Human Fertilisation & Embryology Authority

Authority meeting - agenda

11 May 2016

Venue: Conwy Room, 1st floor, 10 Spring Gardens, London SW1A 2BU

Agenda item		Time
1.	Welcome, apologies and declaration of interests	1:00pm
2.	Minutes of 9 March 2016 **HFEA (11/05/2016) 792**	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 (11/053/2016) 793** For information	1:45pm
7.	Strategy 2017-20 **HFEA (11/05/2016) 794** For decision	2:05pm
	Break	**2:35pm**
8.	Cumulative birth rates from IVF (presentation) Dr David McLernon For information	2:45pm
9.	Information for Quality **HFEA (11/05/2016) 795** For information	3:15pm
10.	Any other business	3:35pm

Minutes of Authority meeting 9 March 2016

Strategic delivery:	☐ Setting standards	☐ Increasing and informing choice	☐ Demonstrating efficiency economy and value
Details:			
Meeting	Authority		
Agenda item	2		
Paper number	HFEA (11/05/2016)		
Meeting date	11 May 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 9 March 2016 held at ETC Venues, Hatton Garden, 51-53 Hatton Garden, London, EC1N 8HN

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

Members

There were 10 members at the meeting, 7 lay members and 3 professional members

1. Welcome, apologies and declarations of interest

1.1. The Chair welcomed Authority members and observers to the second meeting of 2016. 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. Apologies were received from Anthony Rutherford and Anita Bharucha.

1.3. 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)
- Ruth Wilde (Senior Fertility Counsellor at a licensed centre).

2. Minutes of Authority meeting held on 20 January 2016

2.1. Members agreed the minutes of the meeting held on 20 January, subject to one minor amendment, for signature by the Chair.

3. Chair's report

3.1. The Chair began by welcoming Dr Anne Lampe to her first meeting as a new Authority member.

3.2. The Chair informed members that, since the last Authority meeting, she had been recovering from an operation and had therefore not attended as many engagements as usual with organisations in the IVF sector and the wider health and care system.

3.3. However, the Chair advised members that, on 21 January, she and the Chief Executive had visited Bourn Hall Clinic in Cambridge as part of the continuing programme of visits to clinics outside of the regular inspection schedule.

4. Chief Executive's report

4.1. The Chief Executive advised members that, on 26 January, he attended the second meeting of the Health and Social Care Leaders' Scheme which brought together the Department of Health and all of the Chief Executives of the health arm's length bodies (ALBs) to identify senior talent within the system. Both the Director of Compliance and Information and the Director of Strategy and Corporate Affairs had been selected onto the programme, which was testament to their abilities and the stretching roles at the HFEA.

4.2. On 27 January, the Chief Executive attended the Health and Care Partnership Conference and, on 29 January, met with members of the Committee on Standards in Public Life who were conducting an investigation into ethical standards within regulators.

4.3. On 3 February, the Chief Executive advised members that he attended the Scientific and Clinical Advances Advisory Committee (SCAAC) and on 3 March, he spoke at a conference organised by Healthcare UK at Wilton Park on genomics. The event showcased UK expertise in genomics to representatives of government and health systems in the Gulf States, India, the Far East and South America. It was part of a broader initiative to promote UK healthcare overseas. The Chief Executive, together with the Director of Compliance and Information, had met representatives from the United Arab Emirates some weeks earlier and advised members that they were both attending an event later in the day showcasing UK expertise in patient safety.

4.4. The Chief Executive reminded members that, at the last Authority meeting in January, there was a paper setting out a range of activities on better regulation that the Government was promoting. As part of this work, Departments were required to publish innovation plans by spring 2016 and ALBs were now required to follow suit. This work was underway and it was possible it would need to be published before the next Authority meeting. 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 promoted innovation rather than hindered it. It was noteworthy that it was the UK, with its robust regulation, that had led to world firsts like regulated mitochondrial donation and the recent decision to allow genome editing in research. The HFEA's innovation plan would set out those achievements and seek views on where the organisation could improve still further.

4.5. On 18 January, the Chief Executive attended the third Department of Health led project board meeting of the HFEA's triennial review. The Chief Executive reminded members it had long been Government policy that all public bodies should be subject to a periodic review. The review had looked at the functions of the organisation and whether those functions were carried out in the most efficient way possible. The report was nearing its conclusion and, subject to Ministerial sign-off, should be published in the spring.

4.6. Press Coverage: the Chief Executive summarised press coverage since the last Authority meeting, details of which had been circulated to members.

4.7. Genome Editing: the Chief Executive advised members that there had been considerable press coverage, both in the UK and across the world, since the HFEA's Licence Committee had approved the Francis Crick Institute's research renewal application, part of which included a proposal to use the genome editing technique Crispr-Cas9. It was a significant decision, since it was the first time in the world in a regulated system that the technique had been allowed in research. Given the level of interest, the HFEA had issued a short press statement and, as usual, had published the inspection report and the minutes on the website. Outside the UK, there had been articles in Germany, France, Italy, the Czech Republic, Russia and elsewhere. The discussion was largely quite balanced, focusing on the risks and opportunities and the UK's stance on research more generally. The Chief Executive advised members that several countries were now preparing more in-depth responses to this research.

4.8. The 'M' case: the Chief Executive reminded members of this case, where a woman tragically died with her eggs in storage and her mother had applied for special directions to have the eggs exported to the USA so that she could try to conceive with her daughter's eggs and donated sperm. The case was in court again recently and generated some press coverage. The HFEA's Statutory Approvals Committee (SAC) had considered the issue on three occasions and had concluded that the evidence required for consent was not in place. That decision was challenged in the High Court and the judge had agreed with the HFEA decision. However, a Court of Appeal judge had now decided that the case was arguable and had granted leave to appeal. The case would be heard in May.

4.9. Delegated powers: the Chief Executive advised members that, as required by Standing Orders, he wanted to secure their approval to establish an ad hoc sub-committee to consider the lawfulness of a new technique called Augment which was being marketed by a US company, Ovascience. If it was decided that the technique was lawful by the ad hoc committee, Augment would then need to be considered by SCAAC and SAC to see whether it met the statutory tests for a novel process.

4.10. Members were therefore asked to indicate whether they were content to establish a committee, consisting of three Authority members, in order to consider the question of lawfulness. The Chief Executive advised members that the statutory basis to establish a committee for such a purpose could be found in section 9A(2) of the HFE Act 1990 (as amended) and in paragraph two of Schedule one of the Act.

4.11. Authority members unanimously expressed their agreement for the Executive to establish the ad-hoc committee.

5. Committee chairs' updates

5.1. The Chair of the Statutory Approvals Committee (SAC) reported that the committee had met on 28 January and 25 February. There had been four preimplantation genetic diagnosis (PGD) applications in January, all of which were approved, and two requests for Special Directions both of which were granted. At the February meeting, the minutes of which had not yet been published, seven PGD applications had been considered.

5.2. The Chair of the Scientific and Clinical Advances Advisory Committee (SCAAC) informed members that the committee had met on 3 February, and had received reports on:

- Culture media, with a representative from the Medicines and Healthcare Products Regulatory Agency (MHRA) discussing concerns raised on this topic at the October 2015 meeting
- An IfQ update and website content review
- Prioritisation of issues identified through the horizon scanning process, including endometrial receptivity assay as a treatment 'add-on', genome editing, in-vitro derived gametes, the use of ICSI and non-invasive methods of assessing embryo viability
- A discussion on the remit of the committee and its work plan.

5.3. The committee also welcomed Anne Lampe who joined both SAC and SCAAC as a new Authority member.

5.4. The Director of Strategy and Corporate Affairs advised members that the Executive Licensing Panel (ELP) had met three times since the last Authority meeting, on 29 January, 12 February and 26 February. The panel had considered 20 items in total, all of which were approved and noted. There were five interim consideration of treatment licences, four interim consideration of research licences, two voluntary revocations of small treatment centres, seven licence variations and two progress reports.

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. The Director of Compliance and Information summarised the activities within his directorate. Three – out of four - main performance indicators showing as red status were in his directorate. Firstly, the number of working days from the day of inspection to the day the draft report was sent to the Person Responsible (PR) had a target of 90% in 20 working days. In December, performance was at 50%, with two out of four reports being sent at 27 working days, mainly due to unexpected additional workload. There was also one report outstanding from November, which was sent 39 days after inspection. This was due to practical issues in obtaining a suitable peer review.

6.3. The Director of Compliance and Information advised members that the total number of data errors in the system, taking into account the eight weeks centres were given to resolve those errors, had risen by 16% in December to 2,240. This was, in part, due to important IfQ-related work taking higher priority and a number of clinics with high error rates.

6.4. The Director of Compliance and Information advised members that the Fertility Trends Report project required data for analysis, some of which (on egg freezing) required cleansing before it could be used and had been on a red risk rating. This cleansing needed to be performed by the same staff who were currently cleansing the data for the IfQ-related data migration, and had had to be prioritised over that work. In addition, the report needed to be published at the HFEA Annual Conference on 24 March. Since December, the data cleansing required had progressed well and the risk rating had therefore been reduced to amber.

6.5. The Office Move project was also on a red risk rating in December, pending the resolution of some technical issues in relation to the new internet connection. This had since been resolved and the risk rating had accordingly been reduced to amber.

6.6. The Director of Compliance and Information provided an overview of the Directorate's contribution to the HFEA strategy. The Register team was preparing for a new Register which involved ensuring that all the existing data in the current Register was fit for purpose to be migrated. The team was also developing the new data dictionary. The IT team had been heavily involved in ensuring the technical infrastructure behind the new clinic portal and the website was robust, fit for purpose and met current best practice requirements. The IT team had also been busy ensuring that the organisation had all the necessary equipment to function well, with new hardware being issued to all staff.

6.7. In relation to the inspection and compliance activities, members were advised that the 2015/16 inspection year had been a particularly busy one, with 98 inspections taking place in the financial year, 92 of which had already been carried out. This compared to 71 inspections in the previous financial year, a 35% increase in inspection workload year on year.

6.8. The Director of Strategy and Corporate Affairs reminded members of the HFEA annual conference which was due to take place on 24 March. The theme of the conference was the 25th anniversary of the HFEA, which would be marked by a panel discussion where invited speakers had been invited to look back over the 25 years. The session would be chaired by Laurence McGinty, the Science and Medical Editor for ITV news.

6.9. The Director of Strategy and Corporate Affairs advised members that two workshops would also be held at the conference, one on the movement of gametes and embryos across borders, which was the subject of a new EU Directive coming into force next April, and another on avoiding breaches of patient confidentiality in clinics. The annual fertility trends report would also be launched on the day, as mentioned earlier in the meeting. The Director of Compliance and Information would also be showcasing the new Clinic Portal and the Directorate of Strategy and Corporate Affairs the new HFEA website and Choose a Fertility Clinic (CaFC).

6.10. 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 around £200k was forecast for year-end which was partly due

to a lower spend on salaries and legal costs. The Finance team would now be preparing the end of year accounts which would be submitted to the Audit and Governance Committee.

6.11. In relation to the HFEA's office move to Spring Gardens, the Chief Executive advised members that the HFEA, from 11 April, would be sharing office space with the National Institute of Clinical Excellence (NICE) and the British Council. This would mean developing more flexible ways of working for staff and a 'ways of working' group had been set up which would play a key part in this. Visits to the new office were also currently underway for all staff. The Executive would arrange for passes to be prepared for all Authority members on their first visit to the new office. It was hoped that the majority of meetings would be held at the new offices, subject to availability of meeting rooms. The Chief Executive confirmed that SAC on 28 April and the Authority meeting on 11 May would be held at Spring Gardens.

6.12. Following the discussion, members noted the latest strategic performance report, in particular the 35% increase in inspections.

7. Information for Quality: update

7.1. 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
- Combining 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.

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

- The approvals process to proceed to 'beta' phase
- The HFEA annual conference
- Data migration
- Programme timelines and budget implications
- The data dictionary.

7.3. 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. In early May 2016, both the website and clinic portal would again require assessment and, subject to the associated approvals from the Department of Health and GDS, both products would be released to 'public beta'.

7.4. The Director of Compliance and Information advised members that the programme was currently halfway through the beta phase and significant progress had been made on the development of the new website, CaFC and the clinic portal. Despite some delays, which had previously been reported to members, the programme remained on track to meet reported deadlines and the beta assessment deadline.

7.5. The HFEA conference: as mentioned earlier in the meeting, a centre-piece of the HFEA annual conference would be showcasing the progress made and generating a sense of anticipation for the roll-out of the beta version of the updated website, CaFC and the clinic portal. It was anticipated that the demonstration would include aspects of the search tool and the clinic portal 'knowledge base' and 'dashboard'.

