Human Fertilisation & Embryology Authority

Authority meeting - agenda

11 November 2015

Etc Venues, 51-53 Hatton Garden, London EC1N 8HN

Agenda item		Time
1.	Welcome, apologies and declaration of interests	12:45pm
2.	Minutes of 16 September 2015 **HFEA (11/11/2015) 772**	12:50pm
3.	Chair's report (verbal)	12:55pm
4.	Chief Executive's report (verbal)	1:05pm
5.	Committee chairs' updates (verbal)	1:15pm
6.	Strategic performance report **HFEA (11/11/2015) 773** For information	1:30pm
7.	Draft business plan 2016/17 **HFEA (11/11/2015) 774** For decision	1:50pm
8.	Strategic risk register **HFEA (11/11/2015) 775** For information	2:10pm
	Break	**2:30pm**
9.	Information for Quality: update **HFEA (11/11/2015) 776** For information	2:40pm
10.	Choose a fertility clinic: update **HFEA (11/11/2015) 777** For information	3:00pm
11.	HFEA fees 2016/17 **HFEA (11/11/2015) 778** For decision	3:20pm

12.	Scientific and Clinical Advances Advisory Committee: issues from the past year **Presentation** For information	3:40pm
13.	Any other business	4:00pm

Minutes of Authority meeting 16 September 2015

Strategic delivery:	☐ Setting standards	☐ Increasing and informing choice	☐ Demonstrating efficiency economy and value
Details:			
Meeting	Authority		
Agenda item	2		
Paper number	HFEA (11/11/2015) 772		
Meeting date	11 November 2015		
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 16 September 2015 held at ETC Venues, Hatton Garden, 51-53 Hatton Garden, London, EC1N 8HN

Members present	Sally Cheshire (Chair) Dr Susan Price Professor David Archard Dr Andy Greenfield Anthony Rutherford Dr Alan Thornhill	Kate Brian Yacoub Khalaf Margaret Gilmore Anita Bharucha Rebekah Dundas
Apologies	Bishop Lee Rayfield	
Observers	Ted Webb (Department of Health)	Steve Pugh (Department of Health)
Staff in attendance	Peter Thompson Nick Jones Juliet Tizzard Sue Gallone Debra Bloor Catherine Drennan Paula Robinson	Joanne Anton Andrew Leonard Sara Parlett Paula Nolan Joanne McAlpine Charlotte Keen

Members

There were 11 members at the meeting, 7 lay members and 4 professional members

1. Welcome, apologies and declarations of interest

1.1. The Chair opened the meeting by welcoming Authority members and members of the public to the fifth meeting of 2015. 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 Bishop Lee Rayfield.

1.3. Declarations of interest were made by:

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

2. Minutes of Authority meeting held on 8 July 2015

2.1. Members agreed the minutes of the meeting held on 8 July subject to a minor amendment. The Chair agreed to sign the minutes as amended.

3. Chair's report

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

3.2. On 14 July the Chair attended a Ministerial meeting with the Chairs of the health sector's arm's length bodies (ALBs), together with a cyber security seminar for ALB and Executive Agency Chairs and Non-Executive Directors. On the same day the Chair, together with the Chief Executive, attended the Human Tissue Authority's (HTA) 10th anniversary review event.

3.3. The Chair reminded members that the HFEA was currently having its Triennial Review to look at the functions of the organisation and whether those functions were carried out in the most efficient way possible. As part of that review, the Chair advised that she had been interviewed by the Department of Health's review team on 29 July and thanked Authority members and members of the Executive who had also taken part in the review for their contributions.

3.4. On 9 and 10 September, the Chair, together with an Authority member, interviewed for new members of the HFEA's independent Appeals Committee. The Chair of the panel was Dame Elizabeth Filkin and the panel was looking to appoint a Chair, Deputy Chair and two lay members to the committee since the terms of office for those members who were currently sitting on the committee had come to an end. The Chair confirmed that the panel was successful in identifying four high-quality candidates, all of whom had accepted the positions.

3.5. The Chair informed members that she, together with a representative from the Department of Health and an independent person, would be conducting interviews on 17 and 23 September to recruit two new members to the Authority – a nurse or counsellor and a clinical geneticist – to replace two current members who would be stepping down after their terms of office came to an end.

4. Chief Executive's report

4.1. The Chief Executive advised members that, on 13 July, he had attended the first Department of Health led project board meeting in relation to the Triennial Review. The board was also scheduled to meet again on 22 September. A number of stakeholders and Authority members had been contacted and asked to participate in interviews and workshops, and the Chief Executive expressed his thanks to all who had taken part in the process.

4.2. On 17 July, the Chief Executive attended an Association of Chief Executives meeting with Sir Jeremy Heywood, Cabinet Secretary and Head of the Civil Service. On 3 September, he attended the National Information Board (NIB) Leadership summit meeting in Manchester. The Chief Executive reminded members that the NIB was an initiative led by the Department of Health involving all of the health sector's ALBs to make significant changes to the way in which information was used within the health and care system. The HFEA's role was limited given its specialist remit although it was appropriate that it was involved.

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

4.4. National Sperm Bank: the press office had received a lot of calls following reports that the sperm bank had only recruited nine donors.

4.5. Genome Editing: the Chief Executive advised members that there had been a public statement by high-profile scientists, calling for an open debate on genome editing in a treatment context. The Chief Executive emphasised that the so-called CRISPR[1] technique had been legal in a research context in the UK since 2009, although use of such techniques in treatment remain illegal.

4.6. Egg freezing: the Chief Executive advised members that egg freezing had been one of the most popular topics in the press throughout 2015, and it had recently been picked up again by Professor Robert Winston. The HFEA had also received enquiries about the data it held.

4.7. Legal parenthood: the Chief Executive advised members that there had been some press coverage since the judgment by the President of the Family Court granting the families concerned legal parenthood. The cases followed errors made by some clinics in taking consent, after the law had been changed in 2009 to allow the partners of women, who were neither married nor in a civil partnership, and having treatment with donor sperm, to become the legal parent at birth. These hearings had no doubt been very stressful for the families involved and the judgment was clearly welcome news for them.

4.8. As the regulator, the HFEA had worked hard to make sure that clinics understood this complex aspect of the law and, as soon as the first case of this kind had come to light, the HFEA had asked clinics to review all relevant patient records. The HFEA continued to work with the clinics involved to make sure affected patients were contacted and offered the support and advice that they needed. The Chief Executive advised members that the HFEA had also changed its focus on inspection to pay especial attention to consent processes in clinics so as to ensure that they were tightened up where necessary and that staff were properly trained.

4.9. Although the primary responsibility for the errors lay with the clinics concerned, as the regulator the HFEA felt it only right to take responsibility for its role in the matter and had issued a press release to reassure both the patients involved and the public as a whole that the situation was in control. The Chief Executive advised members that he had been interviewed on the Today programme on 12 September and that had been reported in a number of newspapers.

4.10. The HFEA would also review the action it had already taken, alongside the Judge's recommendations, to minimise the risk of this happening again.

5. Committee chairs' updates

5.1. The Chair of the Statutory Approvals Committee (SAC) reported that the committee had met on 30 July and 27 August. There had been four preimplantation genetic diagnosis (PGD) applications in July to consider; three were approved and one was refused. There had been two requests for Special Directions, both of which were granted. In August, there had been four PGD applications and one novel process application, all of which were approved.

5.2. The Chair of the Licence Committee advised members that the committee had met on 16 July and 10 September. At its meeting in July, the committee approved one research renewal application, noted one incident report and two changes to research objectives which had been

[1] CRISPR is a scientific acronym, and stands for 'clustered regularly interspaced short palindromic repeats'.

supported by lay summaries. At the 10 September meeting, the minutes of which had not yet been published, the committee considered four research renewal applications and an initial research application, together with an update following a voluntary revocation.

5.3. The Director of Strategy and Corporate Affairs advised members that the Executive Licensing Panel (ELP) had met five times since the last Authority meeting and had considered one treatment and storage initial licence application, which was granted; four treatment and storage renewal applications, all of which were approved; eight interim treatment and storage inspections, all of which were approved; and ten variations, all of which were approved. ELP also considered one application for Special Directions to extend a research project pending renewal, one voluntary revocation, both of which were granted and, finally, considered one executive update on progress against an initial licence in a new centre.

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 provided an overview of the way in which the HFEA strategy and the 2015/16 business plan were being implemented within the Compliance and Information team. The overarching vision of the HFEA's strategy – high quality care for everyone affected by assisted reproduction – was underpinned by the following functions within the team:

- Setting standards by:
  - Delivering the full compliance cycle to maintain standards for patients
  - Identifying and implementing ways of improving the quality and safety of care
- Increasing and informing choice by:
  - Maintaining the Register of Treatments and Outcomes and supporting clinics in reporting the data
- Efficiency, economy and value by:
  - Modifying the HFEA's way of working to ensure the organisation was responsive, agile, innovative and effective in achieving its strategic and statutory goals.

6.3. The Director of Compliance and Information advised members that the Compliance and Information team was heavily involved in the IfQ programme of work. The inspection year for 2015/16 was also more demanding than the previous year. There was also a full programme of work in processing PGD applications.

6.4. The Director of Compliance and Information informed members that there had been an increase in resilience and capability within the team following an earlier period of turnover. A number of new members of staff had been successfully recruited, with additional resource within the Donor Information team, a strong Business Support team and a full complement of Inspectors.

6.5. The Director of Compliance and Information provided an overview of the PGD application process. The team had experienced a steady increase in the volume of applications, with

applications varying considerably month on month. There had been more applications than usual for this time of year and the team had already processed more applications than in the whole of 2014. Despite activity levels having increased, the applications were still being consistently processed within key performance indicators (KPI) targets, with 100% being processed within 66 days since March. There had also been a steady number of incidents, with between 40 and 50 incidents reported each month.

6.6. The Director of Compliance and Information advised members that, in order to assure the quality of the information held by the HFEA , the Information team carried out two updates of Choose a Fertility Clinic (CaFC) each year, where clinics were required to verify their data. The Information team also played a role in checking the quality of information held at clinics, and the audit team accompanied the inspectors on about 25 inspections a year and reviewed a sample of around 250 patient records at each of those sites. The HFEA also had an obligation to validate its fee income to the National Audit Office (NAO) by checking 1,000 cycles a year to ensure that those cycles reported were carried out.

6.7. The Director of Compliance and Information advised members that the Information team also provided advice and support to clinics, dealing with about 375 email and 85 telephone queries each month. The IfQ programme should help to streamline some of this activity with a much more straightforward system for clinics to interact with.

6.8. The Director of Compliance and Information reminded members that they received a report at their meeting in July on Opening the Register. Members noted that the Donor Information team received on average about 25 applications a month seeking further information, which was a 20% increase on the previous year. In order to improve that experience and outcomes for applicants, the Executive had embarked on a number of policy initiatives, including launching a support service in April 2015.

6.9. The Director of Compliance and Information advised members that the team also provided an IT support service to both clinics and colleagues which included:

- Clinic IT support
  - Running the Electronic Data Interchange (EDI) helpdesk
  - Taking approximately 30 calls per week
- Helpdesk calls for HFEA staff:
  - An ‘office hours’ service to keep the computers and systems running
  - Around 40 formal user generated requests a week
  - Around 25 informal requests a week.

6.10. The Director of Finance and Resources advised members that the Finance team were meeting all of their performance indicators, in particular those on prompt payment and recovery of debts. In terms of the HFEA’s financial position, the strategic performance report included the management accounts as at the end of June 2015. The position at the end of August was quite similar, with the trend of treatment fees being less than expected continuing. There was currently no cause for concern as there had been similar savings on expenditure on salaries in particular, and legal expenses had been less than anticipated.

6.11. Looking ahead to the budget position for the next financial year, the Director of Finance and Resources advised members that the HFEA had not been subject to the spending review requests to model savings of 40% and 25%. Nevertheless, it was still important to look for efficiencies. There was also an uncertainty about the costs for the next financial year and consideration needed to be given to the costs incurred following the office move next spring, and the potential impact on fees, which needed to be increased in 2016 and, over the next month or so, the Executive would be firming up its proposals on how to take that increase forward. Those proposals would be brought to Authority members at their next meeting in November. The Chair emphasised that it was the first time the HFEA had considered raising treatment fee income for many years, and it was unlikely that they would increase substantially.

6.12. The Director of Strategy and Corporate Affairs advised members that, in relation to the strategic performance report, the only issue to note was that there had been a slight reduction in visits to the HFEA website. It was likely that this was, in part, due to communications staff focusing on designing the new website.

6.13. The new refreshed brand identity had been rolled out, making it more clear and recognisable. New leaflets and guidance would be produced incorporating the new identity in time for the alternative parenting show on 19 September and the fertility show scheduled to take place in the first week of November. Both events were an opportunity for the HFEA, as the regulator, to meet prospective patients, donors and recipients of donor gametes face to face, and to provide them with information. The Director of Strategy and Corporate Affairs expressed her thanks to the Communications team for their hard work. The Chair asked for the dates of the alternative parenting show and the fertility show to be advertised on the HFEA website and the Director of Strategy and Corporate Affairs agreed to send a note to members following the shows to provide them with feedback.

6.14. Following a discussion, members noted the presentation and the latest strategic performance report.

7. Regulating mitochondrial donation

7.1. The Chair introduced this item and reminded members that, back in February 2015, Parliament approved Regulations to allow techniques to prevent serious mitochondrial disease. The HFEA had therefore been required to develop a licensing process which would come into effect on 29 October 2015.

7.2. The Policy Manager reminded members that on 29 October, the UK would be the first country in the world to regulate mitochondrial donation for the avoidance of serious mitochondrial disease. This had been a result of extensive work over the last four years, carried out by researchers, campaigners, policy makers and other stakeholders alike. Since the Regulations were passed earlier this year, the HFEA had been tasked with designing a regulatory framework within which the HFEA could put the law into practice. That framework would comprise of three stages that a clinic wishing to offer mitochondrial donation would have to follow. The Policy Manager advised members that the three stages were:

- How to seek approval to carry out mitochondrial donation
- How to run a good quality service

- The clinics' obligations following treatment.

7.3. The Policy Manager advised members that the new regulatory framework would be communicated to clinics on 29 October 2015, when the Regulations came into force. The first stage would be to set out how the clinic would apply to the HFEA to be licensed in order to carry out mitochondrial donation. As with any new treatment, it was important that the treatment must be judged to be safe and effective before it was made available. The HFEA expert panel had considered the safety and efficacy of maternal spindle transfer (MST) and pronuclear transfer (PNT) in three reports and it had recommended that a number of tests should be completed before treatment could be offered. Accordingly, once those tests had been carried out, the panel had been satisfied and the Authority had accepted their recommendations, the formal licensing process could then begin.

How to seek approval to carry out mitochondrial donation

7.4. Before any HFEA-licensed clinic could undertake mitochondrial donation for treatment purposes, it must follow a two-stage process, which had been developed in line with the requirements of the Regulations:

- The clinic would need to apply to vary its licence to include specific permission to carry out MST and/or PNT. Such applications would be considered by the Licence Committee and, if the application was approved, the clinic would be licensed and it would not need to repeat this step unless certain circumstances changed – for example if the clinic wished to seek approval to change its embryologist(s).
- The clinic would need to apply for approval to treat a specific patient. Such applications would be considered by the Statutory Approvals Committee (SAC). This step must be completed for each individual patient, and details concerning this were set out in paragraphs 2.14-2.16 of the paper.

7.5. The Policy Manager advised members that General Directions 0008 set out the necessary evidence needed to support a licence variation and would need to be revised to take into account mitochondrial donation requirements. These directions would require the clinic's Person Responsible (PR) to submit the following evidence:

- Suitable validation of their clinic's equipment and processes
- The clinic's process for monitoring children born following mitochondrial donation (where patients consented to follow-up)
- The competency of the clinic staff and suitability of its premises and processes with specific reference to MST and/or PNT
- The competency of the clinic's MST/PNT embryologist(s)
- Any other information that may demonstrate competency.

7.6. These proposals would require changes to the Authority's Standing Orders, highlighted at Annex two of the paper. Those changes would require a formal vote by Authority members.

7.7. Before the HFEA could issue a licence specifically permitting the clinic to carry out mitochondrial donation, the clinic must acknowledge the licence conditions in the usual manner. The Policy Manager advised members that the new licence conditions specific to mitochondrial donation were set out in paragraph 2.12 of the paper.

Decision

7.8. Following a discussion, members approved, subject to minor amendments:

- The regulatory approach to clinics applying to vary their licence to perform mitochondrial donation
- The individual patient approval process
- The new licence conditions
- The necessary amendments to General Directions 0008 (information to be submitted to the HFEA as part of the licensing process) and revisions to the Standing Orders.

7.9. Members also formally delegated the later amendments to General Directions 0008 and the Code of Practice, to include (but not be limited to) performance indicators for MST/PNT embryologists, to a sub-set of Authority members, in accordance with its powers under section 6.6 of the Standing Orders.

How to run a good quality service

7.10. The Policy Manager advised members that, once a clinic had been licensed to carry out mitochondrial donation and a patient approved for treatment, the clinic would be required to run a good quality service in line with the new regulatory requirements. Putting this in place would entail:

- A registration process
- The use of new consent forms
- A specific, stand-alone Code of Practice guidance note
- Amendments to General Directions.

7.11. The Policy Manager provided an overview of the proposed approach to obtaining patient, partner, and donor consent. The HFEA was proposing to introduce separate consent forms for patients seeking mitochondrial donation and for donors. These forms would reflect the specific information needs of such patients and donors as opposed to standard fertility treatment patients.

7.12. The Policy Manager also asked members to consider an approach to the disclosure of non-identifying information about mitochondrial donors to patients and parents following mitochondrial donation. Members were also asked to consider whether to introduce a similar policy as that for gamete donation, whereby a patient or parent could seek certain non-identifying information about the mitochondrial donor from the clinic or from the HFEA. The HFEA, however, did not propose introducing the same guidance to clinics to encourage the disclosure of that information in the same way as for gamete donation.

Decision

7.13. Following a discussion, members approved:

- The approach for how clinics should run a good quality service, including new guidance, directions, use of new consent forms and the information clinics would submit to the HFEA
- The approach to obtaining consent and the disclosure of non-identifying information
- The mitochondrial guidance note
- Amendments to General Directions 0001 (gamete and embryo donation), 0005 (collecting and recording information for the HFEA) and 0007 (consent).

What to do after treatment

7.14. The Policy Manager advised members that, following treatment, clinics would need to ensure that they continued to comply with their obligations under the new regulatory framework. All clinics would be required to have in place a documented process for monitoring children born following mitochondrial donation, where patients had consented to follow-up. In addition, clinics would need to submit an annual report on patient uptake of follow-up studies and non-patient specific information on the outcomes.

7.15. In relation to the export of MST or PNT eggs or embryos, the Policy Manager advised members that the Regulations did not prevent post MST or PNT eggs or embryos (created following the authorisation by the Authority) from being exported. The Executive felt that the export of post MST or PNT eggs or embryos should not take place under General Directions, but that a specific requirement should be included in General Directions 0006 (imports and exports) to reflect the need for clinics abroad to have equivalent expertise and mechanisms in place. The approval of such an amendment would be delegated to the sub-group of members referred to in paragraph 7.9 above.

7.16. The Policy Manager advised members that consequential changes following the introduction of the new Regulations had been made to the existing guidance in the Code of Practice. These changes were not substantial but were required to ensure accuracy across the Code of Practice.

Decision

7.17. Following a discussion, members approved:

- The regulatory requirements for clinics following mitochondrial donation treatment
- The approach to the export of eggs or embryos
- The consequential changes to the Code of Practice
- Amendments to General Directions 0005 (collecting and recording of information for the HFEA) and 0012 (retention of records).

7.18. It was agreed that, in relation to the approach to follow-up reporting for monitoring children following mitochondrial donation, where patients had consented to follow-up, the Executive should consider this further. Members emphasised that clinics should have robust follow-up mechanisms in place and that patients should be encouraged to consent to the follow-up of children born following mitochondrial donation. The approach would therefore be discussed further and agreed by a sub-group of members.

7.19. Members also approved (with a formal unanimous vote) the necessary revisions to the Standing Orders to take into account the mitochondrial donation approval process at Annex two of the paper.

7.20. Members also voted unanimously for the Standing Orders to be amended to increase the number of members attending the Audit and Governance Committee (AGC) from four to five in order to ensure less risk to quoracy.

8. Business Plan 2016/17: outline objectives

8.1. The Head of Business Planning reminded members of the timetable for the implementation of the 2015/16 business plan and the development of the 2016/17 business plan. The business planning cycle commenced each year in August, with development of the draft plan occurring from September through to December. During October, when the delivery cycle had reached the end of quarter two of the financial year, a review took place to consider progress against the current business plan. This was an opportunity to either re-publish the current plan if any changes were required, or identify what would need to be continued through to the next financial year. The HFEA strategy was also considered, with a three year delivery outline having previously been agreed by the Authority in 2014.

8.2. The Corporate Management Group (CMG) also considered current and future aims, what activities these required and what resources would be needed to deliver them. The Head of Business Planning advised members that, in December, the Department of Health would need to receive a first draft of the business plan for 2016/17, which meant that the draft would be brought to members for consideration at their meeting in November. From January through to April 2016, there would be an iterative process, where discussions took place with the Department of Health about the draft plan, identifying anything that the sponsors or Ministers would like changed or incorporated. The aim was to finalise the plan and associated budget in order for it to be signed off in March and published in April 2016.

8.3. The Head of Business Planning provided members with an overview of the main points and activities proposed for the 2016/17 business plan, which were set out in more detail in the paper. The activities continued to focus squarely on achieving the HFEA's vision of 'high quality care for everyone affected by assisted reproduction'. All the HFEA's statutory work was included (regulation and information provision) and the IfQ programme would be a major part of the plan over the remainder of the current business year and for much of the next. The plan would reflect the HFEA's continued emphasis on being a high-value, high-quality public body.

