioritise and reduce expenditure.	Monthly (on-going) – Sue Gallone	At tolerance. For 2015/16 we achieved a small under-spend but the 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.
	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 – Sue Gallone	
GIA funding could be reduced due to changes in Government/policy	A good relationship with DH Sponsors, who are well informed about our work and our funding model.	Quarterly meetings (on-going) – Sue Gallone	
	Annual budget agreed with DH Finance team alongside draft business plan submission.	December annually – Sue Gallone	
	Detailed budgets for 2016/17 have been agreed with Directors. DH has previously agreed our resource envelope.	In place – Sue Gallone	
Budget setting process is poor due to lack of information from directorates	Quarterly meetings with directorates flags any shortfall or further funding requirements.	Quarterly meetings (on-going) – Morounke Akingbola	
Unforeseen increase in costs eg, legal, IfQ or extra in-year work required	Use of reserves, up to contingency level available. DH kept abreast of current situation and are a final source of additional funding if required. IfQ Programme Board regularly reviews the budget and costs.	Monthly – Sue Gallone Monthly – IfQ Programme Board	

Upwards scope creep during projects, or emerging during early development of 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), though there will be a period of bedding in.
	Staff have access to civil service learning (CSL); organisational standard is five working days per year of learning and development for each member of staff.	In place – Rachel Hopkins	
	Organisational knowledge captured via records management (TRIM), case manager software, project records, handovers and induction notes, and manager engagement.	In place – Rachel Hopkins	
The new UK government may implement further cuts across all ALBs, resulting in further staffing reductions. This would lead to the HFEA having to reduce its workload in some way.	The HFEA was proactive in reducing its headcount and other costs to minimal levels over a number of years. We have also been reviewed extensively (including the McCracken review). Turnover is variable, and so this risk will be retained on the risk register, and will continue to receive ongoing management attention.	In place – Peter Thompson	
Poor morale leading to decreased effectiveness and performance failures.	Engagement with the issue by managers. Ensuring managers have team meetings and one-to-one meetings to obtain feedback and identify actions to be taken.	In place – Peter Thompson	

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

Information for Quality programme: update

Strategic delivery:	☒ Setting standards	☒ Increasing and informing choice	☒ Demonstrating efficiency economy and value
Details:			
Meeting	Authority		
Agenda item	8		
Paper number	HFEA (06/07/2016) 801		
Meeting date	06 July 2016		
Author	Nick Jones, Director of Compliance and Information		
Output:			
For information or decision?	For information		
Recommendation	The Authority is asked to note: • The work in progress now in readiness for public beta, and the approval process to proceed to a fully live service. • Data migration and cleansing • Programme timelines and budget.		
Resource implications	Nil		
Implementation date	During 2016–17 business year		
Communication(s)	Regular, range of mechanisms		
Organisational risk	☐ Low	☐ Medium	☒ High
Annexes			

1. Background

1.1. The Information for Quality (IfQ) programme encompasses:

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

1.2. Given the importance of IfQ to our strategy, we update the Authority on progress at each meeting and seek approval for direction and actions.

1.3. This paper updates Members on:

- Approvals and progress since the previous meeting
- Data migration and cleansing
- Programme timelines and budget.

2. Update on approval stages

2.1. Members will recall that government IT programmes must progress through several stages:

- 'alpha' (build a prototype, test it with users and learn from it)
- 'beta' (scaling up, a working model)
- 'public beta' (going public with a beta version, receiving feedback and preparing to go live)
- 'live' (a tested solution that is ready to release and then continuously improved).

2.2. The IfQ programme must meet the assessments against the 18 Government Digital Service (GDS) standards by the Department of Health (DH). On 11 and 12 May 2016 the new HFEA website and Clinic Portal products were passed as ready to proceed to 'public beta'. As with any useful review process some recommendations for improvement were made, and substantial activity to address those along with activity to finalise the public beta products has largely been completed.

2.3. Our current planning assumption is that both the new HFEA website and the new Clinic Portal will be released to clinics only by the end of June 2016. We have introduced this additional, interim, phase to allow clinic audiences to access the website over a two-week period to enable them to view the new

content - in particular the presentation of data displayed in Choose a Fertility Clinic to identify errors or anomalies. In addition, it will enable clinics to upload information about the clinic – photographs and so on – for display on the clinic's 'profile' page. Following this period, we anticipate the new HFEA website will be made available to all in public beta in mid-July.

2.4. We will take the opportunity at the meeting to demonstrate the website and portal.

2.5. We expect the public beta stage for both the portal and the website will run from mid-July for a period of approximately 8-10 weeks. This is dependent on feedback. For example, if users indicate that there are significant changes required, it is possible to extend the length of public beta. Conversely, if changes required are minimal, we may require less time.

2.6. Following public beta, a further full gateway assessment by the Department of Health against the GDS standards will be required. This is scheduled for September 2016. All being well, this will be followed by 'live' phase – which effectively means turning off the current website and portal.

2.7. The pace does not slacken. The team is now progressing the next significant milestone in the programme – 'Release 2', that is the replacement for the current data submission system, and the new Register. This is where we expect to see substantial improvements experienced by clinic users providing them quantifiable cost-releasing benefits.

2.8. In line with the programme's delivery plan, foundational work on the internal infrastructure and architecture required to support Release 2 is underway, and our current planning assumption is that we will release the EDI component in October 2016.

3. Data migration and the data dictionary

3.1. As members are aware, IfQ involves important changes to the way we collect, use and publish information. Critically, this work will involve significant changes to the HFEA's 'Register of Treatments' (the Register).

- The Register holds information about people receiving fertility treatment, egg and sperm donors, and children conceived following treatment. Keeping the Register is one of the HFEA's statutory obligations and the information currently held in the Register is likely the largest database of assisted reproductive treatments in the world. The Register is critically important for a number of reasons:
    - As a comprehensive record of all treatments, it provides crucial information on the safety and effectiveness of treatments
    - It enables donor conceived people to have knowledge of their genetic inheritance

  - It enables parents to access information about the donor used in their treatment
  - It enables donors to understand the outcome of their donation
  - It enables patients to make more informed choices about their treatment options
  - It supports intelligent regulation and makes possible important research and analysis.