7.6. Data migration: as previously mentioned, the Director of Compliance and Information advised members that the Register team had finalised the extent to which data in the current Register needed to be cleansed in order to effect a smooth transfer to the new Register with a different data structure in line with the HFEA data dictionary.

7.7. The Information and IT teams had been carrying out substantial cleansing activity and the burden placed on clinics to undertake this work had been minimalised. However, it was acknowledged that the quantum required by some clinics would be material. In order to form a clearer picture of the amount of time clinics would need to conduct cleansing, eight clinics had been selected to undertake a pilot of cleansing activity in April. 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. However, it was acknowledged that this was a risk and may be unpopular.

7.8. Timelines and budget implications: the Director of Compliance and Information advised members that a revised 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. Members were reminded that the changes to the timeline meant that the public beta for the website and clinic portal were pushed back approximately three months and two months respectively, with both now expected to be launched for beta testing in July 2016 (subject to the required GDS approvals). Whilst the overall budget for IfQ remained unchanged at £1.134m, 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.

7.9. The data dictionary: the Director of Compliance and Information advised members that a significant part of the IfQ Programme related to restructuring the HFEA Register. Licensed fertility clinics submitted information about each cycle of treatment they carried out, such as patient and donor details, the treatment provided and its outcome. The requirement to keep a Register of Treatments stemmed from the HFE Act 1990 (as amended). At the January 2015

meeting, Authority members had agreed that data should only be collected if it met at least one of the following criteria:

- It was required by law, in particular to enable the HFEA to provide donors, donor-conceived people and their parents with information they were entitled to
- To provide prospective and current patients and donors with sufficient information to allow them to make informed decisions
- To enable the HFEA to assess compliance of individual clinics against agreed standards
- To provide information that enabled the HFEA to alert clinics of performance changes
- To obtain information about current practice that was useful and beneficial
- To provide identifying information that enabled linkage studies about children conceived as a result of licensed treatment
- To enable ethically and scientifically approved research.

7.10. The Director of Compliance and Information advised members that the Register was an extremely valuable asset to both the HFEA and its stakeholders. It was used to:

- Securely hold information about donors and their donations
- Ensure traceability of gametes and embryos
- Provide patient information on success rates
- Monitor clinic performance, and
- Facilitate research into the safety of treatments.

7.11. The Director of Compliance and Information provided members with a summary of progress made thus far on the data dictionary:

- A set of operational adjustments had been made, including additions, removals and amendments, taking into account various factors
- The adjustments were consistent with the determination of the stakeholder group
- HFEA staff had been working with the Standardisation Committee for Care Information (SCCI) staff in order to enable the HFEA Register Data submission to be awarded an official Information Standards Notice (ISN), with the approval process leading to a national dataset in July 2016.

7.12. The Director of Compliance and Information advised members that the changes to the data collected should be seen alongside the planned improvements in the data collection method. The IfQ aim to reduce the burden for clinics had always been firmly based on changing the collection method. The changes in methods of data entry were being developed and would include:

- Improved accuracy of inputting information by using more on screen prompts and access to data descriptions whilst inputting data
- More incentives to improve the quality of information by the use of flagging, and more real-time error information so that issues could be readily understood and problems fixed on the spot

- Saving time and improving quality by having no opportunity for duplicate entries and consequent issues with identifying and deleting previous or copy records
- Minimising the burden of clinics undertaking periodic verification work by real-time confirmation when data is entered.

7.13. Following a discussion, members noted the progress made on the IfQ programme, specifically on the data dictionary.

8. Compliance and enforcement policy

8.1. The Director of Compliance and Information presented this item and advised members that the HFEA's compliance and enforcement policy, in force since 2009, set out the HFEA's general approach in ensuring compliance with regulatory requirements. The Director of Compliance and Information reminded members that the policy set out the routine actions by which the HFEA judged compliance, notably inspection and the licensing process; and, second, more importantly, the steps the HFEA would take to escalate and manage concerns about regulatory compliance.

8.2. At its September 2015 meeting, Authority members considered a proposed revised policy together with changes to two indicative guidance documents provided to licence committees; the first regarding the length of licences granted and the second regarding the potential sanctions that might be applied, where concerns relating to poor performance were evident. Authority members agreed that the proposed documents should be subject to focused consultation and piloting, which had now been undertaken. Members were now presented with the revised policy, and the paper before them proposed a new single guidance document on licensing drawing together the two documents referred to above.

8.3. The Director of Compliance and Information advised members that the revised policy followed better regulation principles and it was important to note that the main proposed changes to the policy did not place any new or additional requirements on licensed centres. The key features of the revised policy were:

- Clearer escalation protocols with more well-defined signalling on the move from routine activity towards enforcement
- Clearer signalling of the significance of the 'management review', carried out when the inspection team became aware of concerns about a clinic's compliance or performance
- Clarity and certainty around 'further investigation' in order to ensure that clinics were only subject to such scrutiny if concerns were suitably serious, whilst empowering the HFEA compliance team in what might otherwise be challenging circumstances
- Amendments to the process by which a warrant might be sought which, whilst very rare, required a particular escalation process.

8.4. The Director of Compliance and Information advised members that the guidance on licensing had been consolidated within a single document. The document provided improved clarity for clinics and others about licensing decisions and a framework for licensing committees and replaced:

- Guidance on periods for which new or renewed licences should be granted

- Indicative sanctions guidance for licence committees.

8.5. In relation to the length of a licence, the Director of Compliance and Information advised members that the Executive believed there were substantial advantages in better linking clinics' relative performance and the length of the licence granted – an evidence based judgement made by a licensing committee at the time the licence was granted. A range of options had been considered and it was proposed that in CaFC the inspectors' rating of a clinic would be based on the length of a licence. Considerations would incorporate:

- The clinic's history of compliance up to the last renewal of the licence
- Evidence of non-compliance with statutory requirements and the scale and impact
- The quality of the service to patients provided by the clinic.

8.6. The Director of Compliance and Information advised members that the purpose of applying sanctions was to:

- Promote compliance with the requirements of the Act and the Code of Practice issued by the Authority
- Protect those using, or affected by, the services offered at clinics licensed by the Authority; and
- To maintain public confidence in the conduct of licensed activities.

8.7. The Director of Compliance and Information explained that the changes in relation to sanctions retained the features of the current guidance, particularly regarding the statutory basis for applying sanctions, and sought to align the guidance more closely with the sections of the Act which set out when the Authority may suspend or revoke a licence. The guidance had also been revised to emphasise the factors that a licensing committee might consider in reaching a decision. The guidance sought to simplify and clarify the aggravating and mitigating features that a licensing committee could consider in relation to any matters of non-compliance reported to it.

Decision

8.8. Following a discussion, members approved the revised compliance and enforcement policy and the new guidance on licensing effective from 1 April 2016, subject to minor amendments for clarity on specific points, including paragraph 3.6 and 3.7 of the policy.

9. Governance and transparency

9.1. Annual review of committee effectiveness: the Director of Strategy and Corporate Affairs advised members that all committees had carried out the required annual review of their effectiveness. Generally the feedback was positive and the key findings were:

- New Authority members had been incorporated well
- Quoracy and succession planning were much improved
- SCAAC wished to strengthen the patient information role in its terms of reference.

9.2. Review of Standing Orders: the Director of Strategy and Corporate Affairs advised members that the Standing Orders had been amended to reflect changes of job titles and the names of guidance documents for licensing, as discussed in item 8 of the meeting. One further

amendment had been made to SCAAC's purpose to reflect its role relating to patient information and the safety and efficacy of treatments.

Decision

9.3. Following a discussion, members noted the committees' annual reviews and unanimously voted to approve the changes to Standing Orders and SCAAC's remit.

10. Strategic risk register

10.1. The Head of Business Planning presented this item to provide members with an overview of the risks, showing the relative risk tolerance positions and residual risk scores. Six of the thirteen risks remained high and were deemed above tolerance:

- Office move: remained above tolerance with tight timelines and practical risks. The residual risk of 16 was higher than tolerance (set at a medium level of 6)
- Legal challenge: a relatively high risk tolerance of 12 was set for this particular risk due to the inevitability of some degree of resource diversion owing to the nature of the HFEA's work. The residual risk was currently higher than tolerance at 15
- IfQ - improved information access: the residual risk of 12 was higher than tolerance (set at a medium level of 8) due to approval process delays at the first stage of the programme, and the risk to the quality of the final product that could be delivered if there were any further approval delays encountered.
- IfQ - delivery of promised efficiencies: the residual risk of 12 was higher than tolerance (set at a medium level of 9) with further GDS approvals delays likely and two further full gateway reviews now likely to be required, contrary to earlier advice
- Data – incorrect data being released: although good controls were in place for dealing with PQs and other externally generated requests, volumes could not be controlled and the HFEA had received extremely high volumes in the first half of the year. The residual risk of 12 was therefore higher than the tolerance threshold of 8
- Capability – knowledge and capability: the residual risk of 9 was above the current tolerance level of 6. Staff turnover could lead to fluctuations in overall capability, and although the period of highest turnover appeared to be ending, two posts at Head level remained vacant pending start dates.

10.2. The Head of Business Planning advised members that the new activity of risk assurance mapping had recently started up at the HFEA as part of the internal audit programme. The Department of Health internal audit team ran a half day workshop with managers on 10 February, focusing on the HFEA's highest risk operational area, capability and resourcing. The workshop approach was well received by staff and the Executive now had a report for consideration internally which made a number of suggestions for possible further risk mitigations in this area.

10.3. Members noted the latest version of the strategic risk register.

11. Business plan 2016/17

11.1. The Head of Business Planning introduced this item and reminded members that they had agreed a draft of the new business plan at the November meeting. The content had now been further developed and the business plan was at an advanced stage.

11.2. Following submission of the earlier draft in December, the Department of Health had only minor comments and had indicated they were broadly content, with publication anticipated by mid-April. Budget confirmation had also been received.

11.3. The Head of Business Planning advised members that some sections could not be incorporated until after the end of the business year on 31 March. These sections included:

- The 'facts and figures' table relating to the previous business year
- Standard HR benchmarking information; and
- The performance indicator section.

11.4. The Head of Business Planning advised members that, since the earlier draft, the following items had been added or refined:

- Work relating to the Government-wide better regulation rules
- More measurable and specific outcomes
- Acknowledgement of the Department of Health's shared delivery plan
- A full account of work on legal parenthood
- Updated information about the HFEA office's post-move sustainability and facilities arrangements.

Decision

11.5. Following a discussion, members noted the current position and formally approved the Business Plan for 2016/17, subject to the awaited approvals, the addition of year end information and formal sign-off by the Department of Health, and also subject to incorporating members' comments on the descriptive text prefacing the activities section.

12. Any other business

12.1. The Chair of the meeting confirmed that the next meeting would be held on 11 May at 10 Spring Gardens, London, SW1A 2BU. Members were asked to confirm their attendance to the Executive Assistant to the Chair and Chief Executive as soon as possible.

13. Chair's signature

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

Signature

Chair

Date

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 (11/05/2016) 793		
Meeting date	11 May 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 a formal accountability meeting every quarter (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 – February data		

1. Introduction

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

1.2. Most of the data relates to the position at the end of February 2016. Two parts cover the period ending 31 March 2016 - these are the finance and strategic delivery totaliser sections. These therefore give an end-of-year view for the 2015/16 financial and strategic year.

1.3. One presentation change has been made in the report following CMG discussion. The eSET graph has been updated to show the relative percentages of eSET for NHS and private treatment, rather than the overall percentage of treatments that are eSET, divided by funding type. This relative approach gives a clearer picture of eSET provision, given that the number of overall cycles completed in the private sector is significantly higher than the number of NHS cycles.

1.4. Overall performance is good, with a single performance indicator 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.