Decision

8.4. Members approved the outline as a basis for drafting the 2016/17 business plan and noted that the full draft would be presented to them at their meeting in November.

9. Information for Quality update

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

9.2. The Director of Compliance and Information provided an overview of progress thus far. The procurement process of selecting suppliers was now complete and suppliers had started purposefully, working on five outward facing elements of the programme. The HFEA was adopting an Agile methodology. The work had been organised successfully, and three 'sprints' (usually a two week period of activity) had now been completed, including a phase called Discovery+ where users' expectations of the new systems were finalised.

9.3. The Director of Compliance and Information reminded members that the externally facing part of the IfQ programme could not proceed beyond the 'Alpha' stage (proof of concept) until further approvals in line with Government Digital Service standards had been granted by the Department of Health. Alpha stage development had now commenced and was expected to last for eight weeks, with a formal decision expected in November 2015. In advance of that, in order to make the process as smooth as possible, the Executive had been in active discussions with colleagues at the Department of Health who were content to provide informal indications along the way.

9.4. The Director of Compliance and Information provided an overview of managing the key risks. It was acknowledged that the programme was very ambitious in terms of what was being achieved with the available resources. The main contractor, Reading Room, had made good progress. The HFEA's internal teams were also heavily involved in development. Specialist, additional, expertise would, however, be required for certain aspects such as IT security and cloud infrastructure.

9.5. The Director of Compliance and Information reminded members that data migration was a key risk to the programme, with 20 years' of treatment data being transferred to the new Register structure. It has always been emphasised that the HFEA would not implement a new system of data submission until the data migration strategy had been completely satisfied. This commitment inevitably introduced a degree of uncertainty as regards a published timetable for implementation.

9.6. The Director of Compliance and Information advised members that, until the necessary procurement processes and approvals had been completed, together with more detailed planning assumptions, the Executive had not thought it appropriate to put a detailed timetable into the public domain. This position was one supported by the external stakeholder group, who continued to play a vital role in an advisory capacity in the IfQ programme. The Director of Compliance and Information, however, provided members with an indicative timeline which would form the basis for external communications, and would provide clinics with a greater degree of certainty in relation to the impact on them relating to changes in the submission of treatment information.

9.7. The timetable was subject, principally, to Alpha stage approvals being granted. The full implementation of the Clinic Portal would be dependent on data migration progressing successfully. With this in mind, a timetable of February to March 2016 was indicated for 'Beta' versions of the website, Choose a Fertility Clinic (CaFC) and the Clinic Portal (without treatment submission functionality) to be launched, with a live version of the Clinic Portal subsequently being released to those clinics with a direct electronic data interchange (EDI) with the HFEA in October 2016. A slightly longer period of time would be needed for those clinics that used third-party systems.

9.8. The Director of Compliance and Information advised members that the Executive was about to start a process of engagement with clinics so they were aware in advance of the requirement to undertake some data cleansing work. The bulk of this work was expected to take place from October 2015 and completed in the spring of 2016.

9.9. Following a discussion relating to the indicative timeline, members noted that a final timeline would be published in due course. Members also noted:

- The progress made on the IfQ Programme
- That Alpha stage development had now commenced and progression for the externally facing part would be dependent on external approval.

10. Compliance activities 2014/15: a review

10.1. The Chief Inspector advised members that the paper introduced a suite of papers which analysed and commented on the impact of the HFEA's regulatory activities.

10.2. Members were advised that the first four items would be treated as one and a single discussion would take place thereafter on the issues raised. The final paper on the compliance and enforcement policy would be subject to a separate discussion.

10.3. The Chief Inspector reminded members that the HFEA's strategy for 2014-17 signalled an ambition for high quality care for everyone affected by assisted reproduction. Within the boundaries of its statutory remit, the HFEA's regulatory activities were directed to the improvement of the quality and safety of care. It was important that the HFEA, from time to time, scrutinised and challenged its regulatory approach and considered recommendations for improvement.

10.4. The cause and effect of regulatory activities were, however, difficult to measure. It was evident that the existence, production and development of the Code of Practice, which provided a set of rules to guide clinics, together with the prospect of inspection, promoted compliance. In addition to providing guidance, the Chief Inspector advised members that the HFEA also provided a framework for clinics through consent forms and the procedures that were in place for reporting information.

10.5. The Chief Inspector advised members that the HFEA also provided guidance to clinics in general and on a one to one basis, and all clinics had access to a dedicated inspector. Clinic performance was also continually monitored between inspections using a risk tool to flag up performance concerns at individual clinics. Any recommendations made at inspection were also monitored to ensure implementation.

10.6. Taking the limitations of the HFEA's statutory remit into account, the Chief Inspector advised members that the Executive aimed to keep the HFEA's regime under review and to continually evolve its regulatory approach in line with its strategic goals.

10.7. The papers presented to Authority members set out what the HFEA could measure in terms of compliance and an analysis of the outcomes of those measures in terms of success.

11. Compliance activities 2014/15: analysis of risk tool alert data

11.1. The Senior Inspector advised members that the HFEA had been using the risk based assessment tool (RBAT) to enhance the monitoring of clinics between inspection visits since April 2011. Members noted that the risk tool measured performance in relation to the following indicators:

- Outcomes in terms of both clinical pregnancy rates and clinical multiple pregnancy rates
- Submission of critical register information relating to treatments using donor gametes
- Timeliness of payment of monthly HFEA invoices.

11.2. Performance was analysed based on the information submitted to the HFEA by clinics. Where the trend analysis performed by RBAT suggested that there may be a dip in performance, an automated alert was sent to the Person Responsible (PR) and clinics were expected to act on

those alerts to investigate any possible causal factors and take corrective action if appropriate. Inspectors and/or members of the Register Information team also carried out targeted follow-up where appropriate.

11.3. The Senior Inspector advised members that the paper provided an update to the review of RBAT outputs completed in 2014 and aimed to identify trends, establish performance against the benchmark analysis undertaken in 2014, and identify actions for the future in relation to the focus of the HFEA's regulatory interventions.

11.4. The Senior Inspector provided members with an overview of the number and type of alerts issued from the risk tool, which were set out in detail in the paper.

11.5. Members noted that clinics' performance between April 2014 and March 2015 had improved in relation to success rates and timeliness in payment of fees, but had worsened in relation to submission of critical register information. However, it was anticipated that the IfQ programme would have a significant impact on the quality of register submissions.

11.6. Members also noted that alerts relating to success rates showed a more promising pattern, with the number of alerts decreasing in each area, evidence that clinics were taking action to continually improve their success rates.

11.7. The small increase in the number of alerts relating to clinical multiple pregnancy rates in 2014/15 was surprising, since clinics had had since October 2012 to adjust to the 10% multiple live birth rate target. However, data for the sector as a whole showed that in 2013/14, 19 clinics had a multiple pregnancy rate that was likely to be higher than the 10% multiple birth rate target, whilst in 2014/15 this had decreased to 15 clinics. This suggested that clinics were taking action to review the effectiveness of their multiple births minimisation strategies and it was thought that the HFEA's proactive real time monitoring through RBAT had played a role in encouraging this behaviour.

11.8. The Senior Inspector advised members that the HFEA felt the risk tool provided useful and timely information to give to clinics in order to prompt them to review processes and take subsequent action where appropriate. It also helped the inspectorate to focus its activities on quality of service and prompted interaction with specific clinics.

12. Compliance activities 2014/15: analysis of inspection findings

12.1. The Senior Inspector advised members that the paper provided an analysis of non-compliances found in the course of renewal and interim inspections between 1 April 2014 and 31 March 2015, and a comparison with the 2013/14 inspection findings.

12.2. The Senior Inspector provided members with an overview of how the inspection team had been successful in meeting the objective of improving the quality and safety of care through the HFEA's regulatory activities. The analysis was set out in detail in the paper and included:

- 323 recommendations in 2014/15 with 215 having been fully implemented to date
- 185 recommendations to correct higher risk critical and major non-compliances with 137 of those implemented to date.

12.3. Members noted that in post-inspection feedback, 35 of 38 respondents inspected in 2014/15 agreed that inspection had promoted improvement to the way their clinic carried out its work.

12.4. The Senior Inspector advised members that in 2014/15 there had been 59 inspections of treatment and/or storage clinics. It was important to note that, although fewer inspections were carried out in 2014/15 than in the preceding year, there had been a higher proportion of inspections at large clinics compared to 2013/14 and a lower proportion at treatment only clinics. Large clinics tended to provide more complex treatments and, as a result, were subject to compliance with more requirements than treatment only clinics.

12.5. Members noted that there had been an increase in critical non-compliances in 2014/15. Recommendations to address all these critical non-compliances had all been fully implemented. The main reasons for this increase in critical non-compliance were:

- Inspection of different areas, including surgical procedures
- Repeat non-compliance at the same clinic upgraded from major to critical
- Sporadic or repeat non-compliance at different clinics, including storage consent and counselling.

12.6. The Senior Inspector provided an overview of some common reasons for non-compliance, which included changes of staff, premises and equipment and processes in clinics, together with understanding of the Code of Practice not being sufficiently widespread within the clinic.

12.7. The Senior Inspector advised members that the HFEA would continue to promote compliance by:

- Developing effective methodologies to inspect clinics in a focused and proportionate manner
- Monitoring the implementation of recommendations made on inspection
- Requiring clinics to have an effective quality management system and, specifically, effective audit procedures, to ensure their compliance and assure the effectiveness of improvements
- Providing advice on the Code of Practice requirements
- Liaising across the HFEA to develop regulatory tools and to flag concerns where clarity was needed relating to existing requirements
- Liaising with other regulators to clarify requirements
- Liaising with, and informing the sector, through the annual conference, workshops and clinic visits to promote knowledge of the Code of Practice requirements and to promote a culture of compliance.

12.8. Members noted that levels of compliance remained high, and the non-compliances identified during inspection related to either high risk or complex areas of practice. Inspections continued to adapt to the regulatory landscape and clinics were clearly making improvements prompted by the HFEA's regulatory activities. Post inspection feedback supported a conclusion that inspection visits led to improvements in service delivery and patient care.

13. Compliance activities 2014/15: clinical governance learning and culture

13.1. The Clinical Governance Inspector advised members that an estimated 1% of the 60,000 cycles of IVF treatment that were carried out in the UK each year were affected by some sort of adverse incident. The HFEA's definition of an adverse incident was 'any event, circumstance, activity or action which has caused, or has been identified as potentially causing harm, loss or damage to patients, their embryos or gametes and also to staff at licensed clinics.'

13.2. The Clinical Governance Inspector advised members that clinics had a statutory duty to report and analyse the cause of incidents. Similarly, the Authority had a duty to investigate and take appropriate control measures in relation to reported incidents. Reported incidents were graded using an incident grading matrix, taking into account the severity of the outcome, the potential outcome and the likelihood of it happening again. 'A' grade incidents were considered the most serious and when one was reported to the HFEA, the clinic was immediately contacted to obtain more information, in light of which the team would agree what action needed to be taken. An incident inspection was also carried out in order to ascertain why the incident happened and identify action needed to minimise the risk of a similar incident happening in the future. Following this inspection, and after the clinic had completed its own investigation, the HFEA produced a root cause analysis report. This information was then presented to the HFEA's Licence Committee which decided if any further regulatory action needed to be taken.

13.3. The Clinical Governance Inspector provided an overview of incidents reported to the HFEA over the previous five years. Members noted that the number of incidents had remained fairly static, and it was disappointing to note that the number of administrative, more avoidable, incidents had also remained static. In October 2010, the decision had been taken to publish 'A' grade inspection reports and Licence Committee minutes on the HFEA website. There had been some concern in the sector that such publication might be seen as a punitive measure and make clinics reluctant to report serious incidents, although it appeared that this had not, in the event, been the case.

13.4. The Clinical Governance Inspector advised members that the HFEA published its first incident report in July 2014, covering the period between January 2010 and December 2012. The report described a number of lessons learned and provided examples of improvements that had been made by clinics following incidents. In December 2014, the HFEA published its first annual incident report, which covered 2013 data, and the report covering 2014 data was due to be published today.

13.5. The analysis of the 2014 data showed that:

- Avoidable incidents were still happening, which was a recurring theme within the wider healthcare setting
- Clinics were not always conducting robust investigations or taking the incidents seriously and they must improve the quality of their investigations.

13.6. The Clinical Governance Inspector provided members with an overview of how the HFEA intended to address this. The aim was to encourage clinics to take responsibility for their own improvement. These actions included:

- Working with clinics collectively (workshops, Clinic Focus articles, annual Incidents Report)

- Working with clinics on a one to one basis to encourage them to fully engage with incident investigations
- Re-focusing inspections to look for evidence that clinics had actually learned from incidents and audits and had acted on guidance.

13.7. In summary, the Clinical Governance Inspector advised members that the HFEA aimed to keep its processes under constant review and to establish collaborative working relationships with NHS Improvement, to ensure that wider learning from colleagues working in patient safety in a healthcare setting fed into the HFEA's own ways of working. Members noted that the HFEA was:

- Seeking to influence the culture in licensed clinics so they developed an embedded learning and safety culture
- Aiming to ensure that the work of the organisation on incident oversight read across to its inspection activities.

Decision

13.8. Following a discussion, particularly around the impact of staffing levels in clinics in relation to their ability to carry out treatments effectively, members:

- Noted the papers and evidence
- Agreed with the current regulatory focus and approach
- Confirmed the future direction of the HFEA's regulatory activities
- Asked the senior management team to consider members' comments and provide an update to Authority members at a later date.

14. Compliance and enforcement policy review

14.1. The Chief Inspector advised members that the Compliance and Enforcement Policy was largely effective. The policy had been in force since 2009 and set out the actions the Compliance team should take to ensure compliance by licensed centres. The policy was part of a suite of documents which also included the Indicative Sanctions Guidance and Applications Guidance.

14.2. The proposals and recommendations for the update of the suite of documents were based on learning from recent experiences, and feedback from Authority members and committee Chairs, on the factors that should be taken into account when considering regulatory sanctions.

14.3. Minor changes were also recommended in order to:

- Rationalise the practical sequence of events
- Set out when a report would be drafted and presented to the Executive Licensing Panel or Licence Committee
- Clarify that forensic scrutiny of a clinic's practices may be undertaken when considered necessary.

14.4. The Chief Inspector advised members that revisions to the applications guidance were also required in order to:

- Emphasise the importance of the licence history that was considered

- Make risks to safety of patients, embryos or gametes central to consideration
- Consider the quality of service
- Take into account the extent to which the PR demonstrated an understanding of the need for improvement, and a commitment to improvement.

14.5. Indicative Sanctions guidance should be aligned with key risks and should be clearer that the following would be considered aggravating factors:

- Failure to ensure the safety of patients, their gametes or embryos
- The PR ceasing to be considered a suitable person
- Failure to ensure suitability of staff, or the use of proper equipment, or the suitability of premises.

14.6. The Chief Inspector advised members that the revised policy would be subject to a focused consultation and would be piloted in the next three months. Final recommendations and proposals would then be referred to the Authority in early 2016 prior to implementation in April 2016.

Decision

14.7. Following a discussion, members agreed in principle to:

- The proposals for the revision of the Compliance and Enforcement Policy and supporting documents
- A focused consultation with the sector, stakeholders and legal advisors
- The proposal that the Licence Committee and the Executive Licensing Panel would pilot the use of the guidance
- The plan to submit the final policy to the Authority in early 2016 with implementation from April 2016.

15. Any other business

15.1. The Chair confirmed that the next meeting would be held on 11 November 2015 at ETC Venues, Hatton Garden, 51-53 Hatton Garden, London, EC1N 8HN.

16. Chair's signature

16.1. 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 (11/01/2015) 773		
Meeting date	11 November 2015		
Author	Paula Robinson, Head of Business Planning		
Output:			
For information or decision?	For information		
Recommendation	The Authority is asked to note and comment on the latest strategic performance report.		
Resource implications	In budget		
Implementation date	Ongoing – strategic period 2014-2017		
Communication(s)	CMG reviews performance in advance of each Authority meeting, and their comments are incorporated into this Authority paper. The Department of Health reviews our performance at each DH Update meeting (based on the CMG paper). The Authority receives this summary paper at each meeting, enhanced by additional reporting from Directors. Authority's views are fed back to the subsequent CMG performance meeting.		
Organisational risk	☐ Low	☒ Medium	☐ High
Annexes	Annex 1: Strategic performance report		

1. Introduction

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

1.2. Most of the data relates to the position at the end of August 2015. The financial data, however, has been updated since CMG to show the position at the end of quarter two of the financial year (ie, the end of September). We have also recently reviewed the indicators for the IfQ programme, since we are now progressing through the alpha phase of the work, so the IfQ performance data also includes September.

1.3. Overall performance is good, 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.

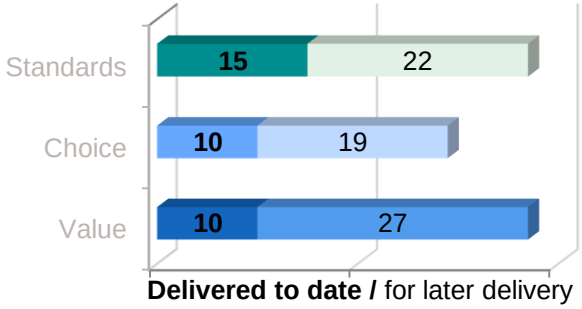
Annex A - HFEA strategic performance scorecard

1. Summary section

Dashboard – August data

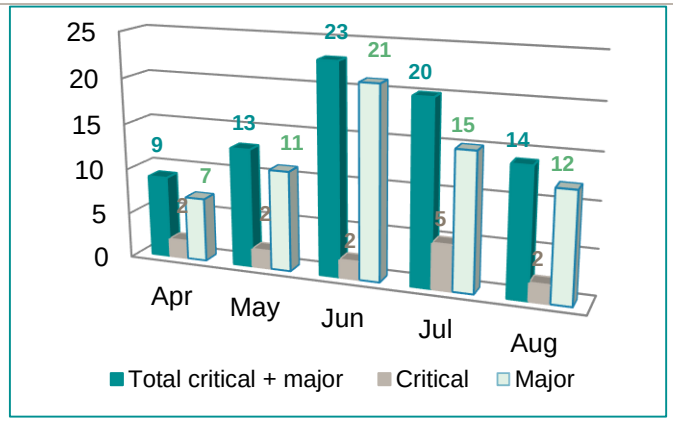
Strategic delivery totaliser

(see overleaf for more detail)



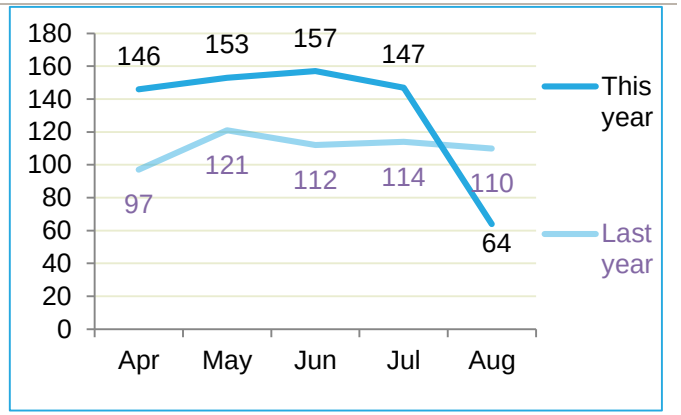
Setting standards:

critical and major recommendations on inspection

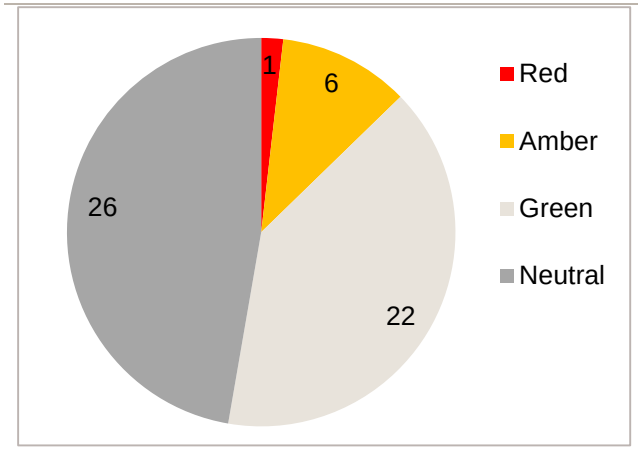


Increasing and informing choice:

public enquiries received (email)



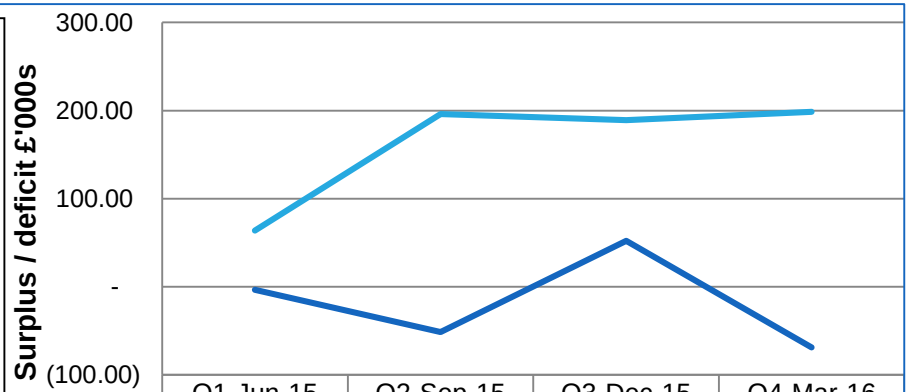
Overall performance - all indicators:



(See RAG status section for detail.)