- A key outcome of IfQ will be changing what information is kept in the Register, how that data is recorded and how it is collected or obtained. To achieve this, a review has been carried out to ensure each item of data collected from clinics can fully justified, and this has subsequently determined a new draft data dictionary (or dataset) that should be collected from clinics.
- Based on this new dataset, we are creating a revised Register, which will use modern database practices and technology. Improvements to the way that data is recorded and stored in the revised Register will result in higher quality data, which is more accessible to us and to other key stakeholders and interest groups – such as researchers.
- The revised Register will work hand in hand with the replacement for EDI to meet key investment objectives for IfQ by reducing the administrative burden for clinic users.

3.2. Data migration process and strategy:

- The revised Register must be populated with data, requiring the transfer of historic information from the existing Register database in to the new Register database structure. This is referred to as the IfQ data migration process. As such a data cleansing effort has been underway since the turn of the year, and more recently clinics have been participating in the effort.
- The Register Information team is currently working with centres on 'severity 1 errors.' The process is being managed carefully so as to ensure that our staff are available to field queries from the centres and to assist them where necessary. Around 3500 errors are being reviewed in all, prior to the data migration. 1240 errors have been fixed – demonstrating good progress. Whilst not vital to the migration we are also taking the opportunity to correct other errors to keep up the momentum.
- A well-managed and successful data migration process is central to realising many of the anticipated benefits of the IfQ Programme, and to managing risk. The Audit and Governance Committee at its June 2016 meeting explored the risks in some depth.
- In recognition of the importance of the data migration process, external suppliers were engaged to provide their expertise and work with us to develop a strategy for completing the data migration process appropriately. That strategy was reviewed and accepted by the HFEA in March 2015, and has been used to inform each key step of the migration process since.
- The strategy required a foundational 'health check' of the data to be conducted. Following the health check the strategy requires five separate

data migration 'loads' of all of the historical data in to the new Register structure. The first four are 'trial loads' in preparation for the fifth and final load.

3.3. Timeline for data migration:

- Currently, the Programme is progressing through trial load 1, having now produced a set of quality assurance reports and documents and having conducted several incremental trial loads. The team is currently finalising the reconciliation and migration exceptions reports in the lead up to commencing trial load 2.
- We anticipate trial load 1 being fully completed by end June 2016 and the team anticipates being ready to complete trial load 5 by the end of September, in line with the current delivery plan for IfQ. Expected timelines have slipped a little, due to competing priorities albeit the variance is manageable.

Programme milestone	Planned completion date	Anticipated completion date
Trial load 1	17 May 2016	end June 2016 [update at meeting]
Trial load 2	28 June 2016	13 July 2016
Trial load 3	13 July 2016	28 July 2016
Trial load 4	28 July 2016	12 August 2016
Trial load 5	21 September 2016	21 September 2016

3.4. Data migration strategy assurance:

- We are seeking external assurance that we are completing the steps required in the data migration strategy, to the appropriate level of quality. A procurement exercise is underway to identify a suitable third party to provide this assurance.

3.5. Safeguards:

- Throughout the entire data migration process and when the new Register structure is operational, the existing Register database will be retained as a reference. This will ensure that there is no risk that the data migration activity compromises the actual data held in the current Register structure.
- A report will be produced during each trial load to identify where data has not been transferred in a usable way, according to the quality standards and technical structure of the new Register. This will ensure the HFEA knows exactly what data has been transferred successfully. In addition, data that doesn't meet these quality metrics will be 'flagged' in the new structure, to ensure it will be addressed and, as stated above, retained in the reference copy of the current Register for information.

4. Programme timelines and budget implications

4.1. As reported previously, a revised IfQ programme plan was finalised and signed off by the IfQ Programme Board in January 2016, in line with the overall £1.134m agreed by Authority.

4.2. On 24 May 2016, SMT decided to allocate an additional (and new) £90k to the overall Programme budget to ensure that critical staff are retained on the team as the transition from delivering release 1 to release 2 is made. This modest additional investment essentially means we can continue working at pace but sharing the load so as not to burden key staff disproportionately.

4.3. 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	£526,199 (16/17)	£769,675 (May 16)	£702,088 (May 16)	£67,586 (due to the security class consultants, IS contingency undrawn and Data migration consultancy not being spent as forecasted – expected to rebalance in June)

4.4. The earned value and spend to date are merging, following the GDS assessment more products have now been completed with a stable spending as forecasted within the programme.

Period	Dec-15	Jan-16	Feb-16	Mar-16	Apr-16	May-16
Earned Value	41.3%	47.5%	53.8%	65.5%	70.0%	75%
Spend to date	59.6%	61.3%	64.8%	67.0%	74.1%	75%

5. Recommendation

5.1. The Authority is asked to note:

- The approval process to proceed to 'live' and recommendations from the last review
- Progress since the last Authority meeting
- The information about data migration and cleansing
- Programme timelines and budget.

Inspection ratings

Strategic delivery:	☒ Setting standards	☒ Increasing and informing choice	☐ Demonstrating efficiency economy and value
Details:			
Meeting	Authority		
Agenda item	9		
Paper number	HFEA (06/07/2016) 802		
Meeting date	6 July 2016		
Author	Ian Brown, Head of Corporate Governance		
Output:			
For information or decision?	For decision		
Recommendation			
Resource implications			
Implementation date	August/September 2016		
Communication(s)			
Organisational risk	☐ Low	☒ Medium	☐ High
Annexes			

1. Background

1.1. Our redesigned Choose a Fertility Clinic tool, due to launch as part of the new website in the autumn, contains a new inspection rating feature. By seeing this rating alongside the patient rating and the success rates, patients are able to get an overall picture of the quality of the clinic and, for self-funded patients, to help them decide whether it is the right clinic for them.

