

Authority meeting - agenda

14 September 2016

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

Agenda item	Time
1. Welcome, apologies and declaration of interests	11:15am
2. Minutes of 6 July 2016 HFEA (14/09/16) 805	11:20am
3. Chair's report (verbal)	11:30am
4. Chief Executive's report (verbal)	11:40am
5. Committee chairs' updates (verbal)	11:50am
6. Strategic performance report HFEA (14/09/16) 806 For information	11:55am
7. Information for Quality programme: update HFEA (14/09/16) 807 For information	12:05pm
Lunch	12:30pm
8. Strategy 2017-20 HFEA (14/09/16) 808 For decision	1:30pm
9. Compliance activities 2015/16: a review HFEA (14/09/16) 809 For information	2:10pm
10. Adverse incidents in fertility clinics HFEA (14/09/16) 810 For information	3:10pm
11. Any other business	3:25pm

Minutes of Authority meeting 6 July 2016

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

Details:

Meeting Authority

Agenda item 2

Paper number HFEA (14/09/2016) 805

Meeting date 14 September 2016

Author Charlotte Keen, Information Access and Policy Manager

Output:

For information or decision? For decision

Recommendation Members are asked to confirm the minutes as a true and accurate record of the meeting

Resource implications

Implementation date

Communication(s)

Organisational risk Low Medium High

Annexes

Minutes of the Authority meeting on 6 July 2016 held at ETC Venues, Victoria, 1 Drummond Gate, London SW1V 2QW

Members present	Sally Cheshire (Chair) Bishop Lee Rayfield Kate Brian Yacoub Khalaf Margaret Gilmore	Anita Bharucha Ruth Wilde Dr Anne Lampe Anthony Rutherford
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Apologies	Professor David Archard Rebekah Dundas Dr Andy Greenfield
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Observers/Presenters	Steve Pugh (Department of Health)
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Staff in attendance	Peter Thompson Nick Jones Juliet Tizzard Catherine Drennan Ian Brown	Helen Crutcher Rosetta Wotton Joanne Anton Charlotte Keen
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Members

There were 9 members at the meeting, 5 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 fourth meeting of 2016. As with previous meetings, it was being audio-recorded and the recording would be made available on the HFEA website to enable interested members of the public who were not able to attend the meeting to listen to the HFEA's deliberations.

1.2. Declarations of interest were made by:

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

2. Minutes of Authority meeting held on 11 May 2016

2.1. Members agreed the minutes of the meeting held on 11 May subject to minor amendments, for signature by the Chair.

3. Chair's report

- 3.1. The Chair provided members with a summary of events that she had attended with organisations in the IVF sector and the wider health and care system since the last Authority meeting.
- 3.2. On 19 May, the Chair, together with the Chief Executive, attended the HFEA Annual Accountability meeting with the Minister for Health, Jane Ellison, and members of the HFEA's sponsor team.
- 3.3. On 23 May, the Chair chaired an Appointments Committee to extend the membership of one of the Audit and Governance Committee (AGC) members for a further 15 months.
- 3.4. On 25 May, the Chair, together with the Chief Executive and the Director of Strategy and Corporate Affairs, met Professor Geeta Nargund, the Medical Director from CREATE Health.
- 3.5. On 7 June, the Chair and the Chief Executive met representatives from Fertility Fairness to discuss NHS commissioning.
- 3.6. On 14 June, the Chair, together with another Authority member, attended a seminar at the Department of Health on board effectiveness, to which all Department of Health's arm's length bodies (ALBs) were invited, and on 29 June the Chair and the Chief Executive met with Dr Alan Thornhill, a former Authority member.

4. Chief Executive's report

- 4.1. The Chief Executive advised members that, on 13 May, he met the Chief Executives of the Human Tissue Authority (HTA) and the Health Research Authority (HRA) to discuss how the three ALBs could work more closely together.
- 4.2. On 16 May, the Chief Executive, together with the Director of Strategy and Corporate Affairs, met officials from the Scottish Executive, to discuss their plans for a national strategy for gamete donation in Scotland.
- 4.3. On 8 June, the Chief Executive, the Director of Strategy and Corporate Affairs and another Authority member, met with Professor Con Michaels from the National Health and Medical Research Council (NHMRC), which carries out a similar role to the HFEA for the Australian Government, to discuss mutual interests in the licensing of embryo research.
- 4.4. On 13 June, the Chief Executive attended the Scientific Clinical Advances and Advisory Committee (SCAAC), the AGC committee meeting on 15 June, and the Infertility Network UK reception at the Houses of Parliament on 27 June.
- 4.5. The Chief Executive informed members that the triennial review, which had looked at the functions of the organisation and whether those functions were carried out in the most efficient way possible, had not yet been signed off. This was not because of any problems, but rather because the sign-off process was complex.
- 4.6. The Chief Executive reminded members that, at previous Authority meetings, he had explained that Departments were required to publish innovation plans by spring 2016 and that ALBs were now required to follow suit. The HFEA's draft plan had issued on 26 April and the consultation

closed on 6 June. Although relatively few comments had been received, these had been largely supportive and the innovation plan had been revised in light of those comments. The revised plan would be circulated to members for any final comments and the timing of the publication of the plan would depend on the Government.

- 4.7.** The Executive believed that the regulatory scheme in place managed to support innovation in a way which also ensured public confidence; indeed it was evident that regulation in bio-sciences had actually fostered innovation rather than hindered it. It was important to note it was the UK, with its robust regulation, that had led to world firsts like mitochondrial donation and the recent decision to allow genome editing in research. The HFEA's innovation plan set out those achievements.
- 4.8.** The Chief Executive advised members that Sue Gallone, the Director of Finance and Resources for both the HFEA and the HTA, had taken the decision to retire in the autumn. Sue would be greatly missed and members would have the opportunity to say thank you to her at the Authority meeting in September. A recruitment advertisement had been issued for a new shared Director and members would be advised on progress.
- 4.9.** Press Coverage: the Chief Executive summarised press coverage since the last Authority meeting, details of which had been circulated to members. It had been a busy few months, with some important emerging issues.
- 4.10.** M case: the Chief Executive advised members the HFEA had received the Court of Appeal judgement regarding the M case, where a mother and father sought to export their deceased daughter's eggs to the US under Special Directions. The judgement of the Appeal Court did not dispense with the need for informed consent, despite the fact that it upheld the appeal and had remitted the case back to the Statutory Approvals Committee (SAC).
- 4.11.** Samantha Jeffries case: the Chief Executive advised members that there had been some media coverage of a case which was not yet in court, involving Samantha Jeffries who was seeking permission to continue to store embryos made with her and her dead husband's gametes. As this case was on-going, the Chief Executive advised members that it would be inappropriate to go into detail, but the HFEA hoped that a satisfactory conclusion could be reached without a full hearing. The Chief Executive emphasised that the HFEA had made it clear to clinics for some time that they must not align the storage period to which a patient consents with the period for which they had paid for storage.
- 4.12.** Treatment add-ons: the Chief Executive advised members that there had been some reporting in the press on the issue of fertility treatment 'add-ons'. The Chair had given a quote to the Independent saying that the HFEA was concerned about the issue. The Chief Executive advised members that the HFEA would be working on this over the coming months and the new website would be an opportunity to provide clear advice to patients.
- 4.13.** Surrogacy: the Chief Executive informed members that, in June, the President of the Family Court made a declaration of incompatibility under the Human Rights Act 1998 in relation to the Human Fertilisation and Embryology (HFE) Act 1990 (as amended) regarding the prohibition on single fathers applying for a parental order. The Department of Health had not contested the case, having already conceded that the relevant statutory provisions were incompatible. There had been a reasonable amount of press attention, although the HFEA were not directly involved given its limited role in the context of surrogacy.

5. Committee chairs' updates

- 5.1.** In the absence of the Chair of SAC, a member reported that the committee had met on 26 May and 24 June. There had been four preimplantation genetic diagnosis (PGD) applications in May, three of which were approved and one adjourned, pending receipt of further legal advice. At the June meeting, the minutes of which had not yet been published, seven PGD applications and one Special Directions application had been considered.
- 5.2.** The Chair of SCAAC reported that the committee had met on 13 June and had considered the following items:
- A novel process application for embryo selection
 - CE marking guidance
 - HFEA website content review – treatment 'add-ons'
 - Alternative methods to derive embryonic and embryonic-like stem cells.
- 5.3.** The Chair of SCAAC also welcomed Tony Rutherford who had joined the committee as a new member.
- 5.4.** The Deputy Chair of AGC advised members that the committee had met on 15 June, and had received reports on:
- People Strategy and HR Risks (staff survey results), from the Chief Executive
 - IfQ risk management, from the Director of Compliance and Information
 - The recent work of the Internal and External Audit teams
 - Implementation of audit recommendations, from the Finance and Accounting Manager
 - Information assurance and security, from the Director of Finance and Resources and the Head of IT
 - Strategic risks, from the Project Risk and Performance Manager
 - The Annual Report and Accounts, including the Annual Governance Statement, from the Head of Finance
 - The AGC forward plan.
- 5.5.** The Deputy Chair of AGC drew members' attention to the AGC annual report, which was produced following the 2015 review of committee effectiveness. The report summarised the committee's work during 2015/16 and the key point to note was that AGC was satisfied with the arrangements the HFEA had in place for risk management and assurance.
- 5.6.** The Deputy Chair of the Licence Committee reported that the committee had met on 20 June and had considered one licence renewal application which was granted.
- 5.7.** The Director of Strategy and Corporate Affairs advised members that the Executive Licensing Panel (ELP) had met four times since the last Authority meeting on 20 May, 6 and 17 June and 1 July. The panel had considered 24 items in total, one of which had been referred to the Licence Committee and the rest of which were approved. There were ten renewal licence applications; six interim inspection reports; two voluntary revocations and six licence variations.

- 5.8.** The Chair also advised members that the Chair of the independent Appeals Committee had prepared a brief report which had been circulated to members, outlining the activity of the committee in 2015. Once the report had been reviewed, it would be made available on the HFEA website.

6. Strategic performance report

- 6.1.** The Director of Strategy and Corporate Affairs summarised her directorate's delivery against the HFEA strategy, including the day-to-day and business as usual activity as well as the high level work being done to achieve the strategy.
- 6.2.** During the last 12 months, the directorate had handled over 300 media enquiries, issued 18 proactive statements and had nearly 300 references to the HFEA in media outlets across 14 countries. 50 PGD applications had been processed, 88 licences had been issued, 68 Parliamentary Questions answered and 99 Freedom of Information requests handled, all within the appropriate deadlines.
- 6.3.** In terms of communications, the HFEA annual conference attracted 220 delegates, 70 Clinic Focus articles had been issued, 77,000 new words for the website drafted, and the HFEA now attracted almost 3000 Twitter followers, an 800 increase over the last 12 months. 20 stakeholder meetings had been held, representatives of the HFEA had spent over 15 hours at fertility shows and over 2000 public enquiries had been handled.
- 6.4.** In terms of the strategy (setting standards), the Director of Strategy and Corporate Affairs advised members that a call for evidence had recently been issued for the expert scientific panel on mitochondrial donation, chaired by Dr Andy Greenfield. The call for evidence was published on 21 June and was triggered by two pieces of research published, one by the Newcastle research laboratory taking a step forward in the assessment of the new mitochondrial donation techniques. The scientific expert panel was subsequently re-convened, with two new members, to consider these new areas of research. The call for evidence, which would close on 12 July, gave people the opportunity to submit other pieces of research and the panel would meet on 18 and 19 July.
- 6.5.** The Director of Strategy and Corporate Affairs advised members that a significant amount of new information had been drafted for the new HFEA website, including on donation and treatment abroad, which would help prospective patients make an informed choice. Future pieces of work included a new project shortly due to commence on embryo research, a review of the Code of Practice, and a consideration of the extent to which the new Clinic Portal could be used to develop learning tools for clinics.
- 6.6.** The Director of Strategy and Corporate Affairs informed members that, on 5 July, the HFEA had published the link, to clinics only, to the beta version of the new website and CaFC. As mentioned earlier in the meeting, SCAAC had considered information about treatment 'add-ons', which would be available on the website once it had been reviewed, and significant progress had also been made on NHS service provision.
- 6.7.** For the autumn, the Director of Strategy and Corporate Affairs advised members that there would be an information campaign to promote the new information on treatment 'add-ons'. The new

HFEA website would also have a new feature for patients to rate their experience of care at the clinic where they had received treatment over the last 12 months.

- 6.8.** The Director of Strategy and Corporate Affairs advised members that the 2015/16 expenditure for her directorate was within budget, with a 45% saving on annual conference costs.
- 6.9.** The Director of Finance and Resources gave an overview of financial performance and advised members that the 2015/16 accounts were finally laid before Parliament on 4 July and were now available on the HFEA website. In relation to the management accounts and the position in 2016/17, the Director of Finance and Resources advised members that there was one correction in the strategic performance report on page five, where the surplus on income was reported as at the end of April. The figure of £436k quoted was, in fact, the year-end position, and the position as at the end of April was actually a surplus of £57k. The Director of Finance and Resources informed members that the trend of surplus on income had continued, although it was very difficult to forecast whether that would continue for the rest of the financial year, particularly with additional legal costs likely.
- 6.10.** The Director of Finance and Resources advised members that debtor control, a partially automated system, was running smoothly and, as a result, the HFEA did not currently have any debts.
- 6.11.** The Director of Compliance and Information summarised activities within his Directorate. Many staff within the Directorate were heavily involved with work on the IfQ programme. In relation to the inspection and compliance activities, members were advised that the 2015/16 inspection year had been a particularly busy one, with a 40% increase year on year. However, members noted that the average number of working days taken for the whole licensing process, from the day of inspection to the decision being communicated to the clinic, was at its lowest which was testament to the hard work of the team.
- 6.12.** Following a discussion, members noted the latest strategic performance report.

7. Strategic risk register

- 7.1.** The Project Risk and Performance Manager provided members with an overview of the risks, showing the relative risk tolerance positions and residual risk scores. Five of the twelve risks remained high and were deemed above tolerance:
- 7.2.** Legal challenge: a relatively high risk tolerance of 12 was set for this particular risk due to the inevitability of some degree of resource diversion owing to the nature of the HFEA's work. The residual risk was currently at tolerance.
- 7.3.** IfQ – improved information access: the residual risk of 12 was higher than tolerance (set at a medium level of 8) due to approval process delays at the first stage of the programme, and the risk to the quality of the final product that could be delivered if there were any further approval delays encountered.
- 7.4.** IfQ – delivery of promised efficiencies: the residual risk of 12 was higher than tolerance (set at a medium level of 9) with further Government Digital Service (GDS) approval delays potentially adversely affecting the quality and extent of the final product.

- 7.5.** Data – incorrect data being released: although good controls were in place for dealing with PQs and other externally generated requests, volumes could not be controlled, nor the complexity of requests. Recent volumes and complexity had been high. The residual risk of 9 was therefore higher than the tolerance threshold of 8.
- 7.6.** Capability – knowledge and capability: the residual risk of 9 was above the current tolerance level of 6. Staff turnover could lead to fluctuations in overall capability, although the period of highest turnover appeared to be ending, with two posts at Head level having been filled, although there would be a period of bedding in.
- 7.7.** Members noted the latest version of the strategic risk register.

8. Information for Quality: update

- 8.1.** The Director of Compliance and Information explained that the IfQ programme was a comprehensive review of the information that the HFEA held, the systems that governed the submission of data, the uses to which it was put and the ways in which the information was published. It included:
- The redesign of the HFEA’s website and Choose a Fertility Clinic (CaFC) function
 - The redesign of the ‘Clinic Portal’ used for interacting with clinics
 - Combining data submission functionality
 - A revised dataset and data dictionary which would be accredited
 - A revised Register of treatments, which would include the migration of historical data contained within the existing Register
 - The redesign of the HFEA’s main internal systems that comprised the Authority’s Register and supporting IT processes.
- 8.2.** The Director of Compliance and Information explained that this presentation was to update members on:
- The work in progress in readiness for public beta, and the approval process to proceed to a fully live service
 - Data migration and cleansing
 - Programme timelines and budget implications.
- 8.3.** Approvals and beta progress: the Director of Compliance and Information reminded members of the several stages that government IT programmes must progress through:
- ‘alpha’ (build a prototype, test it with users and learn from it)
 - ‘beta’ (scaling up, a working model)
 - ‘public beta’ (going public with a beta version, receiving feedback and preparing to go live)
 - ‘live’ (a tested solution ready to release and then continuously improved).
- 8.4.** The IfQ programme was required to pass assessments against the 18 GDS standards by the Department of Health. The Director of Compliance and Information advised members that, on 11

and 12 May, the new HFEA website and Clinic Portal products were passed as ready to proceed to 'public beta'. As with any useful review process, some recommendations for improvement had been made and substantial activity taken place to address those recommendations. Work to finalise the public beta products had also largely been completed.