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

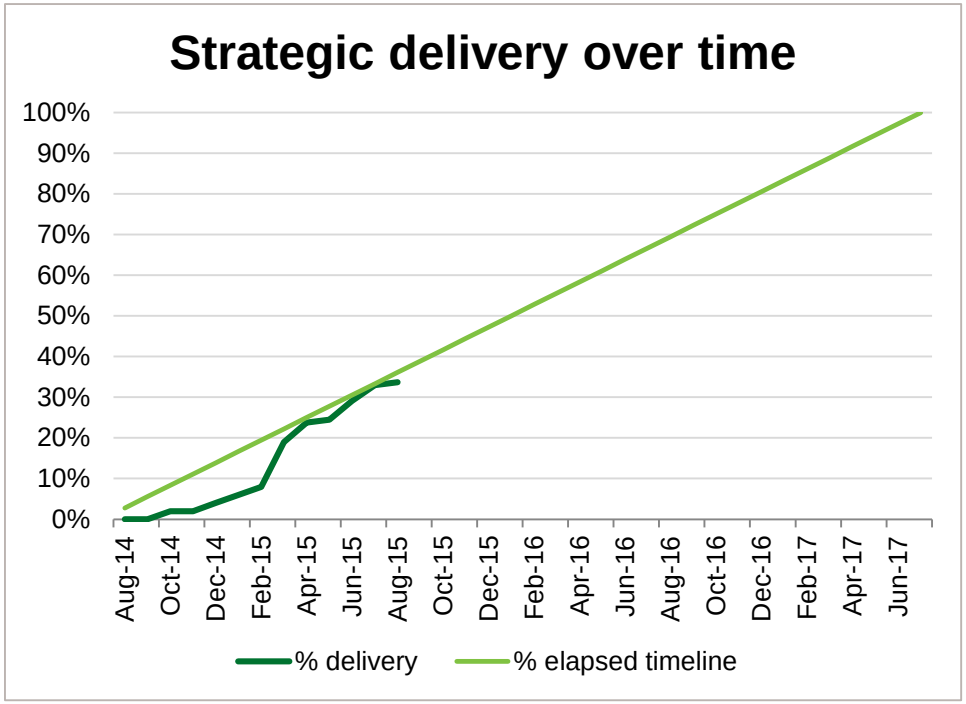
This graph details our overall position as at 30 September 2015 (Q2) and our forecast position as at 31 March 2016. The components making up the surplus/deficit are shown by two other graphs (income and expenditure), in the budget status summary in the commentary section below.

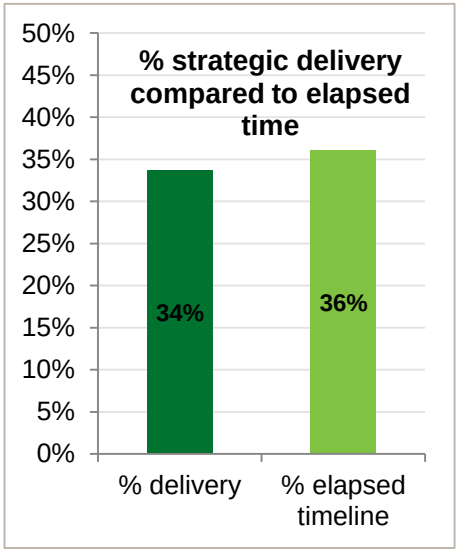


	Q1-Jun-15	Q2-Sep-15	Q3-Dec-15	Q4-Mar-16
Budgeted surplus/deficit	(3.54)	(51.28)	52.14	(68.66)
Forecast surplus/deficit	63.87	196.01	189.28	198.43

Dashboard - Commentary

Strategic delivery (to end of August) – summary:





Strategic delivery in August

We are broadly on track, but there was little progress (in August) in delivering the items that are listed in the strategic deliver calendar, which underpins these graphs. Crucially, however, this picture does not yet reflect the main IfQ sprint products and milestones, because this has not yet been possible. Now that we are progressing through the Alpha stage, the intention is to translate the emerging IfQ plan into more calendar delivery items. This will be done within the next month.

Setting standards

No deliverables were due to be completed in August. Various pieces of important project work were progressed, including, notably the mitochondrial donation project, and the project to review and update the text of the One at a Time section of the website, to reflect our latest report on the minimisation of multiple births.

Increasing and informing choice

No deliverables were due to be completed in August. The work to redevelop the website has been behind schedule as a result of earlier approval delays, but is now going well. Development work has started in earnest, following the earlier Agile sprints to complete the detailed user research.

Efficiency, economy and value

The original plan indicated that the Alpha phase would conclude in August. In fact, owing the earlier approval delays referred to above, Alpha commenced in September.

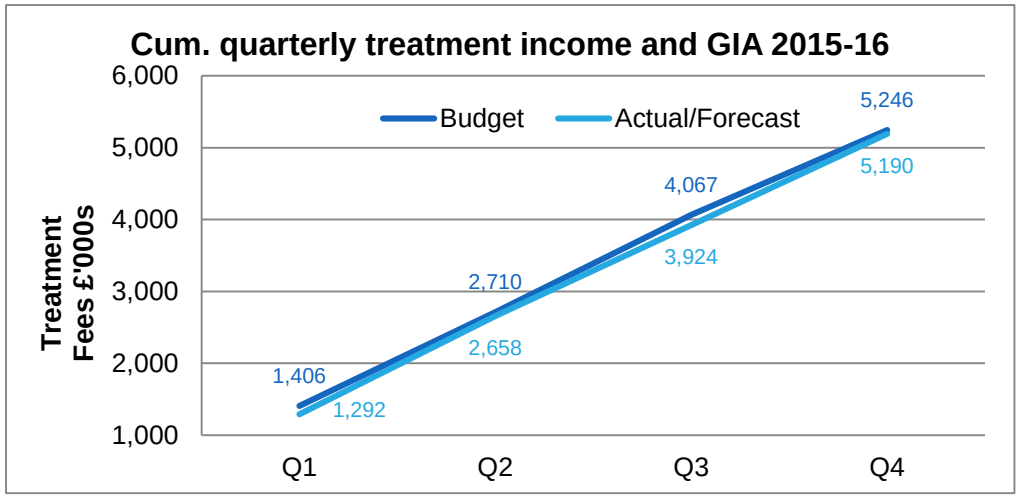
Red/amber/green status of performance indicators

The red key performance indicator (KPIs) shown in the 'overall status - performance indicators' pie chart on the dashboard is as follows:

In August, performance on the average number of working days from day of inspection to the day the draft report is sent to the PR was at 70%, compared with a KPI of 90% in 20 working days. Three reports were delayed (taking between 21 and 28 working days).

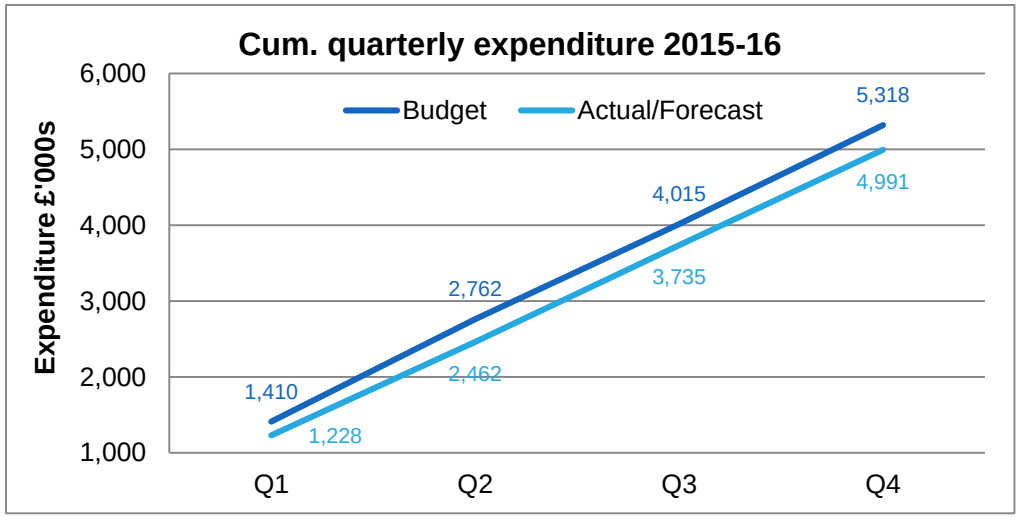
Budget status

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 the second quarter of the year (30/9/15) we are not far off our budget (a shortfall of only £49k). We continue to monitor treatment fees as the trend continues to be downward.



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.

We are currently under spending against budget (£200k) which is relative to our reduced income. The underspend has been added to by inclusion of receipts of £90k from legal cases where we were awarded costs. Our year end forecast is showing an under spend of £177k. This position will change as more information is known and on-going pieces of work are completed.

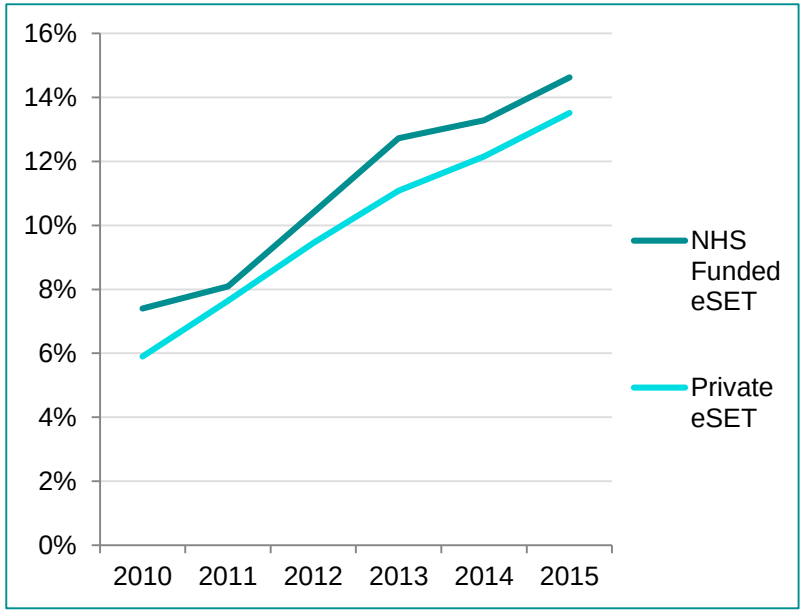
Quality and safety of care

The following figures and graphs were run on 8 October 2015.

ESET split by private/NHS:

Funding	Year					
	2010	2011	2012	2013	2014	2015
NHS Funded:						
Recorded as eSET	4294	4903	6264	7868	8439	7100
	7%	8%	10%	13%	13%	15%
Not recorded as eSET	19284	19492	17868	17720	17832	12746
	32%	30%	29%	28%	26%	33%
Private:						
Recorded as eSET	3422	4629	5696	6854	7719	6614
	6%	8%	9%	11%	12%	14%
Not recorded as eSET	31018	31545	30400	29388	29514	21803
	53%	52%	50%	48%	46%	45%

Graph: eSet % trends NHS/private:

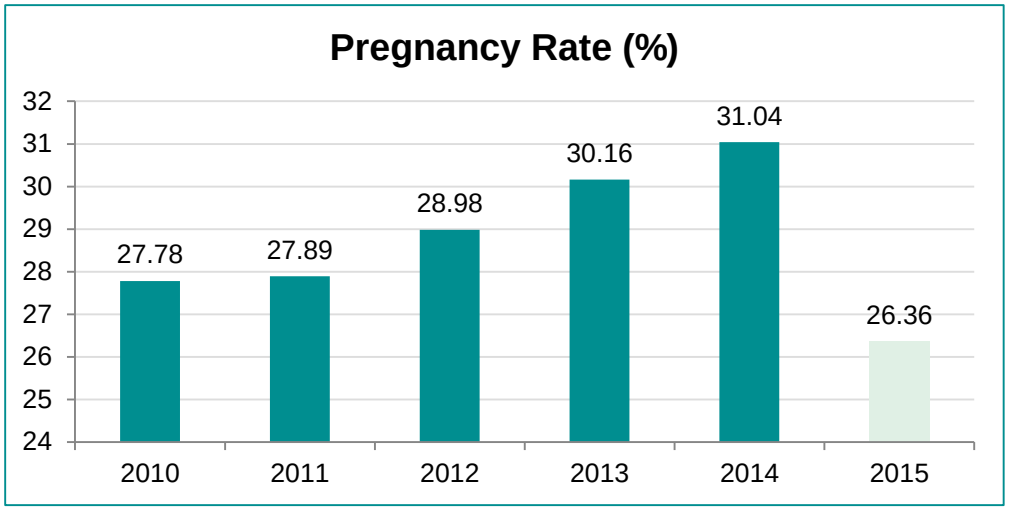


Explanatory text: Looking at all IVF treatment forms; counting those records that the clinics recorded as eSET.

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

Years	All cycles	Pregnancies	Pregnancy rate
2010	58018	16117	27.78
2011	60569	16895	27.89
2012	60228	17453	28.98
2013	61830	18647	30.16
2014	63504	19714	31.04
2015 (partial)	48263	12720	26.36

Graph showing the pregnancy rate over recent years:



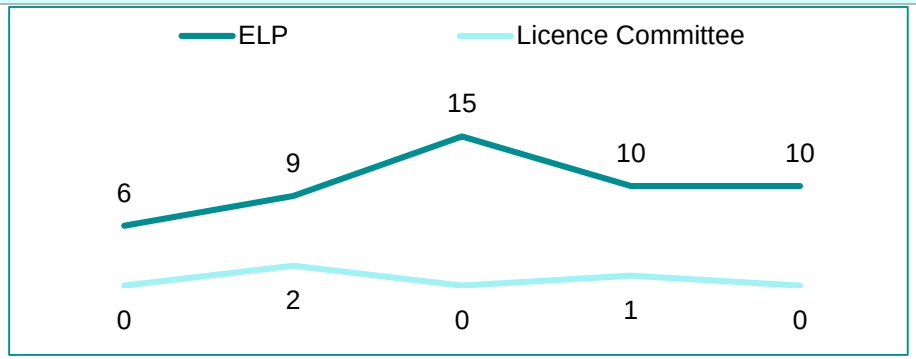
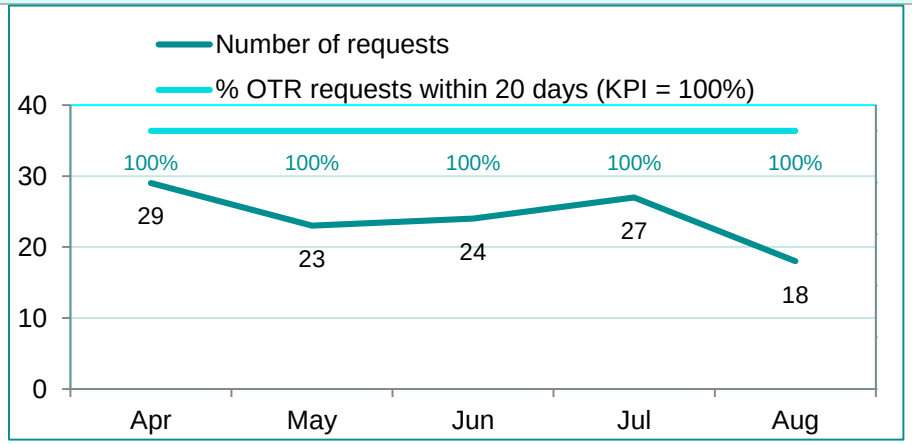
Explanatory text: Looking at all IVF treatment forms, and providing a count of pregnancies - as recorded on the early outcome form.

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:

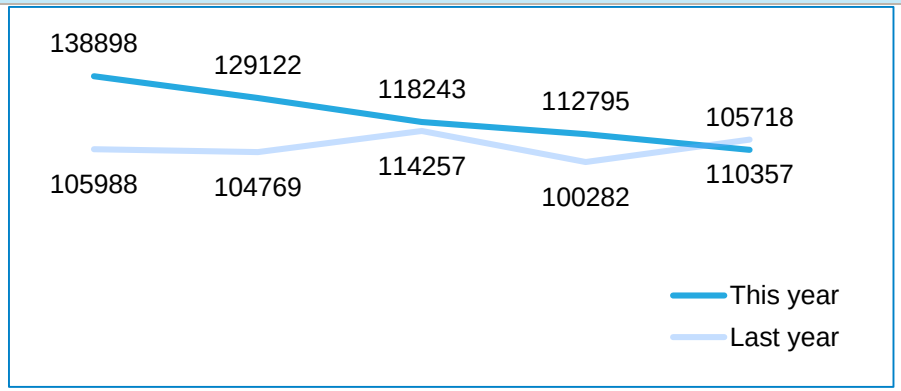
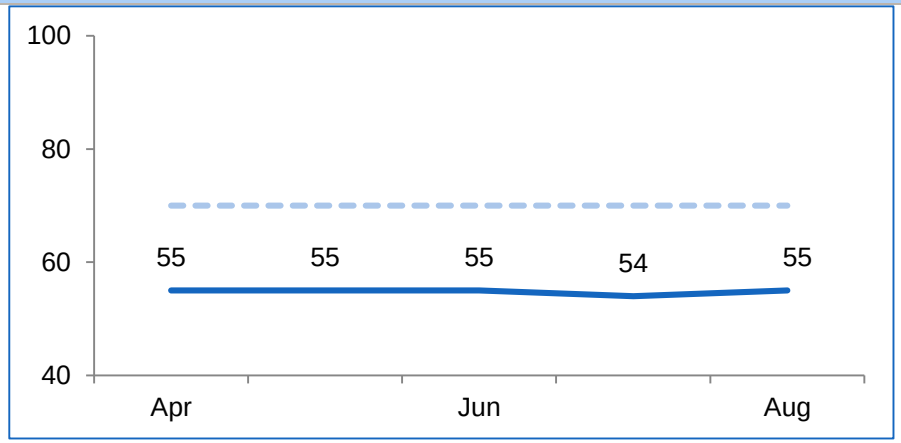
- number of risk tool alerts (and themes)
- common non-compliances (by type)
- incidents report (and themes).

2. Indicator section

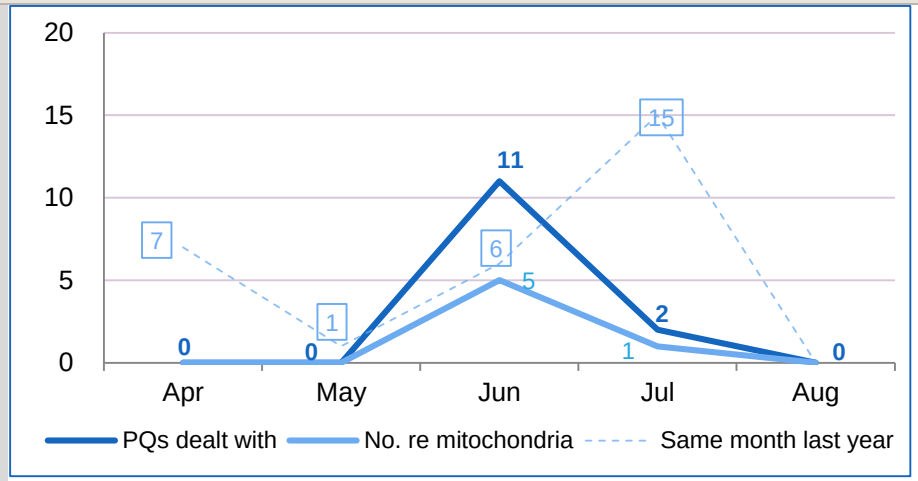
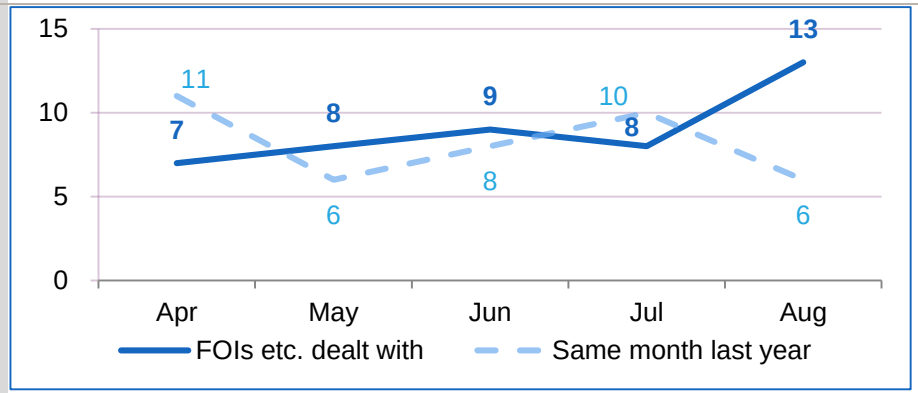
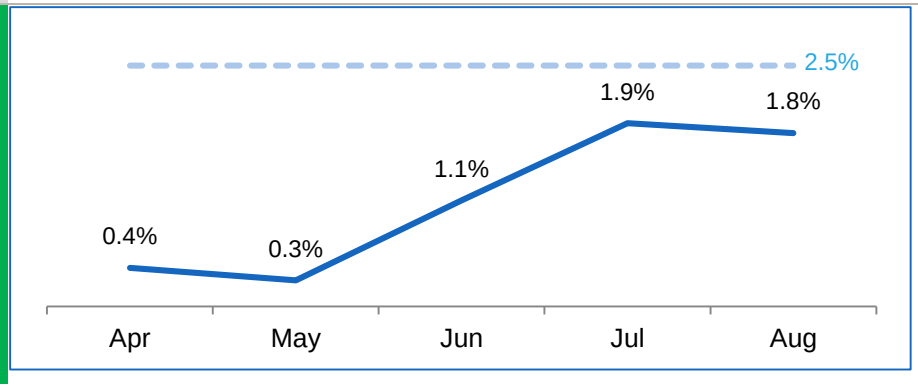
Key performance and volume indicators – August data:

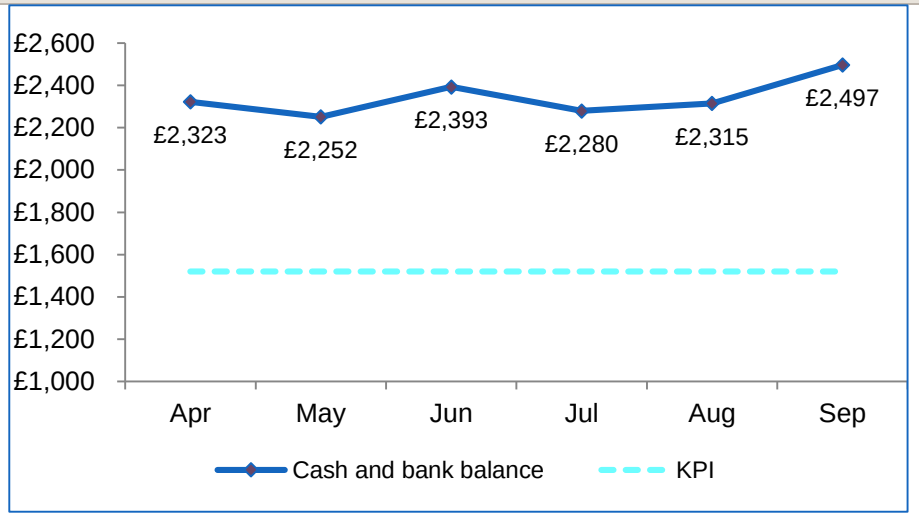
Indicator	Performance	RAG	Recent trend[1]	Aim[2]	Notes
Setting standards: improving the quality and safety of care through our regulatory activities.					
Licensing decisions made: - **By ELP** - **By Licence Committee**	10 0	⇩		No KPI – tracked for workload monitoring purposes	Volume indicator (no KPI target).
Setting standards: improving the lifelong experience for donors, donor-conceived people, patients using donor conception, and their wider families.					
Percentage of Opening the Register requests responded to within 20 working days	100% (18)	★		Maintain at 100% ↑	KPI: 100% of complete OTR requests to be responded to within 20 working days (excluding counselling time) The dip in August reflects the summer holiday period.