1.2. The inspection rating is based on the length of the clinic's licence; a simple, relatively uncontested measure which is decided through our formal licensing process. It is based on the inspectorate's recommendation and decided with reference to the publicly available policies ('Guidance on licensing').

1.3. The inspection rating will not be new to members: we have discussed it at previous meetings and we previewed Choose a Fertility Clinic, including the inspection ratings, at the annual conference in March. This paper is designed to rehearse the reasons for the policy and to ask members to consider handling of exceptional situations which might arise when applying the policy.

2. The rating policy

2.1. We have been publishing inspection reports and licensing committee minutes through Choose a Fertility Clinic (CaFC) for some years now, enabling patients to see the inspection and licensing history of each clinic. Through our user research for the new website, we learned that patients are very interested in our assessment of a clinic. However, they find the inspection reports dense and can't easily get an overall sense of the clinic's regulatory performance.

2.2. In developing the rating policy, we considered a number of ways of meeting this need:

- Re-pitching inspection reports so that they are aimed at a lay audience (rather like OFSTED reports on schools)
- Writing a lay summary of the report
- Developing some kind of rating that could be extracted from the licensing process.

2.3. Whilst the first option was tempting, it is important to remember that the HFEA is a licensing body and that inspections are carried out to gather evidence which is used to make a decision about the clinic's licence to operate. As such, the primary audience for an inspection report is a licensing committee. That licensing process needs to be fair and transparent to clinics, whilst being as meaningful as possible for patients researching clinics.

2.4. In discussion with the inspection team and the IfQ stakeholder group, we developed an approach which addresses that tricky balance. Each clinic's entry on the new CaFC includes:

- A description of the clinic extracted from the 'Brief description of the clinic and its licensing history' section of the inspection report – this will appear at the top of the clinic's CaFC profile page (see Annex 1 for a screen shot). This is a summary of the clinic, rather than of the inspection findings – but the latter is something we could look to doing in future.
- A five-star inspection rating, mapped to the length of the clinic's licence, as follows (we have added the number and proportion of clinics, so you can see that most clinics will have a 5 rating):

Length of licence	Visible rating	No. clinics	Proportion
4 years	5 stars	88	77%
3 years	4 stars	17	15%
2 years	3 stars	3	3%
1 year	2 stars	0	
Special directions	1 star	0	
Null (no rating)	-	6	5%

(*based on a data extraction in May 2016)

- A general explanation of how we derive the ratings and a clinic-specific explanation if no rating is shown
- The date of the clinic's most recent inspection and the date the current licence expires
- A link to the full inspection report and licensing minutes.

3. Applying the policy in particular circumstances

3.1. As you can see from the table above, most clinics are on a four-year licence and will therefore have a 5 rating. All those with 4 or 3 ratings have shorter licences because of concerns about the clinic's level of compliance.

1 ratings

3.2. A 1 rating would apply to a clinic which has such a poor record of compliance or engagement from the PR, that the licensing committee feels unable to grant any licence until certain non-compliances have been addressed. This happens from time to time and is clearly something which should result in a 1 rating. This rating is usually short-lived, assuming that the PR is able to demonstrate compliance and be given a proper licence relatively quickly.

Null ratings

3.3. All of the clinics with a null rating (the feature will be greyed out) are on a two-year initial licence. This is standard practice, as the clinic is not able to demonstrate a history of compliance. However, it is possible that a clinic could

be on special directions through no fault of their own, such as an administrative mistake on our part. This would also appear as a null rating.

3.4. There will inevitably be occasions in which it is arguable whether it really is the clinic's fault that it has been given special directions, as there may be a combination of contributory factors. In such situations, we recommend case-by-case consideration by the licensing committee as to whether a 1 rating or a null rating is shown. As long as the reason for this decision is included in the minutes, we do not recommend further guidance for the committee.

Interim inspections

3.5. The point of an interim inspection is to check regulatory performance and take any action if necessary. One question which has been raised is whether we should reassess the inspection rating after the consideration of the interim inspection report, based on whether the clinic's performance has improved or deteriorated. For example:

- Clinics on a four-year licence are expected to cause no concerns during the licence. They are inspected after two years and, unless inspectors find anything to the contrary, are not inspected again until the licence is close to expiry. If performance shows signs of deteriorating at interim inspection, the licence length remains four years, but another interim inspection may be needed at year three.
- Clinics on a three-year licence are usually inspected after one year. These clinics have been given a three-year (rather than a two-year) licence because they are expected to improve and won't therefore need to be inspected again before renewal. If this happens, the licence length remains three years, but another inspection is not needed at year three.
- Clinics on a two-year licence are not expected to improve at the year-one interim inspection. However, if they have improved, the licence length remains at two years and a renewal inspection occurs within a year.

3.6. We recommend that performance at interim inspection should not affect the inspection rating, for the following reasons:

- Whilst this disadvantages clinics on a three-year licence whose performance improves, it equally advantages those on a four-year licence whole performance deteriorates
- Doing this would move the inspection rating away from the length of licence, introducing the need for further guidance, using judgement at committee and the potential for conflict with clinics affected
- Interim inspections use a different methodology from renewal ones (focussing on observable activities and patient experience) and it could raise issues of fairness if the rating was derived from different types of inspections
- Keeping the rating matched to the length of licence throughout the whole licence creates an incentive to maximise performance at the time of the renewal inspection, rather than during the course of the licence.

4. Recommendation

4.1. Members are asked to:

- Note and endorse the overall policy of using length of licence to determine the inspection rating
- Consider the recommendation regarding null ratings
- Consider the recommendation regarding interim inspection findings.