- 8.5.** The Director of Compliance and Information informed members that the beta version of the new HFEA website had been released to clinics only on 5 July, with the beta version release of the new Clinic Portal imminent. This additional, interim, phase would enable clinic audiences to access the website over a two-week period to view the new content. Following this period, it was expected that the new HFEA website and Clinic Portal would be made available to all in 'public beta' in mid-July for a period of approximately eight to ten weeks. Following public beta, a further full gateway assessment by the Department of Health against the GDS standards would be required. This was scheduled for September 2016.
- 8.6.** Data migration and data cleansing: members were reminded that there was a certain amount of data cleansing that clinics were required to carry out before the data could be migrated to the new Register. The Director of Compliance and Information advised that the Register Information team was currently working with clinics on 'severity one errors'. In total, around 3,500 errors were being reviewed, prior to the data migration to the revised Register. To date, 1,240 errors had been fixed. A well-managed and successful data migration process was central to realising many of the anticipated benefits of the IfQ Programme, and to managing risk, and the AGC, at its meeting in June, had explored the risks in some depth. In recognition of the importance of the data migration process, external suppliers had been engaged to develop a strategy for completing the data migration process appropriately. Members were advised that a procurement exercise was underway to identify a suitable third party, in order to provide assurance that the steps required in the data migration strategy were being completed correctly.
- 8.7.** The Director of Compliance and Information advised that, throughout the entire data migration process, and when the new Register structure was operational, the existing Register database would be retained as a reference. This would ensure that there was no risk that the data migration activity would compromise the actual data held in the current Register structure.
- 8.8.** Timelines and budget implications: the Director of Compliance and Information reminded members that a revised programme plan had been finalised and signed off by the IfQ Programme Board in January 2016, in line with the overall £1.134m agreed by the Authority. On 24 May, the Senior Management Team (SMT) decided to allocate an additional £90k to the overall Programme budget to ensure that critical staff were retained on the team.
- 8.9.** The Director of Strategy and Corporate Affairs provided members with a demonstration of the new HFEA website and CaFC, and the Director of Compliance and Information with a demonstration of the Clinic Portal.
- 8.10.** Following a discussion, Authority members noted:
- The work in progress in readiness for public beta, and the approval process to proceed to a fully live service
 - Progress since the last Authority meeting
 - Data migration and cleansing
 - Programme timelines and budget implications.

9. Inspection ratings

- 9.1.** The Head of Corporate Governance presented this item and advised members that part of the redesigned Choose a Fertility Clinic (CaFC) service would include a new inspection rating, based on the length of the clinic's licence. This simple, evidence-based measure would feature alongside the patient rating and the birth rates, to help patients get an overall picture of the quality of the clinic.
- 9.2.** Each clinic's entry on the new CaFC would include:
- A description of the clinic taken from the inspection report
 - An inspection rating out of five stars based on the length of the licence
 - A general description of how a rating was generated and a clinic specific explanation if no rating was shown
 - The date of the most recent inspection and the date the licence was due to expire
 - A link to the full report and licensing minutes.
- 9.3.** The Head of Corporate Governance explained that most clinics held a four-year licence and would therefore have a five star rating. All clinics with four or three ratings were on shorter licences because of concerns about their compliance. A one rating would apply to a clinic which had such a poor record of compliance or engagement from the Person Responsible (PR) that the licensing committee felt unable to grant any licence until such a time that certain non-compliances had been addressed. The Head of Corporate Governance emphasised that this rating was usually short-lived, assuming that the PR was able to demonstrate compliance and be given a proper licence relatively quickly.
- 9.4.** Some clinics would have no rating appear (a 'null rating'). Clinics with a 'null' rating would be those on a two-year initial licence. This was standard practice since a new clinic would not yet be able to demonstrate a history of compliance. Some clinics on Special Directions might also temporarily appear as having a null rating if, for example, an HFEA administrative error had caused their licence to appear to expire before a new one was issued.
- 9.5.** However, the Head of Corporate Governance explained that situations could arise when it was not clear where the fault lay, perhaps because there was a number of contributory factors. In such cases, the Executive recommended case-by-case consideration by the licensing committee as to whether a one rating or a null rating should be shown. As long as the reason for the decision was included in the minutes, no further guidance would be required from the committee.
- 9.6.** The Head of Corporate Governance explained, in respect of interim inspections, the purpose of which was to check regulatory performance during the period of the licence, there had been a suggestion that the HFEA might review the inspection rating after consideration of the interim inspection report, based on whether the clinic's performance had improved or deteriorated. However, the Executive recommended that latest performance should not affect the inspection rating for the following reasons:
- It would advantage some but disadvantage others
 - It would break the link between licence length and rating, resulting in confusion and inconsistency

- Interim inspections used a different methodology from renewal inspections
- Keeping the rating matched to the length of the licence throughout the whole licence created an incentive to maximise performance proactively at the time of the renewal inspection, rather than reactively later on.

9.7. Members were asked to:

- Note and endorse the overall policy of using the length of a licence to determine the inspection rating
- Consider the recommendation regarding null ratings where the reason was unclear
- Consider the recommendation not to adjust the rating in light of performance at interim inspections.

9.8. Following a discussion, members accepted the recommendations subject to the following caveats in relation to the null ratings:

- New clinics would be listed on the website as being a new clinic (rather than having a null rating)
- If a clinic was on Special Directions through no fault of its own, the previous inspection rating should remain until a new licence was granted (rather than having a null rating)
- If a dispute arose which required resolution through the Licence, Representations or Appeals Committees, the previous inspection rating would remain in place until the matter was resolved.

10. Opening the Register report

- 10.1.** The Donor Information Manager presented this item and updated members on activity in the Opening the Register (OTR) service over the last year and, in particular, the pilot support and intermediary service.
- 10.2.** The Donor Information Manager reminded members that the HFEA strategy put patients (including donors and donor-conceived people) and the quality of care they received at the centre of its work.
- 10.3.** The Donor Information Manager informed members that there had been a steady rise year-on-year in the number of OTR applications handled by the HFEA, with over double the amount in 2015 compared to 2010.
- 10.4.** In addition, the Donor Information Manager advised members that 99 donor-conceived individuals had joined the Donor Sibling Link (DSL), the HFEA's voluntary contact register, since its launch in 2010. Under this scheme, registrants agreed to the HFEA sharing their name and contact details with any of their donor-conceived genetic siblings who had also joined. The number registering was still small, with 11 per year in 2011 and 2012, but increasing to 21 per year in 2013 and 2014, and 24 in 2015, but registration was likely to grow significantly in the coming years. In 2015, the HFEA had made the first DSL match and there had been two further matches so far in 2016.
- 10.5.** The HFEA had also received 157 applications from anonymous donors (those who donated after 1991 but before 1 April 2005) to remove their anonymity. Over the last four years, there had been a slight increase in re-registering although numbers were low, with only 14 applying in 2015.

- 10.6.** In 2013, the HFEA received its first application for identifying information from an adult donor-conceived individual with an identifiable donor. In total, seven applications of this nature had been received; two per year in 2013, 2104 and 2105, and one so far in 2016. In each case, the HFEA offered and coordinated support and intermediary assistance to the donor-conceived individuals and donors concerned.
- 10.7.** The Donor Information Manager described the HFEA's pilot support and intermediary service. In July 2014, the Authority approved recommendations to work with stakeholders to scope out models for a three-year pilot and explore, at the same time, what specialist support should be provided for other people affected by donation.
- 10.8.** The HFEA had worked closely with stakeholders to develop a service which provided both of these recommendations. Members had asked that the HFEA retained control over the quality of the service provided by PAC-UK, to whom the contract was awarded, and evaluated that service during the course of the pilot. The evaluation of the first year of the service, set out in more detail in the paper, covered the cost of the service, the level of demand and its value to users and the quality of the service provided by the contractor.
- 10.9.** The cost of the service: the Donor Information Manager advised members that the Authority had set aside a capped budget of £50,000 for the duration of the pilot. Current indications were that this amount would be more than sufficient.
- 10.10.** The level of demand: members were informed that in the first year a total of just seven cases had been referred. Looking ahead, it was difficult to assess the level of demand for the service in the next two years, but given the demand so far it was not expected to be high.
- 10.11.** The quality of service: the Donor Information Manager informed members that all service users were invited to complete a feedback form which was then sent to both PAC-UK and the HFEA. Although the HFEA had not received any feedback forms thus far, informal feedback received had been positive. There had inevitably been a few teething problems, although the quality of the relationship between the HFEA and PAC-UK had improved significantly in recent months.
- 10.12.** As part of the OTR process, applicants were supplied with a link to an online confidential feedback questionnaire. The Donor Information Manager provided members with a summary of those survey responses.
- The majority of respondents discovered they could apply for information from the HFEA register through the HFEA website
 - Less than a quarter of respondents said they had spoken to someone at the HFEA before applying, although 100% of those who had rated this experience as helpful or very helpful.
 - Expectations among respondents varied in terms of the amount of information they received. 73% considered it adequate, 9% did not have any expectations, 9% expected to receive more information and 9% expected to receive less information.
- 10.13.** The survey also gave respondents the opportunity to add any further comments they had on the information they had received or the process itself, and the majority stated that they had found the process straightforward, efficient and speedy, and were grateful for both the existence of the OTR service and the high level of service received.

10.14. Following a discussion, members noted:

- The significant OTR policy and process developments over the last three years to the OTR service, which were in line with delivering the HFEA 2014-2017 strategy
- The trend showing increases in the number of applications, and the timely and sensitive way in which they were handled
- The first-year evaluation of the pilot support service and informal positive feedback received from service users.

11. Multiple births progress

- 11.1.** The Head of Regulatory Policy reminded members that in 2009 the HFEA, together with professional bodies and stakeholder groups, introduced a multiple births policy with the aim to reduce multiple birth rates by promoting elective single embryo transfer (eSET). Central to that policy was the introduction of a series of targets, starting in 2009 with the maximum multiple births rate of 24% for clinics, with the intention to reduce this in steps over a series of years to 10%, which was the current target.
- 11.2.** In 2011, the HFEA published a multiple births data report, based on the 18 months of data available at the time. This showed there had been an initial growth in eSET, a growth in blastocyst transfers and a corresponding decline in multiple pregnancy rates in that short period of time. Since then the Executive had provided annual updates to Authority members, and also provided updates to the Multiple Births Stakeholder Group.
- 11.3.** In 2008, one in four IVF births was a multiple birth, whilst currently it was about one in seven. In 2008, the vast majority of patients received a double embryo transfer. However, now, elective single embryo transfer (eSET) was more common. This had drastically reduced multiple births, which continued to decrease although progress had been slower in the last few years.
- 11.4.** The Head of Regulatory Policy advised members that the multiple births policy was very much an outcomes based policy, with the aim to reduce multiple births whilst maintaining pregnancy rates. Overall trends were positive, with pregnancies going up and multiple pregnancies going down, although, as mentioned above, progress had plateaued for the last couple of years. The steady increase in pregnancy rates reflected the increasing use of transferring embryos at blastocyst stage (embryos which had been cultured for a longer period (five to six days) in the laboratory) which generally improved the pregnancy rate. Strikingly, where two blastocysts were put back at one time, the multiple pregnancy rate was high at 35% and 40% at the youngest age group.
- 11.5.** The Head of Regulatory Policy provided an overview of the pregnancy and multiple births rate for those having eSET and those having double embryo transfer. Based on the latest available data (as yet unverified) 37% of double embryo transfers resulted in a pregnancy, but with a multiple pregnancy rate of 30%. However, 43% of pregnancies following eSET resulted in only 2% of multiple births.
- 11.6.** The Head of Regulatory Policy provided a summary of national performance on a clinic by clinic basis, which gave an indication of how well individual clinics were doing in meeting the 10% target rate. This was part of a series of tools used by the HFEA as early warnings for clinics who were unlikely to meet the 10% target or had a sudden spike in multiple births. Inspectors would then

work with those clinics to help them bring down their multiple births rate. It was worth noting that of the 19 clinics who were previously above average, only six of those were still above the limit.

- 11.7.** The Head of Regulatory Policy advised members that it was clear clinics were finding it harder to meet the 10% target, with the average being around 14%. It was therefore important to consider how the HFEA could keep up the momentum, a key point raised at the last multiple births stakeholder group meeting. The One at a Time website would soon be embedded into the new HFEA website and the Clinic Portal, which would be an opportunity for the HFEA to continue to promote eSET and the risk of multiple births. After discussions with stakeholders, the headline success rate would be changing to show birth rate as per embryo transferred, as it was felt this was the best indicator of the competence of clinics and sent the right signals to patients about what really mattered when choosing a clinic.
- 11.8.** The Head of Regulatory Policy emphasised that the multiple births rate policy was a good news story for the role of regulation and for public health more generally. Fundamentally, more women were getting pregnant, having healthy pregnancies and babies, and less were going through the increased worry and risk of a multiple birth.
- 11.9.** Following a discussion, members noted the information given in the multiple births report. They supported the proposed steps to reinvigorate the multiple births policy. They also suggested, beyond written information, developing a patient video on this issue.

12. Publication policy

- 12.1.** The Chief Executive advised members that all public bodies were required to operate in an open and transparent way with a key element of this being to publish information in a clear, accessible and easy to find way. The HFEA's publication policy had been in force since 2009, principally covering the publication of Authority and committee papers. This policy had been updated and broadened to include how the HFEA would publish all information on the new website and how information would be disclosed which would not normally be published.
- 12.2.** The Chief Executive informed members that there was an ongoing issue in relation to the amount of supporting information published for licensing decisions. At present, the inspection report and the Licence Committee minutes were routinely published. However, on occasion, with very highly publicised licensing decisions, there had been a call to publish more of the papers presented to the Licence Committee. The Chief Executive advised members that, given the forthcoming project to review the end-to-end process for research licensing, it would be sensible to maintain the status quo regarding the publication of supporting information and lay summaries of research applications. These issues would then be considered as part of that review and by the Authority later in the business year.
- 12.3.** The Chief Executive asked members to email any comments on the revised publication policy and they would be taken into consideration.

13. Any other business

- 13.1.** The Chair confirmed that the next meeting would be held on 14 September at ETC Venues Victoria, 1 Drummond Gate, London SW1V 2QW. Members were asked to confirm their attendance to the Executive Assistant to the Chair and Chief Executive as soon as possible.

14. Chair's signature

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

Signature

Chair

Date

Strategic performance report

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

Details:

Meeting Authority

Agenda item 6

Paper number HFEA (14/09/2016) 806

Meeting date 14 September 2016

Author Helen Crutcher, Project Risk and Performance Manager

Output:

For information or decision? For information

Recommendation The Authority is asked to note and comment on the latest strategic performance report.

Resource implications In budget

Implementation date Ongoing – strategic period 2014-2017

Communication(s) CMG reviews performance in advance of each Authority meeting, and their comments are incorporated into this Authority paper.

The Department of Health reviews our performance at each DH Update meeting (based on the CMG paper).

The Authority receives this summary paper at each meeting, enhanced by additional reporting from Directors. Authority's views are fed back to the subsequent CMG performance meeting.

Organisational risk Low Medium High

Annexes Annex 1: Strategic performance report

1. Introduction

- 1.1. The attached paper summarises the main performance indicators, following discussion by the Corporate Management Group (CMG) at its August performance meeting.
- 1.2. Most of the data relates to the position at the end of June 2016.
- 1.3. Overall performance is good. However, four performance indicators in the red, with progress on delivery of some of our strategic aims delayed.
- 1.4. The cause of these delays is slipped timelines for IfQ deliverables. These are the result of the diversion of resources to important business as usual tasks and the impact of earlier delays to beta timelines. A more detailed account of the slippages in IfQ can be found at item 7 on the agenda, paper number HFEA (14/09/2016) 807.
- 1.5. IfQ is being delivered through an Agile approach, so re-planning of timeframes is a natural part of delivery and delays are being managed. Whereas, the dates of strategic milestones have not been revised since December at the beginning of the beta phase of the programme, and so do not reflect these changes.