[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 (cw previous year)	105,718 110,357	⇩		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'.
			We are researching the downward trend that has become evident in the past six months, which could be attributable to multiple factors. Possibilities include poor performance of the website for the increasing number of users accessing via a mobile device (an issue which will be addressed by our new website); occasional reliability problems with our current content management system (which will be replaced as part of the IfQ work) and the fact that IfQ work on the new website means that staff are updating the existing website less often and are doing less proactive communications which would increase visitors to the website.		
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.	55 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%	★	100% 100% 100% 100% 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.	52	★	44 47 45 47 52		
Annualised (rolling year) percentage of PGD applications processed within three months (66 working days)	96%	⇧	91% 92% 93% 96% 96% (100%)	Reach and maintain 100% ↑	KPI: As above. (Annualised score). Performance has reached target, but the annualised figure is still being adversely affected by complex multi-type applications received during the rolling year, which take longer to process.
Average number of working days taken.	49	★	52 51 50 48 49		

Indicator	Performance	RAG	Recent trend[1]	Aim[2]	Notes
Number of requests for contributions to Parliamentary questions	Total = 0 (recess)	⇩		No KPI – tracked for general monitoring purposes.	Volume indicator. The number received in January 2015 was nine times that received in January 2014.
Number of Freedom of Information (FOI), Environmental Information Regulations (EIR) requests and Data Protection Act (DPA) requests	13	⇧		No KPI – tracked for general monitoring purposes.	Volume indicator.
Staff sickness absence rate (%) per month.	1.8%	★		 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%).

Indicator	Performance	RAG	Recent trend[1]	Aim[2]	Notes
Cash and bank balance	£2,497k	⇧		 Reduce	KPI: To move closer to minimum £1,520k cash reserves (figure agreed with DH).

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

Management accounts:

September accounts (end of quarter two):

Income & Expenditure Account — Sep-2015

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	560	560	-	1,120	1,120	-
Licence Fees	2,098	2,147	- 49	4,070	4,120	- 50
Other Income	53	3	50	56	6	50
Total Income	**2,711**	**2,710**	**1**	**5,246**	**5,246**	**0**
Revenue costs - Charged to Expenditure						
Salaries	1,800	1,896	- 96	3,709	3,807	- 98
Other Staff costs	114	127	- 13	251	258	- 7
Authority/Committee costs	80	86	- 7	162	166	- 4
Other Compliance costs	28	20	8	58	39	19
Other Strategy costs	44	99	- 55	178	175	3
Facilities costs incl non-cash	171	180	- 9	343	355	- 12
IT costs costs	49	53	- 4	106	106	-
Legal costs	133	267	- 134	257	340	- 83
Professional Fees	44	33	10	78	68	10
Total Revenue costs	2,462	2,761	- 299	5,141	5,314	- 173
Total Surplus/(Deficit) before Capital & Project costs	**249**	**- 51**	**300**	**104**	**- 69**	**173**
Capital & Project - Reserves funded						
IFQ	213	416	- 203	935	1,135	- 200
Donor Support	8	7	1	20	20	-
Other Capital costs	-	-	-	100	100	-
TOTAL NET ACTIVITY	**221**	**422**	**- 202**	**1,055**	**1,255**	**- 200**

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

Commentary: Summarised management accounts September 2015 – commentary

Income

Treatment fee income up to the end of September is approximately 2% less than expected and we continue to keep a close eye on this. Grant-in-aid drawn down is on budget (the shortfall from April has been rectified in September). The forecast income reflects the earlier shortfall on treatment fees and the unexpected legal award made.

Expenditure

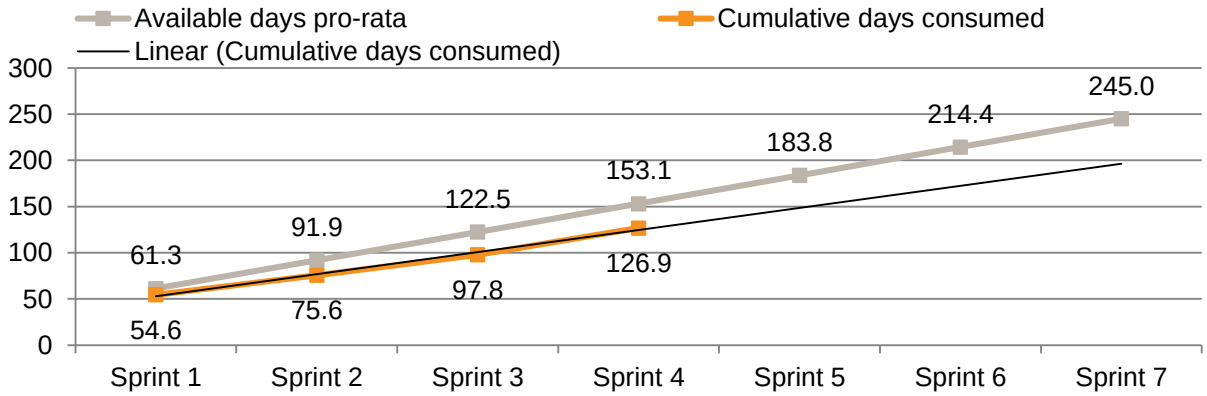
Year to date expenditure is almost 11% below budget at the end of September. Legal costs are less than expected at this point in the year and the salary budget is underspent, due to vacancies.

A detailed review of likely spend for the remainder of the year was conducted after the end of quarter two and the forecast reflects the current expectation. Before spend on IfQ, we are forecasting overall expenditure to be 3% lower than what we have budgeted. The main area of expected underspend is salaries (2.6%). Legal costs to date have been reduced by the receipt of costs of £30k awarded from one case and the forecast includes a second receipt of costs of £10k. However new legal challenges may cause us to revise legal expenditure upwards over the coming weeks.

IfQ and other project costs

Spend has been slower than expected and there is a year to date underspend of 48% (£202k). Likely expenditure for the rest of the year has been reviewed and re-profiled. We expect that £200k (18%) of the total £1,135k will now be spent in 2016/17. We have informed the Department of Health of this development.

IfQ indicators: September update for Alpha 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?	**September:** The annual health check is scheduled to commence in October.
Monthly	Timescales: burndown chart showing remaining estimate of work.	Is there scope creep/over-run?	**September:** Meaningful data is not available at this stage (Alpha). Over the first four sprints, the team has adopted a new system for monitoring sprint delivery and has also been adjusting to the process of estimating the required hours for tasks. To commence from Beta.
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.	**September:** Reading Room is operating under a capped contract, meaning the contracted outputs are required to be delivered irrespective of any potential over utilisation of hours. However it is still in the best interest of both the HFEA and Reading Room to ensure that the rate of resource usage is appropriate. At this stage, it is considered appropriate, with the cumulative rate of days consumed being slightly below the pro-rata rate of available days. 

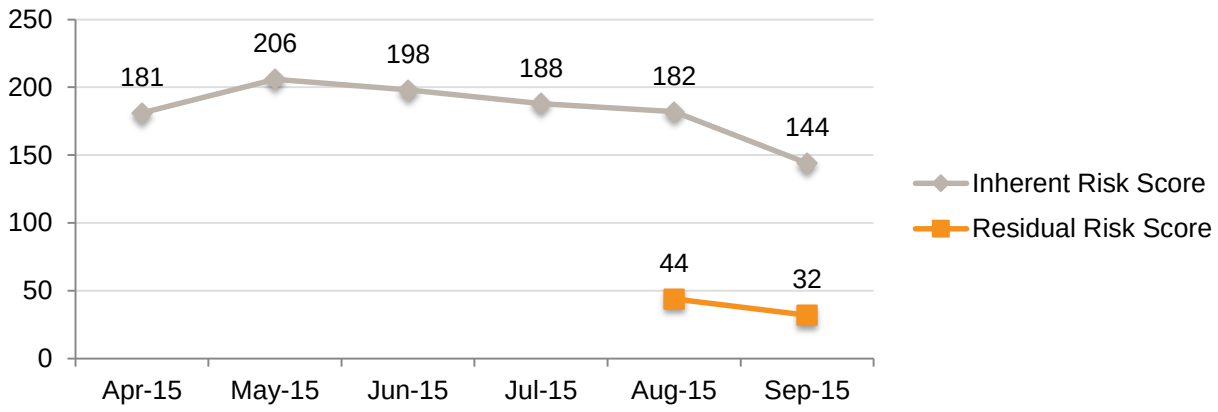
<table>
<tr><th>Frequency / trigger point</th><th>Metric</th><th>Purpose</th><th>Latest status:</th></tr>
<tr><td>Monthly</td><td>Cost: earned value (% complete * estimated spend at completion)</td><td>Is the spend in line with milestone delivery?</td><td>There are four things we can attribute value to: websites and CaFC; Clinic Portal; the Register and internal systems; defined dataset, discovery, stakeholder engagement etc. Currently, 25% of the value of the £1.8M programme cost at completion has been attributed to each project.

September: The earned value is increasing and a significant milestone will be in the next period when Alpha will be completed.

Earned value
<table><tr><th>Project</th><th>Apr-15</th><th>May-15</th><th>Jun-15</th><th>Jul-15</th><th>Aug-15</th><th>Sep-15</th></tr><tr><td>Websites and CaFC</td><td>0.25%</td><td>2.50%</td><td>3.00%</td><td>3.75%</td><td>3.75%</td><td>4.25%</td></tr><tr><td>Clinic Portal</td><td>0.25%</td><td>2.50%</td><td>3.00%</td><td>3.75%</td><td>3.75%</td><td>4.25%</td></tr><tr><td>Register and internal systems</td><td>0.50%</td><td>1.25%</td><td>1.75%</td><td>2.00%</td><td>2.50%</td><td>3.00%</td></tr><tr><td>Discovery</td><td>25.00%</td><td>25.00%</td><td>22.50%</td><td>23.75%</td><td>25.00%</td><td>25.00%</td></tr><tr><td>IfQ Total earned value</td><td>26.00%</td><td>31.25%</td><td>30.25%</td><td>33.25%</td><td>35.00%</td><td>36.50%</td></tr><tr><td>% of spend to date</td><td>37%</td><td>38%</td><td>39%</td><td>43%</td><td>43%</td><td>44%</td></tr></table></td></tr>
<tr><td>Monthly</td><td>Quality: category A requirements dropped or postponed during this period</td><td>Are key requirements being lost from the programme which could trigger a change in the business case?</td><td>September: No key requirements lost.</td></tr>
</table>

Frequency / trigger point	Metric	Purpose	Latest status:
Monthly	Stakeholder engagement: combined stakeholder engagement score	Are we keeping stakeholders with us? Is it getting better or worse?	**September**: In terms of internal stakeholder engagement, there was a spike in IfQ intranet page views across the period July to August, with a slightly declining trend from that peak in following months.

	June 16 - July 15		July 16 - Aug 15		Aug 16 - Sept 15		Sept 16 - Oct 15	
	Page views	Unique	Page views	Unique	Page views	Unique	Page views	Unique
IfQ Homepage	0	0	60	27	45	20	30	14
Juliet's Blog	30	23	9	9	11	10	3	3
IfQ Blog 1	0	0	22	7	6	5	7	5
IfQ Blog 2	0	0	5	3	7	7	4	4
IfQ Blog 3	0	0	0	0	10	10	4	2
IfQ Blog 4	0	0	0	0	10	7	8	5
IfQ Blog 5	0	0	0	0	0	0	9	7
IfQ Blog 6	0	0	0	0	0	0	4	3
IfQ Glossary	0	0	0	0	0	0	10	6

Monthly	Risks: sum of risk scores (L x I)	Is overall risk getting worse or better (could identify death by a thousand cuts)?	

Frequency / trigger point	Metric	Purpose	Latest status:
			September: Key areas of risk for the IfQ programme remain centered on data migration work, in particular regarding decisions about timing for cleansing and migrating 'must' and 'should' data, and striking an appropriate balance with achieving sufficient quality. These risks are being proactively managed, with IfQ Programme Board reviewing the details of the work in August, and deciding appropriate resourcing and timing parameters for the work in September. A second key area of risk for the IfQ programme has been determining the delivery and resourcing plan to support the required internal systems work. A key milestone for addressing this area of risk has been achieved since the last AGC update through finalising the IfQ programme plan.
Quarterly	Benefits: value (£) of tangible benefits planned to the delivered by the programme	Is the value of the benefits increasing or decreasing – could trigger a review of the business case?	**September:** Reporting is expected to be able to commence from the Beta stage onwards.

Draft business plan 2016/17

Strategic delivery:	☒ Setting standards	☒ Increasing and informing choice	☒ Demonstrating efficiency economy and value
Details:			
Meeting	Authority		
Agenda item	7		
Paper number	HFEA (11/11/2015) 774		
Meeting date	11 November 2015		
Author	Paula Robinson, Head of Business Planning		
Output:			
For information or decision?	For decision		
Recommendation	The Authority is asked to approve the draft business plan at its current stage of development, and to note that a draft will be submitted to the Department of Health before the end of December.		
Resource implications	In budget.		
Implementation date	Throughout 2016/17 business year.		
Communication(s)	Publication on HFEA website and Intranet.		
Organisational risk	☒ Low	☐ Medium	☐ High
Annexes	Annex 1: Draft business plan for 2016/17		

1. Background

1.1. The Authority agreed an outline of the new business plan for 2016/17 at its September meeting. Our business plans are designed to help us deliver our overall strategy, year by year, and this will be our second business plan since the strategy was published in August 2014.

1.2. As a reminder, the business planning cycle consists of the following main steps:

August	–	Early thinking by CMG (done)
September	–	Authority agreed indicative outline (done)
October	–	First draft of 2016/17 business plan produced (done)
November	–	Draft approved by Authority (this meeting)
December	–	Draft submitted to Department of Health (DH)
January	–	DH comments received
February	–	DH checkpoint meetings and budget discussions
March	–	Finalisation with Authority and DH
April / May	–	Formal DH approval and publication on website.

2. Early draft

2.1. This draft follows the same basic template as the current (2015/16) business plan, which was redesigned last year to correspond with our strategy. The content is based on the outline plan agreed in September.

2.2. Some sections of the business plan are not written until later in the business year – these are:

- What we did in 2015/16
- Measuring our performance
- Financial picture.

2.3. The activities set out in the main section (delivering our strategy in 2016/17) will still require some further refinement with staff over the next few months.

3. Recommendation

3.1. The Authority is asked to approve the draft at Annex A for submission to the Department of Health in December (or when requested).

3.2. The Authority is asked to note the steps involved in the continuing development of the business plan. If major changes are made to the attached version prior to submission to DH, the new version will be circulated to members for comment.

3.3. The Authority is also asked to note that CMG has reviewed delivery of the current (2015/16) business plan. We always do this after the end of quarter two, and in some business years it is necessary to publish a mid-year revision of the business plan. However this only applies if something of note has changed (additional activities, altered timelines, and so on). This year there is no need for any revision.

Human Fertilisation & Embryology Authority

Annex A

Business Plan

2016/17

www.hfea.gov.uk

Contents

Our role and strategic aims

Who we are

The HFEA is the regulator of fertility treatment and human embryo research in the UK. Our role includes setting standards for clinics, licensing them, and providing a range of information for the public, particularly people seeking treatment, donor-conceived people and donors.

Our vision for 2014–2017 is:

High quality care for everyone affected by assisted reproduction.

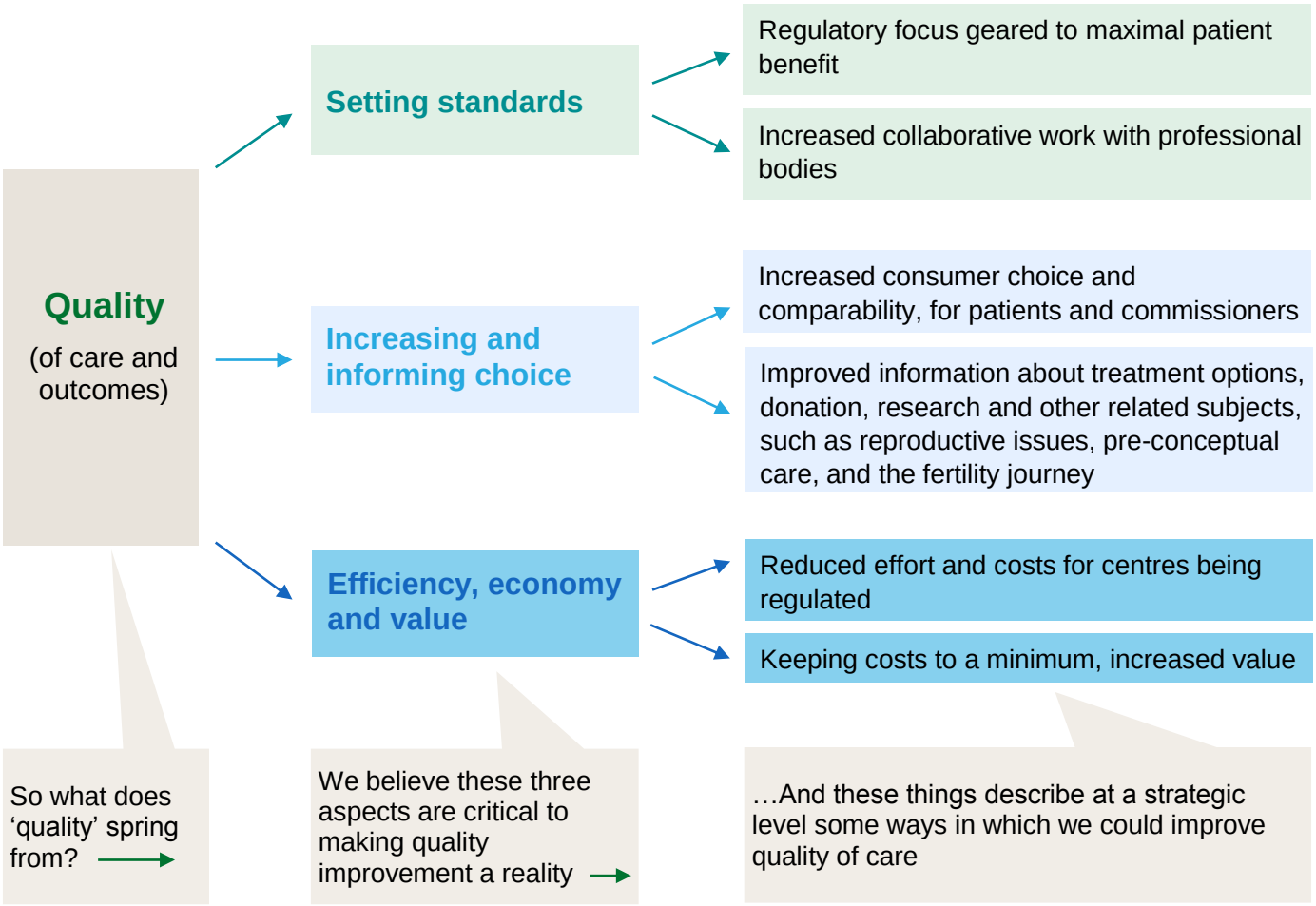
High quality care means…	• safe, ethical and effective care and treatment.
Everyone affected means…	• patients and parents • all those conceived through assisted reproduction • donor-conceived people • egg and sperm donors • clinic staff.
Assisted reproduction means…	• standard fertility treatments • genetic testing and new treatments • innovations in research.

This business plan sets out how we will work towards this vision in 2016/17.

What can we do to achieve high quality care?

We believe that, as the regulator, there are three different means through which we can improve the quality of care:

- Setting standards in clinics and checking compliance with them through inspection.
- Playing a public education role by providing information about treatments and services, so that patients are able to choose better quality care.
- Reducing costs for clinics so that they can focus more of their time on providing care.


Quality
(of care and outcomes)
Setting standards
Regulatory focus geared to maximal patient benefit
Increased collaborative work with professional bodies
Increasing and informing choice
Increased consumer choice and comparability, for patients and commissioners
Improved information about treatment options, donation, research and other related subjects, such as reproductive issues, pre-conceptual care, and the fertility journey
Efficiency, economy and value
Reduced effort and costs for centres being regulated
Keeping costs to a minimum, increased value
So what does 'quality' spring from?
We believe these three aspects are critical to making quality improvement a reality
…And these things describe at a strategic level some ways in which we could improve quality of care

HFEA strategy 2014-2017

Our strategy for 2014–2017, published in July 2014, sets out our vision and how we will achieve it by utilising the quality channels available to us, as described above.