4.2. We will update licensing committee processes as necessary.

Opening the Register report

Strategic delivery:	☒ Setting standards	☒ Increasing and informing choice	☒ Demonstrating efficiency economy and value
Details:			
Meeting	Authority		
Agenda item	10		
Paper number	HFEA (06/07/2016) 803		
Meeting date	6 July 2016		
Author	Rosetta Wotton, Donor Information Manager		
Output:			
For information or decision?	For information		
Recommendation	The Authority is asked to note: • the significant OTR policy and process developments over the last three years, which are in line with delivering the HFEA 2014-2017 strategy • the prospect of the first cohort of post-2005 donor-conceived children turning 18, and developments in genealogy DNA testing sites that will impact on anonymity more generally • the trend showing increases in the number of applications, and the timely and sensitive way in which they are handled • the first-year evaluation of the pilot support service and the informal positive feedback received from service users.		
Resource implications	In budget		
Implementation date	OTR service ongoing		
Communication(s)	OTR service on website		
Organisational risk	☐ Low	☒ Medium	☐ High

1. Introduction

1.1. This paper brings the Authority up to date on the activity in the Opening the Register (OTR) service over the last year and, in particular, the pilot support and intermediary service.

2. Background

2.1. The Human Fertilisation and Embryology Act requires the Authority to keep a *Register* of information about donors and treatments involving the use of donor gametes and embryos in the UK. It also records the notified births resulting from these treatments.[1]

2.2. Donor-conceived individuals and donors have a statutory right of access to information held on the Register as follows:

- 16-year-old donor-conceived individuals can find out:
  - if they are donor-conceived
  - non-identifying information about their donor
  - the number, sex and year of birth of any donor-conceived genetic siblings
  - if their donor has removed their anonymity
  - if they might be related to an intended spouse or partner
- 18-year-old donor-conceived individuals can find out:
  - identifying information about their donor (if the donor is identifiable)
  - identifying information about their donor-conceived genetic siblings, if both sides consent (via Donor Sibling Link, our voluntary contact register)
- Donors can:
  - find out the number, sex and year of birth of any children conceived from their donation
  - remove their anonymity - which is relevant to those who donated before the law changed on 1 April 2005

2.3. Parents have no statutory rights to access Register information although in 2004 they were granted discretionary access rights to the following information:

- non-identifying information about their donor

[1] There is also a Donor Conceived Register specifically for people conceived before the HFEA register was set up in August 1991. It links these individuals through DNA matching and offers advice and support. It can also bring people into contact with others in the same situation. Since 2013 it has been run by the National Gamete Donation Trust.

- the number, sex and year of birth of any donor-conceived genetic siblings
- if their donor has removed their anonymity

2.4. Applications by donor-conceived individuals, donors and parents for Register information are known as Opening the Register (OTR). Applicants submit the relevant application form with proof of identity and address by post to us. We return their identity documents within 5 working days and respond to their application within 20 working days – both by special delivery post. We retain a copy of their identity documents for 5 years to enable applicants who wish to re-apply for updated information at a later date to do so with more ease.

2.5. The OTR service is provided primarily by the Donor Information Manager and Donor Information Officer, with some additional support provided by two other members of the Register Team. All OTR staff have completed a 30-hour Introduction to Counselling Skills course. The Donor Information Manager has worked in the OTR team for 5 years and, in addition to counselling skills training, she has completed an accredited mediation course and Samaritans training on handling challenging contacts. She has also attended BICA study days and a number of Donor Conception Network conferences.

3. HFEA strategy 2014-2017

3.1. The HFEA strategy 2014-2017, puts patients (including donors and donor-conceived people) and the quality of care they receive at the centre of our work.

Vision: High quality care for everyone affected by assisted reproduction

- Support for patients, donors and donor-conceived people
- Excellent service and information from the HFEA

What we will do:

- We will improve the lifelong experience for donors, donor-conceived people, patients using donor conception, and their wider families.

How we will work:

- We will make the quality of care experienced by patients, donors and donor-conceived people our central priority and the primary consideration in our decision making.

3.2. The OTR service is fundamental in the achievement of these strategy objectives. Recent developments and improvements contribute further to this aim.

Information on donor re-registration for past applicants

3.3. A number of donors who donated anonymously before 1 April 2005 have since chosen to remove their anonymity. However, many more have not but may choose to do so in the future.

3.4. We want to enable people who have already made applications and been told that the donation was made anonymously to be able to check whether the donor has since removed their anonymity. To this end, website content was created in 2013 enabling previous applicants to check using a unique reference code provided to them.

3.5. We have also improved the information and guidance on all our application forms and, for donors in the process of re-registering, we have added in steps to ensure they have the opportunity to discover the outcome of their donation first and fully consider the implications of the decision to re-register.

Improving the sharing, quality and disclosure of donor information

3.6. Following publication in 2013 of the 'Lifecycle' leaflet to give donors an idea of what they can write about themselves we expect donor-conceived people will receive better information about their donor in future.

3.7. Following a workshop held at the HFEA Annual Conference in 2014, we developed a guidance pack for clinics to support their disclosure of all non-identifying donor information to patients. This pack was provided to clinics in March 2015 along with the redaction framework and a good practice case study.

3.8. A workshop was also held at the HFEA Annual Conference in 2015 focusing on how clinics can look after their donors and highlighted the importance of supporting donors properly, not only throughout their donation, but afterwards too.

Support and intermediary service

3.9. In April 2013 the Nuffield Council on Bioethics report 'Donor conception: ethical aspects of information sharing' made recommendations relating to donor information and support for applicants to the Register. The McCracken review of the HFEA in 2013 also recognised the importance of this work.

3.10. Support for Register applicants was also identified as a high priority by a group of key stakeholders in June 2013 as no established, professional practice existed for providing support to those accessing donor identifying information from the HFEA Register, and potentially making contact with a donor.

3.11. The Authority approved scoping work in July 2013 and in March 2014 agreed a three-year pilot to provide enhanced support services at a national level. A contract to deliver such a service to people affected by donation was awarded to PAC-UK in 2015, an adoption support agency with relevant expertise and suitably qualified staff.