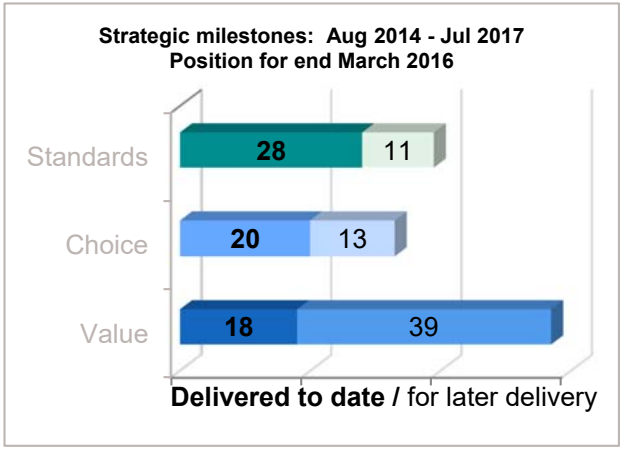
Annex A - HFEA strategic performance scorecard

1. Summary section

Dashboard – February data

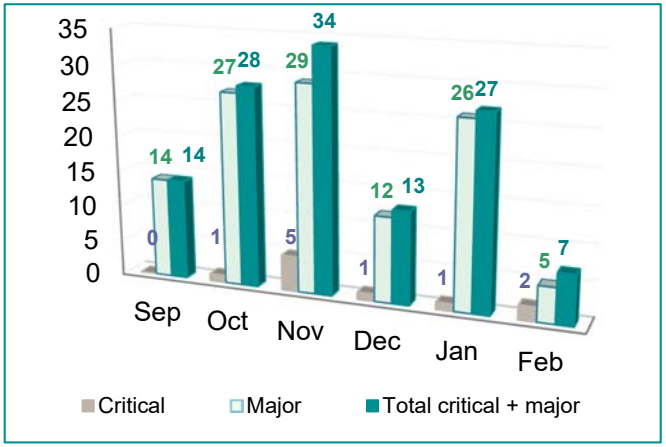
Strategic delivery totaliser

(see overleaf for more detail)



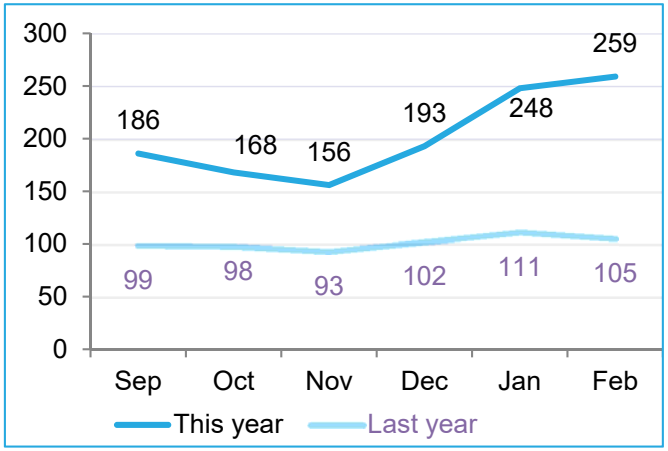
Setting standards:

critical and major recommendations on inspection

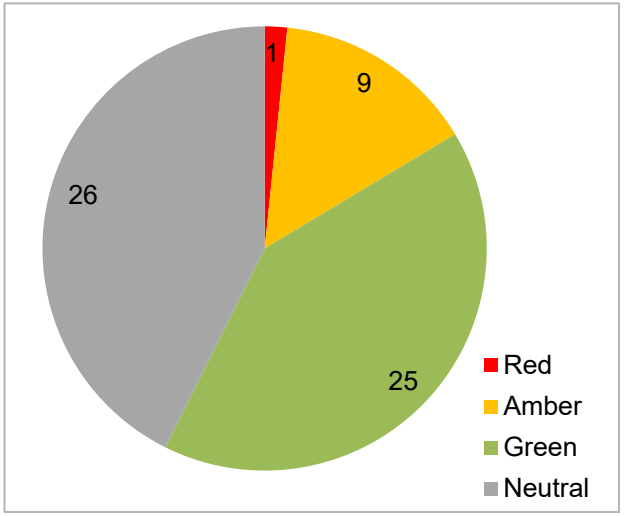


Increasing and informing choice:

public enquiries received (email)



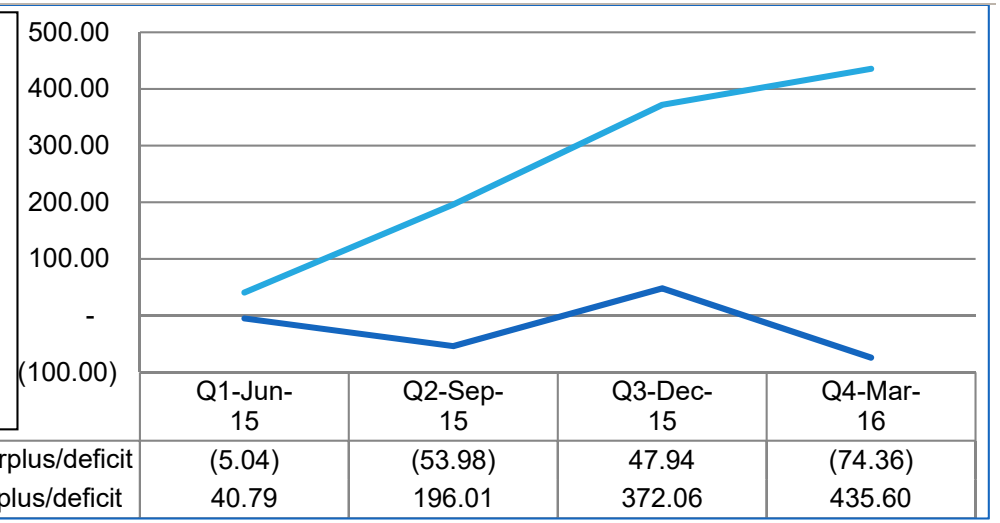
Overall performance - all indicators:



(See RAG status section for detail.)

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

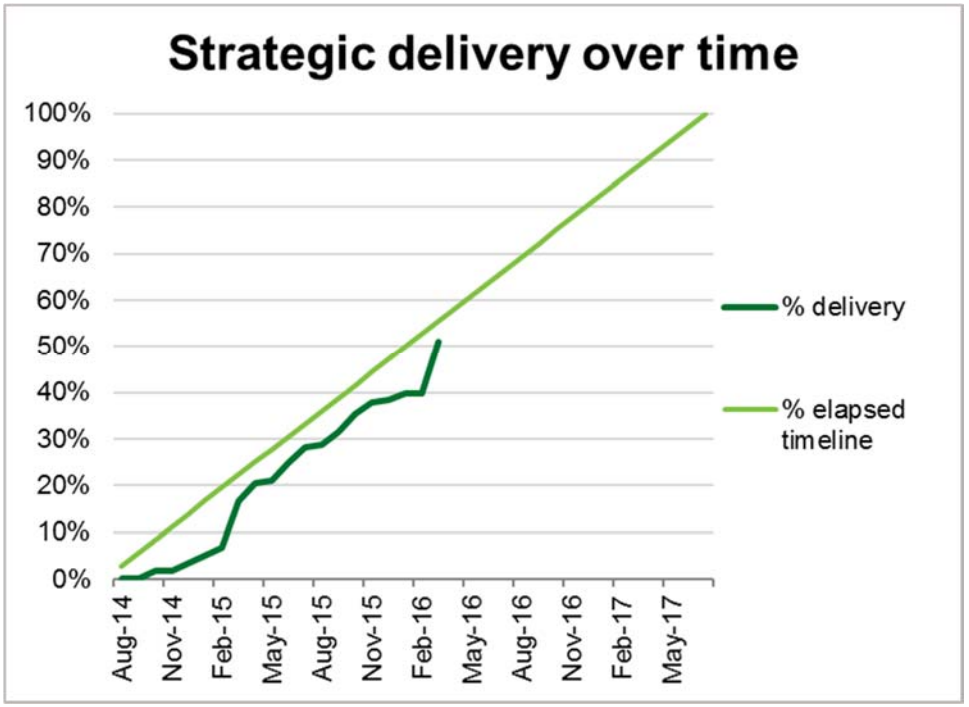
This graph details our net position as at 31 March 2016 (month 12) and our actual year end outturn. The graph shows we performed better than budget ie, we have ended the year at a surplus. The components making up the surplus/deficit are shown in the 'budget status' section by two graphs (income and expenditure).

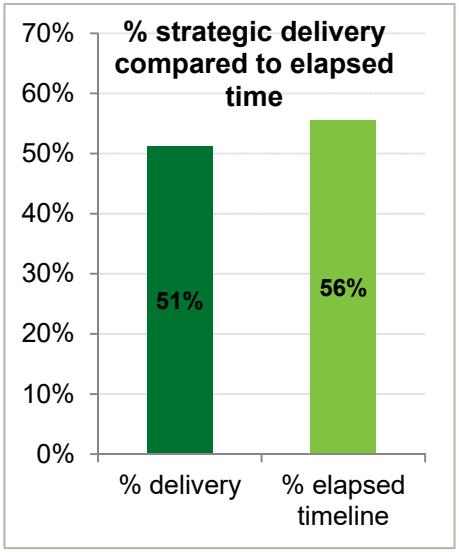


	Q1-Jun-15	Q2-Sep-15	Q3-Dec-15	Q4-Mar-16
Budgeted surplus/deficit	(5.04)	(53.98)	47.94	(74.36)
Forecast surplus/deficit	40.79	196.01	372.06	435.60

Dashboard - Commentary

Strategic delivery (to end of March) – summary:





It was previously necessary to re-cast the timeline for the beta phase of IfQ, which is still in progress. Earlier delays have contributed to us appearing 'behind' on the above graph compared with the original plan. However we have now started to see the 'earned value' of IfQ improving, and over the next few months we expect to see greater convergence between the delivery line and the elapsed timeline in the above graph, especially once beta has been completed and the remaining GDS gateways have been passed. Very little was due for delivery in January and February, so the apparent dip in those months is not a cause for concern. In contrast, a number of business plan items that contribute to strategic delivery were due for completion at the end of the business year, which has improved the overall picture.

CMG's assessment of end of year delivery was that a majority of planned work was either partially or fully delivered in 2015/16. A minority has been carried forward into 2016/17, either because of tie-ins with IfQ products (and the revised timeline for beta delivery), or because it became clear during the year that

some elements of the work would need to be longer term, were more extensive than originally envisaged, or should be re-considered in light of in-year changes or likely future developments.

For the purposes of this totaliser, where there was good progress based on the original intentions in the 2015/16 business plan, this work has been counted as ‘delivered’. Where items have been rescheduled into 2016/17 in their entirety, because of the link with IfQ, these have been counted as ‘not delivered’ in 2015/16 (but will be counted in a few months’ time when the new delivery date is reached). Some items were cancelled in-year owing to other changes, and these were counted as ‘not delivered’. The end of year (final quarter) progress against milestones due is described below.

Strategic delivery for January to March:

Setting standards

In January, a report was made to CMG summarising information gathered from the most recent meeting of the EU competent authorities, which took place in December. The purpose of reporting back is to demonstrate that we continue to fulfil our role as an EU competent authority, and to ensure that CMG is sighted on information that will inform our approach to high quality regulation and may result in internal projects.

We began, some time ago, to include more explicit information about patient experiences in inspection reports to licensing committees. However, building on this work further will require completion of the new Choose a Fertility Clinic function, which will be one of the key outputs of the IfQ programme in 2016/17. When delivered (July 2016), this work will also address our aim to improve the presentation of our data, so as to drive continued improvement in success rates and improved value for money for patients. Clinics already receive performance alerts in relation to success rates, and the HFEA has continued throughout the year to review emerging procedures and to consider and publish evidence.

The HFEA also explored with professional stakeholders the issue of acknowledging that treatment is often unsuccessful. We remain keen to see clinics putting better support in place for patients when treatment is unsuccessful. During this year we have been developing our new website, which will provide more information for prospective patients, so as to ensure that they enter treatment with a realistic understanding of their chances of success, and more signposting information for patients who have experienced unsuccessful treatment.

The HFEA has continued to work with the Lifecycle campaign, making a range of information leaflets available so as to ensure that potential donors, recipients and donor conceived people have better access to clear, authoritative impartial information about a range of issues. The leaflets, together with the pack about donor information produced earlier for clinics, and the new provision of our counselling support service (from June 2015 onwards), have improved role clarity for clinics in relation to donation and information guardianship. We believe this set of actions contributes to an improved experience for donors, donor-conceived people seeking information, and patients and their families.

In March, the HFEA also attended the Association of Fertility Patient Organisations (AFPO) standing stakeholder group meeting, to engage with patients and donor organisations.

Increasing and informing choice

Following the rescheduling of IfQ beta phase work, no final deliverables were due in this area during January to March. However, the majority of the new content and templates for the website have been successfully developed, with the aim of ensuring that patients will have access to high quality meaningful information.

By year-end, the HFEA had also completed significant user research to inform the IfQ Programme, especially to clarify what patients view as the key indicators of quality in treatment. This research has underpinned our approach to developing the new CaFC. Patients' views have been, and will continue to be, integrated into our ways of working and our future plans for the new website.

Through collaborative working with stakeholders and NHS Choices, we have made significant progress with ensuring that patients consistently get good early advice and appropriate referral, regardless of the fertility knowledge of their particular GP. This has been underlined by our user research and is fundamental to the 'user journeys' that are now being implemented in our new website.