We have set out five strategic objectives that will collectively deliver the vision:

Strategic Objectives

Setting standards

We will improve the quality and safety of care through our regulatory activities.	By… • Making the patient experience integral to the way in which we assess clinics' performance. • Seeking patients' views, and understanding their perspective, as part of the way we work. • Publishing more HFEA data to drive improvements in clinic performance. • Acknowledging that treatment is often unsuccessful. • Working with professional groups to improve treatment success rates.
We will improve the lifelong experience for donors, donor-conceived people, patients using donor conception and their wider families.	By… • Providing information about donor conception directly to patients and donors through the Lifecycle campaign. • Ensuring that clinics prepare patients adequately for donation and fully understand their role and importance as a lifelong information provider. • Ensuring that egg and sperm donors are well supported and understand the lifelong commitment that follows from donation. • Collecting and publishing information regarding donor egg and sperm availability in the UK, and addressing impacts for patients (for example, by providing more information about the implications of treatment abroad).

Increasing and informing choice

We will use the data in the HFEA Register of Treatments to improve outcomes and research.	By… • Improving the presentation of clinic comparison information on Choose a Fertility Clinic (CafC). • Working with NHS commissioning bodies to ensure that they commission the best services using available data.

Strategic Objectives

We will ensure that patients have access to high quality meaningful information.	By… • Improving HFEA information about treatments available, scientific research, embryo and stem cell research and other fertility subjects, including reproductive issues, pre-conceptual care. • Working with clinics and scientific experts to publish information about new treatments. • Enhancing CaFC by including user experience scores. • Ensuring that clinics prepare and support patients and donors through the information they give them. • Collaborating with professional stakeholders to put patients in touch with better information and the right sort of care when they first realise they may have a fertility issue.

Efficiency, economy and value

We will ensure the HFEA remains demonstrably good value for the public, the sector and Government.	By… • Ensuring we are easy to deal with and that we offer a professional and cost-effective service in all that we do. • Modifying our ways of working to ensure we are responsive, agile, innovative and effective in achieving our strategic and statutory goals. • Improving the methods used to submit and verify Register data.

In order to implement the above strategic objectives, we are planning to carry out a number of activities and projects, which are set out later in this business plan.

How we work

Our strategy also sets out our ways of working, which are as follows:

- We will make the quality of care experienced by patients, donors and donor-conceived people our central priority and the primary consideration in our decision making.
- We will consult and collaborate widely – listening to, and learning from, those with an interest in what we do.
- We will communicate more with stakeholders before making decisions and explain those decisions more clearly.
- We will take the time to implement decisions with appropriate stakeholder involvement, piloting new initiatives when appropriate.
- We will keep abreast of scientific and clinical innovations and actively consider what these might mean for the future quality of care.
- We will be a more agile and flexible organisation, changing course if needed in order to be responsive (both to stakeholders and to new priorities).
- We will continue to exercise our statutory functions consistently, proportionately, openly and fairly.
- We will observe the highest standards of integrity and professionalism in putting into effect the law as it governs the fertility sector.
- We will continue to treat people and their information with sensitivity, respect and confidentiality.

Our legislation and functions

The following information is provided to give a complete picture of our purpose and core functions, which are defined in law by the following two Acts of Parliament:

- The Human Fertilisation and Embryology Act 1990 (as amended) – generally referred to as 'the 1990 Act'; and
- The Human Fertilisation and Embryology Act 2008 ('the 2008 Act').

The 2008 Act is primarily amending legislation. It extensively amends the provisions of the 1990 Act, which continues to form the main framework governing our duties and responsibilities. However, the 2008 Act also contained new provisions which were not included in the 1990 Act. In particular, these include provisions relating to legal parenthood.

The 1990 Act (as amended) gives us a number of statutory functions:

- To license and inspect clinics carrying out in vitro fertilisation and donor insemination treatment.
- To license and inspect establishments undertaking human embryo research.
- To license and inspect the storage of gametes (eggs and sperm) and embryos.
- To ensure, where a licensed clinic makes use of an external service which does not hold an HFEA licence, that there is a third party agreement in place which is in accordance with any licence conditions imposed by the Authority, for the purpose of securing compliance with the requirements of technical directives under which the third party procures, tests or processes gametes and/or embryos on behalf of the licence holder, or supplies to them goods or services which may affect the quality or safety of gametes and/or embryos.
- To produce and maintain a Code of Practice, providing guidance to clinics and research establishments about the proper conduct of licensed activities.
- To keep a formal register of information about donors, treatments and children born as a result of those treatments.
- To maintain a formal register of licences granted.
- To maintain a register of certain serious adverse events or reactions (this relates to certain specific activities, which are set out in the amended act).
- To investigate serious adverse events and serious adverse reactions and take appropriate control measures.
- To respond to any request from a competent authority in another European Economic Area (EEA) state to carry out an inspection relating to a serious adverse event or reaction and to take any appropriate control measures.
- To collaborate with the competent authorities of other EEA states.

In addition to these specific statutory functions, the legislation also gives us some more general functions, including:

- Promoting compliance with the requirements of the 1990 act (as amended), the 2008 act and the Code of Practice.
- Maintaining a statement of the general principles that we should follow when conducting our functions and by others when carrying out licensed activities.
- Observing the principles of best regulatory practice, including transparency, accountability, consistency, and targeting regulatory action where it is needed.
- Carrying out its functions effectively, efficiently and economically.
- Publicising our role and providing relevant advice and information to the donor-conceived, donors, clinics, research establishments and patients.
- Reviewing information about:
  - human embryos and developments in research involving human embryos

  - the provision of treatment services and activities governed by the 1990 act (as amended).
- Advising the Secretary of State for Health on developments in the above fields, upon request.

We also function as one of the two UK competent authorities for the European Union Tissues and Cells Directive (EUTCD). This directive regulates the donation, procurement, testing, processing, preservation and distribution of human tissue and cells for human application.

What we did in 2015/16

Delivery of the 2015/16 business plan

[DN: This section is written in March]

Delivering our strategy in 2016/17

Delivering the strategy

Our strategic vision for the three years from August 2014 to July 2017 is:

High quality care for everyone affected by assisted reproduction.

We aim to achieve this vision through delivering the following strategic objectives:

1. We will improve the quality and safety of care through our regulatory activities.
2. We will improve the lifelong experience for donors, donor-conceived people, patients using donor conception, and their wider families.
3. We will use the data in the HFEA Register of Treatments to improve outcomes and research.
4. We will ensure that patients have access to high quality meaningful information.
5. We will ensure we remain demonstrably good value for the public, the sector and Government.

These objectives are designed to ensure that we deliver our vision and continue to regulate clinics to a high level of quality, in the interests of patients, donors, donor-conceived people and our other stakeholders. We must manage ourselves effectively as a responsible public body, whilst ensuring that our statutory duties are met, and are met well, for the ultimate benefit of patients and the clinics we regulate. We must also continue to be a reflective and open organisation that constantly seeks improvements and efficiencies. Building on previous work to ensure that we are an efficient and modern regulator, we will continue to review our own performance and effectiveness and to decrease costs where we can.

The activities and projects set out over the next few pages describe how we will meet these strategic objectives in 2016/17.

Activities for 2016/17

Activities	Methods and channels	Benefits and outcomes	Timescale
Setting standards			
Strategic objective 1: improving the quality and safety of care through our regulatory activities			
Delivering the full compliance and licensing cycle to maintain standards for patients.	Inspection, audit and licensing activities.	Clinics are appropriately inspected and monitored against published performance indicators, and issued with licences for up to four years. Continued programme of unannounced inspections. Assurance of standards and safety for the public and other stakeholders. Positive overall impact on quality of care, outcomes, safety, support, and information clinics provide to the HFEA and publish (eg, on their websites).	Throughout year
	Ensuring internal Compliance processes and systems support quality. This may include implementation of any recommendations for the inspection regime resulting from the HFEA's triennial review (in 2015/16).	Consideration of the impact and effectiveness of our regulatory work and identification of further quality improvements that we could make.	September 2016
	Ensuring governance tools underpinning licensing and other decisions are in place and effective.	Efficient and effective decision-making is maintained.	Throughout year

Activities	Methods and channels	Benefits and outcomes	Timescale
	Processing applications for the licensing of preimplantation genetic diagnosis (PGD), human leukocyte antigen (HLA) and mitochondrial donation.	Growing area of work dealt with effectively and efficiently. Public confidence assured in the regulation of the new treatments of mitochondrial donation. Decisions on whether to authorise such treatments made, and communicated, in a proper and timely manner for the direct benefit of patients waiting for treatment.	Throughout year
Identifying and implementing ways of improving the quality and safety of care.	Continuing our relentless focus on quality and safety of care in inspection activities – in particular through focusing on shortcomings in the taking and recording of consents, medicines management, data submission, multiple birth rates, and information published on clinics' websites.	Improved compliance, with a positive impact on the quality of care, outcomes and safety of patients in clinics. Clinics have reduced vulnerability to expensive adverse legal and reputational risks, and greater awareness of these risks. Tracking of non-compliances in these areas, and the responsiveness of clinics in completing actions arising from inspection recommendations, in order to measure our impact. Clinics' understanding of, and adherence to, correct consent procedures and their understanding of the importance of getting this right, is improved. Patients and donors therefore have a better experience of being asked for consent, and feel fully informed. If an issue subsequently arises (such as the death of someone with gametes in storage), the correct consents are more likely to be in place and are legally clear and robust.	Throughout year

Activities	Methods and channels	Benefits and outcomes	Timescale
	Continuing to evaluate areas of regulatory concern and identifying performance levers.	Improved compliance, with a positive impact on the quality of care, outcomes and safety of patients in clinics.	Throughout year
	Continued strong focus on learning from incidents, adverse events and complaints from patients, in dialogue with the sector. This will include a focus on incidents and clinics' learning culture during inspections, and publication of our annual review of clinical incidents.	Publication of report on clinical incidents 2015. Sector provided with useful information about learning points from incidents and adverse events. Learning gained, to inform future inspections. Patients' negative experiences used to make improvements and prevent recurrence. Better understanding of factors contributing to particular types of adverse event. Collaborative relationship established with the recently established NHS Improvement so as to consider wider lessons learned that may have relevance.	November 2016 March 2017
	Improved Register data quality, as a result of work done under the Information for Quality (IfQ) programme.	More 'right first time' data submission from clinics into the Register. Better service quality for Opening the Register (OTR) applicants. Fewer data submission and data accuracy related non-compliances found on inspection and audit.	March 2017

Activities	Methods and channels	Benefits and outcomes	Timescale
	Working with commercial groups of clinics so as to improve quality and compliance on a group-wide basis, when relevant.	Using a clinic group's central Quality Management System (QMS) to best effect across whole group. A benefit in one clinic is shared to others without needing to wait for the next inspection date, for the ultimate benefit of patients. A more efficient, effective and quality-driven way of working for the clinics involved and the HFEA.	March 2017
	Collaborating with professional stakeholders (including the British Fertility Society, the BFS) to put patients in touch with better information and services when they first realise they may have a fertility issue.	More informative signposting on our website, for those who are seeking preliminary information about fertility issues and options. Empowering patients, so they feel more equipped and are able to ask the right questions, regardless of the level of knowledge of their own particular GP about fertility issues and available treatments.	March 2017

Activities	Methods and channels	Benefits and outcomes	Timescale
Acknowledging that treatment is often unsuccessful, and exploring with professional stakeholders how the HFEA and clinics could better address this issue.	Improving the chances of success as much as possible, by publishing more HFEA data to drive improvements in clinic performance. Following on from IfQ, publishing a wider range of performance data on our website. Continuing to publish the annual Fertility Trends report. Ensuring our messaging to clinics conveys the importance of handling the issue of unsuccessful treatment with sensitivity, including offering counselling. Ensuring our own information for patients enables them to have realistic expectations (both of actual success rates and of what they should expect of clinics in the event that their treatment is unsuccessful). Continue to apply pressure on success rates and risk tool alerts related to these, through our inspection reports and other means.	Increased transparency to empower and inform patients. Increased visibility for clinics of sector-wide data so that they can assess their own performance against it. Encouragement of best value and treatment outcomes for patients. Better support where treatment is unsuccessful. Prospective patients enter treatment with a realistic understanding that they may not have a baby, even if they undertake many cycles. More information on our website for prospective patients and specific signposting for patients who have experienced unsuccessful treatment. Clinics more aware of their responsibilities to patients beyond the immediate treatment setting.	March 2017
Maintaining our role as the UK's competent authority for ART in the European Union.	Attendance at competent authority events and implementation of associated EU decisions.	We attend two meetings per year. Up-to-date intelligence gained about European perspective, helping to inform UK approach to patient safety and care. Free movement of gametes and embryos enabled within the UK and standards upheld in the UK that are consistent with the rest of the EU.	Throughout year

Activities	Methods and channels	Benefits and outcomes	Timescale
Reviewing our embryo research policies and regulation.	Reviewing the consent process in collaboration with the Health Research Authority (HRA), the sector and other stakeholders. Reviewing the Code of Practice guidance and relevant licence conditions. Review the end-to-end application and approval process. Research workshop to identify the barriers to research and innovation. Collaborative work with researchers, peer reviewers and Licence Committee to ensure a common understanding. Establishing clarity on what constitutes 'a single programme of research' within the bounds of the Act (which requires a separate licence for every building) to inform a practical review of the licensing model.	No embryos should be allowed to perish where the gamete providers would prefer them to be donated to research. The application and licensing process should be robust but not impose unnecessary burdens. This outcome would help to promote new research for the benefit of the sector and support (or remove barriers to) innovation.	March 2017
Improving the quality of commissioning decisions on fertility services.	Follow-up work with commissioners of NHS services, following road-testing in 2015/16 of the HFEA's guidance leaflet for commissioners. Wider testing (subject to feedback from the initial group) is planned, and consideration will then be given to the scope for further joint working with commissioners.	Improved understanding by commissioners of the key factors to consider in their decision making.	March 2017

Activities	Methods and channels	Benefits and outcomes	Timescale
Strategic objective 2: improving the lifelong experience for donors, donor-conceived people, patients using donor conception, and their wider families.			
Providing information about donor conception directly to patients and donors.	Through the Lifecyle campaign (and through the IfQ work on Choose a Fertility Clinic, CaFC), we will continue to provide information about donation and gamete availability.	Potential donors, recipients and donor conceived people have better access to clear, authoritative impartial information about a range of issues. Improved information about gamete availability. As a result they feel better informed and supported with respect to the legal aspects and obligations of donation. All involved (including clinics) understand the lifelong commitment associated with donor conception and the associated legal issues that are relevant to them.	Throughout year
Ensuring that clinics prepare patients adequately for donation and fully understand their role and importance as a lifelong information provider; and that egg and sperm donors are well supported and understand the lifelong commitment that follows from donation.	Through the Lifecyle campaign (and through the IfQ work on CaFC), we will continue to provide information about donation.	Clarity of role and performance for clinics in relation to donation and associated information guardianship. Improved experience for donors, donor-conceived people seeking information and patients and their families.	Throughout year

Activities	Methods and channels	Benefits and outcomes	Timescale
Continuing the provision of counselling support for donor-conceived people wishing to access information held on the HFEA Register.	Continuing to run the three year pilot of counselling support services for applicants to the Register. Annual evaluation to Authority.	Counselling support is offered for all Opening the Register (OTR) applicants (those seeking non-identifying information) and for donor-conceived applicants receiving donor identifying information. Mediation services are in place for when donors and donor-conceived people meet. Basic mediation training and systems in place for dealing with identity release to donors and donor-conceived people. OTR applicants feel more supported and will be prepared to deal with the information they receive from us.	Piloting continues through to June 2018.
Implementing new EU requirements relating to the import and coding of donor eggs and sperm.	Completion of projects initiated in 2014/15 to implement new EU requirements on the import of donor gametes and new EU coding requirements for human tissue and cells.	Improved clarity for clinics, patients and donors. Improved internal clarity and updated procedures for our decision-making committees. Compliance with new EU directives. Robust processes in place to ensure the quality, safety and traceability of imported gametes and embryos.	April 2017 (the EU implementation date)

Activities	Methods and channels	Benefits and outcomes	Timescale
		Increasing and informing choice	
Strategic objective 3: using the data in the HFEA Register of Treatments to improve outcomes and research			
Maintaining the Register of Treatments and Outcomes and supporting clinics in reporting the data.	Register data and forms continue to be processed and quality assured, through liaison with clinics on errors and omissions and through validation and verification of Register entries.	High quality data available to develop patient information and service requests. Risk-based regulation and evidence-based policy-making are better supported.	Throughout year
Publishing and supplying the information we hold, for the benefit of stakeholders.	Regularly updating CaFC information to assist patient choice.	Six monthly verification and publication schedule in place, maintaining provision of up-to-date and accurate information.	Throughout year
	Continued publication of inspection reports on CaFC.	Inspection reports continue to be published via CaFC, providing useful insights for patients.	Throughout year
	Following the revised CaFC, developed through the IfQ programme, continuing to develop and improve the presentation of clinic comparison information and user experience scores, guided by patient feedback.	Published outcome data is more useful and easier to understand and sets up positive incentives for improvements. Acquisition of ongoing feedback enables us to evaluate the effectiveness and usability of the new presentation, and to plan future improvements.	March 2017

Activities	Methods and channels	Benefits and outcomes	Timescale
	Continuing to facilitate timely access to information from the Register for those who are entitled to it.	Opening the Register requests continue to be met in a sensitive manner and within required time limits (20 working days, excluding time for counselling).	Throughout year
	Information provision for researchers requesting access to Register data.	Information for researchers is provided within 90 calendar days of approval. Register information is used to best effect, to promote understanding and facilitate good research, and ultimately patient benefit.	Throughout year
	Facilitating access to information under various regimes and fulfilling Government requests.	Legal and Parliamentary requirements continue to be met within time limits.	Throughout year
	To continue to publish statistical and other reports.	'Fertility treatment in 2015' report covering 2014–2015. - Provides patients, clinic staff and others with up-to-date, high quality information about a range of topics. - Provides important information to those affected by donor conception, to patients seeking treatment and to us, to help us to enhance the quality of care that patients and donors receive in clinics, through our regulatory work. - Report carries 'official statistics' status.	November 2016

Activities	Methods and channels	Benefits and outcomes	Timescale
		Statistical report on multiple births. - Provides up-to-date, high quality information on progress in reducing the incidence of multiple births following ART.	June 2016
		Report on incidents and alerts. - Contributes to a culture of openness and information sharing where clinic staff are empowered to report mistakes and learn from each other. - Promotes transparency and maximises opportunities for learning from incidents to improve quality of care for patients. - Provides the sector with the most up-to-date information.	November 2016
Maintaining collaborative information management relationships	Maintaining our good working relationships with relevant other bodies, such as the Government Digital Service (GDS) the Health and Social Care information Centre (HSCIC) and being an active member of the National Information Board (NIB).	We contribute to the objectives of the wider health system, with respect to information management. Learning from best practice and sharing expertise, so that we can make use of each other's strengths and knowledge in data management, systems integrity and security.	March 2017

Activities	Methods and channels	Benefits and outcomes	Timescale
Strategic objective 4: ensuring patients have access to high quality meaningful information			
Improved HFEA website information about treatments available, scientific research, embryo and stem cell research and other fertility subjects.	Continuing the development of new and additional content for our website (redesigned in 2015/16) to provide an expanded range of educative and scientific information about current and future treatment options, the scientific evidence associated with these, and other fertility issues.	Increased information for patients and others. Information is accessible, engaging and meaningful. Patients better informed and better placed to deal with treatment issues and decisions. Patients feel safe and know they can expect certain standards in clinics. Prospective patients have clearer information and signposting. Patients more aware of the potential risks of new/different treatments as well as the possible benefits.	March 2017
	Conducting our annual horizon scanning exercise to ensure we identify relevant new scientific developments.	Policy developments and website material are informed by expert input and an understanding of scientific issues and future developments. Future work planning is improved by early identification of upcoming issues.	March 2017
Working with clinics and scientific experts to publish information about new treatments.	Establishing mechanisms for producing and publishing informative and accurate material when new treatment options emerge, working in collaboration with clinics and experts.	Increased public understanding of emerging new science and future treatment possibilities. Patients better informed and better placed to deal with treatment issues and decisions when emerging new treatments begin to be offered by clinics and better placed to judge the merits of any media speculation about potential new treatments.	Throughout year

Activities	Methods and channels	Benefits and outcomes	Timescale
Enhancing the patient voice in all of our work, including information provision.	Further developing our communications with, and information provided to, patients so as to help them to make informed choices about fertility matters. Ensuring patient feedback is continuously incorporated into our core business, for example through user experience ratings of clinics.	Patient views and needs are better incorporated into our work and are reflected in the style and content of the information we provide. There are increased feedback opportunities for patients via the website, and easier interaction with us.	March 2017

Demonstrating efficiency, economy and value

Strategic objective 5: ensuring the HFEA remains demonstrably good value for the public, the sector and Government

Ensuring the HFEA is easy to deal with and offers a professional service.	Completion of the work started in 2015/16 to modernise the HFEA's Register function and processes (EDI, data submission and verification, the Clinic Portal, and the data dictionary).	Reduced transactional costs for clinics and increased satisfaction. 'Right first time' data quality. Reduction in unnecessary effort by clinics submitting the data.	October 2016
	Continuation of the engagement arrangements with clinics on fees charged, established in 2014/15.	Accountability and transparency in respect of the fees we charge clinics. Fees Group continues to be run effectively. Annual review of fees takes place.	Throughout year