3.12. We delivered a two-day training event to PAC-UK in May 2015 and developed a suite of leaflets to compliment, or act as an alternative to, the support service which launched on 1 June 2015.

3.13. The HFEA funds a limited number of 1-hour contact sessions, which can be delivered flexibly, for:

- adult donor-conceived people who have or are considering applying for identifying information about their donor; or are considering joining Donor Sibling Link and making contact with their donor-conceived sibling(s)
- donor-conceived people over the age of 16 who have or are considering applying for non-identifying information about their donor
- donors considering re-registering to be an identifiable donor
- donors who are aware that an adult person conceived from their donation has applied for their identifying information.

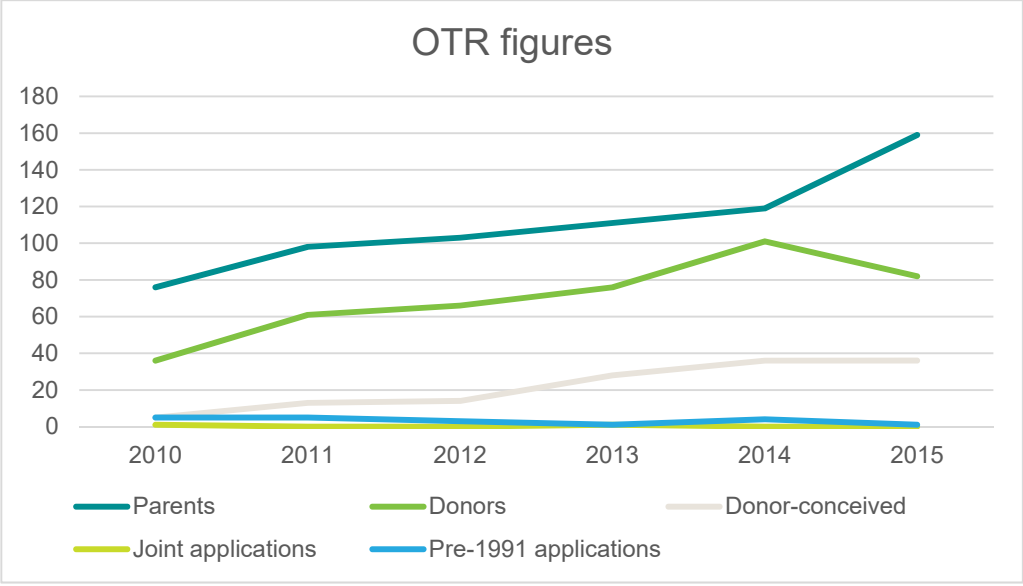
Looking ahead

3.14. The Authority will soon be thinking about the HFEA Strategy for 2017-2020. It is worth noting that the strategy after that will need to take into account the coming of age of the post-2005 donor-conceived cohort. There were approximately 1,250 to 1,500 donor-conceived births per year following the April 2005 law change so it will be necessary to keep an eye on the support service in this light.

3.15. In any event this could all be somewhat immaterial given the huge growth of DNA testing sites for genealogy purposes. There are significant implications for donors and donor conception families in terms of how this affects the notion of donor anonymity.

4. Performance

4.1. We have seen a steady rise year-on-year in the number of OTR applications handled, with over double the amount in 2015 compared to 2010 (see table below).



	2010	2011	2012	2013	2014	2015
Parents	76	98	103	111	119	159
Donors	36	61	66	76	101	82
Donor-conceived	5	13	14	28	36	36
Joint applications	1	-	-	1	-	-
Pre-1991 applications	5	5	3	1	4	1
Total	**123**	**177**	**186**	**217**	**261**	**278**

4.2. In addition, since launching in 2010, 99 adult donor-conceived individuals have joined Donor Sibling Link (DSL). This is our voluntary contact register, whereby registrants agree to us sharing their name and contact details with any of their donor-conceived genetic siblings who have also joined. Numbers registering are still small - 11 per year in 2011 and 2012, increasing to 21 per year in 2013 and 2014, and 24 in 2015 – but will likely grow significantly in the coming years. In 2015 we made the first DSL match and there have been two further matches so far this year.

4.3. We have also received 157 applications in total from anonymous donors (those who donated after the HFEA was set up but before 1 April 2005) to remove their anonymity. Over the last four years there have been slight increases year-on-year in such applications however; numbers are disappointingly low with only 14 doing so in 2015.

4.4. In 2013 a first application for identifying information from an adult donor-conceived individual with an identifiable donor was received. In total seven applications of this nature have been received; two per year in 2013, 2014 and 2015 and one so far this year.

4.5. In each case we offered and coordinated support and intermediary assistance to the donor-conceived individuals and donors concerned.

Feedback

4.6. As part of the OTR service, applicants are provided with a link to an online confidential feedback questionnaire. A summary of the feedback received since the last update to the Authority in July 2015 will be provided in a presentation when the Authority meets on 6 July 2016.

5. Support service evaluation

5.1. At the time of agreeing the three-year pilot support and intermediary service in 2014, the Authority asked that the HFEA retained control over the quality of any service provided and evaluated the service during the course of the pilot.

5.2. We developed an evaluation framework for this purpose and an evaluation of the service will be presented to the Authority on an annual basis in July 2016 (here), July 2017 and a final paper in January 2018.

5.3. The evaluation of the first year of the service covers:

- The cost of the service
- The level of demand for the service and its value to users
- The quality of the service provided by the contractor

Cost

5.4. The Authority set aside a capped budget of £50,000 for the duration of the pilot. This amount covers the cost of PAC-UK's initial service set up and training, and from then on a 'pay as you go' arrangement for each session provided at a fixed rate (£99 + VAT). The initial set up and training cost was £7248 and the total charge for sessions (inclusive of VAT) provided over the first year (period 1 June 2015 – 31 May 2016) was £594. This second sum would indicate that the amount set aside for the pilot will be more than sufficient for its duration.