2. Recommendation

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

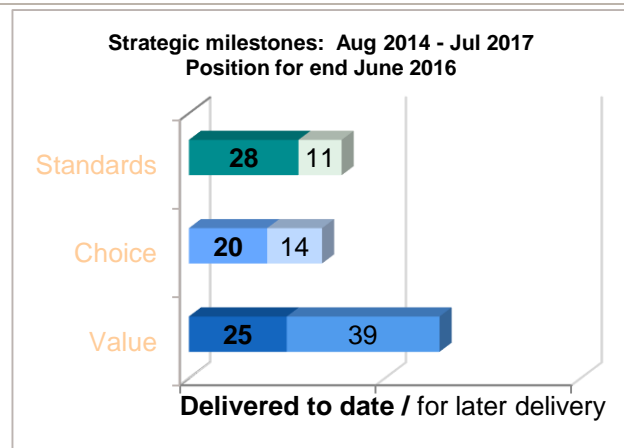
Annex A - HFEA strategic performance scorecard

1. Summary section

Dashboard – June data

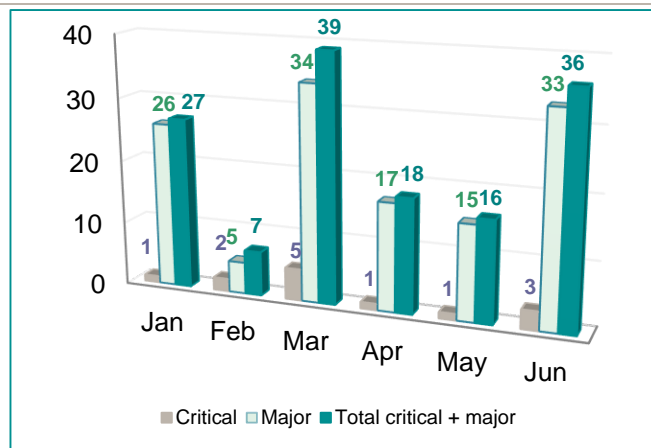
Strategic delivery totaliser

(see overleaf for more detail)



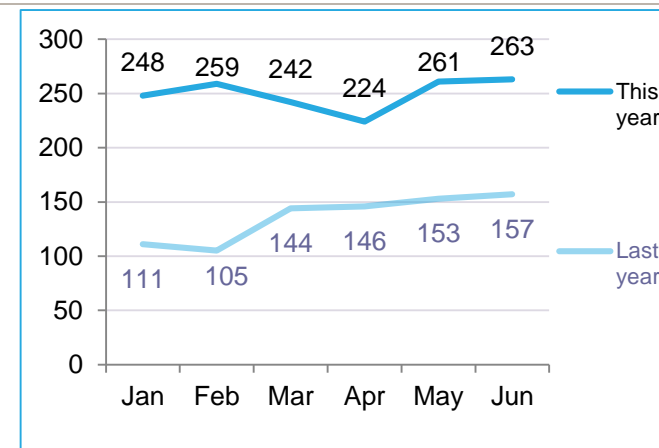
Setting standards:

critical and major recommendations on inspection

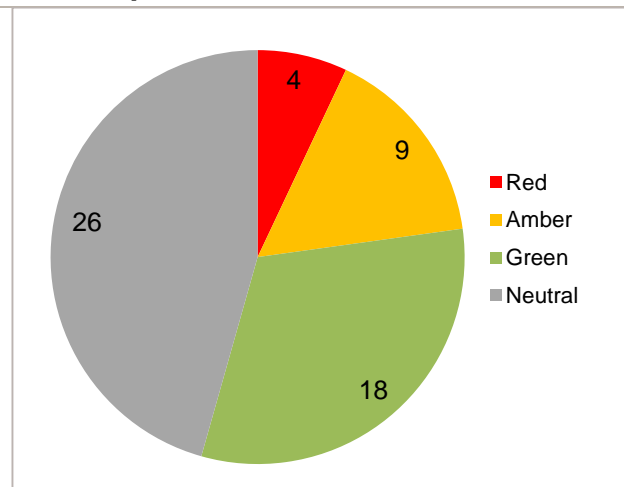


Increasing and informing choice:

public enquiries received (email)

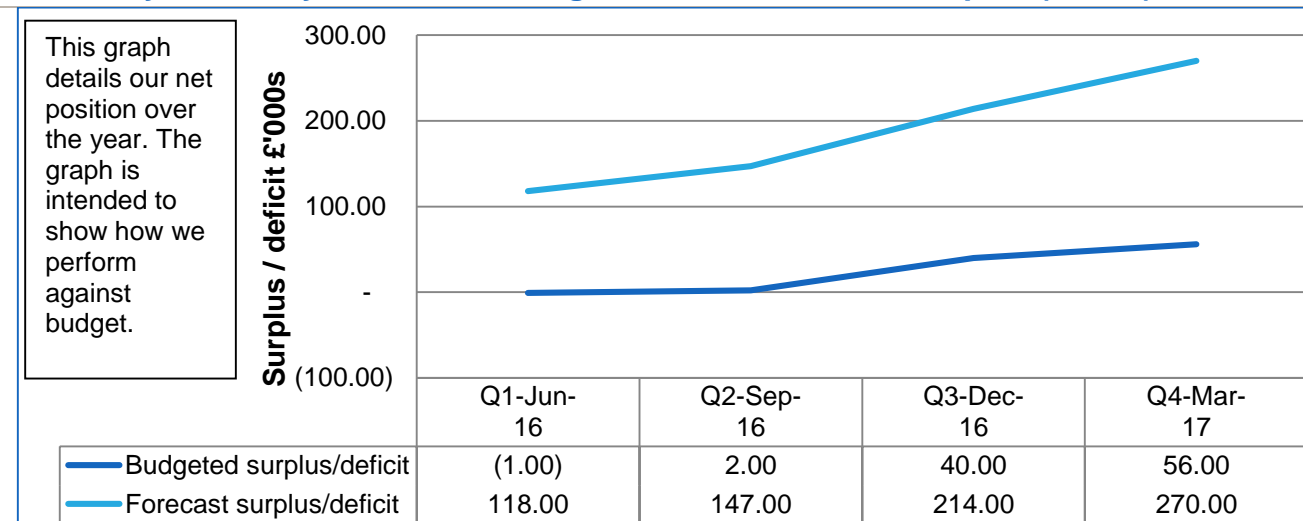


Overall performance - all indicators:



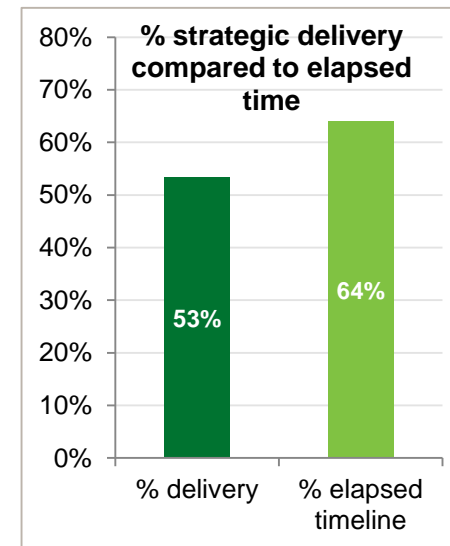
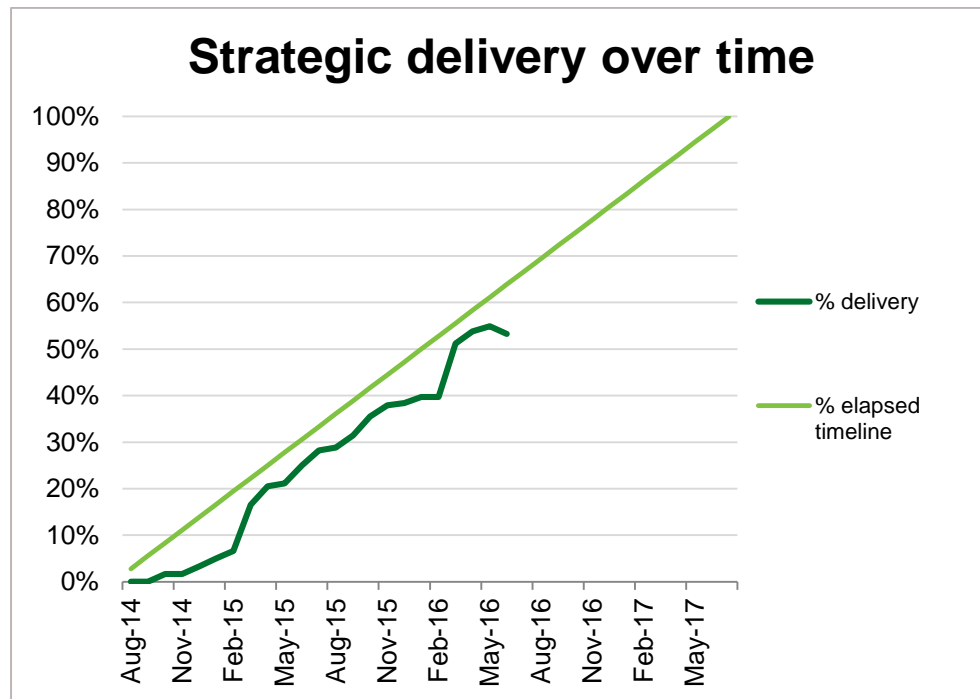
(See RAG status section for detail.)

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



Dashboard - Commentary

Strategic delivery (to end of June) – summary:



It was previously necessary to re-cast the timeline for the beta phase of IfQ. We reached our next GDS gateway review point in mid-May, and passed the reviews for both the website and clinic portal (with a number of recommendations).

This meant that we could then proceed towards the public beta phase of work. Some IfQ milestones have been delayed, mainly as a result of earlier gateway process delays or because of technical interdependencies with products that are not yet ready, causing some knock-on delays for other milestones. However, we are still making good progress, and both products reached the milestone of being ready for a beta release in July (just after the period of this report). Some of our original milestones for this quarter will be delivered later than originally planned, since we will need to allow for some agile development time and iteration of the products in response to beta feedback and the continuing work on data cleansing.

Strategic delivery in May and June:

Setting standards

There were no delivery milestones for this area in May and June.

Increasing and informing choice

There were no delivery milestones for this area in May and June.

Efficiency, economy and value

In May, we successfully prepared for and passed two DH GDS assessments, for the clinic portal and for the new website and CaFC. We also commenced trial load one in preparation for our future migration of data to the new Register. We did not complete trial load one as quickly as hoped and it has been delayed from the originally anticipated date of end June 2016 to end September 2016, due to:

- Delays finalising the Data Dictionary, which inform the trial load process
- Delays finalising Release 1 of the Clinic Portal and Website which diverted resource away from trial load one.

As noted above, there are a number of linked delays owing to slippages in the IfQ programme having knock-on effects. This is manageable through agile re-planning, and work is still going well, with planning for the next stage, release two work for the Portal and EDI, well under way.

Four milestones originally planned for completion in June have been deferred to August or September. The total number of delayed items is now 11, but these are all linked to the same changes to the IfQ timeline, and are being addressed. They are:

- Data cleansing (this was originally expected to complete in April, but has taken longer)
- Getting more explicit patient experience data into inspection reports (this was originally due to be in place by the end of June, but depends on the new CafC, which is not yet in place).
- Release 1 of the clinic portal was originally due to reach private/limited beta in March, and has been delayed.
- The first full 6 monthly update of the new CafC was originally due to take place in April, but this depends on moving into first live beta, and then full live.
- The original plan was for the clinic portal to go to early adopters for user testing as part of moving to live beta – this has been delayed from April.
- Organisational 'blueprinting'. The planned departmental review of processes has been deferred to December, since more early 'vision' work on the future conformation of the organisation is needed first. Early thinking on this has started.
- Trial load 1 completion prior to other trial loads prior to data migration – this was originally due to finish in May, but has taken longer than expected, as indicated above.
- Portal R1 full (post-private) beta was originally due to be in progress during June.
- The Portal 'go live' gateway review was originally scheduled for June, and will now be rescheduled for later (this is dependent on obtaining and addressing feedback from live beta).
- Similarly, the website was originally scheduled to go live in June or July, and will need to have a later gateway review (again, dependent on obtaining live beta feedback first).
- Trial load 2 has been delayed from an original intended date of June, by the over-running of trial load 1.

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

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

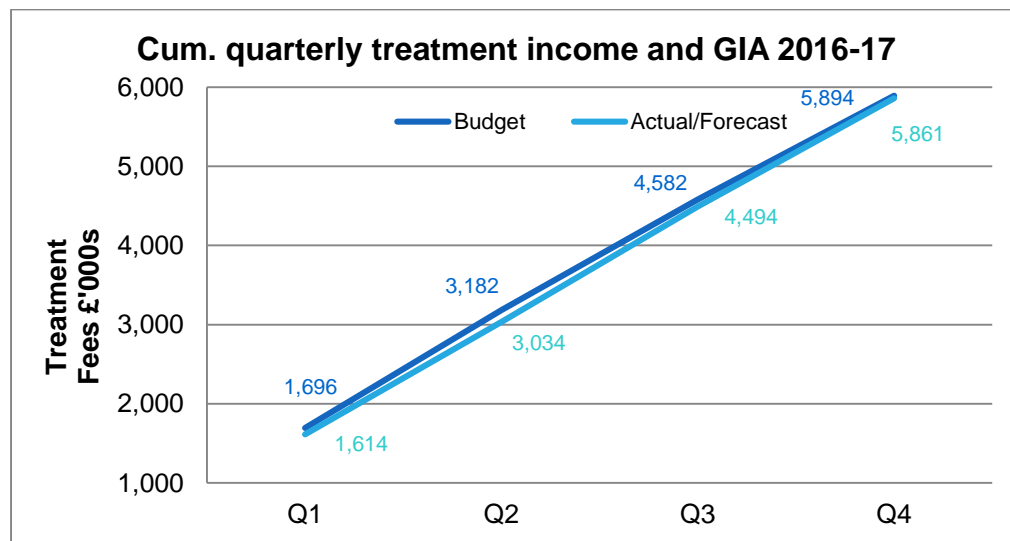
In June unexpected loss of power to the HFEA offices affected three indicators. The power outage lasted for three working days and resulted in no access to the organisation's documents and licensing database. The first affected indicator is the percentage of finalised Licence Committee, SAC, representations hearing and ELP decisions published on HFEA website within five working days of Chair sign-off. The KPI for this indicator is 100%. In June this was 65% due to seven sets of minutes being published later than expected. The second of the affected indicators was the average number of working days between minutes being finalised and decision communicated to clinics (minutes forwarded and licence issued or letter sent explaining refusal of licence). The KPI for this indicator is 100% published within two days however, again, because there was no access to the organisation's documents and database, only 81% of the 21 decisions (17) were sent on time, with 4 delayed. The third indicator affected by the power outage was the subset of the figure above, which only includes those items that followed from an inspection (renewals, interims, unannounced, change of premises and new centres).

In June we also missed the KPI for the average number of working days from day of inspection to the day the draft report is sent to the PR. The KPI for this indicator is 90% to be sent to clinics within 20 working days. In June 50% (3 of the 6 reports) were sent within this timeframe. Of the three late reports, one report was sent at 23wd. One report was sent at 28wd due to a complex inspection with a number of considerations which required the undertaking of a management review which delayed the report. One report was sent at 31wd due to the inspection process being delayed because of difficulty finding peer reviewer. The inspector was unable to complete the assessment (and inspection report) until the peer review was returned.

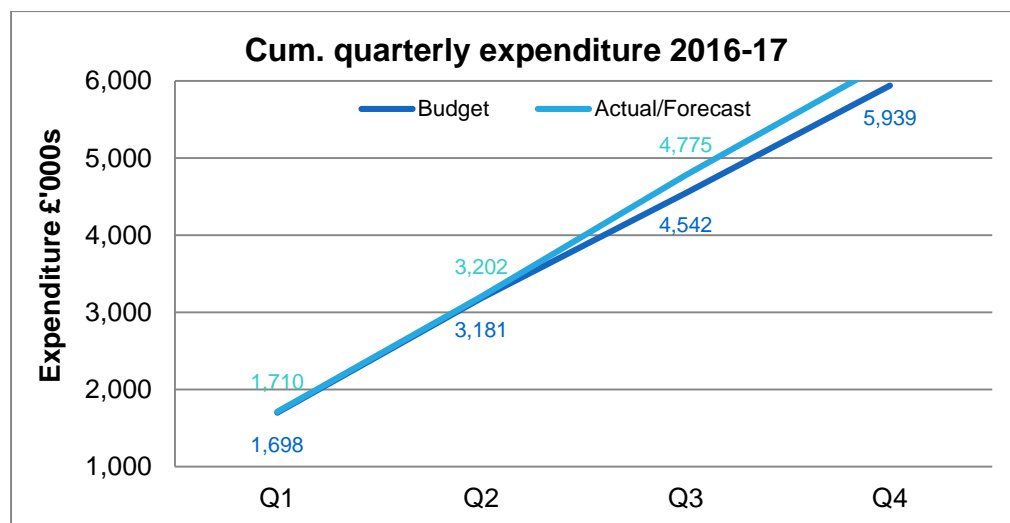
No projects were on a red risk rating in June.

Budget status – June data

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



This graph shows our budgeted (planned) income including grant-in-aid (GIA) compared to what is actually happening. The remaining ten months (3 quarters) are based on budget hence the closeness of the two lines. As of month 3 (30 June 2016) we have exceeded our budgeted income by £262k. A detailed analysis of treatment cycles has been undertaken, see commentary for explanation.



This graph is the second component that makes up the surplus/deficit. This includes costs relating to IfQ, although they are being funded from reserves and will be transferred to the balance sheet at year end.

We are three months into the new business year and have undertaken a review of costs and plans for the remainder of the year. The forecast figures therefore have been adjusted to take into account known expenses to be incurred throughout the year.