Activities	Methods and channels	Benefits and outcomes	Timescale
Ensuring the HFEA is a good value organisation and makes best use of its limited resources.	Using our strategy to prioritise our activities and manage our limited resources to best effect.	Resources are deployed in the interests of high quality care for everyone affected by assisted reproduction. Speedier service to patients when they interact directly with us. Achieving measurable 'added value' and internal efficiency.	Throughout year
	Ensuring internally provided support services run smoothly and are efficient.	Our infrastructure is effective and supports the delivery of the strategic vision. Central systems, processes and tools are efficiently run, giving good value and service.	Throughout year
	Responding to the 2015 Government Spending Review and/or the HFEA's triennial review, as required.	Ensuring the organisation is soundly run, providing best possible value, and compliant with Government targets.	Timescales not yet known
	Building and maintaining our staff capacity and skills, in line with our people strategy.	We are able to maintain the staff capacity and capability to deliver our strategy and our core statutory duties.	Throughout year

Activities	Methods and channels	Benefits and outcomes	Timescale
Ensuring the HFEA is an effective collaborator and partner in the interests of the efficiency of the wider Department of Health group of ALBs and other health organisations.	Continuing to share services and infrastructure with other organisations as practicable: Maximising benefit of finance resources shared with HTA. Continuing with service level agreements (SLAs) with relevant other organisations for certain HR services and using Civil Service Learning as a key learning and development provider. Continuing to receive support services from the landlord of our office premises, via an SLA.	We continue to operate in as efficient a way as possible, extracting maximum value from shared support arrangements and seeking other opportunities.	Throughout year
	Moving to new office premises, alongside other arms length bodies (ALBs).	Best overall use made of Crown Estate property. Overall saving on accommodation achieved for the group of health ALBs as a whole, even if the HFEA's individual accommodation costs have to increase in order to enable this. Further shared services and efficiencies possible for and with other similar organisations in the health ALB family.	April 2017 onwards
	Continued collaborative and partnership working with other ALBs and health regulators (eg, MHRA, UKAS, DH NIB)	Continued ability to address issues that require joint working in an efficient and coordinated way, or to establish the best ways of working if any new areas of regulatory overlap should arise.	Throughout year

Measuring our performance

Facts and figures

The following facts and figures give a wider picture of the type and volume of our work between 1 April 2015 and 31 March 2016. **[DN: Data is added after year end]**

Number of:	2014/15	2015/16
Active clinics and research establishments	127	
Clinics and research establishments inspected	61	
Licences inspected	62	
New licence applications processed and presented to the Licence Committee	6	
Licence renewals processed and presented to the Licence Committee/Executive Licensing Panel	35	
Applications for Human Leukocyte Antigen (HLA) testing for tissue match processed and presented to Licence Committee/Executive Licensing Panel	9	
New preimplantation genetic diagnosis (PGD) applications processed and presented to Statutory Approvals Committee	44	
Incident reports from clinics processed	453	
Alerts issued	0	
Formal complaints about clinics	9	
Opening the Register requests closed within 20 working days	260	
Donor Sibling Link applications processed	23	
Licensed Centres Panel meetings held	2	
Meetings with patient organisations held	1	
Public and stakeholder meetings	48	
Freedom of Information (FOI) requests dealt with	105	
Environmental Information Regulations (EIR) requests dealt with	0	
Enquiries responded to under the Data Protection Act (DPA)	0	
Parliamentary questions (PQs) responded to	136	
Information for researchers requests received	0	
Visits to the anonymised Register download page	462	
Unique visits to our website	1,337,484	
Most popular/viewed page on our website	IUI - What is intrauterine insemination (IUI)	

Required HR benchmarking information

In common with other ALBs, we are required to maintain a record of the following standard benchmarking data:

[DN: Data is added after year end]

Very senior manager (VSM) to staff complement ratio
Number of staff earning more than £142,500 now and any planned change during the next planning period
HR staff to employee ratio
Training budget as a percentage of pay bill
Projected reductions in non payroll staff

Key performance indicators

In March 2015, we revised our in-house strategic performance report so as to enable us to keep track of our performance, with a particular focus on monitoring strategic delivery. This document is presented in summary form at every Authority meeting, and the associated papers are published regularly on our website.

The table below shows our performance in 2015/16 for a small sample of these indicators. We will continue to track the same indicators, and more, throughout 2016/17.

[DN: Data is added after year end.]

Performance indicator	Target for 2015/16	Performance
Setting standards		
Average number of critical/major recommendations at clinics in inspection reports that were considered by ELP/LC.	This indicator is for monitoring purposes and does not have an associated target. In 2015/16 we plan to focus on the timeliness with which inspection recommendations are met after non-compliances are identified.	xx critical xxx major (from xx inspections during the year)
Percentage of Opening the Register requests responded to within 20 working days.	100% of complete OTR requests to be responded to within 20 working days (excluding counselling time).	xxx% (xx no. of requests)
Increasing and informing choice		
Percentage of finalised Licence Committee, SAC, representations hearing and ELP decisions published on HFEA website within five working days of Chair sign-off.	100% published within five working days of Chair sign-off.	x% (x items published, of which x were published within the target)
Number of emailed public enquiries successfully responded to.	No target, since the nature, volume and complexity of enquiries received varies widely.	X,xxx
Efficiency, economy and value		
Average number of working days taken for the whole licensing process, from the day of inspection to the decision being communicated to the centre.	Less than or equal to 70 working days.	Average for year = xx.x working days Range: xx-xx working days
Cash and bank balance.	To move closer to minimum £1,520k cash reserves.	Year start = £2,038k Year end = £xxxxxk

Financial picture

[DN: this section is written in December, following initial discussions with the Department of Health.]

The high level budget for 2016/17 is shown below.

Income	£000s
Department of Health funding	x
Treatment and licence fees	x
Other income	x
Total income	x
Operating costs, of which	x
Staff costs	x
Other operating costs	x
Total operating costs	x
Capital charges	x
Total revenue expenditure	x

Other required information

Introduction

A sound delivery framework and a well-maintained organisational infrastructure are prerequisites for the successful delivery of any strategy or business plan. It is also important that we remain compliant with Government rules that apply across the whole family of arms length bodies (ALBs).

The HFEA's governance structure includes corporate governance tools, an HR framework and policies, and a business continuity plan. These enable us to manage our work effectively and meet external and internal requirements such as information requests, compliance with the Equality Act 2010, the production and laying in Parliament of our annual report, and the management of organisational risks and performance.

The information below is provided to explain those aspects of our organisation that are structural or which help us to meet particular Department of Health or cross-Government requirements.

Organisational structure and establishment

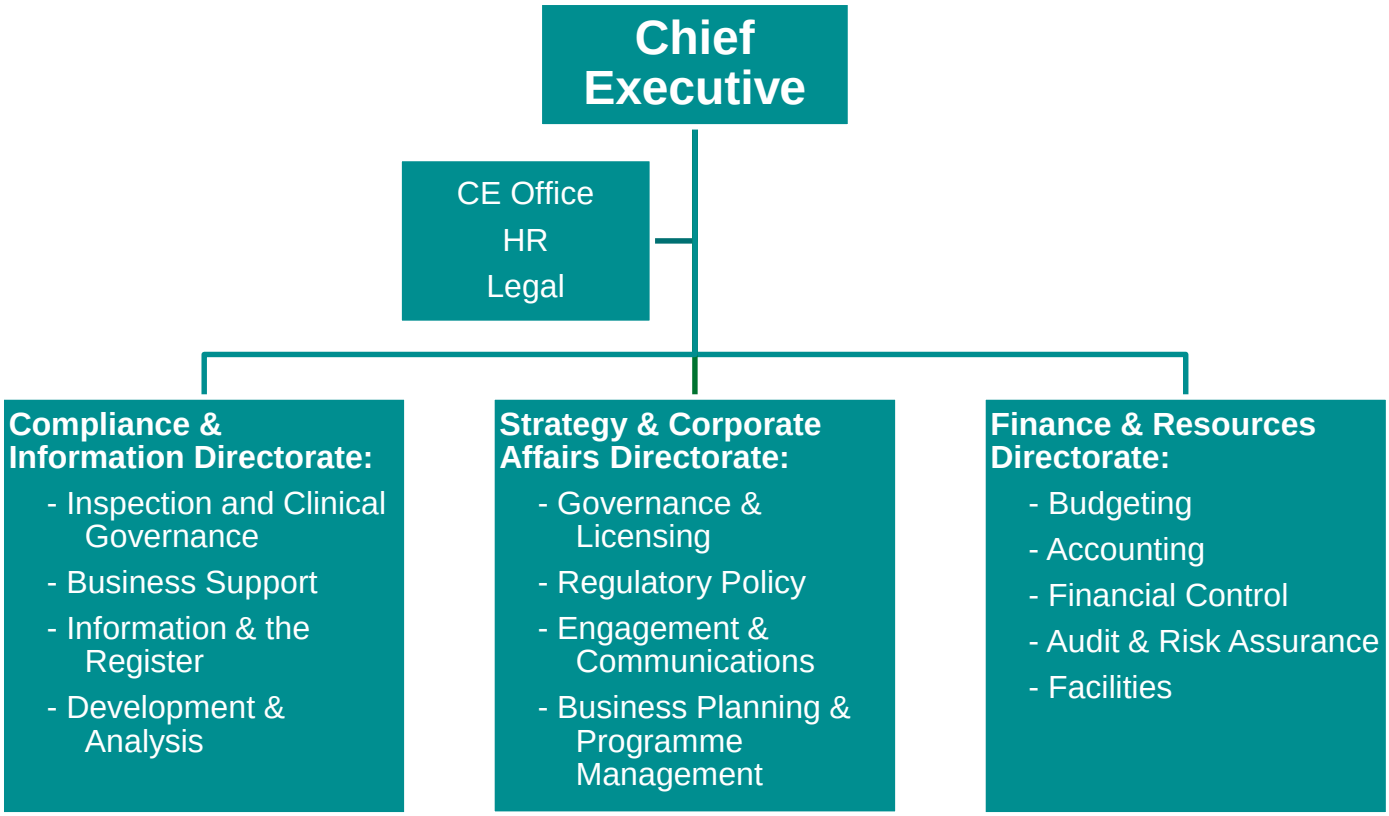
Over the past few years the HFEA has significantly reduced its staffing, in keeping with overall pressures on the public sector and Government expectations. Our staff complement has reduced from 86 in 2010/11 down to 67 2015/16. We have put in place shared services arrangements with other bodies, where feasible. For example, we share part of our finance and resources team staffing with the HTA, our facilities management service is provided by the CQC (since we currently occupy the same premises, although this is likely to change in 2016/17) and we also have a shared services agreement with CQC for recruitment. We believe we have reached a point where, having made considerable savings, our size will now need to remain stable for the foreseeable future. Our people strategy, published in 2015, sets out how we will ensure we retain the capability and capacity to deliver our overall strategy for 2014–2017.

Our learning and development activities continue to equip our staff with the skills they need. Services are procured in accordance with continuing Government requirements to ensure value for money, using Civil Service Learning, and their associated suppliers, or other ALB provision, as appropriate.

Together with other ALBs, we continue to participate in a talent management consortium which aims to provide cost effective leadership development programmes and other development opportunities.

All staff pay is determined in line with HM Treasury annual guidance. We adhere to the formal pay remit when it is announced.

The following diagram shows our current organisational structure.



Financial management systems

We continue to maintain sound financial governance and business planning processes. We will continue to manage our processes efficiently and to continue to develop and deepen our various collaborative relationships and shared services with other bodies, which provide increased value as well as some economies of scale.

Internal audit

We continue to be part of the Department of Health group assurance framework and to work with the co-sourcing provider on delivering the annual internal audit plan for each year. The programme of internal audits has been streamlined to meet the HFEA's needs and to make best use of the group audit arrangement, which helps to improve the overall levels of assurance for the group.

Assurance framework

A framework agreement with the Department of Health (in 2014) sets out the critical elements of the relationship between the HFEA and the department, and other ALBs where relevant. As an ALB, the HFEA will continue to manage its assurance and risk management independently and report this to the Authority. The HFEA recognises that, on rare occasions, its risks or assurance may have a significant impact or

interest within the Department of Health and understands the correct dialogue and escalation mechanisms for communicating the issues and relevant mitigations.

Equality Act 2010

The HFEA remains compliant with the requirements of the Equality Act 2010. There is an equality champion on the Authority. We will collectively continue to ensure, throughout the year, that the HFEA fulfils its obligations under the Equality Act.

Whistleblowing policy

We value staff who raise concerns over potential wrongdoing and are committed to ensuring that staff have access to, and a clear understanding of, public interest disclosure (whistleblowing). Our policy is reviewed each year to ensure that the details are up to date and reflect latest legislation and guidance. Should any individual raise a concern through this route, we are committed to ensuring that their confidentiality is appropriately protected and that they will not suffer any detriment as a result of whistleblowing.

Transparency requirements

We will continue to comply with the various data requests and requirements for the publication of data on our own website and on data.gov.uk, arising from the transparency agenda that was first introduced in 2010. We regularly publish all required spending data openly, in the required file format, via data.gov.uk.

All of our Authority meetings are held in public and the papers and audio recordings are published on our website. Committee papers and a wealth of other information are also routinely published on our website.

Information technology (IT) and data security

The HFEA maintains an information asset register identifying our key IT systems and their owners. Our IT systems ensure we comply with the data management requirements of legislation, including the HFE Act 1990 (as amended) and support the significant databases we hold.

HFEA databases are currently held on highly secure servers within the premises. While we occupy the same premises as the CQC, this necessarily entails sharing a communications room on-site to house the servers. Security measures are in place so as to ensure that ‘section 33A patient-identifying data’ is appropriately protected.

The HFEA remains fully compliant with Cabinet Office rules regarding data security and with its own legislative requirements regarding confidentiality of information under the HFE Act 1990 (as amended).

Since we are likely to move offices during the course of the coming year, we developed, in March 2015, an IT strategy for the future. This includes making new secure arrangements for our servers, while adhering to any applicable central Government requirements at the time.

The robust information security arrangements the HFEA has in place, in line with the information governance toolkit, include a security policy for staff, secure and confidential storage of and limited access to Register information and stringent data encryption standards. All staff complete the annual mandatory

training on information security and new starters complete this on their first day of employment before starting work.

We also operate a clear desk policy and have on-site shredders and confidential material disposal arrangements in place.

Business continuity

We further developed our business continuity plan in 2014/15 to ensure it remained fit for purpose. The plan is regularly updated and periodically tested. There is an operational disaster recovery site available if needed.

We currently have an interdependency with the CQC with regards to building-related and system matters. Assuming our office move goes ahead early in the 2016/17 financial year, as anticipated, business continuity will be considered afresh in collaboration with other relevant ALBs.

Estates strategy

The HFEA has no estate. Our office strategy remains to be a tenant or co-tenant of a larger Department of Health organisation.

Our current office space of 525 square metres includes flexible hot desking and we previously rezoned the office (in 2013/14) to enable better use of space (with smaller desks).

Our tenancy with the CQC will end when the CQC moves completely from the Finsbury Tower in 2016. Until the resulting office move takes place, the HFEA and the CQC will continue to work together on health and safety services. We have adopted the CQC's online system for individual workplace assessment and meet with the CQC lead on fire evacuation procedures and fire warden liaison. Similarly, new, arrangements will be put in place as appropriate in our new premises.

Sustainable development

We recycle paper, card, glass, plastic cups, containers and bottles, metal cans and toner cartridges. We have two multi-function devices (for secure printing, scanning and photocopying) that are pre-set to print on both sides of the paper and in black-and-white. Our IT equipment is re-used and working lives extended where possible and is switched off when not in use. Surplus equipment is either sold or donated. A proportion of our staff are able to work from home, allowing reduced travel impacts.

We do not procure energy or other items with significant environmental impacts.

Procurement

The HFEA complies with all relevant Department of Health and Cabinet Office efficiency controls. Where we are the purchaser, we procure the mandated procurement categories from Government or other public sector frameworks: energy (N/A), office solutions, travel, fleet (N/A), professional services, eEnablement, property (N/A), ICT, advertising and media, print and print management, learning and development, legal services and conference and events bookings. These frameworks were first established in 2011.

We are aware of the green agenda in relation to procurement. However, we rarely set our own contract terms or purchases directly and are dependent on CCS and other framework holders for integrating sustainability features in their contract letting.

Nearly all of our procurement is done through CCS. So, as far as we are able, we aim to meet the public sector procurement target of 18% of procurement spend going to SMEs but we are dependent (as with sustainability) on CCS ensuring that SME suppliers are present on the relevant frameworks in the first place. Where we have a choice of supplier, our criteria do include both sustainability and SME usage.

We are too small to have a procurement pipeline. The only procurement of significance in 2016/17 will relate to the IfQ programme, which has been subject to specific business cases agreed by the Department of Health and the Government Digital Service through various robust mechanisms. All related procurement in 2015/16 has been conducted using CCS frameworks and with close CCS oversight. There will be no procurements over £100,000 in 2016/17.

There is no significant non-pay spend that is not via CCS, CQC or Department of Health frameworks or contracts.

We remain committed to the principles of the voluntary sector compact and work with the voluntary sector where applicable. For examplewe have worked for some years with other organisations to reduce the prevalence of multiple births in the fertilty sector and we routinely open developments to our policies and processes to a wide range of inputs and influences, including voluntary organisations.

Finsbury Tower
103-105 Bunhill Row
London
EC1Y 8HF
T 020 7291 7200
E enquiriesteam@hfea.gov.uk

Strategic risk register

Strategic delivery:	☒ Setting standards	☒ Increasing and informing choice	☒ Demonstrating efficiency economy and value
Details:			
Meeting	Authority		
Agenda item	8		
Paper number	HFEA (11/10/2015) 775		
Meeting date	11 November 2015		
Author	Paula Robinson, Head of Business Planning		
Output:			
For information or decision?	For information		
Recommendation	The Authority is asked to note and comment on the latest edition of the strategic risk register.		
Resource implications	In budget		
Implementation date	Ongoing		
Communication(s)	The risk register is reviewed quarterly by the Corporate Management Group (CMG), and presented at every Audit and Governance Committee (AGC) meeting. AGC reviewed the risk register at its meeting on 7 October.		
Organisational risk	☐ Low	☒ Medium	☐ High
Annexes	Annex 1: Strategic risk register		

1. Latest reviews

1.1. CMG reviewed the risk register at its meeting on 2 September. Five of the twelve risks remain above tolerance. CMG reviewed all risks, controls and scores. CMG's specific comments are contained in the risk register at Annex A.

1.2. The risk register was also discussed at AGC on 7 October. No changes were proposed. AGC also noted progress towards implementing risk assurance mapping in the HFEA, which will be taken forward early next year as part of the internal audit programme, with the support of the Department of Health internal audit team.

2. Recommendation

2.1. The Authority is asked to note and comment on the latest edition of the strategic risk register.

Annex A - HFEA strategic risk register 2015/16

Risk summary: high to low residual risks

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

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

Recent review points:

CMG 20 May 2015 ⇨ AGC 10 June 2015 ⇨ CMG 2 September 2015 ⇨ AGC 7 October

[1] Strategic objectives 2014-2017:

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

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

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

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

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

CMG overview

CMG reviewed the risk register and discussed each risk in detail at its meeting on 2 September.

In addition, CMG recognised that the office move, which will most likely occur in April 2016, will present certain risks, and may interact with risks and controls already listed. As soon as we have confirmation of the move date and location, the move will be explicitly added to the risk register, either as a separate risk, or as a specific source/cause of risk in relation to several of our existing strategic risks. It is already mentioned in several places, but not yet in any detail.

Since CMG met, the Family Court has passed judgement on several cases where consents to legal parenthood were in doubt. That judgement may have administrative consequences for the HFEA. Further cases can be expected over the coming months, although the HFEA is unlikely to participate in legal proceedings directly. Nonetheless, a decision has been taken that the impact of this work ought to be reflected in the legal challenge risk (LC1), and accordingly the risk score for the likelihood component of the residual risk has been increased to 3 (having been briefly reduced to 2 following the conclusion of another outstanding case). This means that this risk, which briefly dipped within tolerance, is now above tolerance.

AGC noted the above information at its meeting on 7 October. Controls and risk management for IfQ were discussed briefly, following an earlier item covering latest IfQ developments in greater depth. No changes were proposed to scores and tolerances.

Criteria for inclusion of risks:

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

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

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

Risk scoring system
See last page.