Demand

5.5. In the first year of the service we referred a total of just seven cases for HFEA-funded support to PAC-UK.

- A sperm donor following an application for his identifying details
- Two egg donors – one whose identifying details were requested and one who was considering removing her anonymity
- An embryo donor couple considering removing their anonymity
- Three donor-conceived adults – one who had requested their donor's identifying details, one following a sibling match on Donor Sibling Link and the other following the provision of non-identifying information from us.

Out of the seven cases, six contacted PAC-UK within its first year and four received support (several of these cases are ongoing).

5.6. Looking ahead, it is difficult to assess the level of demand for the service in the next two years, but given demand so far it is not expected to be high.

5.7. In 2015 there were nearly 19,000 children aged 16 or above conceived following donor treatment between 1991 and 2005, and who had therefore reached the age where they could access non identifying information about their donor(s) and donor-conceived genetic siblings from the Register.

5.8. There were also nearly 4,500 additional individuals aged 18 or above in 2015. Out of this number of adults, only the small percentage whose donor(s) had removed their anonymity could access identifying information about them, and only those who have donor-conceived genetic siblings would be eligible to join Donor Sibling Link. The rate of donors re-registering is also very low.

5.9. The cohort of people eligible to seek funded services is therefore small and many may not know they are donor-conceived. Of those who do know, some may not be interested in accessing information at all and some may not feel a need for professional support. Where anonymous donors are concerned, many who contact the HFEA are not aware that they can request information on the outcome of their donation, let alone re-register as identifiable.

5.10. The support service is also available on a self-funded basis to those who are not eligible for HFEA-funded support (e.g. parents etc.) but there has not been any demand in this area. This may be down to several factors including; a lack of awareness of the existence of the service, the cost to those self-funding (£89 per session) and the availability of free informal support from charitable organisations such as Donor Conception Network.

Quality

5.11. All service users are invited to fill in a feedback form, which is then sent to both PAC-UK and the HFEA. The form also states that if there is anything the user would like to tell the HFEA in confidence, they can contact us directly.

5.12. We have not received any feedback forms so far, which may be because some referrals are ongoing and some have not begun yet. Despite a lack of formal feedback, the informal feedback received from users in correspondence with the HFEA has been positive. Users have expressed gratitude that such a service exists and have found it helpful.

5.13. We have not received any formal complaints from users regarding the service, although we did receive an informal complaint from the first person we referred to the service who, at the time, had yet to receive any sessional support. The complaint concerned the difficulty and delay the user was experiencing with accessing support from PAC-UK and distress at a request from a support worker for sensitive personal information by email. PAC-UK acted very quickly once we brought the complaint to their attention. The user chose to proceed with a different support worker and reported it had been a positive experience.

5.14. Although PAC-UK did not meet the KPI for providing support within the required timeframe to the above user, since then they have met all their KPIs where users are concerned.

5.15. The quality of the relationship between the HFEA and PAC-UK has improved significantly in recent months (e.g. ease of interactions, PAC-UK's level of engagement and commitment; whether we have had to chase information). However; there has been some cause for concern at times particularly with late submission of information and a frequent need to chase up any information requested.

5.16. PAC-UK took a little time to adjust to providing a support service which required the unavoidable, and integral, involvement of the HFEA to (a) refer funded people to PAC-UK and (b) hold PAC-UK accountable to the same standards of service delivery as the HFEA holds for itself.

5.17. Furthermore, our contract with PAC-UK only represents a tiny percentage of the work their organisation does, given the cohort of eligible users is small and the service uptake has been low.

5.18. As noted above, the support service is a pilot scheme and, as with any pilot, it will inevitably involve some trial and error. It's clearly preferable that any teething problems occur while the number of service users is low rather than when numbers rise and any issues could potentially have a wider impact.

5.19. It is very encouraging, however, that all informal user feedback has been positive following support sessions. The outcome of the HFEA's meeting with PAC-UK earlier this year was also very reassuring. Both the HFEA and PAC-UK share a common goal of providing an excellent service to all concerned and the HFEA looks forward to further collaborative working as the pilot proceeds.

6. Recommendation

6.1. The Authority is asked to note:

- the significant OTR policy and process developments over the last three years, which are in line with delivering the HFEA 2014-2017 strategy.
- the prospect of the first cohort of post-2005 donor-conceived children turning 18, and developments in genealogy DNA testing sites that will impact on anonymity more generally.
- the trend showing increases in the number of applications, and the timely and sensitive way in which they are handled.
- the first-year evaluation of the pilot support service and the informal positive feedback received from service users.

Publication and disclosure policy

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

Meeting	Authority
Agenda item	12
Paper number	HFEA (06/07/2016) 804
Meeting date	6 July 2016
Author	Ian Brown, Head of Corporate Governance Jo Triggs, Head of Engagement
Output:	
For information or decision?	For decision
Recommendations	• To consider the Publication and disclosure policy at Annex A • To approve the continuation of the current practice not to publish supporting information or research lay summaries.
Resource implications	Part of baseline activities of the Communications and Corporate Governance teams
Implementation date	1 August 2016
Communication(s)	We will publish the new policy on our website
Organisational risk	X Low ☐ Medium ☐ High
Annexes	Publication and disclosure policy

1. Introduction

1.1. All public bodies the UK are required to operate in an open and transparent way, so that the public can see that they are well run. A key element of this involves publishing information clear, accessible and easy-to-find information.

1.2. The Authority has had a publication policy since 2009, principally covering the publication of Authority and committee papers. This policy has been updated and broadened to include how we will publish all information on the new website and how we disclose information not normally published on the site.

1.3. This paper seeks Authority approval of the new policy. In particular, members are asked to consider two issues relating licensing decisions.

2. Publication of licensing decisions

2.1. The policy includes our continued commitment to publish inspection reports and minutes relating to treatment and research licences applications. It also includes a continued commitment to publish information about grade A incidents. However, it does *not* include a commitment to publish:

- supporting information (such as the application form, peer reviewers' comments) relating to licence applications, or
- lay summaries of research projects before the application is considered by a committee.