We also set an objective of ensuring that clinics give accurate and sufficient information to patients in their websites and literature. During renewal inspections, we ask patients directly about these points, and we conduct desk-based research to provide factual feedback to clinics and encourage best practice.

During the 2015/16 business year, we started to consider how we might work with NHS commissioning bodies to help them to commission the best services for patients using available data. Some of this work will need to follow on from IfQ, since it relies on being able to make more use of our data. A draft guide for commissioners was developed and road tested with the multiple births stakeholder group in 2015/16. A deeper look at commissioning is likely to form part of our strategy for 2017-2020.

In March we published our 'Fertility treatment in 2014' report, covering treatments in 2013-2014, including a statistical report on donation and donor conception. We launched this publication at our Annual Conference on 24 March.

Efficiency, economy and value

Based on the original IfQ timeline, the cleansing of 'priority one' data in preparation for data migration should have been completed this month. Owing to prior resource pressures, the volume of cleansing work needed, and the changes made to the timeline for IfQ, this work is still ongoing into 2016/17. Good progress is being made on HFEA-based cleansing (important in reducing the burden of cleansing for clinics). Clinic based cleansing is starting up now, and the process and rationale for this were explained to delegates at the Annual Conference.

Since overall IfQ beta phase delivery was re-timed to the summer, the completion of the clinic portal (release one), website and CaFC, will be carried forward into 2016/17. However a great deal of work has been done during 2015/16, including good progress towards user testing for a public beta phase of the website (which was completed in April 2016).

Alongside continuing IfQ programme delivery, we have maintained the existing Register of treatments and outcomes, throughout the year, so as to ensure that patients and others have ongoing access to high quality information. This also ensures that we continue to have high quality data available to help us to deliver new patient information and publications, and to support risk-based regulation and evidence-based policy-making.

We have continued to maintain our shared services and collaborative arrangements so that we are efficient, and perpetuate savings made in earlier years. This helps us to achieve measurable ‘added value’ and demonstrate our internal efficiency.

Our accountability to the sector for fee rates was maintained through the continuing Fees Group, which enables us to evidence the value of what we do in return for the fees paid by clinics. This group has become well established and is working effectively.

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

The single red key performance indicator (KPI) shown in the ‘overall status - performance indicators’ pie chart on the dashboard is as follows:

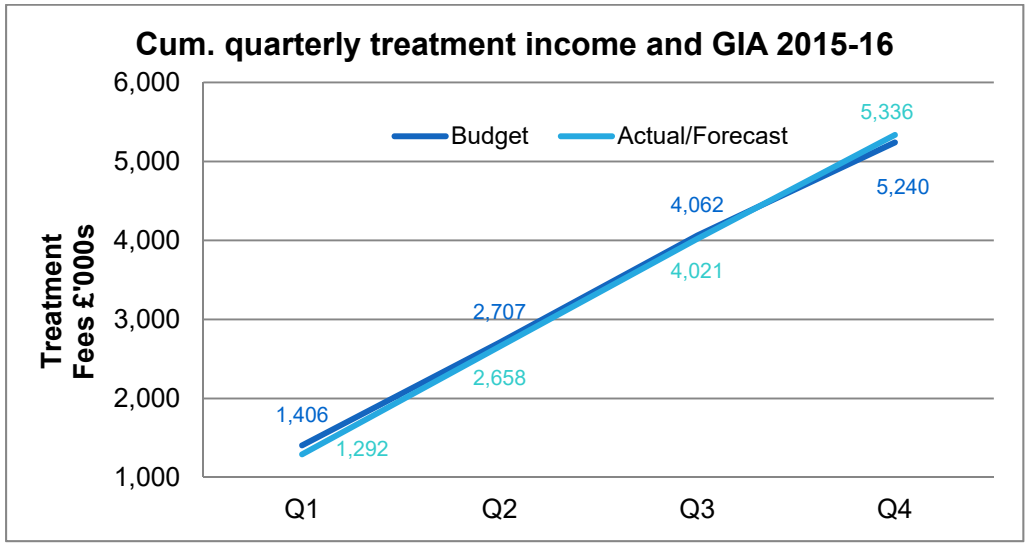
The number of working days from the day of inspection to the day the draft report is sent to the PR has a target of 90% in 20 working days. In February, performance was at 22% - much lower than expected, with seven reports missing the target. Four reports were sent within 7 days of the target. Three reports took longer, up to 39 working days. A report outstanding from January was sent at 63 working days, and there are still two reports which remain outstanding for February which will be followed up in next month’s strategic performance report.

Reasons for delays are varied, but mainly relate to either workload or complexity (or both), or sometimes because legal advice is needed. The team always prioritises robustness and quality over speed. The team’s performance in this area is managed closely, and breaches are always known and managed at the time they occur, in their own particular context.

No projects were on a red risk rating in February.

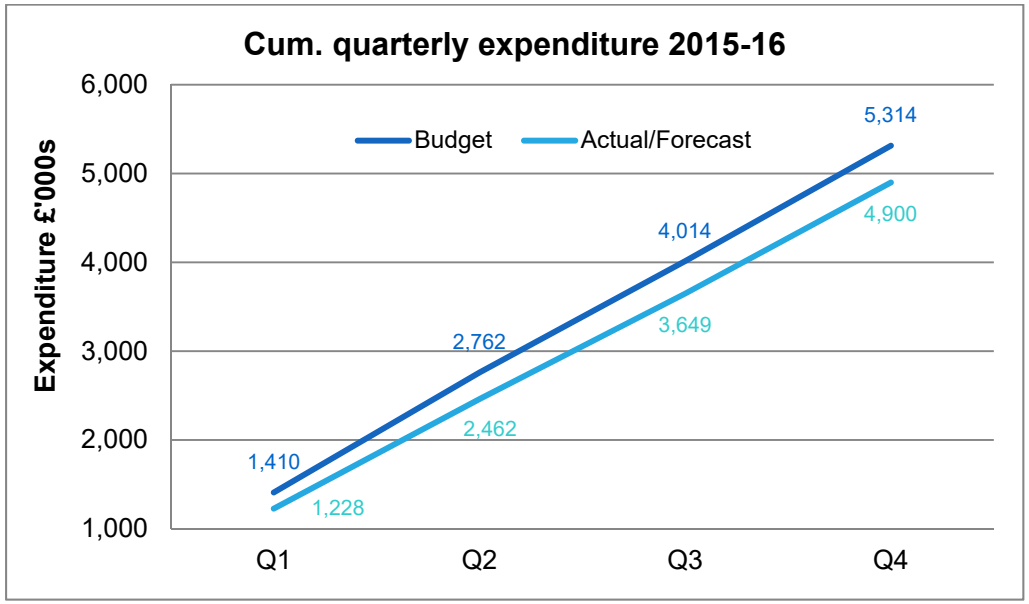
Budget status – March data

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) licence fee income and grant-in-aid (GIA) compared to what is actually happening.

As of month 12 (31 March 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.

Our actual outturn (year-end position) shows an underspend on expenditure of over £300k. This underspend has been helped by inclusion of receipts from legal cases where we were awarded costs. Our year end position has also been impacted by underspends within salaries and other staff costs. The Strategy and Corporate Affairs directorate has ended the year under spending in key areas such as the Annual Conference and publications.

Quality and safety of care

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

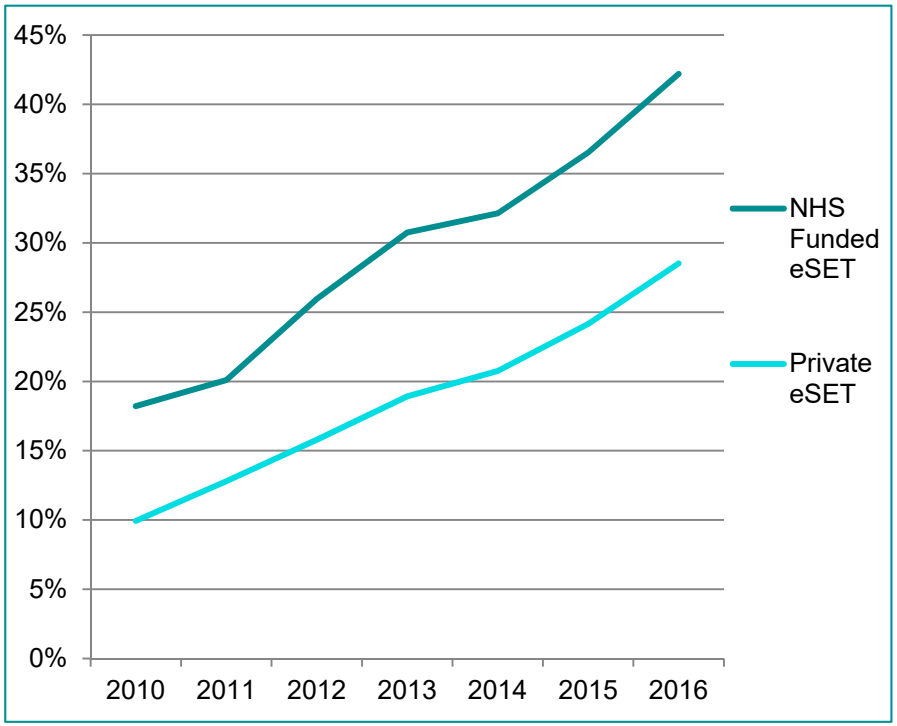
- number of risk tool alerts (and themes)
- common non-compliances (by type)
- incidents report (and themes).

The following figures and graphs were run on 4 April 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	9725	2774
	7%	8%	10%	13%	13%	15%	18%
Not recorded as eSET	19283	19491	17869	17719	17830	16906	3801
	33%	32%	30%	29%	28%	26%	24%
Private:							
Recorded as eSET	3422	4629	5699	6857	7736	9309	2576
	6%	8%	9%	11%	12%	14%	17%
Not recorded as eSET	31021	31546	30398	29391	29536	29234	6458
	53%	52%	50%	48%	46%	45%	41%

Graph: eSET relative % trends NHS/private:

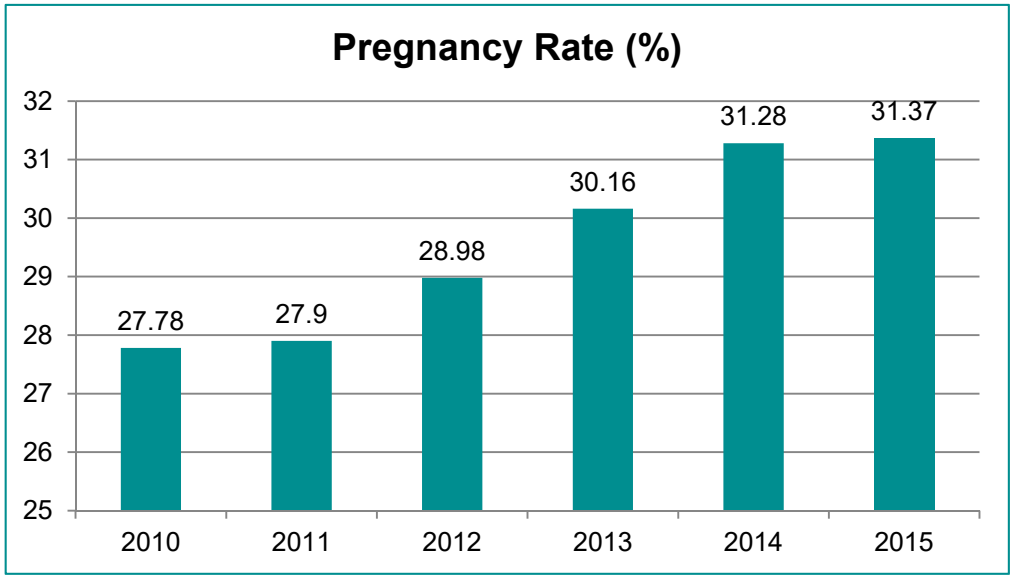


Explanatory text: Showing the total of all reported IVF treatment forms and counting those that the clinics recorded as eSET

As of February data, we have updated the 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	58020	16117	27.78
2011	60569	16896	27.9
2012	60230	17453	28.98
2013	61835	18648	30.16
2014	63545	19875	31.28
2015	65174	20445	31.37
2016	15609	2565	16.43