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

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

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

Causes/sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Inspection/reporting failure.	Inspections are scheduled for the whole year, using licence information held on Epicentre, and items are also scheduled to committees well in advance.	In place – Debra Bloor	Below tolerance.
	Audit of Epicentre to reveal any data errors. All queries being routed through Licensing, who have a definitive list of all licensing details.	Due for completion October 2015 – Sam Hartley (report and recommendations to October CMG)	
	Inspector training, competency-based recruitment, induction process, SOPs, QMS, and quality assurance all robust.	In place – Debra Bloor	
Monitoring failure.	Outstanding recommendations from inspection reports are tracked and followed up by the team.	In place – Debra Bloor	
Unresponsiveness to or mishandling of non-compliances or grade A incidents.	Update of compliance and enforcement policy.	Significant progress – revision discussed at September 2015 Authority – revised policy Spring 2016 - Debra Bloor	
	Staffing model changed to increase resilience in inspection team for such events – dealing with high-impact cases, additional incident inspections, etc..	In place – Debra Bloor – May 2015	
Insufficient inspectors or licensing staff	Inspection team up to complement following several recruitments.	In place – Debra Bloor	
	Licensing team up to complement following recruitment.	In place – Sam Hartley	

Recruitment difficulties and/or high turnover/churn in various areas; resource gaps and resource diversion into recruitment and induction, with impacts felt across all teams.	So far recruitment rounds for inspectors and support staff have yielded sufficient candidates, although this has required going beyond the initial ALB pool to external recruitment in some cases.	Managed as needed – Debra Bloor
	Additional temporary resources available during periods of vacancy and transition.	In place – Rachel Hopkins
	Group induction sessions put in place where possible.	In place – Debra Bloor
Resource strain itself can lead to increased turnover, exacerbating the resource strain.	Operational performance, risk and resourcing oversight through CMG, with deprioritisation or rescheduling of work an option.	In place – Paula Robinson
Unexpected fluctuations in workload (arising from eg, very high level of PGD applications received, including complex applications involving multiple types of a condition; high levels of non-compliances either generally or in relation to a particular issue).	Staffing model developed (May 2015), to release an extra inspector post out of the previous establishment. This increased general resilience so as to enable more flex when there is an especially high inspection/report writing/application processing workload (as there is, so far in 2015).	In place – Debra Bloor
	PGD workshop annually (or biannually, as appropriate) with the sector to increase their insight into our PGD application handling processes and decision-making steps; coupled with our increased processing times from efficiency improvements made in 2013 (acknowledged by the sector).	In place – Debra Bloor
Some unanticipated event occurs that has a big diversionary impact on key resources, eg, several major Grade A incidents occur at once.	Addressed by revised staffing model.	In place – Debra Bloor
	Update of compliance and enforcement policy.	Significant progress – revision discussed at September 2015 Authority – revised policy Spring 2016 - Debra Bloor

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

Causes/sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Failures or weaknesses in decision making processes.	Keeping up to date the standard operating procedures (SOPs) for licensing, representations and appeals.	In place – Sam Hartley	At tolerance.
	Learning from recent representations and Appeal Committee experience incorporated into processes.	In place – Sam Hartley	
	Appeals Committee membership maintained – vacancy filled earlier in year; 4 new members recruited in September. Ongoing process in place for regular appointments whenever vacancies occur or terms of office end.	In place – Sam Hartley	
	Staffing structure for sufficient committee support.	In place – Sam Hartley	
	Decision trees; legal advisers familiar.	In place – Sam Hartley	
	Proactive management of quoracy for meetings.	In place – Sam Hartley	
	New (ie, first application) T&S licences delegated to ELP. Delegations to be revisited during 2016 review of Standing Orders. Licensing Officer role to take certain decisions from ELP – implementation due end of 2015.	To be put in place – Sam Hartley Licensing Officer role – December 2015 (postponed from June 2015) Delegations in SOs – April 2016	
Failing to demonstrate competence as a regulator	Update of compliance and enforcement policy.	Significant progress – revision discussed at September 2015 Authority – revised policy Spring 2016 - Debra Bloor	

	Inspector training, competency-based recruitment, induction process, SOPs, quality management system (QMS) and quality assurance all robust.	In place – Debra Bloor
Effect of publicised grade A incidents.	Staffing model changed (May 2015) to build resilience in inspection team for such events – dealing with high-impact cases, additional incident inspections, etc.	In place – Debra Bloor
	SOPs and protocols with Communications team.	In place – Debra Bloor
	Fairness and transparency in licensing committee information.	In place – Debra Bloor
	Dedicated section on website, so that the public can openly see our activities in the broader context.	In place – Debra Bloor
Administrative or information security failure, eg, document management, risk and incident management, data security.	Staff have annual information security training (and on induction).	In place – Dave Moysen
	TRIM training and guidance/induction in records management in place. Head level 6 month contract to be recruited to manage the office move and review records management.	In place – SMT Head post recruitment in progress September 2015 - SMT
	The IfQ website management project has reviewed the retention schedule.	Completed – August 2015 – Juliet Tizzard
	Guidance/induction in handling FOI requests, available to all staff.	In place – Sam Hartley
	Further work to be planned on records management in parallel with IT strategy	Linked to IT strategy work – in progress – Dave Moysen/Sam Hartley
Negative media or criticism from the sector in connection with legally disputed issues or major adverse events at clinics.	HFEA approach is only to go into cases on the basis of clarifying legal principles or upholding the standards of care by challenging poor practice. This is more likely to be perceived as proportionate, rational and necessary (and impersonal), and is in keeping with our strategic vision.	In place - Peter Thompson
HFEA process failings that create or contribute to legal challenges, or which weaken cases that are otherwise sound.	Licensing SOPs, committee decision trees in place. Mitochondria tools in development.	Existing tools in place; mitochondria tools due by October 2015 – Sam Hartley

Update of compliance and enforcement policy.	Significant progress – revision discussed at September 2015 Authority – revised policy Spring 2016 - Debra Bloor
QMS and quality assurance in place in inspection team.	In place – Debra Bloor

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

Causes/ sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Inability to extract reliable data from the Register.	Detailed planning and programme management in place to ensure this will be possible after migration. Migration strategy developed, and significant work being done to identify all of the data that will require correction before migration can be done. Decisions are being made about the degree of reliability required in each data field. For those fields where 100% reliability is needed, inaccurate or missing data will be addressed as part of project delivery.	All aspects – detailed project planning in place – Nick Jones	Above tolerance. Managing these risks has formed an intrinsic and essential part of the detailed project planning and tendering, throughout. Following a lengthy delay, we received formal approval for both the data and digital elements of IfQ in late April 2015. The digital side of the programme has received only partial approval; full delivery will still require additional approvals after the first phase of work. There is a risk that this could lead to further long delays which would have a further
Unable to work out how best to improve CaFC, and/or failure to find out what data/information patients really need.	Stakeholder engagement and user research is in place as intrinsic part of programme approach. This was elaborated further during sprint 1, in Aug/Sept 2015.	In place and ongoing – Dec 2014 onwards – Nick Jones	
Stakeholders not on board with the changes.	In-depth stakeholder engagement to inform the programme's intended outcomes, products and benefits – including user research consultation, expert groups and Advisory Board.	In place and ongoing – Juliet Tizzard / Nick Jones	
Cost of delivering better information becomes too prohibitive.	Costs were taken into account as an important factor in consideration of contract tenders and negotiations.	In place and now completed – Dec 2014 to June 2015 – Nick Jones	

Redeveloped website does not meet the needs and expectations of our various user types.	Programme approach and dedicated resources in place to manage the complexities of specifying web needs, clarifying design requirements and costs, managing changeable Government delegation and permissions structures, etc. User research done, to properly understand needs and reasons. Tendering and selection process included clear articulation of needs and expectations.	In progress – delivery by end Mar 2016 – Juliet Tizzard	negative impact. This would adversely affect the quality of the final product (rather than the existence of a final product).
Government and DH permissions structures are complex, lengthy, multi-stranded, and sometimes change mid-process.	Initial external business cases agreed and user research completed. Final business case for whole IfQ programme was submitted and eventually accepted.	In place (Nov 2014) – Juliet Tizzard In place (Dec 2014) – Nick Jones (decision received April 2015)	
Resource conflicts between delivery of website and business as usual (BAU).	Backfilling to free up the necessary staff time, eg, Websites and Publishing Project Manager post backfilled to free up core staff for IfQ work.	In place – Juliet Tizzard	
Delivery quality will be very supplier dependent. It is also likely to involve multiple different suppliers and could become very resource-intensive for staff, or the work delivered by one or more suppliers could be poor quality and/or overrun, causing knock-on problems for other suppliers.	Programme management resources and quality assurance mechanisms in place for IfQ to manage (among other things) contractor delivery. Agile project approach includes a 'one team' ethos and requires close joint working and communication among all involved contractors during the Sprint Zero start-up phase. Sound project management practices in place to monitor. Previous lessons learned and knowledge exist in the organisation from managing some previous projects where poor supplier delivery was an issue requiring significant hands-on management. Ability to consider deprioritising other work, through CMG, if necessary.	In place – Juliet Tizzard	
New CMS (content management software) is ineffective or unreliable.	CMS options being scrutinised as part of project.	In progress – December 2015 – Juliet Tizzard	
Communications infrastructure incapable of supporting the planned changes.	Needs to be updated as part of IfQ in order to support the changes.	In place – set out in business case – Juliet Tizzard (Dec 2014)	

Benefits not maximised and internalised into ways of working.	During IfQ delivery, product owners are in place, as is a communications plan. The aim is to ensure that changes are developed involving the right staff expertise (as well as contractors) and to ensure that the changes are culturally embraced and embedding into new ways of working.	In place (June 2015) – Nick Jones
Potential risks associated with the HFEA's likely office move in April 2016, in that this will coincide with the delivery period for some IfQ milestones.	Early awareness of the potential for disruption means that this can be managed through careful planning.	For further thought once there is certainty about the timetable for the move (September 2015) – Nick Jones/Sue Gallone

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

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

Potential risks associated with the HFEA's likely office move in April 2016, in that this will coincide with the delivery period for some IfQ milestones.	Early awareness of the potential for disruption means that this can be managed through careful planning.	For further thought once there is certainty about the timetable for the move (September 2015) – Nick Jones/Sue Gallone

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

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

Benefits not maximised and internalised into ways of working.	During IfQ delivery, product owners are in place, as is a communications plan. The aim is to ensure that changes are developed involving the right staff expertise (as well as contractors) and to ensure that the changes are culturally embraced and embedding into new ways of working.	In place (June 2015) – Nick Jones	
Potential risks associated with the HFEA's likely office move in April 2016, in that this will coincide with the delivery period for some IfQ milestones.	Early awareness of the potential for disruption means that this can be managed through careful planning.	For further thought once there is certainty about the timetable for the move (October 2015) – Nick Jones/Sue Gallone	

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

Causes/sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Complex and controversial area.	Panel of legal advisors from various firms at our disposal for advice, as well as in-house Head of Legal.	In place – Peter Thompson	Above tolerance. One case decided in the HFEA's favour at summary judgement, but is now to be appealed. Appeal completed in September (the decision was to award the licence). A recent judgement on consents for parenthood may have administrative consequences for the HFEA. Further court cases are also likely, although the HFEA is unlikely to participate in legal proceedings directly.
	Evidence-based policy decision-making and horizon scanning for new techniques.	In place – Hannah Verdin	
	Robust and transparent processes in place for seeking expert opinion – eg, external expert advisers, transparent process for gathering evidence, meetings minuted, papers available online.	In place – Hannah Verdin/Sam Hartley	
Lack of clarity in HFE Act and regulations, leading to the possibility of there being differing legal opinions from different legal advisers, that then have to be decided by a court.	Panel in place, as above, to get the best possible advice.	In place – Peter Thompson	
Decisions and actions of the HFEA and its committees may be contested.	Panel in place, as above.	In place – Peter Thompson	
	Maintaining, keeping up to date and publishing licensing SOPs, committee decision trees etc. Standard licensing pack completely refreshed and distributed to members/advisers April 2015.	In place – Sam Hartley	

Subjectivity of judgments means the HFEA often cannot know in advance which way a ruling will go, and the extent to which costs and other resource demands may result from a case.	Scenario planning is undertaken at the initiation of any likely action.	In place – Peter Thompson
HFEA could face unexpected high legal costs or damages which it could not fund.	Discussion with the Department of Health would need to take place regarding possible cover for any extraordinary costs, since it is not possible for the HFEA to insure itself against such an eventuality, and not reasonable for the HFEA's small budget to include a large legal contingency.	In place – Peter Thompson
Legal proceedings can be lengthy and resource draining.	Panel in place, as above, enabling us to outsource some elements of the work.	In place – Peter Thompson
	Internal mechanisms (such as the Corporate Management Group, CMG) in place to reprioritise work should this become necessary.	In place – Peter Thompson
Adverse judgments requiring us to alter or intensify our processes, sometimes more than once.	Licensing SOPs, committee decision trees in place.	In place – Sam Hartley.

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

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

Business continuity issue.	BCP in place and staff communication procedure tested. A period of embedding the policies is now in progress.	In place (January 2015) – Sue Gallone
Register data becomes corrupted or lost somehow.	Back-ups and warehouse in place to ensure data cannot be lost.	In place – Nick Jones/Dave Moysen
Other HFEA data (system or paper) is lost or corrupted.	As above. Staff have annual compulsory security training to guard against accidental loss of data or breaches of confidentiality.	In place – Dave Moysen

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

Causes/ sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Poor record keeping	Refresher training and reminders about good records management practice. Head level 6 month contract to be recruited to manage the office move and review records management.	In place – SMT Head post recruitment in progress September 2015 - SMT	Above tolerance. Although we have some good controls in place for dealing with PQs and other externally generated requests, it should be noted that we cannot control incoming volumes, which in January 2015 were among the highest we have ever experienced. It is not yet possible to tell if further high volumes will occur during the mitochondria project and the subsequent start-up of applications processing.
	TRIM review and retention policy implementation work – subsumed by IT strategy.	To sync in with IT strategy – Dave Moysen/Sam Hartley	
	Audit of Epicentre to reveal any data errors. All queries being routed through Licensing, who have a definitive list of all licensing details.	Completed October 2015 – Sam Hartley	
Excessive demand on systems and over-reliance on a few key expert individuals – request overload – leading to errors	PQs, FOIs and OTRs have dedicated expert staff/teams to deal with them. If more time is needed for a complex PQ, attempts are made to take the issue out of the very tightly timed PQ process and replace this with a more detailed and considered letter back to the enquirer so as to provide the necessary level of detail and accuracy in the answer. We also refer back to previous answers so as to give a check, and to ensure consistent presentation of similar data.	In place – Juliet Tizzard / Nick Jones	
	PQ SOP revised and log created, to be maintained by new Committee and Information Officer/Scientific Policy Manager	In place - Sam Hartley	

Answers in Hansard may not always reflect advice from HFEA.	The PQ team attempts to catch any changes to drafted wording that may unwittingly have changed the meaning. HFEA's suggested answer and DH's final submission both to be captured in new PQ log.	In place – Sam Hartley / Peter Thompson
Insufficient understanding of underlying system abilities and limitations, and/or of the topic or question, leading to data being misinterpreted or wrong data being elicited.	As above – expert staff with the appropriate knowledge and understanding in place.	In place – Juliet Tizzard / Nick Jones
Servicing data requests for researchers - poor quality of consents obtained by clinics for disclosure of data to researchers.	There is a recognised risk of centres reporting research consents inaccurately. Work to address consent reporting issues is being planned.	Actions to be confirmed end of September – Nick Jones

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

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

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

Causes/ sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Lack of counselling availability for applicants.	Counselling service pilot established with external contractor in place.	In place (June 2015) – Nick Jones	At tolerance. The pilot counselling service has been in place since 1 June, and we will make further assessments based on early uptake and the delivery experience. Reporting to the Authority will occur annually during the pilot period.
Insufficient Register team resource to deal properly with OTR enquiries and associated conversations.	Additional member of staff dedicated to handling such enquiries.	In place – Nick Jones	
Risk of inadequate handling of a request.	Trained staff, SOPs and quality assurance in place.	In place – Nick Jones	
	SOPs reviewed by Register staff, CMG and PAC-UK, as part of the pilot set-up. Contract in place with PAC-UK for pilot delivery.	Done (May 2015) – In June the ongoing management of the Pilot transferred to Rosetta Wotton.	

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

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

Upwards scope creep during projects, or emerging during early development of projects eg, IfQ.	Finance presence at Programme Board (PB) level. Periodic review of actual and budgeted spend by PB.	Ongoing – Wilhelmina Crown
	Cash flow forecast updated.	Monthly (on-going) – Morounke Akingbola

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

Causes/ sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
High turnover, sick leave etc. leading to temporary knowledge loss and capability gaps.	People strategy will partially mitigate. Mixed approach of retention, staff development, and effective management of vacancies and recruitment processes.	Done – May 2015 – Rachel Hopkins	Above tolerance. This risk and the set of controls remains focused on capability, rather than capacity. There are obviously some linkages, since managing turnover and churn also means managing fluctuations in capability and ensuring knowledge and skills are successfully nurtured and/or handed over. When the period of highest turnover appeared to be ending (May 2015), CMG reduced (slightly) the likelihood of this risk, but still decided to retain it, given that high turnover could recur. In May 2015, CMG also reviewed the tolerance level for this risk, and agreed it should
	A programme of development work is planned to ensure staff have the skills needed, so as to ensure they and the organisation are equipped under any future model, maximising our resilience and flexibility as much as possible. Staff can access civil service learning (CSL); organisational standard is five working days per year of learning and development for each member of staff.	In place – Rachel Hopkins	
	Organisational knowledge captured via records management (TRIM), case manager software, project records, handovers and induction notes, and manager engagement.	In place – Rachel Hopkins	

The new UK government may implement further cuts across all ALBs, resulting in further staffing reductions. This would lead to the HFEA having to reduce its workload in some way.	The HFEA has already been proactive in reducing its headcount and other costs to minimal levels over a number of years. We have also already been reviewed extensively (including the McCracken review). Although turnover is currently reducing to more normal levels, this risk will be retained on the risk register, and will continue to receive ongoing management attention.	In place – Peter Thompson	remain at 6. Since the HFEA has become a much smaller organisation over the past few years, leaving less intrinsic resilience, it seems prudent to have a low tolerance for this risk.
Poor morale leading to decreased effectiveness and performance failures.	Engagement with the issue by managers. Ensuring managers have team meetings and one-to-one meetings to obtain feedback and identify actions to be taken.	In place – Peter Thompson	
	Staff survey and implementation of outcomes, following up on Oct 2014 all staff conference.	Survey done (Jan 2015) – Rachel Hopkins Follow-up communications in place (Staff Bulletin etc.) – Peter Thompson	
Differential impacts of IfQ-related change and other pressures for particular teams could lead to specific areas of knowledge loss and low performance.	Staff kept informed of likely developments and next steps, and when applicable of personal role impacts and choices.	In place – Nick Jones	
	Policies and processes to treat staff fairly and consistently, particularly if people are ‘at risk’.	In place – Peter Thompson	
Additional avenues of work open up, or reactive diversions arise, and need to be accommodated alongside the major IfQ programme.	Careful planning and prioritisation of both business plan work and business flow through our Committees. Regular oversight by CMG.	In place – Paula Robinson	
	Early emphasis given to team-level service delivery planning for 2015, with active involvement of team members. Delivery (and resources) in Q1 to date were also considered at monthly CMG in May, and delivery is currently on track. CMG will continue to review this.	In place (Jan 2015) – Paula Robinson	

	Moratorium on new project work under consideration in planning for remainder of 2015/16 and for 2016/17, so as to prioritise IfQ delivery and therefore strategy delivery) within our limited resources.	Ongoing dialogue about this in place as part of business planning (August 2015 onwards) – Paula Robinson
	IfQ has some of its own dedicated resources.	In place – Nick Jones
	There is a degree of flexibility within our resources, and increasing resilience is a key consideration whenever a post becomes vacant. Staff are encouraged to identify personal development opportunities with their manager, through the PDP process, making good use of Civil Service Learning.	In place – Peter Thompson
Regarding the current work on licensing mitochondrial replacement techniques, there is a possible future risk, beyond October 2015, that we will need to increase both capability and capacity in this area, depending on uptake (this is not yet certain).	Future needs (capability and capacity) relating to mitochondrial replacement techniques and licensing applications are starting to be considered now, but will not be known for sure until later. No controls can yet be put in place, but the potential issue is on our radar.	New issue for consideration – Juliet Tizzard

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 (11/11/2015) 776		
Meeting date	11 November 2015		
Author	Nick Jones, Director of Compliance and Information		
Output:			
For information or decision?	For information		
Recommendation	The Authority is asked to: • Note the progress made on the Programme.		
Resource implications	Nil		
Implementation date	During 2015–16 and 2016–17 business years		
Communication(s)	Regular throughout 2015–16		
Organisational risk	☐ Low	☐ Medium	☒ High
Annexes	N/A		

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 EDI (Electronic Data Interchange) system (used by clinics to submit treatment data to the HFEA)
- A revised dataset and data dictionary which will be submitted for approved 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 the programme to the achievement of the Authority's strategy, updates on progress are provided to each meeting of the Authority and approval for direction and actions sought.

1.3. This brief paper updates Members on:

- the outcome of user research activity conducted during 'Discovery +'
- Department of Health approval to proceed beyond Alpha phase
- key progress made towards a proof-of-concept during the Alpha phase
- the agile methodology being applied to IfQ and 'sprint' progress
- details of the Programme's budget and timelines for delivery.

2. User research outcomes of 'Discovery +'

2.1. The 'Discovery+' research conducted by Reading Room and the HFEA is now complete, having been conducted during July and August 2015. Its purpose was to expand on the knowledge and evidence from an earlier IfQ Discovery phase. Its scope was to evidence the full end-to-end user journey, expanding it from looking at the HFEA website in isolation as well as increasing the sample size of individual user types.

2.2. Primary research was conducted in the form of one to one interviews with a broad range of people using, or considering using, fertility services. This included people considering fertility treatment as an option for the first time, through to people who have been through treatment, and also donors of eggs and sperm. Desk research and stakeholder interviews were also undertaken.

2.3. The key insights from this work have been:

- The identification of a cognitive behavioural model that defines three categories of clinic user. This is of crucial importance for designers of the HFEA website and Choose a Fertility Clinic service.
- A greater understanding of how people first approach the topic of fertility and fertility treatment and how the HFEA needs in the future to integrate with the NHS Choices (and future NHS.uk) online services, and the face-to-face provision from GPs, gynaecologists and fertility doctors.
- An understanding of the importance of personal friendship groups and their role in decision making and emotional support around fertility issues, choice of clinics and treatment options.
- Evidence of unmet user needs, especially around the 'big picture' of fertility treatment and the various patient pathways and decision points that people go through.

3. Approval to proceed beyond 'Alpha' phase

3.1. As members have been previously advised, the externally facing part of the programme cannot proceed beyond 'Alpha' (proof-of-concept) stage until approvals in line with Government Digital Service Standards have been granted by the Department of Health (DH). Work to date in IfQ has been closely focused on adhering to those standards, and upon the basis of close and ongoing discussions with DH colleagues we expect to be granted approval to proceed.

3.2. This assessment is scheduled to occur on 12 November 2015 and we hope approval will follow soon after. The senior management team has been closely involved in the development of the submission.

4. Alpha phase progress – Show and Tell

4.1. The overwhelming majority of the Alpha phase development of a proof-of-concept has now been completed. This includes the completion of front-end design samples of the Clinic Portal and website (including CaFC), and important foundational 'back-end' systems work.

4.2. A sample of the front-end proof-of-concept work will be presented at the meeting. This proof-of-concept work has been tailored to meet the needs of our users, as established during the Discovery and Discovery + phase research activity, and to comply with Government Digital Service Standards.