Quality and safety of care

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

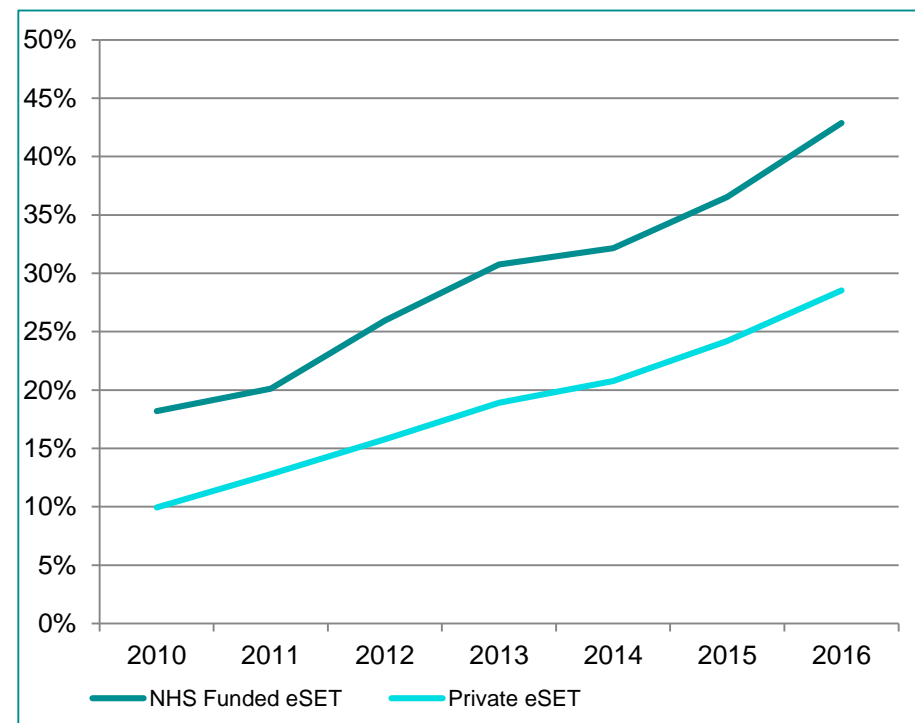
- number of risk tool alerts (and themes)
- common non-compliances (by type)
- incidents report (and themes).

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

ESET split by private/NHS:

Funding	Year						
	2010	2011	2012	2013	2014	2015	2016
NHS Funded:							
Recorded as eSET	4289	4903	6264	7870	8444	9746	6683
	7%	8%	10%	13%	13%	15%	18%
Not recorded as eSET	19287	19490	17870	17718	17824	16922	8904
	33%	32%	30%	29%	28%	26%	23%
Relative eSET %	18%	20%	26%	31%	32%	37%	43%
Private:							
Recorded as eSET	3422	4630	5699	6857	7737	9340	6452
	6%	8%	10%	11%	12%	14%	17%
Not recorded as eSET	31024	31547	30398	29392	29502	29244	16156
	54%	52%	51%	48%	47%	45%	42%
Relative eSET %	10%	13%	16%	19%	21%	24%	29%

Graph: eSet % trends NHS/private:



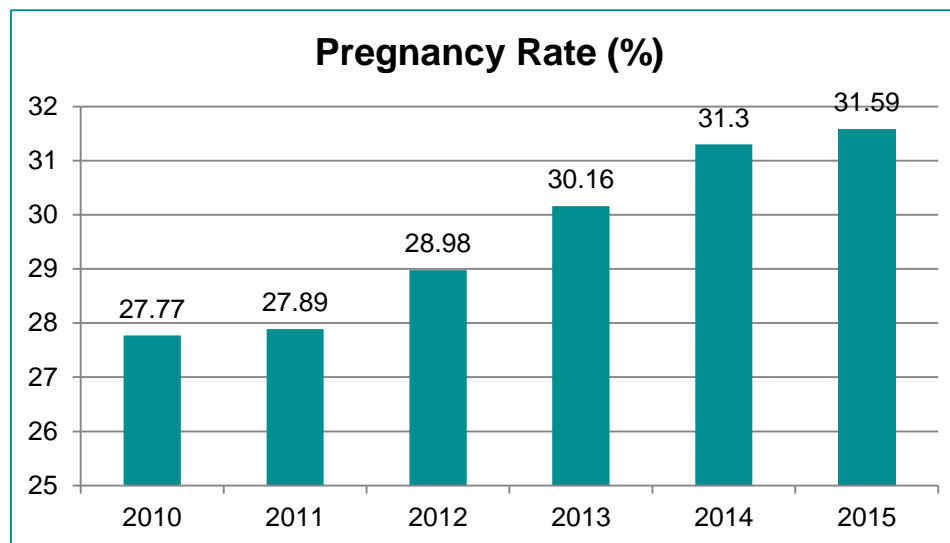
Explanatory text: Showing the total of all reported IVF treatment forms and counting those that the clinics recorded as eSET

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

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

Years	All cycles	Pregnancies	Pregnancy rate %
2010	58022	16112	27.77
2011	60570	16896	27.89
2012	60231	17455	28.98
2013	61837	18650	30.16
2014	63507	19875	31.3
2015	65252	20611	31.59
2016	38196	9650	25.26


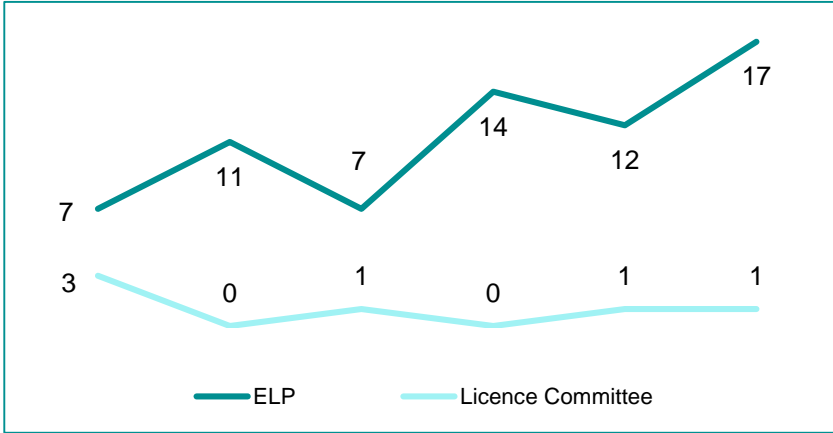

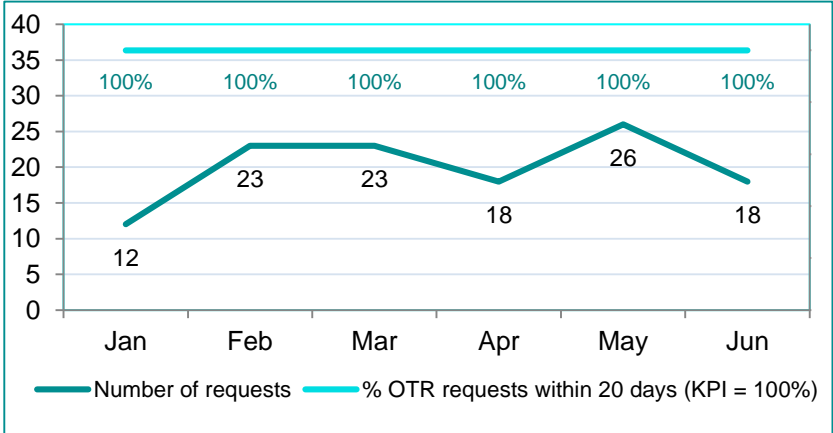

Graph showing the pregnancy rate over recent years:



Explanatory text: Looking at all IVF treatment forms, and providing a count of pregnancies - as recorded on the early outcome form. 2016 figures are in grey since it is still quite early in the year, and there is always a lag in reporting pregnancies.

2. Indicator section

Key performance and volume indicators – June 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	17 1			No KPI – tracked for workload monitoring purposes	Volume indicator (no KPI target).
Setting standards: improving the lifelong experience for donors, donor-conceived people, patients using donor conception, and their wider families.					
Percentage of Opening the Register requests responded to within 20 working days	100% (18)			Maintain at 100% 	KPI: 100% of complete OTR requests to be responded to within 20 working days (excluding counselling time)

¹ Blue dashed line in graphs = KPI target level. This line may be invisible when performance and target are identical (eg, 100%).

² Direction in which we are trying to drive performance. (Are we aiming to exceed, equal, or stay beneath this particular KPI target?)

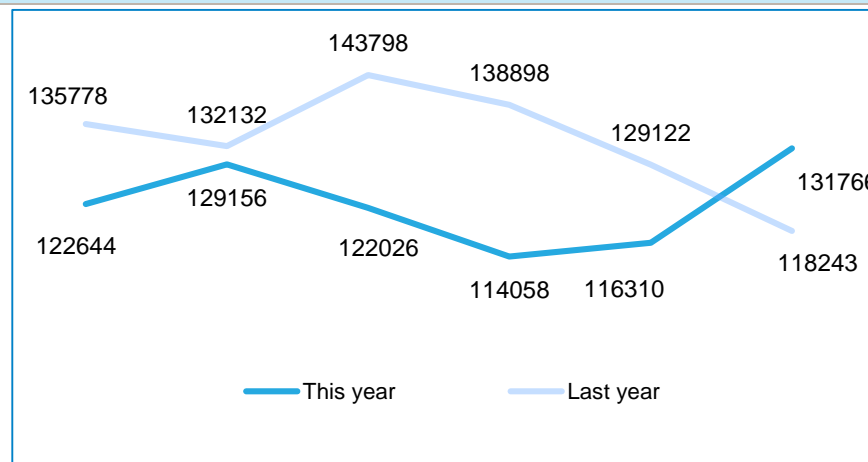
Indicator	Performance	RAG	Recent trend ¹	Aim ²	Notes
Increasing and informing choice: using the data in the Register of Treatments to improve outcomes and research.					

See graphs focused on quality of outcomes – after dashboard page.

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

Number of visits to the HFEA website (compared with previous year)
 (trend arrow indicates movement since previous month)

131,766
 (118,243)



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'.
 The increase in visits in June is explained in the comments below.

Commentary: This measure may vary significantly during public beta or when the new website becomes live. This will mean that new data will not be comparable with the previous year until we have a year's worth of this new data.

June saw a huge surge in interest in the surrogacy options page, with an increase of some 300% on the previous year and a rate two and a half times higher than the average top ranking pages. The spike – which occurred between Monday 27 to Wednesday 29 June (peaking on Tuesday) saw 23,000 page views, compared with normal traffic which varied between around 6,000 and 10,000 page views a day over the month.


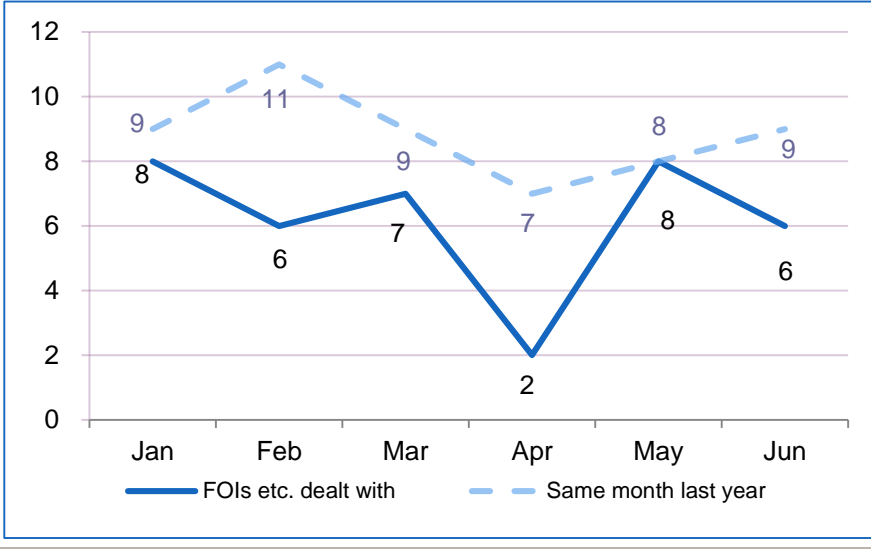

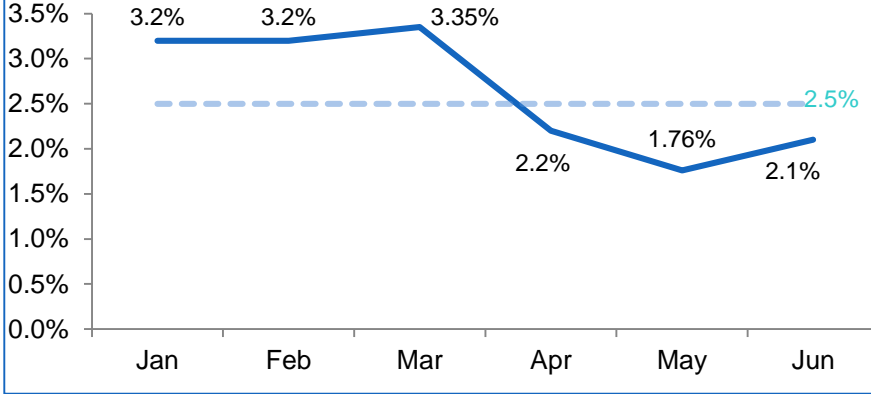

Investigation has shown that 44% of the traffic in that time period came from India (compared to 18% in the UK). Initial views in identifying the cause of the spike was the recent ban on surrogate services in India to foreigners – however this is still not passed in law. The more likely reason was the news that a Bollywood, single male, actor, Tusshar Kapoor, had become a father via surrogacy which was announced in the Indian media around the dates quoted above

Indicator	Performance	RAG	Recent trend ¹	Aim ²	Notes														
Efficiency, economy and value: ensuring the HFEA remains demonstrably good value for the public, the sector and Government.																			
<p>Average number of working days taken for the whole licensing process, from the day of inspection to the decision being communicated to the centre.</p>	67 working days	★	<table border="1"> <caption>Average number of working days taken for the whole licensing process</caption> <thead> <tr> <th>Month</th> <th>Working Days</th> </tr> </thead> <tbody> <tr> <td>Jan</td> <td>58</td> </tr> <tr> <td>Feb</td> <td>69</td> </tr> <tr> <td>Mar</td> <td>62</td> </tr> <tr> <td>Apr</td> <td>50</td> </tr> <tr> <td>May</td> <td>60</td> </tr> <tr> <td>Jun</td> <td>67</td> </tr> </tbody> </table>	Month	Working Days	Jan	58	Feb	69	Mar	62	Apr	50	May	60	Jun	67	<p>↓</p> <p>Maintain at 70wd or less</p>	<p>KPI: Less than or equal to 70 working days.</p>
Month	Working Days																		
Jan	58																		
Feb	69																		
Mar	62																		
Apr	50																		
May	60																		
Jun	67																		
<p>Monthly percentage of PGD applications processed within three months (66 working days).</p>	80%	↔	<table border="1"> <caption>Monthly percentage of PGD applications processed within three months</caption> <thead> <tr> <th>Month</th> <th>Percentage</th> </tr> </thead> <tbody> <tr> <td>Jan</td> <td>100%</td> </tr> <tr> <td>Feb</td> <td>100%</td> </tr> <tr> <td>Mar</td> <td>100%</td> </tr> <tr> <td>Apr</td> <td>100%</td> </tr> <tr> <td>May</td> <td>80%</td> </tr> <tr> <td>Jun</td> <td>80%</td> </tr> </tbody> </table>	Month	Percentage	Jan	100%	Feb	100%	Mar	100%	Apr	100%	May	80%	Jun	80%	<p>↑</p> <p>Maintain 100%</p>	<p>KPI: 100% processed (i.e. considered by SAC) within three months (66 working days) of receipt of completed application.</p>
Month	Percentage																		
Jan	100%																		
Feb	100%																		
Mar	100%																		
Apr	100%																		
May	80%																		
Jun	80%																		
<p>Average number of working days taken.</p>	54	★	<table border="1"> <caption>Average number of working days taken</caption> <thead> <tr> <th>Month</th> <th>Working Days</th> </tr> </thead> <tbody> <tr> <td>Jan</td> <td>51</td> </tr> <tr> <td>Feb</td> <td>56</td> </tr> <tr> <td>Mar</td> <td>57</td> </tr> <tr> <td>Apr</td> <td>51</td> </tr> <tr> <td>May</td> <td>59</td> </tr> <tr> <td>Jun</td> <td>54</td> </tr> </tbody> </table>	Month	Working Days	Jan	51	Feb	56	Mar	57	Apr	51	May	59	Jun	54		
Month	Working Days																		
Jan	51																		
Feb	56																		
Mar	57																		
Apr	51																		
May	59																		
Jun	54																		

Commentary: Performance has dropped below the target due to two complex applications falling outside the KPI in May and June 2016. In each case this was due to the committee deferring the items in order to obtain additional legal advice on the 'significant risk' test.

Indicator	Performance	RAG	Recent trend ¹	Aim ²	Notes
<p>Annualised (rolling year) percentage of PGD applications processed within three months (66 working days)</p> <p>96%</p>	96%	↓	<p>100% 100% 100% 100% 98% 96%</p>	Maintain 100%	<p>KPI: As above. (Annualised score). Per the above measure, performance has dropped below the target due to two complex applications falling outside the KPI in May and June 2016. The annualised figure will now be impacted until 2017.</p>
<p>Average number of working days taken.</p> <p>53</p>	53	★	<p>49 49 51 51 52 53</p>	↑	
<p>Number of requests for contributions to Parliamentary questions</p> <p>Total = 3</p>	Total = 3	↓	<p>40 35 30 25 20 15 10 5 0</p> <p>Jan Feb Mar Apr May Jun</p> <p>— PQs dealt with — No. re mitochondria - - - Same month last year</p>	No KPI – tracked for general monitoring purposes.	<p>Volume indicator. Last year's numbers were notably high. Many of those PQs related to the work we were then doing on mitochondria. scientific review.</p>

Commentary: Although there have not been mitochondria related requests to report over the last few months, it is likely that interest in mitochondria will increase once more in the coming months once the report of the most recent expert panel scientific review is published.