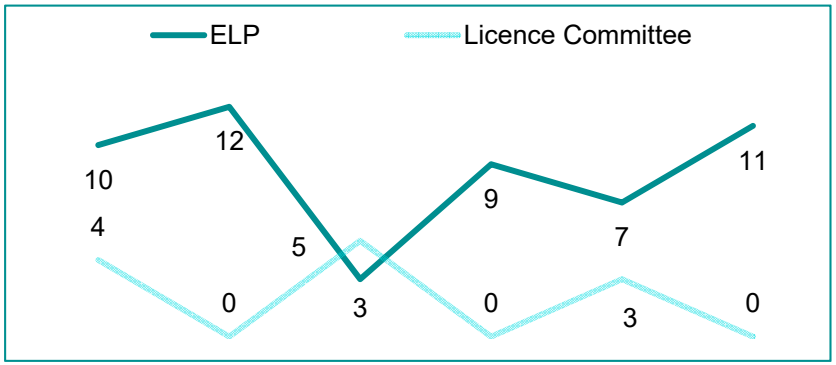
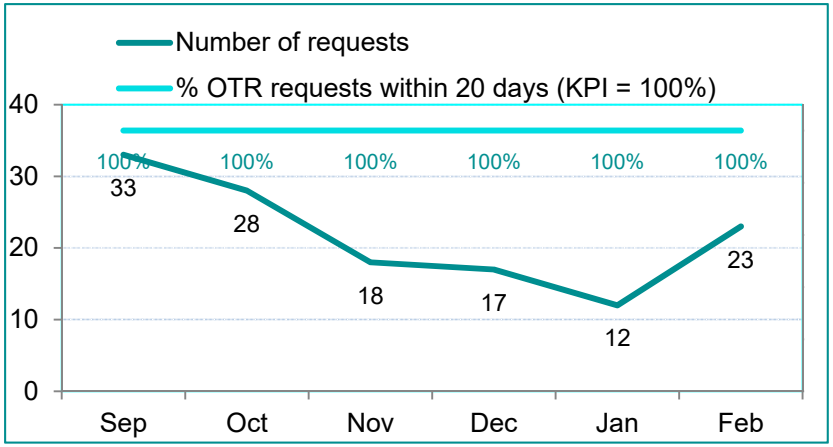
Graph showing the pregnancy rate over recent years

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

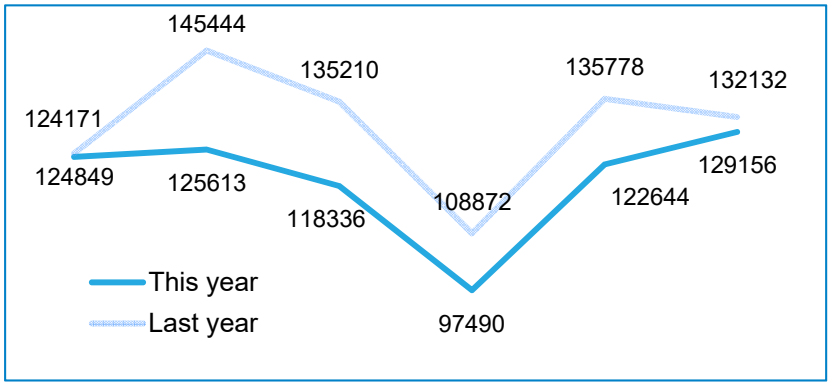
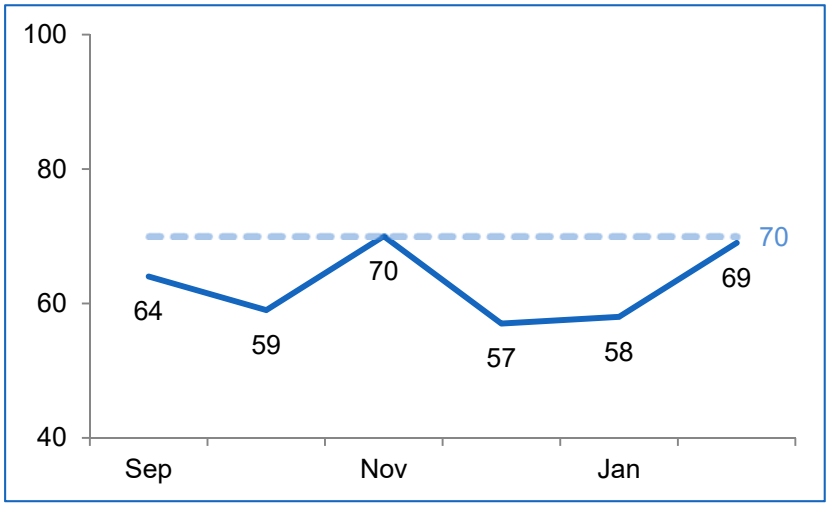
2016 figures are in grey since it is still quite early in the year, and there is always a lag in reporting pregnancies.

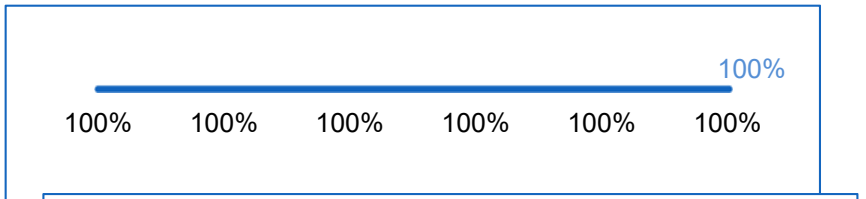
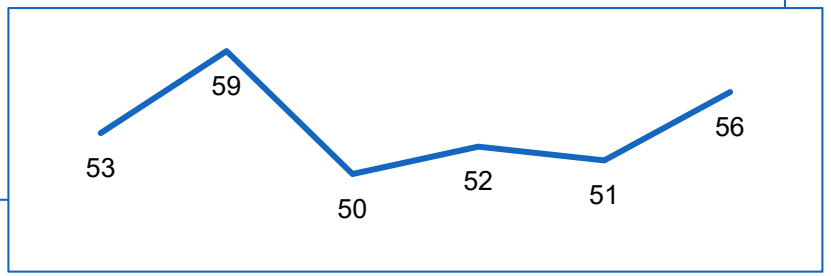
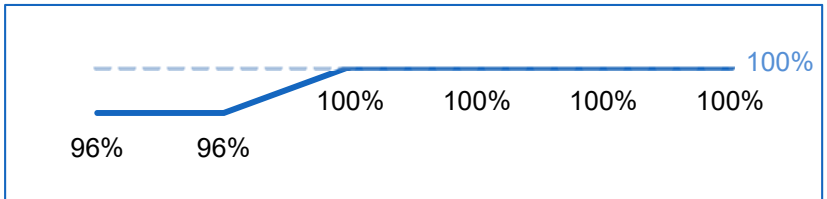
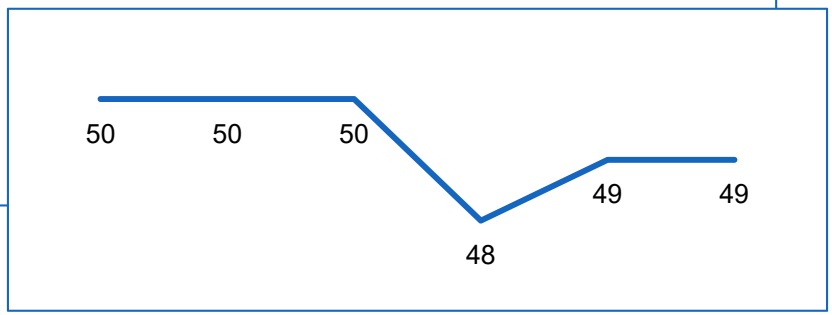
2. Indicator section

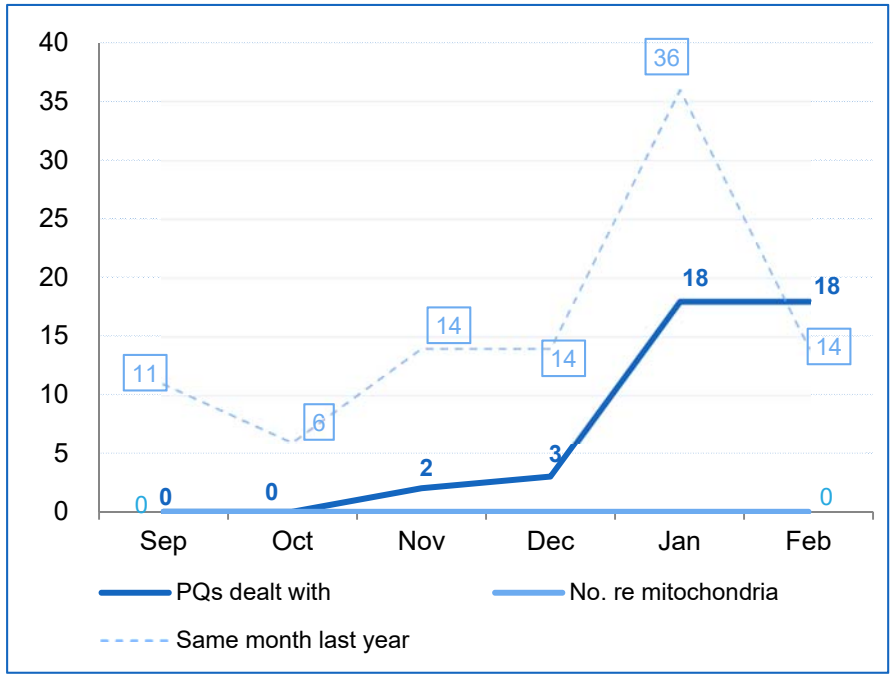
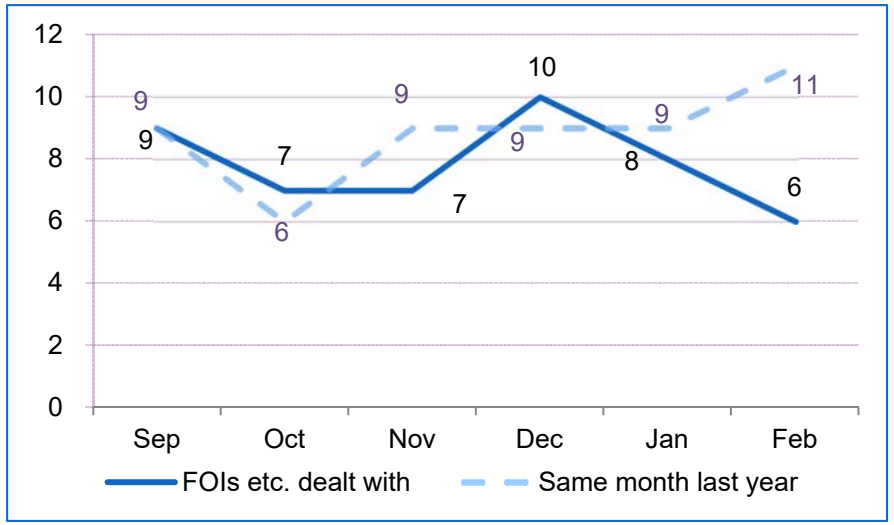
Key performance and volume indicators – February data:

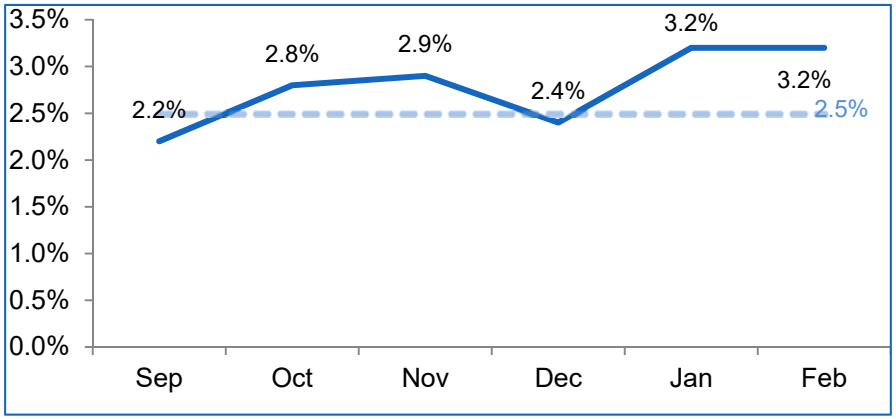
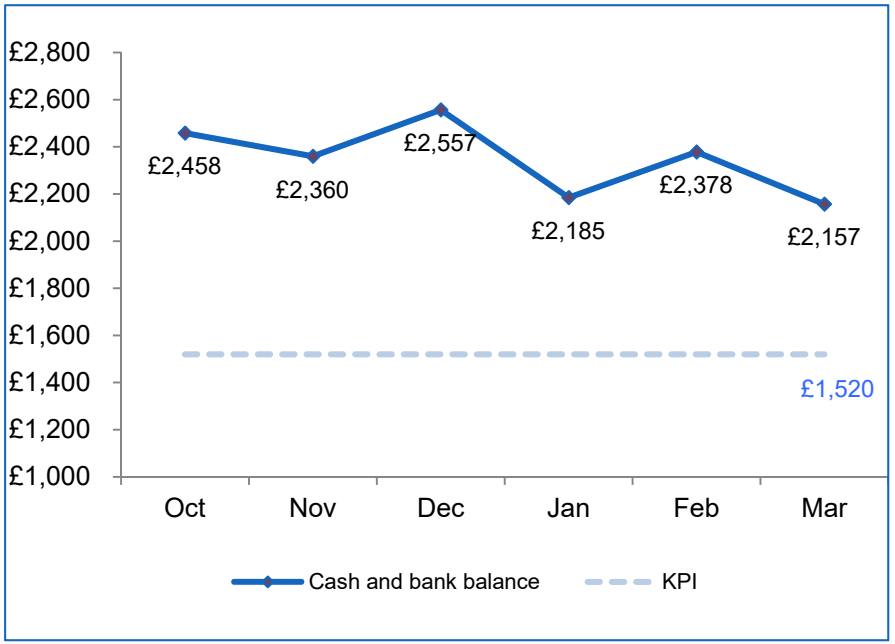
Indicator	Performance	RAG	Recent trend[1]	Aim[2]	Notes
Setting standards: improving the quality and safety of care through our regulatory activities.					
Licensing decisions made: - **By ELP** - **By Licence Committee**	11 0	⇧		No KPI – tracked for workload monitoring purposes	Volume indicator (no KPI 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% (23)	★		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)	129,156 (132,132)	⇧		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'.
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.	69 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 LC/ELP) within three months (66 working days) of receipt of completed application.
Average number of working days taken.	56	★			
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, which earlier was adversely affected by some complex multi-type applications received during the rolling year, has attained 100%.
Average number of working days taken.	49	★			