4.3. The work samples presented represent only a small portion of the work completed during Alpha phase. There has been significant progress made on internal systems work (such that it all fits together), including:

- Publishing new HFEA application program interfaces (APIs) to a test environment, which use live CaFC data.
- Extracting live data in the legacy register database into a new database structure (an important data migration proof-of-concept for the way cleansed data will be extracted to the new register when formal data migration occurs). This extract process was designed in accordance with our data migration strategy. A task that previously took a week (due to the overly complex extract design) now takes less than 20 minutes.

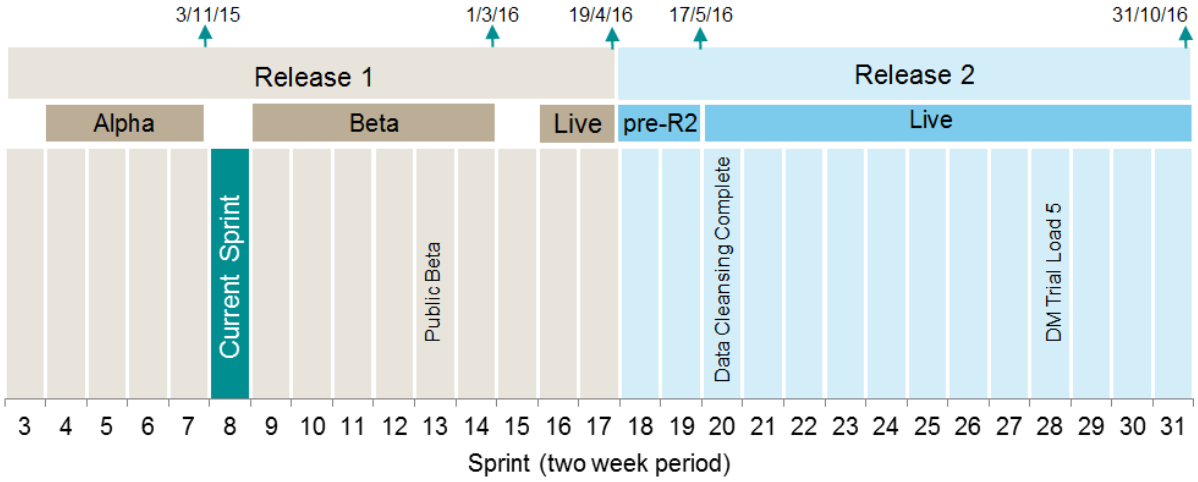
4.4. The programme is progressing well, with each project well placed to progress beyond Alpha phase proof-of-concept, to building functionality during Beta phase.

5. Agile methodology and our 'sprint' progress

5.1. The programme management methodology for IfQ is Scrum – an agile methodology

5.2. Incorporating an agile methodology ensures software is delivered effectively, in a user needs driven and iterative way that puts software in the hands of users as quickly as possible. Within Scrum, the programme's delivery timeline and development schedule is broken down in to two week 'sprints'

5.3. The following figure shows how the programme is progressing through sprints, in relation to the overall delivery timeframes for the Programme. As shown below, the programme is in the final sprint before the commencement of Beta phase.



6. Programme budget and delivery dates

6.1. A detailed IfQ Programme Plan was finalised and signed off by the IfQ Programme Board in October 2015, in line with the overall £1.134m agreed by Authority.

6.2. Whilst applying a Scrum based agile methodology to the Programme means that the exact outputs of each sprint remain subject to sprint planning, the anticipated programme budget and key milestones have been agreed and the programme is progressing in line with expectations.

6.3. The IfQ Programme Budget remains consistent with the original business case. As members were previously advised, expenditure will extend to next financial year, and the budget has been recently adjusted to reflect this.

6.4. The following table shows the current IfQ Programme budget.

	2015–16	2016–17	Total 2015-2017
IfQ forecast (incl VAT)	£934,576	£200,000	£1,134,576

6.5. The key IfQ delivery milestones and dates are as follows:

Milestone	Finish
Website & CaFC	
Release 1	
Website R1 public beta	01-Mar-16
Website R1 live	19-Apr-16
Release 2	
Website & CaFC R2	16-Oct-16
Clinic Portal	
Release 1	
Early adopters	19-Apr-16
CP R1 live	23-May-16
Release 2	**28-Oct-16**
Internal Systems	**28-Oct-16**
Register Data Migration	**20-Sep-16**
Business Transformation activities	**12-May-17**
Development of the blueprint	31-Mar-16
Review & adapt processes - given new systems	06-Feb-17
Benefits realisation activities	12-May-17

7. Programme management

7.1. The IfQ Programme is supported by a dedicated Programme Manager, appointed in October 2013 to set up the Programme and establish an effective framework for delivery of the Programme so that it could be taken in house at an appropriate time.

7.2. The IfQ Programme is now making arrangements to effect a smooth transition to HFEA's in house programme management office, having developed a succession plan for a handover at end December 2015.

8. Recommendation

8.1. The Authority is asked to

- Note the progress made on the IfQ Programme.

Choose a fertility clinic: update

Strategic delivery:	☐ Setting standards	☒ Increasing and informing choice	☐ Demonstrating efficiency economy and value
Details:			
Meeting	Authority		
Agenda item	10		
Paper number	HFEA (11/11/2015) 777		
Meeting date	11 November 2015		
Author	Juliet Tizzard, Director of Strategy and Corporate Affairs, Trisram Dawahoo, Digital Communications Manager		
Output:			
For information or decision?	For information		
Recommendation	Members are asked to: • consider the approach to patient ratings, in particular the issues listed at 2.9; and • note the progress made on presenting statistics.		
Resource implications	Part of IfQ budget		
Implementation date	February 2016		
Communication(s)	To be tested at the end of the 'alpha' stage, in late November		
Organisational risk	☐ Low	☒ Medium	☐ High
Annexes	Annex A: Questions for patient ratings and inspection questionnaire		

1. Background

1.1. Choose a fertility clinic is our web-based tool which allows users to see information about individual licensed clinics, including licensing information and outcome statistics. It has been a market leader in clear, unbiased information for patients but, six years old, it has become a little outdated. Information is hard to find and patients find that success rate information, while statistically correct, is confusing to the extent that some patients prefer the simpler presentation on clinic websites.

1.2. Choose a fertility clinic is being completely redesigned as part of the Information for Quality programme. This involves publishing new information about clinics and changing the way we present outcome statistics. It will go live, albeit in 'beta' form, in February 2016.

1.3. The Authority first discussed changes to Choose a fertility clinic in January 2015, when it agreed that the new service will offer:

- a better balance between statistical and non-statistical information
- easier comparison between clinics
- non-statistical information that includes patient reviews, inspection findings and the availability of donated eggs, sperm or embryos (the latter two are not discussed here)
- patient reviews which should not consist of free-text feedback
- information about the availability of donated eggs, sperm or embryos consisting of types of donors available, the source (ie, imported or UK) and waiting times for treatment
- top-line statistical information consisting of births per embryo transferred, followed by the cumulative success rate (ie, births per egg collection and all subsequent transfers).

1.4. We returned in July to update the Authority on progress, focussing on what outcome statistics we present and how we present them, and patient ratings. Members endorsed the direction of travel and the emphasis on testing out new approaches on users. There was some concern expressed about reducing the number of age bands from 6 to 2, something that we have explored further with the stakeholder group. Members also stressed the need to achieve a good balance between patient ratings, inspection findings and outcome statistics.

1.5. This paper updates Members on progress since July in two areas:

- Patient ratings
- Presenting statistics

2. Patient ratings

2.1. The idea of including in Choose a fertility clinic, for the first time, ratings from patients who have used a particular service has been well received, both by patients and clinic staff. As users of lots of different kinds of services, they are used to giving feedback. And as people who work in or use health services, they are familiar with the 'Friends and family' test. Indeed, NHS Choices offers patients the chance to write a free-text review of an individual service – something which we have decided not to do.

2.2. Despite this openness to a patient rating feature, some stakeholders' have misgivings about it. They worry that:

- reviewers won't actually be patients at the clinic, but staff giving false, negative reviews of other clinics or false, positive reviews of their own;
- only the very unhappy (or very happy) patients will give their views;
- hardly anyone will give reviews at all.

2.3. We agreed that the best ways of tackling these worries are to:

- remind clinics that it is an offence (under the Consumer Protection from Unfair Trading Regulations 2008) for businesses to falsely represent themselves as consumers
- invest time and money (though less than £5000) in marketing the patient review service, so that clinics without marketing departments avoid being disadvantaged and patients with mixed experiences give feedback
- use the close relationships we have with our clinics through inspectors to apply moral pressure to not 'game' the system. A simple phone call prompted by unusual activity in their patient reviews will have an impact
- remind clinics that successful patients won't necessarily give a positive review – and the contrary for unsuccessful patients.

Patient ratings questions

2.4. Since July, we have refined the wording of the questions and thought about how it integrates with the patient questionnaire which informs inspections.

2.5. For the past few years, we have asked patients at individual clinics to complete a questionnaire about their experience of treatment at that clinic. The questionnaire is available on our website (though it is hard to find) and is sent out to patients by the clinic. The Inspection team would like to simplify the questions asked in the questionnaire and increase the number of people completing it.

2.6. We plan to increase the number of respondents by linking the patient ratings feature on Choose a fertility clinic to the inspection questionnaire. Originally we had planned to keep them separate – the ratings questions first, then a link to the inspection questionnaire. However, the questions in the patient ratings

feature and the inspection questionnaire have so many areas of overlap that we have decided to combine them.

2.7. As Annex A shows, we will ask a question which has a five point scale for ratings. We will then ask users if they want to give more information, making it clear that what they say in the free-text box will be sent to the clinic's inspector to inform the next inspection report. Only the ratings will be published on Choose a fertility clinic.

Presenting patient ratings

2.8. An overall rating will appear for each clinic in the search results (alongside other quality measures). On the clinic page itself, we will show the overall rating, with the option to expand the section for more detail. Here, we will show the average score for each of the six questions, making it clear how many people have responded.

2.9. There are a number of other issues to resolve around presenting ratings:

- Should we only present an average rating for a clinic when it has received a certain number of reviews? If yes, how many?
- Should the overall rating be based just on the 'Friends and family' test question (question 1, Annex A) or all of the questions? Our current view is that it should be based on the 'Friends and family' test as this is an overall impression in itself. However, are the other questions equally important?
- Should the average ratings be limited to a particular time period – the past year, for example? This would be fairer for clinics which have responded to feedback and improved their service, but it would limit the sample size, thereby reducing reliability.

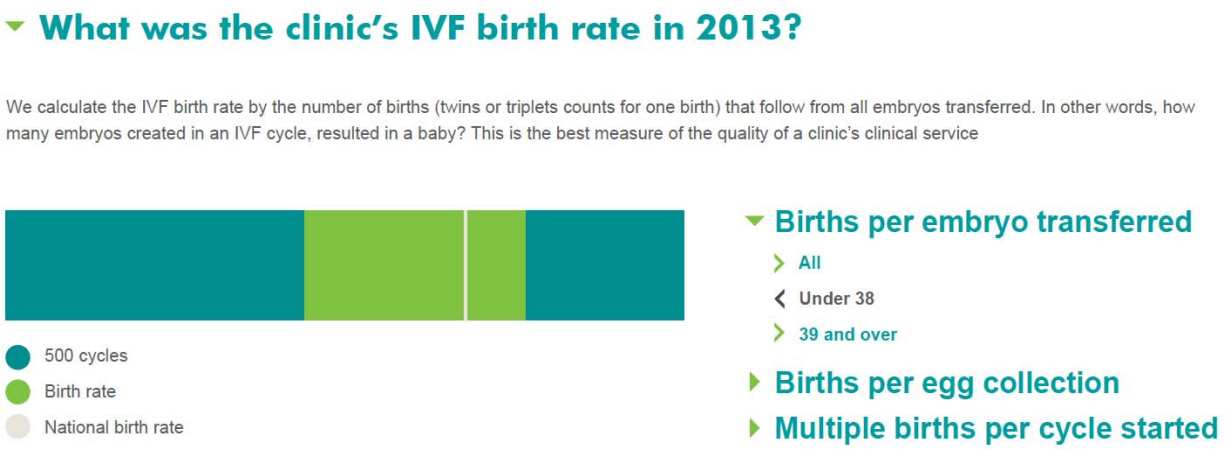
2.10. We would welcome members' views about these issues.

3. Presenting statistics

3.1. We discussed, at the July Authority meeting, the difficulties inherent in publishing outcome data for individual (often very small) clinics in a meaningful yet comprehensible way.

3.2. Whilst funnel plots are probably the most statistically accurate way of presenting results in a way that takes account of sample size, they don't make much sense to non-statisticians. Instead, we plan to use a simple bar.

3.3. This includes the total number of cycles, a single percentage point for the national average and the clinic's rate as a band. We will need to explain to users that the narrower the band, the more reliable the percentage point.



Please note: this presentation is in its earliest draft. The colours, labelling and design are in development.

3.4. You will see that there are only two age bands presented. This makes sense for top-level information. Those who would like more detail can dig down on level to find more detailed tables broken down into the six age bands we have currently.

3.5. We think this is will be easier for patients to understand than the data tables we present on the current website and focus them on the important information: how does this clinic's performance relate to the national average. However, the proof of this will be by testing it out on real users, which we will do during user testing later this month.

4. Recommendation

4.1. Members are asked to:

- consider the approach to patient ratings, in particular the issues listed at 2.9; and
- note the progress made on presenting statistics.

Annex A: Questions for patient ratings and inspection questionnaire

1. How likely are you to recommend this clinic to friends and family if they needed similar care or treatment?

(five point scale)

2. To what extent did you feel you were treated with privacy and dignity?

(five point scale from 'never' to 'always')

Tell us more (optional)

Your comments will help us understand your rating and improve standards at the clinic. They will be shared with our inspections team, could be included in the clinic's inspection report and may be shared with the clinic.

3. To what extent did you feel you understood everything that was happening throughout your treatment?

(five point scale from 'never' to 'always')

4. Was your level of involvement in decisions about your treatment…?

(five point scale from 'unacceptable' to 'excellent')

Tell us more (optional) [free text box as above]

5. Was the level of empathy and understanding shown towards you by the clinic team…?

(five point scale from 'unacceptable' to 'excellent')

Tell us more (optional) [free text box as above]

6. Did you pay what you expected?

- ☐ It was cheaper
- ☐ It was about right
- ☐ It was more expensive

- ☐ It was way above the estimate
- ☐ I was treated on the NHS

Tell us more (optional) [free text box as above]

Do you have anything else you'd like to add about this clinic?

[free text box]

HFEA fees 2016/17

Strategic delivery:	☐ Setting standards	☐ Increasing and informing choice	☒ Demonstrating efficiency economy and value
Details:			
Meeting	Authority		
Agenda item	11		
Paper number	HFEA (11/11/2015) 778		
Meeting date	11 November 2015		
Author	Sue Gallone, Director of Finance and Resources		
Output:			
For information or decision?	For decision		
Recommendation	• To increase the IVF treatment fees the HFEA charges licensed clinics from £75 to £80 and remove the eSET discount. Other fees would remain unchanged.		
Resource implications	The fee increase is necessary to provide sufficient income to cover the costs of regulation. Removing the eSET discount will be simpler to administer.		
Implementation date	The increase, and end of eSET discounts, would take effect for all embryo transfers from 1 April 2016.		
Communication(s)	The new fees would be communicated to establishments in December, subject to Treasury approval.		
Organisational risk	Due to uncertainties, the change in fee could generate a small surplus or loss and this will be monitored carefully. ☐ Low	☐ Medium	☐ High
Annexes	Annex A: Current fees		

1. Background

1.1. The HFEA is funded from a combination of fees from the sector we regulate and Grant-in-aid (GIA) from the Department of Health (DH). Fees are expected to cover the full cost of regulation; GIA should cover the cost of wider public policy purposes. The HFEA currently receives around 80% of our funding from fees. We charge fees for:

- new licences and renewals
- premises changes
- IVF treatments
- Donor Insemination (DI) treatments

1.2. There are different fee levels for new licences and renewals for storage, research involving stem cells and IUI centres (who pay an annual fee rather than fees per treatment). A list of current fees is at Annex 1.

1.3. 98% of income is from IVF treatment fees. Currently £75 is charged per embryo transfer, or when gametes are mixed or ISCI takes place but there is no fertilisation, with no fee charged for subsequent transfers from the same batch of eggs where the initial embryo transfer was an elective single embryo transfer (the eSET discount).

Previous fees

1.4. The current fees structure has been in place since 2001. We last increased fees in 2006. In the years that followed treatment numbers increased more than forecast to a degree that fee income exceeded needs. Following a review, we decreased fees in 2012 from £104.50 to £75 and introduced the eSET discount. The surplus income from fees that was built up between 2006 and 2012 is now being used to fund the Information for Quality programme.

Future needs

1.5. We have cut costs drastically since 2010, and absorbed inflation. But it is now clear that fees will no longer meet our costs from 2016. This is mainly because of treatment numbers falling below forecast and rising accommodation costs. It is, therefore, necessary to consider the fee levels required going forward.

2. Approach to fee setting

2.1. Each year we consider the total funding required for the HFEA, reflecting future needs and making efficiencies where possible. We determine how much is to be funded by GIA and how much by fees. The amount of GIA required is based on a long-standing agreement with the DH of what GIA funds, which we have embedded into our costs model.

2.2. The structure of our fees (what activities we charge for) as set out in Annex 1, is well established. It serves us well and is understood and accepted by the clinics and research centres who pay fees. We charge relatively small amounts for new licences and renewals with income from treatment fees contributing to the cost of all our fee funded activities, reflecting all of the regulation around treatment.

2.3. In making any changes to fees, we consider whether the present structure remains appropriate and what the fee levels should be, based on the funds required.

3. 2016/17 fees

Funding required

3.1. A high level estimate of requirements is as follows. The detailed allocations will be considered as part of business planning but would be contained within this total.

		£000s
Salaries		3,800
Other Staff costs		260
Authority/Committee costs		150
Other Compliance costs		60
Other Strategy costs		175
Accommodation	1	350
Office costs		35
IT costs	2	100
Legal costs		300
Professional Fees		80
Total		5,310

Notes:

1 –The office will move in April 2016 and costs of rent, rates, service charge and external meeting rooms are not yet certain. A most likely estimate of an extra £90k has been included.

2 – IT arrangements are changing towards the end of 2015/16 and costs are not yet certain. Current costs have been included.

3.2. Of the £5310k, our costs model indicates that the HFEA requires GIA admin funding of £938k for 2016/17. This is a saving of over 4% from 2015/16, before the share of additional accommodation costs. (Admin GIA in 2015/6 was £960k, £920k plus £18k for accommodation required for 2016/17.)

3.3. On this basis £4372k is required from fees for 2016/17.

Fees structure

3.4. We propose to retain the present agreed structure for charging fees, for the reasons set out in section 2 above. However, we believe that the time has come to recommend that the eSET discount should cease from 1 April 2016.

3.5. We introduced the eSET discount in 2012 with the aim of encouraging the take up of eSET and so reduce the incidence of multiple births, which are the largest single health risk to mothers and babies from IVF. It is difficult to be sure how much the discount has helped encourage single embryo transfer (but the number has increased significantly from 3583 eSETs in 2012/13 to 6248 in 2014/15) and multiple births have now fallen to 17% and the downward trend is continuing.

3.6. There is now accepted evidence that eSET leads to better pregnancy rates and it is embedded into clinical practices. This suggests that the modest eSET discount may no longer be needed to drive behaviour (if it ever did). In addition, we know that the eSET discount is complex to administer for clinics.

3.7. If the Authority agrees to remove the eSET discount we will need to make it clear that the HFEA is not reducing the drive to reduce multiple births further, to the target of 10%. Rather, we believe that the eSET discount has done its job in giving initial encouragement and is no longer needed. We will continue to monitor multiple births and maintain a strong focus on clinic's performance in this area.

3.8. A decision to remove the eSET discount would also mean that the overall increase in treatment fees would be lower than it would have been otherwise.

Fees for 2016/17

3.9. With the current fees structure, which we propose to retain, the vast majority of fee income is from treatment fees, as noted earlier. Therefore we propose to leave all fees except IVF treatment fees unchanged.

3.10. Around £70k of the cost of regulating would be recovered from fees that are not for IVF treatments. In order to recover the remaining costs of £4302k from IVF treatments, we need to estimate future numbers of treatments.

3.11. Although treatment numbers which were billable or attracted the eSET discount have been increasing since 2012, in 2015/16 to date there has been a decrease. Embryo transfer statistics have also varied in recent times and it is hard to make accurate predictions. Our best estimate at present is that we might expect around 55,000 treatments in 2016/17, from which we need to

recover £4302k. This reflects recent decreases and assumes that they will continue.

3.12. On this basis, IVF treatment fees would need to increase to £78.22 for 2016/17, assuming we also stopped the eSET discount. In view of the uncertainty about accommodation costs and treatment numbers, and for simplicity, we suggest that IVF treatment fees increase to £80.

3.13. If we retained the eSET discount, the increasing take up of eSET would mean that chargeable IVF treatment fees would have to rise more significantly. Under this scenario fees would need to increase to £90.

3.14. On balance, we recommend that the removal of the eSET discount and an increase in IVF treatment fees to £80 is the most sustainable option, for the reasons set out above.

4. Next steps

4.1. Our proposals have been put to DH for agreement with Treasury, in parallel with bringing them to the Authority.

4.2. We have discussed the likely change with the Fees group (on 4 November) and will feed back views to the Authority at the meeting.

Annex A: Current fees

DI/IVF treatment and storage centres	
Chargeable IVF treatment	£75
DI treatment	£37.50
New/renewal licence application	£500
Storage only centres	
New/renewal licence application	£200
Research establishments	
New/renewal licence application	£500
Involving stem cells	£750
IUI treatment only centres	
New licence application	£975
Renewal licence application	£500
Annual activity	£2950
All	
Chargeable variations (premises)	£500