Indicator	Performance	RAG	Recent trend ¹	Aim ²	Notes
<p>Number of Freedom of Information (FOI), Environmental Information Regulations (EIR) requests and Data Protection Act (DPA) requests</p>	6			<p>No KPI – tracked for general monitoring purposes.</p>	<p>Volume indicator. There does not appear to be any trend or predictability in the volume or focus of our FOI (and other) requests.</p>
<p>Staff sickness absence rate (%) per month.</p>	2.1%			<p style="text-align: center;">  Maintain 2.5% or less </p>	<p>KPI: Absence rate of ≤ 2.5%. Public sector sickness absence rate average is eight days lost per person per year (3.0%).</p>

Commentary: The current absence rate has returned to below KPI following an earlier rise which was due mainly to long-term sick leave and seasonal illnesses. This was investigated and did not demonstrate a trend towards problematic sickness absence, though we will continue to monitor this.

Indicator	Performance	RAG	Recent trend ¹	Aim ²	Notes																					
Cash and bank balance	£2,235k	↑	<p>The chart displays the monthly cash and bank balance over a six-month period. The y-axis represents the balance in thousands of pounds, ranging from £1,000 to £2,600. The x-axis shows the months from January to June. A solid blue line with diamond markers represents the 'Cash and bank balance', and a dashed light blue line represents the 'KPI' target at £1,520k. The current performance in June is £2,235k, which is significantly above the KPI target.</p> <table border="1"> <caption>Cash and bank balance data</caption> <thead> <tr> <th>Month</th> <th>Cash and bank balance (£k)</th> <th>KPI (£k)</th> </tr> </thead> <tbody> <tr> <td>Jan</td> <td>£2,185</td> <td>£1,520</td> </tr> <tr> <td>Feb</td> <td>£2,378</td> <td>£1,520</td> </tr> <tr> <td>Mar</td> <td>£2,157</td> <td>£1,520</td> </tr> <tr> <td>Apr</td> <td>£2,220</td> <td>£1,520</td> </tr> <tr> <td>May</td> <td>£2,108</td> <td>£1,520</td> </tr> <tr> <td>Jun</td> <td>£2,235</td> <td>£1,520</td> </tr> </tbody> </table>	Month	Cash and bank balance (£k)	KPI (£k)	Jan	£2,185	£1,520	Feb	£2,378	£1,520	Mar	£2,157	£1,520	Apr	£2,220	£1,520	May	£2,108	£1,520	Jun	£2,235	£1,520	<p>Reduce</p>	<p>KPI: To move closer to minimum £1,520k cash reserves (figure agreed with DH).</p>
Month	Cash and bank balance (£k)	KPI (£k)																								
Jan	£2,185	£1,520																								
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Jun	£2,235	£1,520																								

Indicator	Performance	RAG	Recent trend ¹				Aim ²	Notes
Management accounts:	Management accounts: May 2016:							
	Income & Expenditure Account							
Accounting Period	May-2016							
	Year to Date				Full Year			
	Actual YTD	Budget YTD	Variance YTD	% Variance YTD	Forecast	Budget	Variance	
	£	£	£	%	£	£	£	
Grant-in-aid	-	-	-	0	958	958	-	
Licence Fees	928	756	(172)	(23)	4,472	4,472	-	
Other Income	-	1	1	61	6	6	-	
Total Income	929	757	(172)	(0)	5,436	5,436	-	
Revenue Costs - Charged to Expenditure								
Salaries (excluding Authority)	447	452	4	(1)	2,666	2,679	(13)	
Shared Services	20	20	-	0	97	81	17	
Employer's NI Contributions	42	42	-	1	254	247	7	
Employer's Pension Contribution	93	97	4	(4)	572	573	(1)	
Authority salaries inc. NI Contributions	24	24	-	1	146	146	-	
Temporary Staff costs	21	-	(21)	0	30	-	30	
Other Staff Costs	40	38	(2)	5	265	265	-	
Other Authority/Committee costs	36	50	14	(28)	301	301	-	
Other Compliance Costs	3	7	4	(61)	28	28	-	
Other Strategy Costs	6	13	7	(53)	142	142	-	
Facilities Costs incl non-cash	121	115	(6)	5	488	488	-	
IT costs Costs	21	15	(6)	36	93	93	-	
Legal Costs	47	56	9	(16)	400	400	-	
Professional Fees	14	11	(2)	20	67	67	-	
Total Revenue Costs	936	940	5	(1)	5,547	5,507	40	
Total Surplus/(Deficit) before Capital & Project costs	(7)	(183)	(177)	(96)	(111)	(70)	(40)	
IFQ & Other Project Costs - Reserves funded	92	104	12	(12)	472	472	-	
Other Capital Costs	1	-	(1)	0	100	100	-	
TOTAL NET ACTIVITY	86	(79)	(166)		462	502	(40)	

Indicator	Performance	RAG	Recent trend ¹				Aim ²	Notes
Management accounts: June 2016:								
Income & Expenditure Account			Jun-2016					
Accounting Period	Period 3 16-17							
Cost Centre Name	All Cost Centres							
Department Name	All Departments							
	Year to Date				Uncommitted	Full Year		
	Actual YTD	Budget YTD	Variance	% Variance	Bal for the Year	Forecast	Budget	Variance
	£	£	£	%	£	£	£	£
Grant-in-aid	234	235	(1)	(0)	719	953	958	(5)
Licence Fees	1,380	1,118	262	23	3,542	4,922	4,472	450
Other Income	1	2	(0)	(18)	5	6	6	-
Total Income	1,615	1,354	262	19	4,266	5,881	5,436	445
Revenue Costs - Charged to Expenditure								
Salaries (excluding Authority)	667	677	9	(1)	2,000	2,668	2,679	(11)
Shared Services	26	26	(0)	0	71	97	81	17
Employer's NI Contributions	65	62	(3)	4	190	255	247	7
Employer's Pension Contribution	140	145	5	(3)	429	569	573	(3)
Authority salaries inc. NI Contributions	37	36	(0)	1	109	146	146	0
Temporary Staff costs	32	-	(32)		55	55	-	55
Other Staff Costs	59	57	(0)	1	193	252	265	(13)
Other Authority/Committee costs	56	75	19	(25)	237	294	301	(8)
Other Compliance Costs	5	9	4	(47)	18	22	28	(5)
Other Strategy Costs	12	23	11	(47)	123	135	142	(7)
Facilities Costs incl non-cash	181	152	(29)	19	310	492	488	5
IT costs Costs	28	23	(5)	21	61	89	93	(4)
Legal Costs	206	88	(118)	135	390	596	400	196
Professional Fees	19	17	(2)	14	47	67	67	-
Total Revenue Costs	1,533	1,391	(141)	10	4,235	5,737	5,507	230
Total Surplus/(Deficit) before Capital & Project costs	82	(37)	403	1,074	32	144	(70)	215
IFQ & Other Project Costs - Reserves funded	226	343	117	(34)	342	567	477	90
Other Capital Costs	1	-	(1)		99	100	100	-
TOTAL NET ACTIVITY	(146)	(380)	288		472	812	507	305

Indicator	Performance	RAG	Recent trend ¹	Aim ²	Notes
Commentary:	Summarised management accounts – commentary May 2016				
	Income				
	As of 31 May (month 2) of the 2016/17 business year, we have seen a positive variance against our budget of £172k. Our treatment fees are above that expected and it is possible it relates to new clinics coming on line and the increase in treatment fee by £5 approved by HMT early this year.				
	Expenditure				
	At the end of May the accounts show that we have underspent against budget by £5k or 1%. It is too early in the year to analyse in detail where these underspends are, however there are key areas which are overspending. These are; facilities costs (£6k) which relates to archiving work undertaken, (£5.6k) within IT and (£2k) within professional fees.				
	IfQ and other project costs				
	IfQ is underspent against budget by £12k or 12%. The costs for IfQ will be reviewed each quarter as we progress towards final build of its components with a view to capitalising them at year end which will impact positively on the Income and Expenditure account.				
	Last year we transferred over £400k of cost of IfQ to Assets under Construction, it is expected that a similar figure will be capitalised at year end subject to review.				
	Summarised management accounts – commentary June 2016				
	Income				
	At the end of Q1 (30 June) we have a YTD variance on Treatment fee income of 23% (£262k more than budget). Q1's income relates to treatment fees billed in April and May and an accrual based on data from our billing system for June's treatments. We have now undertaken a detailed analysis of treatment cycles over the last three years to assess whether there is a pattern to clinics reporting. A conservative adjustment has been factored into the yearend forecast figure of £450k but it could be higher. We continue to monitor and update our analysis to ensure we capture figures that are as accurate as our data allows.				
	Expenditure				
	Year to date expenditure is currently £141k (15%) above budget. The main areas of overspend are within Legal £118k or 35% over budget. This over spend is due to accruing for costs relating to number of litigations and a compensation payment (£116k which is yet to be confirmed). Our facilities costs are slightly up against budget due to charges from CQC for occupation costs for April and May which are the final rental charges payable at the end of our lease.				

Indicator	Performance	RAG	Recent trend ¹	Aim ²	Notes
					<p>IfQ and other project costs</p> <p>IfQ is currently under spending against budget by 34%. Year to date and forecast to overspend by 19% at year-end in line with extra budget agreed by SMT. The costs for IfQ will be reviewed each quarter as we progress towards final build of its components with a view to capitalising them at year end which will impact positively on the Income and Expenditure account.</p> <p>Overall we are forecasting an over-spend against budget of £230k, however this does include IfQ. It is expected that on capitalisation of IfQ and a tight control of legal spend we could end the year on a positive note.</p>

IfQ indicators: April update for beta project phase

Frequency / trigger point	Metric	Purpose	Latest status:
At programme set-up / major reorganisation / new tranche	MSP health check overall score achieved / maximum score as a %	Is the programme set up to deliver?	<p>June update:</p> <p>The MSP health check has been completed with the final report circulated to the IfQ programme board. More work is to be scheduled in order to comply with the original health check assurance agreed by CMG especially on the IS side.</p>
Monthly	Timescales: we changed the burndown chart showing remaining estimate of work to a chart showing percentage of works complete.	Is there scope creep/over-run?	<p>June update:</p> <p>The programme team continued to press towards releasing both the website and clinic portal to public beta, throughout June. This involved addressing a number of bugs on the website related to data quality, to ensure our data was being presented correctly. On the Clinic Portal, the focus was around ensuring the correct user access privileges and security measures were in place in advance of sending login credentials to centres. In addition, significant bugs were discovered around the performance charts on the portal, that required attention prior to release to public beta.</p> <p>Following approval, Release 2 work was progressed throughout June with the team finalising the development environment architecture and commencing work on prototype for EDI. The first few weeks of R2 EDI prototype work are focused on building a system that allows basic information to be entered about <i>people</i> – participants, donors and partners.</p> <p>The below charts provide weighted data on the work completed for both website and CP. The data includes all the features completed on each project for front end, back end design and API related work. The weighting takes into consideration the level of complexity for each feature to calculate the percentage complete. It should be noted that each is completed by the product team for that product, so there isn't an objective measure of completion between the two – for this measure.</p>

IfQ indicators: April update for beta project phase

Frequency / trigger point	Metric	Purpose	Latest status:																												
			<div style="display: flex; justify-content: space-around;"> <div data-bbox="846 304 1485 772"> <p>Percent Complete - Clinic Portal R1 to June 2016</p> <table border="1"> <caption>Percent Complete - Clinic Portal R1 to June 2016</caption> <thead> <tr> <th>Total Beta Sprint</th> <th>Percent Complete</th> </tr> </thead> <tbody> <tr><td>3</td><td>42%</td></tr> <tr><td>4</td><td>45%</td></tr> <tr><td>6</td><td>60%</td></tr> <tr><td>7</td><td>68%</td></tr> <tr><td>10</td><td>82%</td></tr> <tr><td>13</td><td>88%</td></tr> </tbody> </table> </div> <div data-bbox="1503 304 2119 772"> <p>Percent Complete - Website R1 to June 2016</p> <table border="1"> <caption>Percent Complete - Website R1 to June 2016</caption> <thead> <tr> <th>Total Beta Sprint</th> <th>Percent Complete</th> </tr> </thead> <tbody> <tr><td>3</td><td>35%</td></tr> <tr><td>4</td><td>40%</td></tr> <tr><td>6</td><td>45%</td></tr> <tr><td>7</td><td>60%</td></tr> <tr><td>10</td><td>62%</td></tr> <tr><td>13</td><td>68%</td></tr> </tbody> </table> </div> </div>	Total Beta Sprint	Percent Complete	3	42%	4	45%	6	60%	7	68%	10	82%	13	88%	Total Beta Sprint	Percent Complete	3	35%	4	40%	6	45%	7	60%	10	62%	13	68%
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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.	<p>June update:</p> <p>The below graph shows days consumed by sprint, against a pro-rata trend of those days divided equally by the number of sprints in beta. We have largely exceeded the number of days allocated for beta. Due to the nature of the capped time and resource contract with Reading Room, they are contractually required to continue building the beta product at their own cost.</p>																												

IfQ indicators: April update for beta project phase

Frequency / trigger point	Metric	Purpose	Latest status:																																							
			<p style="text-align: center;">Reading Room Resource beta Burndown Chart (Days)</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th>Sprint</th> <th>Cumulative days consumed</th> <th>Available days pro-rata</th> </tr> </thead> <tbody> <tr><td>Sprint 1</td><td>20</td><td>21</td></tr> <tr><td>Sprint 2</td><td>59</td><td>43</td></tr> <tr><td>Sprint 3</td><td>97</td><td>64</td></tr> <tr><td>Sprint 4</td><td>129</td><td>86</td></tr> <tr><td>Sprint 5</td><td>174</td><td>107</td></tr> <tr><td>Sprint 6</td><td>215</td><td>129</td></tr> <tr><td>Sprint 7</td><td>247</td><td>150</td></tr> <tr><td>Sprint 8</td><td>299</td><td>171</td></tr> <tr><td>Sprint 9</td><td>345</td><td>193</td></tr> <tr><td>Sprint 10</td><td></td><td>214</td></tr> <tr><td>Sprint 11</td><td></td><td>236</td></tr> <tr><td>Sprint 12</td><td></td><td>257</td></tr> </tbody> </table>	Sprint	Cumulative days consumed	Available days pro-rata	Sprint 1	20	21	Sprint 2	59	43	Sprint 3	97	64	Sprint 4	129	86	Sprint 5	174	107	Sprint 6	215	129	Sprint 7	247	150	Sprint 8	299	171	Sprint 9	345	193	Sprint 10		214	Sprint 11		236	Sprint 12		257
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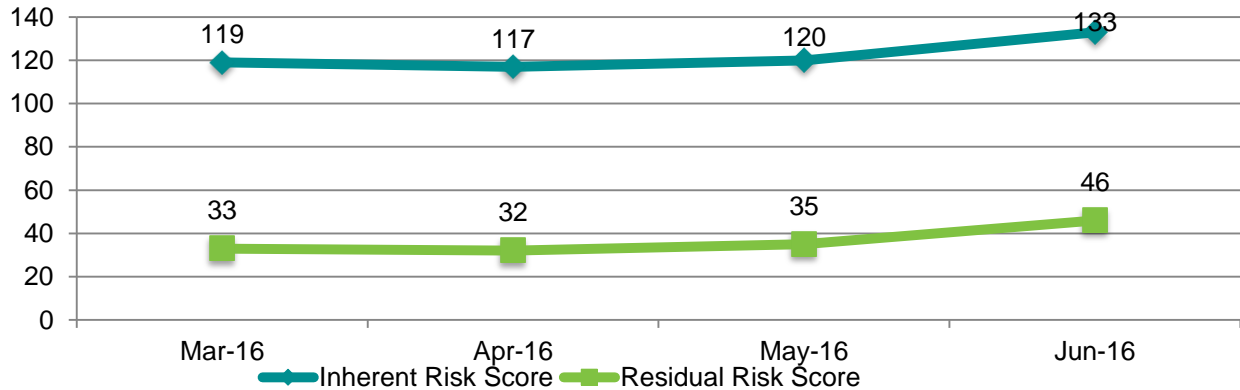
IfQ indicators: March update for beta project phase

Frequency / trigger point	Metric	Purpose	Latest status:
Monthly	Cost: earned value (% complete * estimated spend at completion)	Is the spend in line with milestone delivery?	<p>There are four things we can attribute value to: website and CaFC; Clinic Portal; the Register and internal systems; defined dataset, discovery, stakeholder engagement etc. 25% of the value of the 1.8M programme cost at completion has been attributed to each project.</p> <p>June update:</p> <p>A slight gap between the earned value and spend to date is to be noted, although we should consider that the spend to date take into consideration RR beta cost which in reality has not been spent yet.</p>