Indicator	Performance	RAG	Recent trend[1]	Aim[2]	Notes
Number of requests for contributions to Parliamentary questions	Total = 18	⇔		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	6	⇩		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.	3.2%	⇔		 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 risen above the KPI, but this is due mainly to long-term sick leave and seasonal illnesses. This has been investigated and does 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:** March's balance is approximately 9% below February's levels, helped by the increase in payment of March purchase invoices. See below for full end-of-year position and commentary.

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

Management accounts:

March accounts:

Income & Expenditure Account — Mar-2016

Accounting Period
Cost Centre Name
Department Name

	Year to Date			Full Year		
	Actual YTD £	Budget YTD £	Variance YTD £	Forecast £	Budget £	Variance £
Income						
Grant-in-aid	1,120	1,120	-	1,120	1,120	-
Licence Fees	4,216	4,120	96	4,564	4,120	445
Other Income	55	6	49	56	6	50
Total Income	5,391	5,246	145	5,740	5,246	495
Revenue costs - Charged to Expenditure						
Salaries	3,654	3,807	-153	3,608	3,807	-199
Other Staff costs	221	258	-37	225	258	-33
Authority/Committee costs	144	166	-22	150	166	-16
Other Compliance costs	56	39	17	61	39	22
Other Strategy costs	100	175	-75	107	175	-69
Facilities costs incl non-cash	339	355	-16	359	355	3
IT costs costs	115	106	9	110	106	4
Legal costs	204	340	-136	275	340	-65
Professional Fees	67	67	0	80	68	12
Total Revenue costs	4,900	5,313	-413	4,975	5,314	-340
Total Surplus/(Deficit) before Capital & Project costs	491	-67	559	766	-69	834
Capital & Project - Reserves funded						
IFQ	683	1,100	-417	633	1,100	-467
Donor Support	8	20	-12	8	20	-12
Other Capital costs	69	100	-31	69	-	69
TOTAL NET ACTIVITY	760	1,220	-1,212	641	1,120	-479

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

Commentary:

Summarised management accounts – commentary Q4

Income

January saw treatment fees down against budget by 3%, with February turning around and up by 1%. March saw a positive increase against budget of 2% (£96k). We believe this is due to clinics submitting data late due to issues with submissions in earlier months.

Our year end outturn (actual result) resulted in a 3% increase on budget. We drew down our full grant-in-aid (GIA) for both revenue and capital.

Expenditure

In January we overspent by 1% against budget with overspends in the areas of other staff costs (T&S) within the Compliance directorate, IT and legal costs.

February saw an improvement with underspends totalling £32k, around 8%. There were underspends within salaries, Authority and Committee costs.

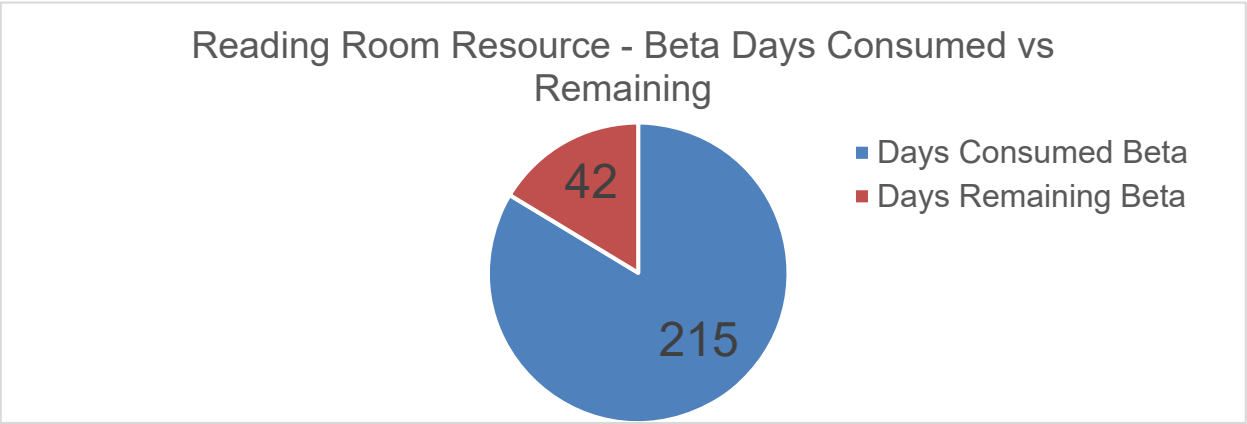
At year-end (March 2016), we underspent on our expenditure by 2% (£23k). Salaries due to vacancies were under spent by 4% and were the main reason for this. There were smaller underspends across directorates. Our legal costs were significantly down against budget due to receipts from cases won over the year.

IfQ and other project costs

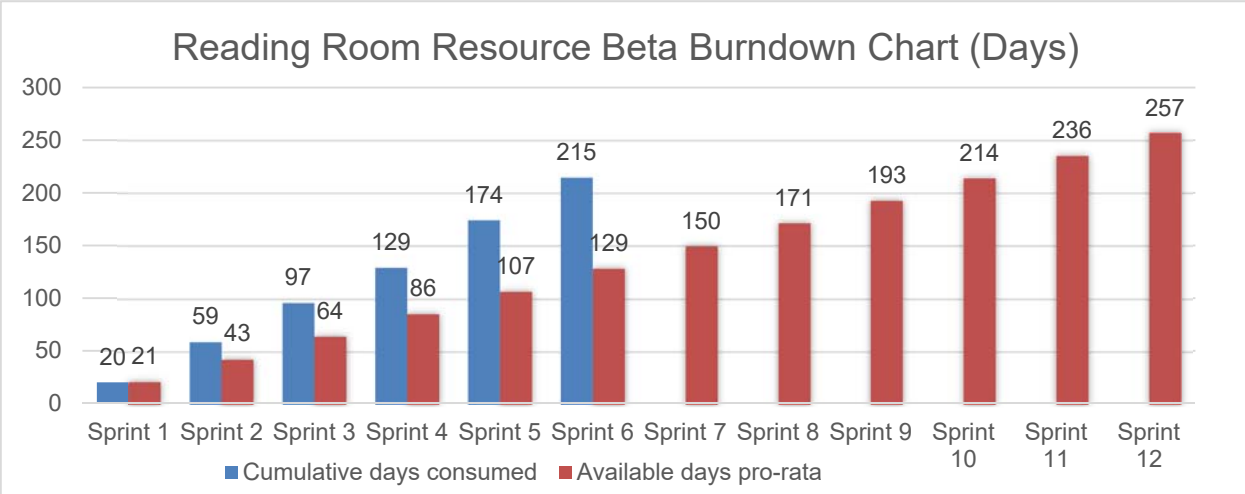
The costs of IfQ at year-end were removed from the Income and Expenditure Account and transferred to the Balance Sheet. This is because these costs are being capitalised. This means that they will be amortised (released) over a period of time. This is in line with our policy to capitalise anything that releases economic benefit for more than a year.

The year-end position for IfQ was a total cost of £638k which is largely made up of developer/project management and the cost of building the key components of IfQ. The project is expected to incur costs in Q1-3 of the 2016/17 business year. It is expected that these too will be capitalised.

IfQ indicators: February 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?	**January/February update:** The MSP health check process was commenced, with interviews taking place with a range of key internal stakeholders. (Final interviews subsequently took place at the end of March 2016, with the final report to be completed by end April 2016.)
Monthly	Timescales: Sprint progress and estimate of remaining work.	Is there scope creep/over-run?	**January/February update:** Work has progressed well through sprints two to sprint seven. There have been continued challenges progressing through the work according to schedule, with the trend of work running over to the following sprint continuing. This has increased the pressure on the last sprints of beta and may have further consequences on the features that are brought forward to user testing and DH/GDS Assessment. This issue is discussed regularly at IfQ Programme Board (which meets monthly).
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.	**January/February updates** Reading Room had a total of 257 days allocated to IfQ at HFEA, for Release 1 Beta. This does not include days to be allocated to user testing activities. A total of 215 days have been consumed to the end of beta sprint 6, with 42 days remaining. 

IfQ indicators: February update for Beta project phase

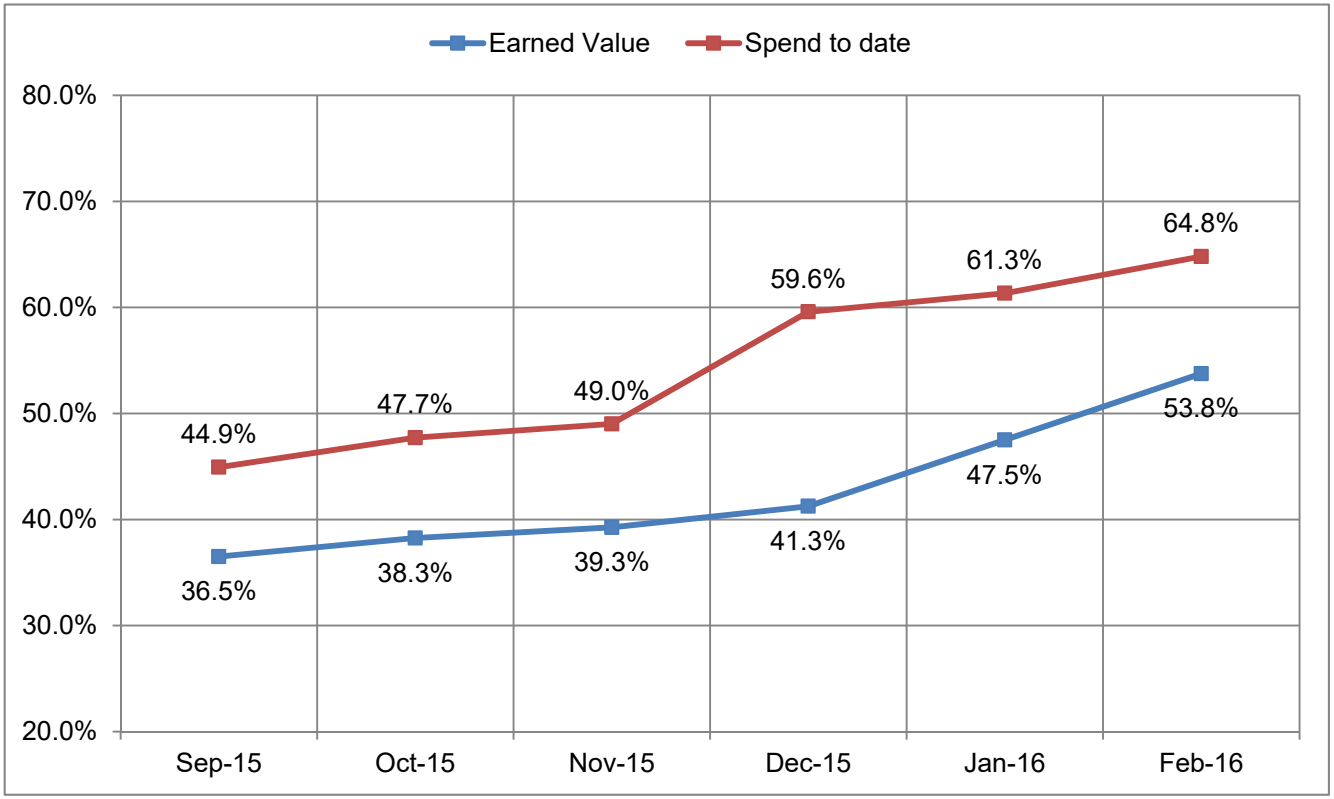
Frequency / trigger point	Metric	Purpose	Latest status:
			The below graph shows days consumed by sprint, against a pro-rata trend of those days divided equally by the number of sprints in Beta. At the current rate of resource usage, Reading Room will have consumed all their estimated days by the end of Sprint 7. Due to the nature of the capped time and resource contract with Reading Room, they are contractually required to continue building the Beta product at their own cost. This may lead to some requirement for further contractual conversations with Reading Room. 