2.2. As members will know, earlier this year we considered an application to add gene editing to a research licence. There was huge public interest in the application and our decision to approve it, prompting a wider discussion about what information, beyond inspection reports and minutes, we should publish, particularly around licensing matters with high public interest. We committed to reviewing our current practices in time for the launch of the new website.

Supporting information

2.3. Supporting information - such as the application form, comments from a peer reviewer, consent forms, patient information and other papers dependent on the complexity of the application - is not currently published. There are three options for how this could be done in future:

- Routinely publish all supporting information alongside the inspection report and minutes
- Only publish documents relating to licence applications which are in the wider public interest
- Continue to publish only the inspection report and minutes of the decision.

Lay summaries of research applications

2.4. Applicants for a research licence are asked to provide a lay summary of their proposed research. In the past, this summary was published on the website before the committee considered the application, giving members of the public an opportunity to comment. This service was discontinued but could be reinstated on the new website.

3. Recommendation to the committee

3.1. We have just started a project to review the end-to-end process for research licensing, inspection and consent and we expect this to conclude early next year. It seems sensible, given this project, to maintain the status quo regarding the publication of supporting information and lay summaries of research applications. These issues will be considered as part of the review and considered by the Authority later in this business year.

3.2. We therefore recommend to the committee:

- To consider the Publication and disclosure policy at Annex A
- To approve the continuation of the current practice not to publish supporting information or research lay summaries.

3.3. It should be noted that any decision to publish supporting information would affect the licensing of treatment clinics, as well as research laboratories. If the Authority decides to change the approach to research licensing in future, we will consider the implications for treatment clinics too.

Publication and disclosure policy

1. About this policy

1.1. This policy sets out how the Human Fertilisation and Embryology Authority (HFEA) will be open and transparent about the information we hold, publish and disclose.

1.2. The policy sets out our approach to:

- the publication and disclosure of information relating to regulatory decisions
- the routine publication of information on our website
- the routine disclosure of information to interested parties, and
- how we deal with individual requests for information.

2. Policy statement

2.1. When making decisions on what information to publish we are committed to adhering to the following principles:

- being open and transparent about the processes we adopt and the decisions we make while protecting confidentiality;
- ensuring that commercially sensitive information is treated confidentially;
- ensuring that we comply with the legal duties placed upon us with regard to data protection and the common law duty of confidentiality;
- that any disclosure of information is lawful and proportionate in all circumstances
- that information is published in an accessible format where possible.

3. Legislative framework

3.1. We will take into account the following non-exhaustive list when making decisions about disclosing the information that we hold:

- the Human Fertilisation and Embryology Act 1990 (as amended)
- the relevant provisions of other legislation, such as the Freedom of Information Act 2000, Data Protection Act 1998 and the Human Rights Act 1998

- the Environmental Information Regulations 2004 ('EIR')
- relevant case law.

4. Freedom of Information

4.1. Under the Freedom of Information (FoI) Act 2000, we are required to give information we hold to anyone who asks for it, except in circumstances where the disclosure requested is exempt. We have a model publication scheme, available on our website, which details the information we publish and the retention period for certain classes of information. Anything not included within our publications scheme or in our committee and authority minutes can be requested under the Act.

5. HFEA model publication scheme

5.1. Our model publication scheme is based on the Information Commissioner's Office guide for non-departmental public bodies. As part of our publication scheme we publish information relating to the following areas.

Who we are and what we do

5.2. We publish information about our people and our activities, including:

- an explanation of our internal structure and roles and responsibilities within it
- senior executives and board members
- an explanation of the legislative basis of our activities
- lists of, and information relating to, partner organisations
- details of meetings of the Chief Executive or board members with Ministers and external organisations (including meetings with newspaper and other media proprietors, editors and senior executives)
- organisational information and structure
- staff roles and responsibilities
- locations and contacts.

What we spend and how

5.3. We publish financial information for the current and previous two financial years, including:

- details of expenditure over £25,000 (monthly)
- details of contracts and tenders worth over £10,000
- details of government procurement card expenditure over £500
- senior staff and board members' allowances and expenses (senior staff are defined as those earning at least £58,200 per annum)
- pay and grading structures
- procurement and tendering procedures
- financial statements for projects and events
- internal financial regulations.

Our priorities and progress

5.4. We publish information for the current and previous two years on:

- strategic plans
- annual business plan
- annual report
- internal and external performance reviews
- reports to Parliament
- privacy impact assessments (in full or summary format)
- service standards
- statistics produced in accordance with the HFEA's requirements
- public service agreements.

Policies and procedures

5.5. We publish current written policies and procedures relating to:

- the conduct of HFEA business
- the provision of services
- the recruitment and employment of staff
- making enquiries and complaints
- records management and personal data.

Lists and registers

5.6. We publish:

- a list of information that has been provided in response to FoI requests
- a register of gifts and hospitality provided to board members and senior staff.

The services we offer

5.7. We publish information about our services, including:

- printed information
- subscription services
- information access services.

How we make decisions

5.8. We publish details of major policy and service decisions and how we arrived at those decisions, including information relating to:

- public consultations and other engagement exercises
- stakeholder groups
- scientific reviews.

6. Corporate and licensing decisions

Agendas and minutes

6.1. We publish the agenda, papers and minutes of the following committees:

- The Authority
- Appeals Committee
- Appointments Committee
- Audit and Governance Committee (AGC)
- Executive Licensing Panel (ELP)
- Licence Committee
- Oversight Committee
- Remuneration Committee
- Scientific and Clinical Advances Advisory Committee (SCAAC)
- Statutory Approvals Committee (SAC)
- Register Research Panel
- Register Research Review Panel.

Authority meetings

6.2. Subject to section 7, the following documents will normally be published on the website two working days in advance of any Authority meeting:

- agenda
- papers to be relied on at the meeting.