IfQ indicators: March update for beta project phase

Frequency / trigger point	Metric	Purpose	Latest status:																					
			<table border="1"> <caption>Chart Data: Earned Value vs Spend to date</caption> <thead> <tr> <th>Month</th> <th>Earned Value (%)</th> <th>Spend to date (%)</th> </tr> </thead> <tbody> <tr> <td>Jan-16</td> <td>47.5%</td> <td>61.3%</td> </tr> <tr> <td>Feb-16</td> <td>53.8%</td> <td>64.8%</td> </tr> <tr> <td>Mar-16</td> <td>65.0%</td> <td>67.0%</td> </tr> <tr> <td>Apr-16</td> <td>71.3%</td> <td>74.1%</td> </tr> <tr> <td>May-16</td> <td>75.0%</td> <td>75.0%</td> </tr> <tr> <td>Jun-16</td> <td>79.3%</td> <td>87.9%</td> </tr> </tbody> </table>	Month	Earned Value (%)	Spend to date (%)	Jan-16	47.5%	61.3%	Feb-16	53.8%	64.8%	Mar-16	65.0%	67.0%	Apr-16	71.3%	74.1%	May-16	75.0%	75.0%	Jun-16	79.3%	87.9%
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Monthly	Stakeholder engagement: combined stakeholder engagement score (internal plus external stakeholder events or communications)	Are we keeping stakeholders with us? Is it getting better or worse?	<p>May – The professional stakeholder group met in May and also the multiple births stakeholder group. The product owners for the website and clinic portal gave presentations to the professional stakeholder group. At the multiple births stakeholder group the website product owners and content write talked the group through the proposal to transfer the content of the one at a time website to the new HFEA website for the patient information and to clinic portal for the professionals information. This was agreed by the group so will be implemented over the coming months. There was a show and tell session</p> <p>Total combined score = 4</p>																					

IfQ indicators: March update for beta project phase

Frequency / trigger point	Metric	Purpose	Latest status:															
)		<p>June - In June the IfQ stakeholder group met and were shown the products that had been developed in preparation for public beta. This was the only stakeholder engagement.</p> <p>Total combined score = 1</p>															
Monthly	Risks: sum of risk scores (L x I)	Is overall risk getting worse or better (could identify death by a thousand cuts)?	<p>June update: The below line graph represents the overall IfQ risk score, which combines the perceived impact and likelihood of the current risks on hand each month. The overall risk score for the IfQ Programme has increased this month mainly due to the remaining beta phase and the potential impact on R2 progress.</p>  <table border="1"> <caption>Risk Score Data</caption> <thead> <tr> <th>Month</th> <th>Inherent Risk Score</th> <th>Residual Risk Score</th> </tr> </thead> <tbody> <tr> <td>Mar-16</td> <td>119</td> <td>33</td> </tr> <tr> <td>Apr-16</td> <td>117</td> <td>32</td> </tr> <tr> <td>May-16</td> <td>120</td> <td>35</td> </tr> <tr> <td>Jun-16</td> <td>133</td> <td>46</td> </tr> </tbody> </table> <p>The major risk scores are associated with timescales, data security, development and business continuity</p>	Month	Inherent Risk Score	Residual Risk Score	Mar-16	119	33	Apr-16	117	32	May-16	120	35	Jun-16	133	46
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IfQ indicators: March update for beta project phase

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Quarterly	Benefits: value (£) of tangible benefits planned to be delivered by the programme	Is the value of the benefits increasing or decreasing – could trigger a review of the business case?	<p>June update: The benefits realisation value should be reviewed based on the business case. No issues have been raised regarding benefits realisation to date.</p>																																							

Information for Quality programme: update

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

Details:

Meeting Authority

Agenda item 7

Paper number HFEA (14/09/2016) 807

Meeting date 14 September 2016

Author Nick Jones, Director of Compliance and Information

Output:

For information or decision? For information

Recommendation The Authority is asked to note:

- The update on work in progress
- 'Release 2' progress
- Data migration and cleansing
- Programme timelines and budget.

Resource implications No additional resource implications above that already budgeted

Implementation date During 2016–17 business year

Communication(s) Regular, range of mechanisms

Organisational risk Low Medium High

Annexes

1. Background

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

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

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

1.3. This paper updates Members on:

- Progression to public Beta for 'Release 1' products and plans for live release
- Progress in relation to Release 2 component and progress with regards to the dataset; data migration and cleansing
- Programme timelines and budget.

2. Update on work in progress

2.1. First, it is important to remind Members that government IT programmes must progress through several approval stages:

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

2.2. At the July 2016 meeting of the Authority it was noted that the website had been launched the day before in a private version of beta for clinics only to access. This step was taken to enable clinics to familiarise themselves with the presentation of their Choose a Fertility Clinic data on the website, and to use the Clinic Portal to upload other information to the site, for a two-week period (extended to three weeks) prior to full beta public launch.

2.3. The Clinic Portal was released to public beta one week later on 12 July 2016. Further development and improvements will continue throughout beta. We will also seek user feedback, including a structured session in early September in a

'lab' setting where users can feed back their experience directly to our contractor. An update will be provided at the meeting. The Government Digital Service (GDS) assessment of the Clinic Portal to enable progression to 'live' is scheduled for October 2016.

- 2.4.** We had planned to make the beta version of the website available to the public a few weeks after showing it to clinics. However, we were prevented from doing so due to an injunction granted by the High Court on 14 July following an application brought by a clinic. This injunction was lifted following our application and the website proceeded to full public beta on 12 August 2016. The clinic concerned has issued judicial review proceedings and a rolled up hearing is scheduled to take place on 19 and 20 December 2016.
- 2.5.** Now that we have gone to public beta, we have launched a significant period of user testing and the gathering of feedback about aspects of the website, including the ease of access, the presentation of headline measures, and so on. Visitors to the website are asked to complete a survey, and to date there have been over 500 visits to the beta site.
- 2.6.** The feedback from public beta will be one element of the evidence that will inform the Authority's decision on the final shape of the new website. We will also be inviting the IfQ Advisory Group to meet again to help inform the set of recommendations that we will put to the Authority at its meeting in November.
- 2.7.** With the Judicial Review pending we are of the view that it would make sense to postpone the GDS assessment until any legal disputes are resolved. We have therefore scheduled the GDA 'live' assessment for late January 2017.
- 2.8.** There are several consequences that flow from this delay. Two operational issues worth highlighting here are:
 - The current HFEA website content management system is dated and is no longer supported by the original supplier, which can lead to instability from time to time. This has been managed to date but this risk remains as long as it remains as our official site.
 - There has been a concentration of resources in preparing the website for beta launch. This reallocation of resources has had an effect on planning assumptions, in particular relating to development work necessary for Release 2 – the data submission module.

3. Progress on Release 2

- 3.1.** Release 2 work is now progressing with much endeavour. Substantial work has been completed on all the necessary processes and proof of concept such that development work and design work can progress at pace. However, the additional work set out in section 2 above has meant that our end-October 2016 release expectations for EDI users (those clinics submitting directly to the

HFEA) are unlikely to be met. A revised plan is now being developed and an update will be provided at the meeting.

- 3.2.** That said we are engaging with EPRS providers (suppliers of patient reporting systems to around half of all clinics) and who have been notified of the development path to March 2017 (the latest acceptable implementation date) such that they are well prepared. They have access to the technical architecture that will underpin the system – which has met with general approval. We plan to maintain close levels of engagement to enable gradual adoption of the necessary ways to ‘connect’ to the Authority and maintain necessary security.
- 3.3.** The Standardisation Committee for Care Information (part of NHS Digital) accreditation process for the ‘UK ART dataset’ and its implementation is on-track. It is an intensive process requiring the submission of substantial documentation considered by several committees but is a good external test of the thoroughness by which we have gone about our work.
- 3.4.** Data migration and cleansing
 - Data Cleansing and Migration work is a little behind schedule, also as a result of diversion of some resources. Data cleansing work remains primarily focused on dealing with ‘severity 1 issues’, with all issues expected to be resolved this month.
 - If necessary, the data migration of the existing (cleansed) database to a new structure can still occur by October 2016. However, this issue will be further addressed alongside broader discussions about overall timeframes for the Programme.
 - Arrangements to provide assurance services for the data migration are now in place. We have commissioned an expert in data migration to provide a review of all steps we have taken and will take prior to transfer. This is intended to provide a further check and balance to the Senior Responsible Owner, and in turn the Audit and Governance Committee.
 - Whilst most clinics have been cooperative in fixing errors (and we worked hard to minimise the quantum of tasks they had to undertake) there are issues with some centres in failing to deal swiftly with our requests and we continue to monitor progress closely, escalating our action as necessary.

4. Programme timelines and budget implications

- 4.1.** As reported previously, a revised IfQ programme plan was finalised and signed off by the IfQ Programme Board in January 2016, in line with the overall £1.134m agreed by Authority.
- 4.2.** This month variance is explained by an underspend originally forecasted for the security consultant. The underspend should balance in the upcoming months once the work is completed and invoiced.

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

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

4.4. The spend to date has raised slightly comparing to the earned value, this is mainly due to the delay caused by the injunction and the impact on Beta completion..

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

5. Recommendation

5.1. The Authority is asked to note:

- Progress since the last Authority meeting
- The potential for delay to Release 2 – the new data submission system
- Programme timelines and budget.

Strategy 2017-20

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

Details:

Meeting Authority

Agenda item 8

Paper number HFEA (14/09/2016) 808

Meeting date 14 September 2016

Author Paula Robinson, Head of Business Planning
Juliet Tizzard, Director of Strategy and Corporate Affairs

Output:

For information or decision? For decision

Recommendation To approve the outline strategy, prior to discussion with stakeholders in the autumn.

Resource implications Within budget.

Implementation date 1 April 2017 onwards

Communication(s) Publication on website.

Organisational risk Low Medium High

Annexes A: Draft Strategy 2017-20

1. Background

- 1.1.** Earlier this year, the Authority started to consider the next phase of its strategy, which will run from 2017 to 2020. We have prepared an early outline of the strategy (annex A), informed by workshops and discussions with Authority members and staff. This paper presents a draft strategy to be opened up for feedback and comments during the autumn.
- 1.2.** Our existing strategy – the first for some years – has brought us a long way towards achieving our vision of high quality care for everyone affected by assisted reproduction. By April 2017, we will have a promising range of assets and capabilities at our disposal, some of them new:
- Good stakeholder networks and more patient input
 - A good understanding of what various users want and need
 - New information for patients, published primarily through our website
 - A redesigned Choose a Fertility Clinic service, making clear to patients what high quality means in a clinic
 - A new Register database, enabling greater analysis
 - A new clinic portal and data submission system
 - An established process for assessing the safety and efficacy of existing and new treatments
 - Effective regulatory tools (Code of Practice, inspection approaches) and methods for helping the sector learn and improve
 - Inspection and monitoring information about clinics, and potential to analyse this more deeply
 - A warmer tone and refreshed brand
 - New communications strategy incorporating social media
 - The funding we need to operate
 - A dedicated and talented workforce.
- 1.3.** These assets put us in a great position to take the next step in our ambitions for high quality care. We will need to develop new approaches and processes in the next three years. But what we have done in 2014-17 will enable us to work with patients and with clinics to improve services and, crucially, the experience of care.

2. Strategy 2017-2020

- 2.1.** At the centre of the new strategy is our ongoing vision for **high quality care for everyone affected by assisted reproduction**. Based on our research during the current strategy, we have identified stages along the patient and donor pathway and set out their needs at each stage. We have also developed three

main areas of strategic focus, based on the 'quality' diagram discussed in earlier workshops:

- Consistent support and outcomes for patients
- Safe, ethical, effective, proven treatment
- Improving standards through intelligence.

Audience

- 2.2.** Based on earlier discussions, we have focused on existing and prospective patients, donors and donor conceived people. Although we also want to reach the general public (and future fertility patients and donors), there is still much to do with 'our' public, so our strategic aims and benefits start with our main audiences.

Donor conception

- 2.3.** We have situated our ambitions for donor conception patients and for donors within the strands of the strategy relating to support throughout treatment, good experience of care and evidence-based, effective treatments. This will enable us to stay focused on high quality care for everyone.
- 2.4.** When we started work on our donation strategy back in 2012, we needed a separate campaign (which became known as Lifecycle) because we were seeking to reach new audiences (such as those thinking about going abroad for treatment). However, with our new website and tone of voice, and a willingness to reach that wider patient audience, there is much less justification for a dedicated donation campaign and the resources to support it.
- 2.5.** Re-registration of donors is an important area, and an option that we will highlight on our website and through other channels. Doing more on improving re-registration rates, such as reaching past donors who have moved on and no longer follow the fertility sector, would require a sustained effort with significant advertising and PR costs (£50,000 plus), and we have therefore decided this would not be practical, for resource reasons.

Our own role

- 2.6.** As a regulator, our role should be both to raise the bar and to push the bar for clinics. We can raise the bar by driving up sector standards to encourage greater consistency and excellence between and within clinics, being directive and challenging when it is necessary and proportionate to do so. We will also sometimes need to push the bar, setting new standards and expectations where there were none before.

3. Engagement and next steps

- 3.1.** When we developed our current strategy, we put it out to consultation. Given that the Authority has decided to retain the vision for the next phase of the

strategy and that it builds on what we have achieved so far, we don't think there is a need to have such a wide consultation and research exercise this time.

- 3.2.** Instead, we will discuss the developing new strategy with stakeholders at meetings in the autumn and winter, and we will continue the strategy conversation with staff. We also plan to arrange some focus groups with patients in the winter.
- 3.3.** In November, we will bring you the feedback gathered so far, for discussion. This will help us to shape a final draft, ready for sign off at the January Authority meeting. We will also bring a draft business plan for 2017-18 and an outline of the work for the following two years.
- 3.4.** Our plan is to publish the strategy on 1 April, with a launch slightly earlier at our annual conference. It is anticipated that we will be able to make the finished document shorter and more concise than the attached annex, once we have obtained the stakeholder input, in keeping with the general design of the current strategy.

4. Questions for the Authority

- 4.1.** We are not, at this stage, asking members to sign off a final strategy. Rather, we are asking that you approve it as a draft outline strategy that we can discuss with stakeholders during the autumn.
- 4.2.** At this stage, we would, in particular, welcome thoughts on the following areas:
 - Do you think we have taken the right approach in setting the strategy around the different needs of patients and donors through the various stages of treatment and donation?
 - Do you think we have taken the right approach around data and embryo research? Should we be focusing on facilitating patient choice in this area or promoting research and innovation and increasing consent rates?
 - Are you happy with our approach of including donor conception issues in all fertility treatment? And do you agree that the Lifecycle campaign should come to an end (bearing in mind that we will of course continue to use the good work that the campaign has produced)?

Annex A: Draft strategy 2017-20

Our vision

In 2017-2020 we will retain the same strong vision:

High quality care for everyone affected by assisted reproduction

Our strategy over the past three years has focused on developing new information systems and services to further our vision for high quality care. We now have:

- New information for patients and donors to help them understand their options, research treatments and find the clinic that is best for them
- Easy-to-understand measures of quality in clinic services
- A patient ratings system for clinics, encouraging better support through treatment
- A new, simpler data submission and clinic performance system, allowing clinics better oversight of their data and their outcomes
- A new HFEA register of treatments, enabling better analysis of treatments, outcomes and trends in clinical practice.

Through our 2017-2020 strategy, we will capitalise on these new services to reap the benefits for patients, donors and for clinics. We will make sure that patients get access to the right information, at each stage of their fertility journey and that they have a good experience of treatment, whatever the outcome. And we want to ensure that the clinical service they receive is consistent, evidence based, effective and represents good value for money. Our role as the regulator is to drive up sector standards, identifying areas that require some improvement, drawing on our data and our regulatory intelligence.

The following drivers inform our new strategy:

- Although standards have improved over recent years, clinics still need to be more consistent within the areas they offer, and to improve in some particular areas of service, for example consent taking and support for patients and donors.
- Not all treatments offered are safe, effective, ethical and proven.
- Patients sometimes struggle to find accurate, good quality information, at various points in their research and treatment.
- The improvements we have made to our data systems and information services make it possible for us to do more to meet patients' needs and to focus on areas for improvement in clinics.

What do we want for patients, donors and donor-conceived people?

Patients, donors and donor-conceived people are at the heart of our strategy, and our work. Having completed extensive user research with our audiences whilst developing our new services, we know that patients and donors go through a number of stages in their journey through fertility services, and

may interact with us, as well as with clinics, at each stage. In deciding what objectives and actions will improve the quality of care, we will focus on the varying needs people have as they go through each stage.

Early research on fertility and IVF or donation

Prospective patients and donors, and their partners/families, need to be able to find information to help them understand their options, where to go for further advice and what steps to take next.

Our goals:

- Those in need of information can easily find and use our website, can learn about us and our role, and can readily find information that is useful and relevant and that informs their next steps.
- Prospective patients realise that they should seek an assessment and diagnosis first, before commencing IVF or other treatment (in case this is not the right option for them), and feel equipped to obtain this assessment.
- Patients start treatment with a realistic idea of their chances of success.

Contact with a clinic and making initial treatment or donation decisions

People who have decided that they will seek treatment (or become a donor) and have contacted a clinic, need more detailed information to help them make choices and be prepared for treatment or donation.

Our goals:

- When patients or donors first walk into a clinic, they know what they should expect, what questions to ask, and what initial decisions they may need to make. They feel prepared and are able to get more out of the initial conversation as a result.
- Patients know that whichever clinic they go to, it will be well-regulated, safe, appropriately licensed and working constructively with its regulator to address any problems.
- Patients understand in advance what the price of a treatment at a given clinic will be, and whether or not they can get any NHS funding.
- Patients understand the risks of having a multiple birth and the advantages of having a single embryo transfer if possible, subject to individual considerations with their doctor.