IfQ indicators: February update for Beta project phase

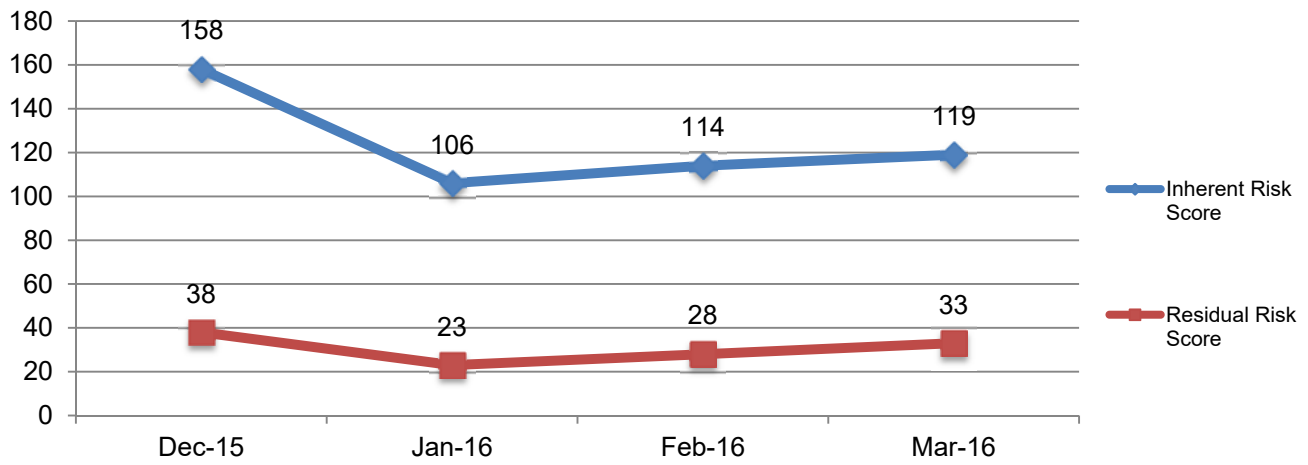
Frequency / trigger point	Metric	Purpose	Latest status:
Monthly	Cost: earned value (% complete * estimated spend at completion)	Is the spend in line with milestone delivery?	There are four things we can attribute value to: websites and CaFC; Clinic Portal; the Register and internal systems; defined dataset, discovery, stakeholder engagement etc. 25% of the value of the 1.8M programme cost at completion has been attributed to each project. **January/February update:** The graph below indicates that the earned value has been increasing since Beta started in December.

IfQ indicators: February update for Beta project phase

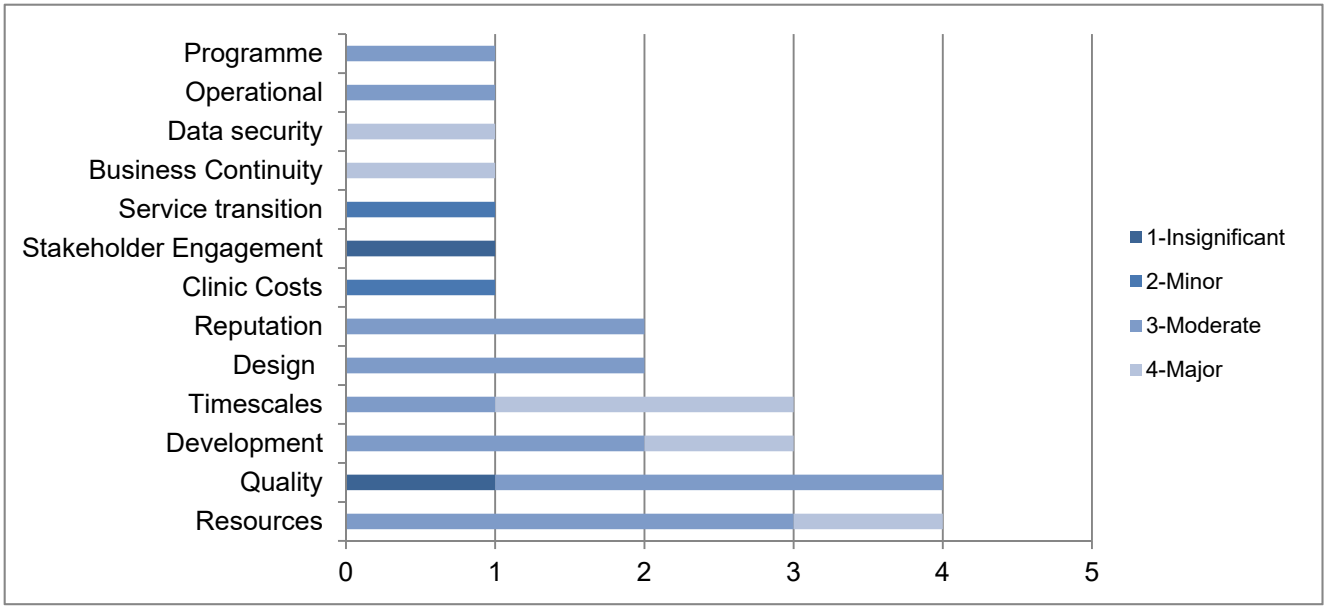
Frequency / trigger point	Metric	Purpose	Latest status:
			At this stage we are not expecting any significant spend untill the end of Beta currently scheduled for June 2016. The following graph shows the earned value starting to increase in January/February. In the separate IfQ item on the agenda, the Authority will receive an update on progress for March.



IfQ indicators: February 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 communications)	Are we keeping stakeholders with us? Is it getting better or worse?	**January:** We held two show and tell sessions in January which were well attended by staff. We updated the IfQ intranet pages and distributed some snippets to keep colleagues up to date. The IfQ stakeholder group didn't take place in January as we decided there wasn't enough to share with them at this point in the project. Total combined score = 2 **February:** The IfQ stakeholder group took place in February and went through some of the draft website content. We held one show and tell session. Total combined score = 2
Monthly	Risks: sum of risk scores (L x I)	Is overall risk getting worse or better (could identify death by a thousand cuts)?	**January/February 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 Programme has increased. 

IfQ indicators: February update for Beta project phase

Frequency / trigger point	Metric	Purpose	Latest status:
			The major risks score are associated with resources, development, timescale, business continuity and data security. 
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?	**January/February update:** The benefits realisation value should be reviewed periodically based on the business case; this will be looked at by IfQ Programme Board. No issues have been raised regarding benefits realisation to date.

Strategy 2017-20

Strategic delivery:	☒ Setting standards	☒ Increasing and informing choice	☒ Demonstrating efficiency economy and value
Details:			
Meeting	Authority		
Agenda item	7		
Paper number	HFEA (11/05/2016) 794		
Meeting date	11 May 2016		
Author	Juliet Tizzard, Director of Strategy and Corporate Affairs Paula Robinson, Head of Business Planning		
Output:			
For information or decision?	For decision		
Recommendation			
Resource implications			
Implementation date	1 April 2017		
Communication(s)			
Organisational risk	☐ Low	☒ Medium	☐ High
Annexes			

1. Background

1.1. Our strategy has been very successful for the HFEA. With the simple and compelling vision of 'high quality care for everyone affected by assisted reproduction', it has focused our minds on that one important goal. Our board, our senior leadership team and our staff have that vision uppermost in their minds when designing services, planning work and carrying out everyday regulatory activities. Our stakeholders, too, understand and support our strategy and rightly hold us to account against its vision and ambitions.

1.2. The strategy runs until July 2017 and much of it is already achieved. And the more ambitious service changes, encompassed in Information for Quality, will be completed by the end of this calendar year. Now is the time to think about our next strategy, one which will lead us through to the next general election in 2020.

1.3. This paper is designed to prompt an early conversation amongst Authority members about our next strategy, which we would like to launch in April 2017.

2. How have we done so far?

2.1. Our ambition in developing our strategy was that a high quality of care for donors, patients and their future children should be central to how we see our role and what we do. Of course IVF services should be safe, lawful and reflect good practice, but clinics must also make the experience of treatment a good one. Patients should feel well prepared, treated with respect and supported throughout and beyond treatment.

2.2. Information for Quality is central to that ambition. With slick, efficient systems for engaging with us which play back valuable performance information, clinics can improve their services and spend more time with patients. With clear, helpful information and a balanced assessment of quality in clinics, patients and donors can feel better prepared for treatment and more confident about the decisions they need to make.

2.3. We have made great headway in these areas. In summary, we have so far achieved:

- A great deal of progress through the IfQ programme, towards:
  - Patient ratings through the new, improved, CaFC
  - User research to identify what quality means to patients
  - Publishing more data to encourage better outcomes
  - Wider range of information for patients on the new website
  - Publishing donor gamete availability information on CaFC
- Regular publication of reports on clinical incidents and fertility trends

- Range of actions to encourage highest possible success rates, including better outcome data presentation and tools to allow clinics to benchmark their performance
- Lifecycle leaflets for donors and recipients
- Information about treatment abroad and unregulated sperm donation
- Best practice guide for clinics about handling donor information
- Introduction of the counselling service pilot
- Savings and efficiencies gained by developing shared services and service level agreements with other ALBs
- HFEA participation in the 'one stop shop' for life sciences, launched in 2014.

2.4. In some areas we have more progress to make in:

- addressing the support gap for patients whose treatment has been unsuccessful
- ensuring that clinics fully prepare and support patients and donors, and that they appreciate the importance of their lifelong role as an information provider
- pursuing further work with NHS Commissioners to improve the commissioning of IVF services
- realising the benefits of IfQ, including an improved data submission and verification experience for clinics, more accurate data being submitted to the Register, and efficiency gains for clinics (reduced transactional costs) and for ourselves.

2.5. The wider environment in which we work (our sector, society, patient's expectations, political drivers, and so on) is ever changing. When we think about our future strategy, we will need to look outwards and into the future, as well as picking up any pieces of work we would like to conclude, or re-define, based on progress with our strategy. We will need to continue to be an open organisation, and one that constantly seeks improvements and efficiencies and ensures it continues to be an effective and modern regulator.

2.6. The focus of our strategic activities is already shifting forward a gear in 2016/17. Having started work in earnest on IfQ in 2015/16, this year we will really see the results. This will change our internal landscape, and enable us to reap the benefits of a better website, better data and better information systems. The next strategy will be situated in a world where IfQ has happened.

2.7. What will we need to do next to achieve 'high quality care for everyone affected by assisted reproduction' by 2020?

3. Our strategy to 2020

3.1. Set out below are some early thoughts about what our next strategy might focus on. This is not necessarily an exclusive list, but reflects some recent discussions and developing trends, and the increased quality of our information infrastructure and provision after IfQ.

3.2. High quality care will remain centre stage. For the next three years we will want to set out new ambitions to ensure that patients, whether treated privately or in the NHS, receive even better care. Some of the following areas of work are new, or emerging, while others would be the natural sequel to previous work.

Treatment add ons

3.3. One area of work that we have already started is treatment 'add ons' which have become a feature of many IVF services. Increasingly, patients are being offered a variety of treatments – including drug regimes, methods for culturing embryos and treatment procedures – with the claim that they improve the chances of a successful pregnancy. Some patient feedback indicates that many now see such treatments as an indicator of a good service. Yet the evidence base for many of these treatments is weak. Our new website will give information about these add ons and we are discussing collaborative work with the professional bodies and patient groups. How might we want to progress this work further in 2017-20?

Treatment costs

3.4. We are not an economic regulator, and have no direct levers to pull around the cost of treatment, but this is one of patients' top concerns. Although our new website won't list prices for each clinic, it will give patients information about the range of costs across UK clinics. It will also give patients a chance to give feedback on the patient ratings feature about whether they paid what the clinic estimated treatment would cost.