6.3. Subject to section 7, tabled papers considered at the Authority meeting which were not published in advance of the meeting will normally be published on the website within two working days of the Authority meeting.

6.4. A note of the decisions taken at the Authority meeting will normally be published on the website within two working days of the Authority meeting.

6.5. The minutes of the Authority meeting will normally be considered at the next meeting of the Authority and, subject to section 7, the approved minutes will normally be published on the website within eight working days of the day on which the minutes were ratified by the Chair.

6.6. An audio recording of the Authority meeting will normally be published on our website within 10 working days of the Authority meeting.

Committees not concerned with licensing

6.7. Subject to section 7, the following documents will normally be published on the website two working days before of any committee meeting not concerned with licensing:

- agenda
- papers to be relied on at the meeting
- signed minutes of the previous meeting.

6.8. The publication of papers and presentations made to the Scientific and Clinical Advances Advisory Committee are considered on a case-by-case basis as there may be legitimate concerns about the confidential nature of research.

6.9. Subject to section 7, tabled papers considered at the committee meeting which were not published in advance of the meeting will normally be published on the website within eight working days of the meeting at which they were considered.

Committees, panels and decisions concerned with licensing and authorisations

6.10. Subject to section 7, the following documents will normally be published on the website within 15 working days of the meeting of a committee concerned with licensing, or decision of a Licensing Officer:

- a note of the decision of a Licensing Officer to make any administrative variation of a licence, and any accompanying supporting documentation
- minutes of the meeting where the panel or committee considered an initial or renewal licence application, or an interim inspection report
- minutes of the meeting where the panel or committee considered whether to vary, suspend or revoke a licence
- minutes of meetings relating to consideration by the panel or committee of grade A incidents, serious adverse events or serious adverse reactions
- minutes of meetings where the panel or committee considered applications for embryo testing
- minutes of meetings where the panel or committee considered applications for the import/export of gametes
- any inspection report relating to an initial inspection or a renewal or interim inspection which was considered by the panel or committee, or any other type of inspection report on which the panel or committee made its decision to vary, suspend or revoke a licence
- subject to ensuring patient and commercial confidentiality, supporting paperwork relating to grade A or grade B incidents or serious adverse reactions considered by the panel or committee.

6.11. The documents above are redacted where necessary to preserve the anonymity of any patients concerned and, in the case of papers relating to applications for research, redacted to preserve any commercially sensitive information or sensitive personal data relating to clinic staff, which is exempt from publication in accordance with the provisions of the Freedom of Information Act 2000.

6.12. Other documents considered by the Licence Committee and Executive Licensing Panel, such as the application form, comments from peer reviewers, consent forms and patient information, are not published on our website but can be requested under the Freedom of Information Act 2000.

6.13. In the case of sensitive decisions (including, but not only, those relating to applications for HLA testing, or the import/export of gametes) the executive may take steps to ensure the patient is aware of the decision, before publishing the minutes on the website.

6.14. When hearing representations under section 19(4) of the Act, publication of the relevant documentation and minutes are at the discretion of the Chair of the Licence Committee, subject to the relevant regulations.

6.15. Publication of the relevant documentation and minutes of proceedings of the Appeals Committee are at the discretion of the chair, subject to the relevant regulations.

7. Documents that are not published on the Authority's website

7.1. The following documents and information are not normally published on our website:

- information that is in draft form
- information that has been archived
- confidential reports and unpublished papers relating to ongoing research presented to the Scientific and Clinical Advances Advisory Committee
- confidential and/or sensitive personal information considered by Remuneration Committee or Appointments Committee
- certain confidential or sensitive material relating to grade A or grade B incidents, serious adverse events or serious adverse reactions or relating to embryo testing
- material that is covered by copyright not held by the Authority. In instances where the publication of papers on the Authority's website is prohibited by copyright the full title and reference of the paper will be provided
- information which is exempt from disclosure under the Data Protection Act 1998 or Part II of the Freedom of Information Act 2000
- information, the disclosure of which would be a breach of section 33A of the Human Fertilisation and Embryology Act 1990 (as amended)
- transcripts of representations hearings. The resource implications of redacting the transcript before publication would be disproportionate. However, requests for copies of any transcripts that are held by the Authority would be considered for disclosure under the Freedom of Information Act 2000.

8. Roles and responsibilities

8.1. All of the information in our publication scheme is available on our website. The website also contains comprehensive information about treatment types and all licensed centres.

8.2. The communications team has overall responsibility for the website. Each team within the HFEA has access to the Content Management System (CMS) so they can make amendments to their content on the website. Any changes required should be actioned within five working days to make sure the information is always up to date.

8.3. The secretary to the Authority or relevant committee or panel is responsible for ensuring that documents, which include the agenda, any papers and presentations, and minutes, are published on the website in accordance with this document.

8.4. Where there is an issue as to whether documents, or parts of documents, should be redacted or withheld from publication, the secretary will refer the matter to the Chair of the Authority or Chair of the relevant committee or panel for decision.

9. Retention periods and updating

9.1. All information on the website is retained for three years from the date of publication, with the following exceptions:

- Information relating to centre licensing, which will be kept for five years to accommodate the standard length of licence.

9.2. Any information which has been removed after the relevant retention period will be made available on request.

9.3. Any request for inspection reports and minutes of committees concerned with licensing before 2004 would be considered for disclosure under the Freedom of Information Act 2000.

9.4. We have internal processes to ensure that information published on the website is kept up to date. Each page has a date stamp indicating when it was last updated.

9.5. Clinic statistics on Choose a Fertility Clinic are updated every six months.

10. Translation of information into different formats

10.1. Upon request we will translate our information into braille, audio. We will also translate it into a foreign language if that is specifically requested.

11. Information access policy

11.1. This policy should be viewed in conjunction with the information access policy which gives details of the information we make available to members of the public and how they can access it.