Having treatment or being a donor

People who are in treatment, or are donating, need a deeper understanding of particular topics (eg, additional treatments they are offered, consent, donating spare embryos) and need good support through treatment to know how to ask a question or raise an issue regarding their care.

Our goals:

- Patients and donors have a consistently positive and safe experience of care, including properly taken consents (eg, for treatment, legal parenthood, storage of gametes or embryos, use of data for research) and experience wrap-around support from the clinic at all stages, regardless of outcome.
- Patients (and also clinicians, researchers and others) turn first to the HFEA for a clear, unbiased and authoritative explanation of scientific developments and current treatment types, and can clearly see whether or not there is established evidence of the efficacy and safety of a given treatment.
- People are able to make informed choices and challenge or question if they are offered an unproven treatment.

- Patients know that they can take part in research (whether embryo research or research using their data) what they need to consider before doing so and how it might benefit future patients.

Treatment / donation outcomes and longer term needs

People who have completed at least one treatment cycle, whether successful or not, or who have donated, may require further information, emotional support, and in the event of an unsuccessful outcome they will have 'what next' questions and decisions to make.

Our goals:

- At the end of their treatment, patients will have paid what they expected to pay.
- Regardless of the outcome of their treatment, but especially if it was unsuccessful, patients know they should expect appropriate care and support from the clinic beyond their final treatment cycle.
- Donors, parents and donor-conceived people understand how and where their information has been stored, the responsibilities of the clinic and the HFEA, what their rights are, and how to apply to access information from the Register.
- Patients, donors and donor-conceived people can have confidence that their clinic has fully understood the importance of their life-long role as an information guardian and information provider, and that the clinic staff are rigorous in meeting their responsibilities through excellent and timely records management and data submission practices to the HFEA Register.

Elements of quality

Based first and foremost on the above patient-focused considerations, this diagram summarises the issues that we believe our new strategy should include in order to achieve our quality goals.



Consistent support and outcomes for patients and donors

Patient needs	What should change?	How should we approach this?	Outcomes and measures of success
Effective treatment	<p>Birth rates are, and will remain, an obvious prime concern for patients.</p> <p>Our aim should be to increase birth rates if this is possible, and to ensure that other outcomes (including multiple births) are addressed within our thinking.</p> <p>Using the new data presentation on our website as the starting point, we will work with our professional stakeholders to uncover, with the help of our data, any areas where there is scope for improving success rates further without driving up multiple births or having any other adverse effects.</p>	<p>Making headway in this area will be challenging, and will require a lot of thought, including consideration of the various available statistics and their meaning.</p> <p>Our main tactics will be:</p> <ul style="list-style-type: none"> • Look at this topic afresh, and with the help of our professional stakeholders. • More sector-wide analysis, such as the impact of emerging treatments on birth rates. • Analysing and exploring the data for different factors such as patient age. • Identify areas where there is genuine scope to improve success rates and make them more consistent without driving up multiple births. • By publishing open and transparent comparative information, empower patients to drive clinic improvements - to the extent that these are needed/possible. 	<p>Patients start treatment with a realistic idea of their chances of success.</p> <p>Patients understand the risks of having a multiple birth and the advantages of having a single embryo transfer if possible, subject to individual considerations with their doctor.</p> <p>Measures:</p> <p>To be able to define success and what affects it.</p> <p>To have reconfigured the debate about 'success' according to our new understanding of it, including multiple births.</p> <p>To be able to actively promote a set of substantiated success factors.</p>
Value for money	<p>Patients often raise concerns about the cost of treatment.</p> <p>We would like to see informed and discerning patients, expecting the price quoted to be the price paid, and for these charges to represent good value in return</p>	<p>A benchmarking exercise for treatment costs in IVF is underway and this will provide some initial transparency as a starting point.</p> <p>Our main tactics will be:</p>	<p>Patients understand in advance what the price of a treatment at a given clinic will be, and whether or not they can get any NHS funding.</p> <p>At the end of their treatment, patients will have paid what they expected to pay.</p>

Patient needs	What should change?	How should we approach this?	Outcomes and measures of success
	<p>for effective and proven treatments and services.</p> <p>Patients should be able to compare treatment costs and payment packages with each other and between clinics, equipped with more knowledge about each of the things they might be charged for, so that people are able to negotiate or shop around.</p> <p>NHS commissioners should pay a fair price for fertility services.</p>	<ul style="list-style-type: none"> • To examine the benchmarking report when it is available, and consider how we can use the information. • To encourage further feedback from patients, especially on aspects that are common sources of concern. • To get feedback from patients through our website as to whether they paid what they expected to pay at the outset. 	<p>Measures:</p> <p>Patients question costs more often and behave more like consumers when discussing prices with clinics. (Survey and analysis of website feedback.)</p> <p>Ultimately, less variation in the price of treatment (through specific research to see whether or not this is the case).</p>
<p>Good access (to treatment and to donation)</p>	<p>Although the position is better in Scotland than in the rest of the UK, access to NHS cycles and to treatment using donated gametes (particularly sperm) remains inconsistent and problematic for many people seeking treatment. NHS provision is in some difficulty in places.</p> <p>There is fairly good availability of donor eggs, but much less availability of donor sperm.</p> <p>We also believe access to sperm donation could be improved.</p>	<p>Our main tactics will be:</p> <ul style="list-style-type: none"> • To inform those thinking about going abroad for treatment how they might get access at home. • To encourage more and better support for people going through the donation process (both patients and donors). • To get relevant information to the right patients, promoting it through the right channels. • To work with clinics, sperm banks and voluntary organisations to improve the availability of donor sperm. 	<p>Those in need of information can easily find and use our website, can learn about us and our role, and can readily find information that is useful and relevant and that informs their next steps.</p> <p>Measures:</p> <p>People understand the process and the hurdles, and are prepared for treatment (measured through patient/donor surveys).</p> <p>An increase in UK-based sperm donation.</p>
<p>Well supported throughout treatment</p>	<p>We want to see more support by clinics for patients, particularly those whose treatment is unsuccessful.</p> <p>We believe there is insufficient support and care by clinics, particularly after</p>	<p>Our main tactics will be:</p> <ul style="list-style-type: none"> • To define and promote best practice to clinics, above and beyond offering counselling, working with professional stakeholders. 	<p>Prospective patients realise that they should seek an assessment and diagnosis first, before commencing IVF or other treatment (in case this is</p>

Patient needs	What should change?	How should we approach this?	Outcomes and measures of success
	<p>unsuccessful treatment, when patients tell us that the final bill is also the final contact from the clinic. We also believe that ‘support’ includes facilitating easy access to high quality counselling, making time to explain treatment recommendations and other advice in depth, or helping people to understand consent requirements, storage limits, data held and its future importance, depending on the patient’s needs and situation.</p> <p>People’s emotional experience of care in clinics can be improved. We could help clinics to recognise what should constitute best practice in this area.</p> <p>Donors need better support in preparation for donation and in giving information about themselves to be share with donor conception parents and donor-conceived children.</p>	<ul style="list-style-type: none"> • To ensure best practice is applied to donors and donor-conceived people as well as to patients. • To be clear with clinics that good support includes both post-treatment care and information for donor conceived people in the future; and that ‘treatment’ has a much longer duration and impact than just the clinical period of time when a patient is attempting to get pregnant. • To highlight and promote particular issues we believe are relevant. • To make excellent support for patients a core message. • To continue to focus on this – including at inspection. 	<p>not the right option for them), and feel equipped to obtain this assessment.</p> <p>Patients and donors have a consistently positive and safe experience of care, including properly taken consents (eg, for treatment, legal parenthood, storage of gametes or embryos, use of data for research) and experience wrap-around support from the clinic at all stages, regardless of outcome.</p> <p>When patients or donors first walk into a clinic, they know what they should expect, what questions to ask, and what initial decisions they may need to make. They feel prepared and are able to get more out of the initial conversation as a result.</p> <p>Regardless of the outcome of their treatment, but especially if it was unsuccessful, patients know they should expect appropriate care and support from the clinic beyond their final treatment cycle.</p> <p>Measures:</p> <p>Patient and donor feedback through website and surveys.</p> <p>Inspection focus (once best practice is agreed and shared), with tracking of findings over time (including patient feedback obtained on or before inspection) to see if support is improving.</p>

Patient needs	What should change?	How should we approach this?	Outcomes and measures of success
<p>Safe, regulated care, with consistent standards</p>	<p>We want patients to be offered high quality treatment at the right stage in their pathway. This includes advising patients on initial contact about the need to seek an assessment and diagnosis before setting out on a particular course of action.</p> <p>Our inspection regime ensures continuous good regulation, but we know that there is still scope for improvement in clinics in a number of areas, particularly consent.</p> <p>We want to encourage an increase in the quality and consistency of the service provided between inspections. We will have easier access to a range of data following IfQ, some of which will prospectively enable us to make more targeted regulatory interventions and provide more frequent information to clinics on some aspects of their compliance (such as timely data submission to the HFEA).</p>	<p>In recent years, we have worked hard to become more consistent, clearer and more transparent in our regulatory approach. We include success rates, multiple births data and information about incidents and alerts in our inspection reports. However, multiple non-compliances are still too common on inspection.</p> <p>Our main tactics will be:</p> <ul style="list-style-type: none"> • To develop a more strategic view of how much a clinic needs to do to meet (or get up to) key performance benchmarks. • To work out constructive ways of using our data and the skills of our inspectorate to help clinics to be more compliant, more of the time. • To persuade, encourage, and regulate clinics in the interests of consistency. 	<p>Patients know that whichever clinic they go to, it will be well-regulated, safe, appropriately licensed, and working constructively with its regulator to address any problems.</p> <p>Measures:</p> <p>Reduction in average/median number of critical, major and other compliances, over time.</p> <p>Reduction in number of clinic incidents over time, owing to increased compliance.</p>

Safe, ethical, effective, proven treatment

Patient need	What should change?	How should we approach this?	Outcomes and measures of success
<p>New and emerging treatments/developments</p> <hr/> <p>Evidence based treatments</p>	<p>Scientific stories are frequently poorly reported or sensationalised, giving patients and others an incorrect impression of what is possible and what the evidence is saying. The evidence itself (published research) is written by expert scientists and is often not readily available outside academia, or an accessible read for those without scientific training.</p> <p>We want to increase patients' insight into subjects they may be researching, like potential new treatments, and we want to ensure they do not have unrealistic expectations about these.</p> <p>We want to ensure that patients have the right treatment for them, at the right time (ie, they are not offered IVF too soon and they are not offered more high-tech interventions than they need).</p> <p>We also want to ensure that when patients are offered treatment 'add-ons', they can obtain information as to the efficacy and safety of such treatments, which will normally have an associated additional cost.</p>	<p>Our new website has clear and impartial material to help patients and others make sense of complex scientific information.</p> <p>We also have a respected scientific committee to assess the evidence and to help develop information on established and emerging treatments. We are able to monitor outcome data on existing treatments.</p> <p>To gain further traction on this issue, our main tactics will be:</p> <ul style="list-style-type: none"> • To be an up to date information provider, with regularly updated accessible factual information about new and emerging topics (eg, gene editing in research). • To refine the statistical and scientific data we present so that it is as easy as possible to understand. • To establish a myth-busting or rapid intervention function within the HFEA to correct misperceptions or incorrect reporting. • To use our channels including social media to inform patients and the wider public. • To define for clinics, in guidance, what good quality treatment is – what works, what doesn't. 	<p>Patients (and also clinicians, researchers and others) turn first to the HFEA for a clear, unbiased and authoritative explanation of scientific developments and current treatment types, and can clearly see whether or not there is established evidence of the efficacy and safety of a given treatment.</p> <p>People are able to make informed choices and challenge or question if they are offered an unproven treatment.</p> <p>Measures:</p> <p>Surveying patients to check that they can find and understand the written information we provide, and that they can make intelligent choices or challenge clinic staff if they are offered a dubious treatment add-on.</p> <p>Guidance being completed and in place for clinics.</p> <p>Clear and up to date information on our website about treatment types, new treatments, emerging science, developments in genetics and genomics, and treatment add-ons.</p>

Patient need	What should change?	How should we approach this?	Outcomes and measures of success
		<ul style="list-style-type: none"> To incentivise clinics to run an effective, safe and ethical service, using our regulatory mechanisms where appropriate. To make clear which treatment add-ons are proven, effective and safe and which ones either lack an evidence base or have been found to be ineffective. 	
<p>High quality research (data and embryo)</p>	<p>Both forms of research are supported through our research regulation function and our Register data research panel.</p> <p>Some inspections uncover examples of consent to the use of data for research being incorrectly reported to the HFEA, or not being properly sought, which could have serious consequences.</p> <p>We want to see an increase in patient consent rates for research (where they wish to), and for those consents to be fully informed and recorded properly so that patients can be confident their personal data or embryos will only be used in ways they have consented to.</p> <p>We want data researchers and embryo researchers to be able to access the data and the embryos that they need for their work.</p>	<p>A policy project in the second half of the 2016/17 business year will review our embryo research policies, and this work will inform our approach.</p> <p>Our main tactics will be:</p> <ul style="list-style-type: none"> To promote and explain research findings and research in progress (both licensed research and data research). To encourage more patients to participate in both data research and donating embryos for research. <p>(More to be developed stemming from this year's policy project.)</p>	<p>Patients know that they can take part in research (whether embryo research or research using their data), what they need to consider before doing so and how it might benefit future patients.</p> <p>Measures:</p> <p>That patients can easily donate embryos to research where they want to and research centres can gain access to donated embryos for their projects.</p> <p>Higher rate of consent to research from patients.</p>

Improving standards through intelligence

Patient need	What should change?	How should we approach this?	Outcomes and measures of success
<p>Use treatment data in our Register and our inspection intelligence to drive improvements in treatment standards and outcomes.</p>	<p>Our new data systems allow us to make better use of treatment data.</p> <p>We want to turn this, and our inspection intelligence, into useful and reliable information, that can be analysed and published more easily and quickly, and that can drive various quality improvements for patients.</p>	<p>To make full use of our treatment data, we will need to adopt the following main tactics:</p> <ul style="list-style-type: none"> • To produce an information strategy setting out how we will use our data, with what tools, to what ends and with what outputs. • To ensure that we have enough analytical capability and capacity to get more value from the data we hold. • To use our improved data, together with our scientific sources, to radically improve the range and quality of information available to patients and others. • To use our data to improve the quality of NHS commissioning decisions, and therefore the quality and standard of care received by patients. 	<p>Donors, parents and donor-conceived people understand how and where their information has been stored, the responsibilities of the clinic and the HFEA, what their rights are, and how to apply to access information from the Register.</p> <p>Patients can have confidence that their clinic has fully understood the importance of their life-long role as an information guardian and information provider, and that the clinic staff are rigorous in meeting their responsibilities through excellent and timely records management and data submission practices to the HFEA Register.</p> <p>Measures:</p> <p>Information strategy sets out our plans in this area.</p> <p>Further work to be determined based on the information strategy.</p>
<p>Continually able to receive, use and act upon to patient feedback</p>	<p>We want to use the new patient rating service on Choose a Fertility Clinic to understand patient experience in clinics and encourage clinics to act on patient concerns. We also want to promote good practice across the sector, based on positive feedback.</p>	<p>With the new information systems and services we have built, our main tactics will be:</p> <ul style="list-style-type: none"> • To collect more patient feedback through new routes; and to analyse it and feed it back into the system as intelligence to inform our activities. 	<p>Measures:</p> <p>Improvement in the quality of services and patient/donor support as a result of patient ratings and other feedback</p> <p>Quantifiable increase in the amount and frequency of patient feedback available</p>

Patient need	What should change?	How should we approach this?	Outcomes and measures of success
	<p>We want to use additional feedback sent to inspectors to improve standards in clinics and make it clearer in inspection reports.</p> <p>We commissioned extensive user research in order to shape our IfQ website information. However, we have not engaged with patients directly on our other services. We will make good use of new channels and opportunities available through which to engage with patients on what matters to them.</p>	<ul style="list-style-type: none"> • To establish what ongoing input we will collect from patients, through which routes and methods, and with what outputs. • To establish how we will analyse and use patient feedback to improve both the quality of our service and the quality of care. • To share the feedback we receive with professional stakeholders. • To use patient feedback to focus inspections. 	<p>to the HFEA and our professional stakeholders.</p>
Regulatory performance	<p>Our existing regulatory regime and compliance and enforcement policy are performing well. But we would like to be able to use our data, as described earlier, to make more targeted and responsive regulatory interventions in the interests of both quality and consistency.</p>	<p>In addition to work described elsewhere in this strategy, our main tactic will be:</p> <ul style="list-style-type: none"> • To work out how we can use the intelligence available to us from clinics, patients and our data to improve the quality and consistency of regulatory performance across the sector. 	<p>Measure:</p> <p>Ability to make earlier and more responsive regulatory interventions, rather than awaiting the next renewal or interim inspection point.</p>
A lean and efficient regulator	<p>Over the past six years, the HFEA has significantly reduced its size and costs. Part of the purpose of the IfQ Programme has been to enable us to work more smartly with the resources we have.</p> <p>To capitalise fully on the changes brought about from IfQ, we will need to re-shape our organisation so as to enhance our efficiency and effectiveness.</p>	<p>Our main tactics will be:</p> <ul style="list-style-type: none"> • To identify the capabilities we will need in order to make the best use of our new website and Register, re-shaping our organisation in the process. • To continue to demonstrate that we are a good value regulator. 	<p>Measure:</p> <p>Organisational re-shaping achieved and the right capabilities and capacity in place.</p> <p>Stakeholder feedback/survey.</p>

Compliance activities 2015/16: a review

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

Details:

Meeting	Authority
Agenda item	9
Paper number	HFEA (14/09/2016) 809
Meeting date	September 2016
Author	Sharon Fensome-Rimmer Contributory Authors, Erin Barton, Andrew Leonard, Sara Parlett

Output:

For information or decision?	For information
Recommendation	To note the report and the summary of actions in section 4
Resource implications	In budget
Implementation date	Through ongoing compliance activities.
Communication(s)	Through Authority report, and then targeted communications with key findings
Organisational risk	<input type="checkbox"/> Low <input checked="" type="checkbox"/> Medium <input type="checkbox"/> High

Annex – Risk tool and inspection findings charts

1. Background

- 1.1** This is the second annual report to Authority on ‘compliance activities.’ It provides an overview of the type and number of non-compliances found on inspection or identified through our risk tool or other reporting mechanisms. It also reviews the actions we have taken in the inspection year April 2015 to end March 2016 to promote compliance by licensed clinics and research centres with the Act. The paper is therefore also an assessment of the effectiveness of the regulatory methods we employ and, most importantly, the extent to which they have had an impact on the sector.
- 1.2** Our Strategy signals an ambition for high quality care for everyone affected by assisted reproduction and our regulatory activities are directed to the improvement of the quality and safety of care.
- 1.3** The Act (at section 8ZA (2)) requires that the Authority, when carrying out its functions, must have regard to best regulatory practice (transparency, accountability, proportionality and consistency). At the same time, it must also ensure added value for the public, the sector and the Government.
- 1.4** The aim here is to provide the Authority with an opportunity to scrutinise our regulatory approach to ensure that not only are our statutory obligations met, but that it contributes to our strategic intent – high quality care.
- 1.5** The structure of this paper is as follows. Section 2 suggests a frame for considering the regulatory impact we hope to have; section 3 summarises our activities in relation to the tools at our disposal, forming some conclusions from the analysis in the annex to this report. Section 4 sets out how we intend to adapt our work going forward in the light of this review by way of recommendations to the Authority.