Capitalising on IfQ

3.5. The new clinic portal, website and Choose a Fertility Clinic will make a huge difference to patients and to clinics. For the first time patients will have a fully rounded picture of each clinic, making it much easier to make an informed decision. The new portal will make data submission for clinics much more straightforward, freeing up time to treat patients and reducing costs. It will also allow clinics to compare their performance against the national average and will, we hope, help drive an improvement in service quality over time.

3.6. But the launch of those services will be just the beginning. We will need to encourage and monitor use – and refine things over time in response to feedback. And we will need to see whether the changes we want to see happen are actually happening.

3.7. We also want to use our improved data systems to assess practices in clinics or challenge treatments being offered or the basis on which they are being offered. We can use our data more effectively to provide more/better information on the website and clinic portal. Our data holds the potential to identify poor areas of sector/clinic performance, to create more empowered consumers, and to support innovation and research. And we want to ensure that data submitted by clinics really is more accurate and easier to submit.

3.8. IfQ will also make a significant shift in greater transparency with easier access to inspection reports, new patient feedback mechanisms and other information on the new website and CaFC. We view transparency not as an end in itself but also as a driver of both patients' and professionals' behaviours, both of which are crucial to motivating higher quality care.

NHS commissioning

3.9. NHS commissioning of IVF is patchy and a constant source of complaints from patients across England. The issue has four principal elements. There is a widespread mismatch between supply and demand such that patients find it difficult to access treatment. Access varies across the UK depending on the decisions of individual CCGs (with some withdrawing the service altogether). Many CCGs lack the information or knowledge to make well evidenced commissioning decisions. And there is no wider knowledge among CCGs of the right price to pay for these services. Access and geographical variability are an inevitable consequence of local commissioning but we can make progress on information and price, if there is the will to do so among the relevant organisations in the health system.

Technological developments

3.10. Genetics and genomics are an area of focus for the Government and the Department of Health. Embryo testing technology and the associated genetics knowledge are developing at a fast pace which shows no signs of slowing. Tests are getting faster, cheaper and more accurate. Last year we approved more than 50 new conditions for PGD, about one a week. Most of the conditions are rare but the PGD tests offer hope, where there previously was none, that families can avoid passing on a serious inherited condition. We also expect more applications for research involving genome editing in the future and some are calling for a wider debate about the use of such techniques in treatment.

3.11. This is clearly a growth area and will lead to an increase in the availability of and demand for these services, people's level of awareness and understanding of what is possible, and their knowledge about their own genetic make-up.

4. Next steps

4.1. In developing our strategy for 2014-2017, we consulted widely and took our time. Because the strategy was such a step change for us and because the vision of high quality care for everyone affected by assisted reproduction is still central to our approach, we feel that more 'low-key' consultation on the strategy to 2020 will be sufficient. We will use existing stakeholder groups and forums and we may focus on particular narrow areas with different stakeholder groups, rather than engage all of them with the whole document.

4.2. A rough timetable might be:

May 2016	Early discussion with Authority members and staff
June 2016	Draft strategy themes and activities
July 2016	Authority workshop to discuss
August 2016	CMG item to coincide with business planning for 2017/18
September 2016	Authority agree draft strategy
October 2016	Engagement with stakeholders, staff and wider?
November 2016	Authority workshop on early engagement feedback
December 2016	Continued engagement/follow-up as needed
January 2017	Authority agree new strategy
March 2017	Annual conference launch
April 2017	Publication

5. Recommendation

The Authority's views are sought on the ideas outlined in this paper. It is early days, and we would appreciate members' input in shaping this process, as well as thoughts about our future vision as we move towards the next strategic period.

Information for Quality programme: update

Strategic delivery:	☒ Setting standards	☒ Increasing and informing choice	☒ Demonstrating efficiency economy and value
Details:			
Meeting	Authority		
Agenda item	9		
Paper number	HFEA (11/05/2016) 795		
Meeting date	11 May 2016		
Author	Nick Jones, Director of Compliance and Information		
Output:			
For information or decision?	For information		
Recommendation	The Authority is asked to note: • 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.		
Resource implications	Nil, albeit a larger than anticipated budget carry-over to 2016/17		
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:

- 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.

2. Update on approvals stages

2.1. Members will recall that all government IT programmes needs to pass through a number of stages before they can go 'live': 'alpha' (build a prototype, test it with users and learn from it); 'beta' (scaling up, a working model) 'public beta' (going public, receiving feedback and prepare to go live) and only then is the programme 'live' (a tested solution that is ready to release and then continuously improved). At each stage the programme is assessed by the Department of Health (DH) and the Government Digital Service (GDS).

2.2. IfQ passed 'alpha' in November 2015 and we are preparing for the 'public beta' assessment of both the website and Clinic Portal on 11 and 12 May 2016.

2.3. We are also engaging with our CLAS security consultant[1] to ensure appropriate security accreditation prior to the DH/GDS Assessment. Security is, of course, a key consideration for us.

[1] CLAS is a subdivision of GCHQ which provides advice to the public sector on technical security threats, risks and mitigating countermeasures.

3. Contract-related considerations

3.1. Work has continued on the programme throughout the period of our office move, with HFEA staff co-locating with Reading Room, our key contracting partner, who were kind enough to offer us space at their premises for this purpose. It was also evident there was a shortfall in the available developer resource, leading to time pressures. Following escalation at senior level additional resource has been provided by Reading Room. As we are on a capped cost contract this limits our financial exposure.

4. Beta progress and user testing

4.1. As indicated above, we are nearing the end of beta development. Our website and portal were demonstrated at the Annual Conference, and were very well received. The recent focus has been towards user testing (a key component of 'Agile') which took place in late April.

Website and Choose and Fertility Clinic

4.2. Work has continued on the drafting of new website content which has involved working with internal HFEA teams, sharing material with Authority members and working with external stakeholders. In preparation for the testing 34 approved pages of content were made available for users to test.

4.3. The user testing was carried out successfully and the website and CaFC received a good reception from all those who tested it. Although there were a number of issues raised, as you would expect from testing, for the large part these were minor additions and adjustments involving refinements and enhancements rather than fundamental changes.

Clinic Portal

4.4. Aspects tested included the general look and feel of the portal, basic navigation and usability and certain tasks representing key 'user stories' (for example, updating clinic information that will appear on the public Choose a Fertility Clinic website, searching by subject matter across regulatory requirements and guidance information – and so on).

4.5. Testers included a mix of users from small, medium and large centres and comprised PRs and lab managers, Quality Managers, a nurse and an administrator.

4.6. The user feedback was positive and useful. Feedback included alternative and more logical locations for a couple of page items and requests for additional functionality that can be considered for future releases. Designs for each section of the portal have largely been completed, with some further work on online applications expected.

Internal systems

4.7. The internal systems work underpins all of the above as well as the Register changes, and the team has progressed to the final stages of the majority of work to support the website and clinic portal beta stage.

4.8. For the website, the team has also been progressing work on surfacing the summary statistics that will appear on the CaFC profile pages for clinics.

4.9. Other 'under the hood' work done by the team includes:

- developing a 'staging/live' deployment area, to transition the overall service from the current 'development' environment in which it is located
- finalising the synchronisation piece that ensures all components of the internal architecture can 'talk' to one another in the most efficient and secure way
- Engaging with our CLAS security consultant, as noted above, to have the release one build to date assessed for accreditation prior to DH/GDS assessment
- Commencing procurement of penetration testers, who will assess the security vulnerabilities of our release one build, and make recommendations about mitigating those

5. Life after beta

5.1. Although delivering beta successfully remains an intense focus, pending the necessary gateway approvals, we need to be ready to move forward into release two development.

5.2. With this in mind, we have started to work up a plan for release two and EDI delivery, and a team workshop to surface the necessary details will be held shortly. Background work is already taking place, and the information systems team has been progressing the foundational architecture to support the new Register and overall architecture to support release two functionality.

6. Data migration and the data dictionary

6.1. As previously advised, and as signalled at the Annual Conference, there is a certain amount of data cleansing that needs to be done by clinics before the data can be migrated to the new Register. We have been communicating with clinics preparing them all for the requirement to cleanse data, and we remain hopeful that the prospective benefits offered by the new system will act as an incentive.

6.2. Whilst the office move delayed us a little the first eight clinics identified to undertake a pilot of cleansing activity have now received notification. There has been no negative feedback from clinics as yet – given our communications were proactive and the volume of work for each clinic is modest.

6.3. The majority of errors can be resolved by us and centres will generally only receive a small number to correct. There has been much hard work by colleagues in the Register team.

6.4. While the recent emphasis has been firmly on data cleansing, we are also still progressing the paperwork needed to get our data dictionary accredited. We will make our submission next month, via NHS Digital (the new name of the Health and Social Care Information Centre).

7. Programme timelines and budget implications

7.1. 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.

7.2. Whilst the overall budget for IfQ remains unchanged at £1.134m, this revised timeline resulted in circa £450,000 being carried into this financial year from the last financial year. As much delivered product as possible was capitalised before year end, but this had only a limited impact since we had not quite reached product testing (achieved in mid-April).

7.3. The budget position (excluding VAT) for the end of 2015/16 is as follows:

Total IfQ budget	Budget 2015/16	Planned spend	Actual spend 2015/16	Variance (exc accrual)	Variance (inc accrual)
£1,134,576	£962,409 (Approved beta budget)	£594,747	£631,313 (March 2016)	£331,096 (F/Y 2015/16)	£274,389 (F/Y 2015/16) (£56,698 accrued)

7.4. In 2016/17, the total value of the IfQ budget has increased slightly to £1,157,512. This increase of £22,936 is due to the website project manager post, which has been extended to cover the longer beta timeline through to June 2016.

7.5. The budget for 2016/17 is £526,199 (excluding accruals for beta).

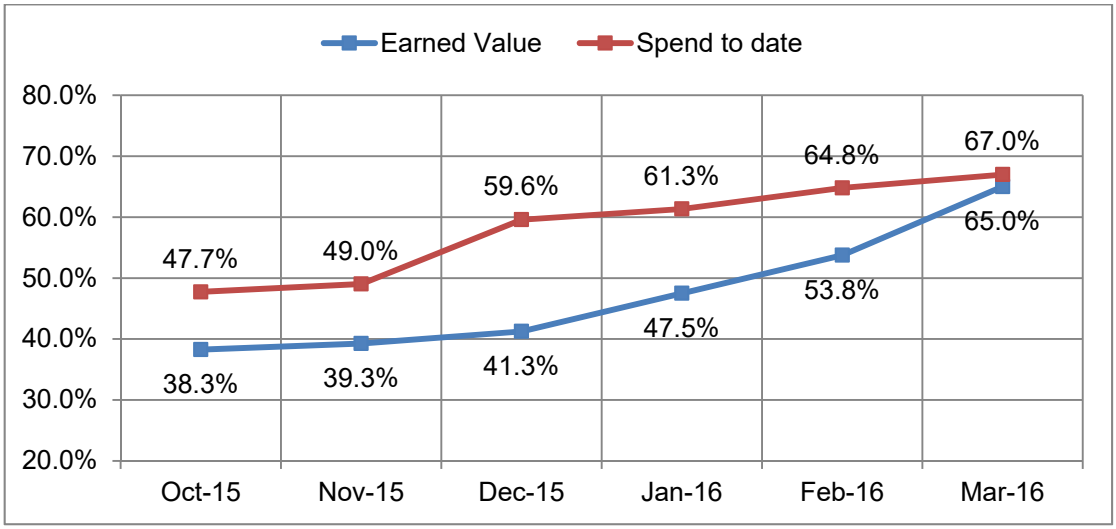
Total budget to date (April 2016)	Total budget IFQ	Variance	Total budget 2016/17 (April 16)
£1,157,512	£1,134,576	£22,936	£526,199

7.6. Our latest 'earned value' figures (also reported regularly in the strategic performance report) indicate that the work achieved is now nearly equal to the

spend to date. This is good news, since it means we are now successfully extracting the intended value from the money spent – despite the budgetary inconvenience of carrying over costs from one financial year into the next due to the earlier changes to the beta timeline.

Period	Oct-15	Nov-15	Dec-15	Jan-16	Feb-16	Mar-16
Earned Value	38.3%	39.3%	41.3%	47.5%	53.8%	65.5%
Spend to date	47.7%	49.0%	59.6%	61.3%	64.8%	67.0%

7.7. This improving picture is shown in graphical form below.



8. Recommendation

8.1. The Authority is asked to note:

- The approval process to proceed to 'public beta' phase, and later to 'live'
- Progress since the HFEA annual conference
- Data migration and cleansing
- Programme timelines and budget.