2. Assessing our own performance

- 2.1** It is relatively easy to assess our performance in terms of inputs (inspections carried out etc.); far harder to do so in terms of outcomes (quality of service at a given clinic etc.). This paper covers a lot of ground, covering both inputs and outcomes. In reaching an assessment of impact it may be helpful to have in mind both some externally established criteria for what makes effective regulation, and also the ‘tone’ that shapes how we go about our task.
- 2.2** A starting point for an assessment of our regulatory performance is to have in mind the Regulators’ Code (2014) that we are bound by, and which the Authority must have regard to when considering the standards we set, and the way we go about testing clinics’ performance in meeting those standards.

In brief, the Code requires us to

- Carry out our activities in a way that supports those we regulate to comply and grow

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- Provide simple and straightforward ways to engage with those we regulate and hear their views
 - Base our activities on risk
 - Share information about compliance and risk – to avoid duplication and overlap of regulatory activity carried out by others
 - Ensure our approach to regulatory activities is transparent

2.3 The ‘tone’ we adopt in going about our work can be summarised as follows. The Authority may wish to comment on whether this strikes the right balance as there should be an alignment (as we believe there is) between the Authority (in reviewing our activities at a strategic level, and as members of licencing committees) and the Executive. As such we:

- Try to balance identifying and reducing harms, and promoting improvement;
- Are resolute in applying informal and formal powers when necessary – which isn’t very often – combining this with being approachable, customer facing, preventive and problem-solving. We are skilled in moving from one to the other;
- Adopt a high-trust model – but a model in which trust is earned through disclosure of problems; our requirements are implemented and ‘insight’ is demonstrated. This approach has come under pressure this year in the face of significant ‘tests’ that some clinics have not been up to meeting – in relation to legal parenthood consent failures;
- Adapt and change to new requirements - this year has seen no significant new requirements being introduced nor changes to inspection methodology, albeit significant challenges as regards long-established requirements (e.g. consent);
- Try to focus on how clinics’ activities in undertaking audits and root cause analysis identify opportunities for improvement which are then implemented. Whilst this approach aims to support the continued development of a learning culture it is long and slow work. But one that we must persevere with.

3. The year – in summary

3.1 This section summarises the main aspects of our work, alongside the particular challenges seen this year. The findings are drawn from two principal sources: information on non-compliances from inspections and performance alerts from our risk tool. The annex to this report sets out these findings in detail and the relevant figures and charts are referred to throughout to aid understanding.

3.2 The key headlines from this data is as follows:

- There was 60% more inspection activity than in the previous year and we met our target of completing the licensing of a clinic within 70 days from the date of inspection to the licensing decision being communicated to the clinic.
- A large majority of clinics perceive the inspection to be effective and it promotes improvement. Very few significant or serious concerns are identified at inspection. There is a robust process for escalating concerns.
- Clinics inspected further to a renewal of licence this year did not have a significant difference as regards the number or seriousness of non-compliances compared to the same type of inspection four years' ago but there were differences as to the type of non-compliance.
- The areas where non-compliance is most prevalent are equipment and materials, QMS, consent and surgical procedures. Neither the types of activities a clinic undertake, nor its size influence the numbers of critical, major and other non-compliances reported.
- Analysis of risk tool 'alerts' suggests they catalyse improvement. However, the number and type of adverse incidents reported remains consistent and there needs to be a shift in culture towards learning from incidents.
- The compliance and enforcement policy introduced in October 2015 has been effective in ensuring the consistency of regulatory interventions. However, a significant number of legal parenthood problems have emerged during the year. We have been, and continue to be, active in ensuring families are supported and action taken with clinics. Nevertheless, it underlines some of the limitations of any regulatory regime.

The programme of inspection

3.3

The inspection year was a very full one – around 30% more activity than in the previous year (due to the anniversary of licences, largely but not completely out of our control).

- 104 inspections were carried out.
- There were 35 treatment and or storage renewal inspections,
- And 36 treatment and or storage interim inspections.
- There were 15 research renewal inspections and five research interims.
- There were 13 additional inspections of which four were initial license inspections.

3.4 The inspectorate team is well-established, knowledgeable and hardworking. We measure the efficiency of our inspection activities by means to two principle targets:

- The average number of working days taken for the whole licensing process, from the day of inspection to the decision being communicated to the centre – our target is 70 days and our performance was 60.2 days
- 90% of inspection reports returned to the Person Responsible (PR) following inspection for review within the 20 working days - around half of reports met this target with the majority of the balance missing the target by a few days. These are usually sensible judgment calls and (given the overall target is met) is not a cause for concern or heightened managerial oversight.

Clinic feedback on inspection

3.5 For the most part the inspection process works: the inspectors judgements are recognised as fair and their recommendations help clinics to improve. We know this because around two thirds of PRs in the year responded to our invitation to provide feedback following their inspection using a formal online survey tool. Some 93% of respondents considered that their inspection visit had promoted improvements to the way the clinic carries out its work. And 88% of respondents were satisfied with their inspection report and with the recommendations and timescales for implementation within it.

3.6 Of those that responded, fewer than five clinics made negative comments, relating either to the disruption to the clinic's ability to carry out its work during an unannounced inspection, imprecisely worded recommendations for improvement, or the timescales by which recommendations were to be implemented. Where PRs have expressed dissatisfaction with an aspect of the inspection it is usually, though not always, where multiple and/or serious breaches were observed.

Findings from inspection

3.7 The evidence presented here suggests that assisted reproduction sector is a largely compliant one. That is to say that in 2015/16 we saw very few, under five, serious or significant concerns that resulted in a management review and escalation to Licence Committee for consideration. That is clearly good news, but it is not grounds for complacency. As chart 1 (annex) shows there are still too many inspections which find a significant number of critical and major non-compliances.

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- 3.8** Our inspection activity is greatly informed by the capability presented by our 'licensing' system – Epicentre, which Members will recall was the subject of some investment in 2010-12. Epicentre holds a database of the licensing history and other valuable information relating to every clinic and allows us to prepare a pre-inspection notebook with all key historical data about that clinic. It also enables the team to log all actions identified at inspection and monitor to the point of satisfactory implementation. Chart 2 (annex) shows the different types of severity of non-conformities correlated to centre activity and size. Chart 3 (annex) shows the number of non-compliances (of varying severity) by inspection types, and chart 4 (annex) shows that 445 non-conformities were identified resulting in recommendations for improvement - an average of 5.6 per inspection. In effect these are 5.6 opportunities for improving the quality of care, per inspection. We have a very good system for ensuring these opportunities are carried through. Chart 4 also shows the number of frequently observed non-compliances by clinic size and suggests the most common types of non-compliance relate to equipment and materials, QMS, consent and surgical procedures. This is further correlated in chart 5 (annex).
- 3.9** Given the depth of information we hold about clinics' performance going back over time, we have been able to compare performance of some clinics since the time of their last renewal inspection. There were 29 clinics that were inspected in 2011/12 and in 2015/16. The average number of non-compliances overall was similar, with marginally more critical and major non compliances observed in 2015/16. For individual clinics there is no clear relationship between the numbers of non-compliances observed between the two periods. An increase was observed in non-compliances related to confidentiality, counselling, import/export, infection control and medicines management. This is as much a function of a change in the inspection focus as a dip in performance. As such, the level of non-compliance at one renewal inspection does not apparently predict the level at the next inspection.
- 3.10** Non-compliance relating to surgical procedures and consent-type non compliances were amongst the six most prevalent types in 2015/16, as charts 4 & 5 (annex) shows. Along with equipment and materials and the clinic's quality management system. Other trends have also been observed such as procuring, processing and transporting gametes and embryos; and premises and facilities.

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- 3.11** Moreover, looking at the compliance history over time it can also be concluded there is no relationship between the number of non-compliances (either all or combined critical and major) and the number of incidents reported, or risk tool alerts issued and the compliance level on renewal inspection.
 - 3.12** Neither the types of activities a clinic undertake, nor its size influence the numbers of critical, major and other non-compliances reported. – see table 1 (annex). This supports a conclusion that the same inspection regime should be applied to all licensed clinics.
 - 3.13** As the inspectorate team become more experienced it is reasonable to conclude more non-conformities will be observed. At the same time, clinics become more experienced and knowledgeable at conforming, to the point of status quo.
 - 3.14** From charts 1 through to 5 (annex) it is reasonable to conclude that the inspection process is robust and effective.
 - 3.15** The inspectorate team continues to maintain its focus on a clinic's quality management system given the (wider) evidence that an effective QMS improves outcomes. We also see merit in undertaking workshops with clinics to embed practices – in relation to root cause analysis, the effect of 'human factors' on practice, and improvements to auditing techniques.

The risk tool

- 3.16** Our ability to undertake ongoing monitoring of a clinic's performance between inspection visits has been greatly enhanced by the introduction in 2011 of the risk-based assessment tool (RBAT) that provides information about clinics' performance in near to real-time. RBAT provides us with a number of important performance indicators, notably relating to outcomes in terms of both clinical pregnancy rates and multiple pregnancy rates; the submission of register information relating to treatments using donor gametes; and the timeliness of payments of our monthly invoices.
- 3.17** Our assessment of clinic performance is based on the analysis of information submitted to us. Where the trend analysis performed by RBAT suggests that there may be a dip in performance, an automated alert is sent to the PR and the clinic is expected to act on this alert and investigate any possible causal factors and take corrective action if appropriate. Inspectors and/or members of the register information and finance teams also carry out targeted follow-up where appropriate.

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- 3.18** The data from alerts in RBAT is set out in Charts 6 and 7 (annex) and can be summarised as follows. Clinics' performance in 2015-16 has worsened compared to the previous year in relation to the submission of critical treatment information – mainly due to the activity being undertaken by our teams elsewhere (relating to IfQ developments) and for these reasons we do not adopt a punitive approach here. The number of alerts relating to invoice payments has significantly decreased suggesting that clinics' performance in meeting our now enhanced performance expectations have been successful. Further, in relation to success rates and multiple birth rates the volume of alerts has remained constant albeit the population of clinics receiving these alerts has changed – suggesting an improvement in performance by some.
- 3.19** Of the 10 clinics receiving the highest number of alerts last year, five of those clinics remain in the same category – suggesting either difficulties that can take time to improve (e.g. shifting multiple birth rates) or limitations in terms of those clinics' culture of improvement. It is clear that some refocusing of our performance as regards some clinics' multiple birth minimisation plans is necessary to move the overall sector average performance closer to the 10% target.
- 3.20** By providing the information required for clinics to monitor their own performance in comparison to national norms, we help clinics that may be struggling to improve the quality of care given to patients. The risk tool alerts are having an effect. Success rates have improved since the introduction of the system, but the overall trend in success rates since 1991 is up, reflecting a range of factors, notably improvements in clinical practice. However, what the tool does is enable the Executive to focus its efforts on potential poor performers and help those clinics that may be struggling to improve the quality of care given to patients.

Adverse incidents

3.21 There is a separate and detailed report relating to incidents on the agenda. An estimated 1% of the c70,000 cycles of IVF treatment that are carried out in the UK each year are affected by some sort of adverse incident. The PR for a licensed clinic has a statutory duty to report and analyse the causes of incidents¹. However, the numbers will vary each year depending on the number of cycles carried out and incidents reported. For the calendar year 2015 we received reports of 517 incidents out of c.70,000 treatment cycles. We have a duty² to investigate and take appropriate control measures in relation to reported incidents³, and the incidents reported during the year represent an increase of around 4% after adjustments for increases in activity volumes. Receiving reports of adverse incidents, logging and monitoring root cause analyses carried out by clinics and carrying out focused visits or workshops, and addressing trends at inspection is part of the team's work. Our effectiveness in ensuring lessons are learned to prevent the recurrence of avoidable incidents must be considered alongside our other activities.

Policy

3.22 Following last year's report to Authority a revised compliance and enforcement policy was introduced, from 1 October 2016. This has been effective in both focusing our interventions and in maintaining a level of consistency across those interventions at different clinics. The challenge for all regulatory bodies is an environment where regardless of the identity of the 'regulation officer' a regulated body can expect similar treatment based on objective standards. The policy has been particularly effective in establishing the centrality of the 'management review' where a concern is identified with the potential for escalation. In the year a number of management reviews were undertaken by the executive and documented.

3.23 The policy also clarified and made more explicit the relationship between a clinic's performance and a recommendation as regards the length of licence it can expect. The new HFEA website (currently in public beta) will provide greater transparency to this decision as it will appear on the Choose a Fertility Clinic profile page of each clinic. It is important to recognise that whilst the event of an inspection is key and at a point where we hope to see good services and a demonstration of how those standards will be maintained throughout the year by audit and improvement – there is also an opportunity for a clinic to deal with (some) concerns identified following the inspection and prior to the consideration by a licensing committee.

¹ An incident is a serious adverse event or reaction as defined at 27.2 and 27.3 of the Code of Practice.

² S.15A of the Act.

³ Further information on our approach to incident handling can be found at <http://www.hfea.gov.uk/6678.html>

Legal parenthood

- 3.24** Our response to failures by clinics to take consent to legal parenthood correctly has formed a significant, and additional, part of our activity throughout the year – and continues to do so. Since 6 April 2009, the partners of women treated with donor sperm or embryos, where the couple is neither married nor in a civil partnership, have had to give their written consent in order to become the legal parent of any child born as a result of treatment. Legal parenthood is important as it gives a lifelong connection between a patient and a child, and affects things like nationality, inheritance, contact and financial responsibility.
- 3.25** We have been working in support of families affected since the issue first came to light (in 2013). In particular, in September 2015⁴, we had in-depth contact with all clinics in relation to seeking their assurance as to understanding better the number and type of anomalies. Around half of all clinics had cases where it was possible that a declaration of parenthood where there was a defect in the arrangements for consent (c.70 cases).
- 3.26** Some of those cases have since been the subject of a declaration of parenthood in court; and some families (in the light of clear advice) have decided not to take action; and a significant number have still to be determined in court.
- 3.27** To date, no cases have come to light where treatment took place after September 2015. While it is impossible to predict if any will, the steps we have taken (in our communications, at conferences, and through inspection) have raised sector awareness of the problems created by defective arrangements relating to consent. That such a high volume of cases came to light indicates the limitations of any regulatory or inspection regime – regulators set standards and inspect against those standards; they do not treat patients directly.

⁴ Further to the judgment made in September 2015 by Sir James Munby, President of the Family Division of the High Court

4. The Authority is asked to note this report, in summary:

- 4.1** The tools we have are generally well calibrated and effective in motivating regulatory compliance, overall. We meet the statutory tests and we have a stable team using a range of tools which are now established and work well.
- 4.2** We must continue to do our job and to do it well – and continue to seek feedback from those we inspect that is largely positive. It is preferable to work with people and organisations than to do things to them – the results will be more effective.
- 4.3** Our analysis shows that recommendations for improvement are implemented within prescribed timescales supporting a conclusion that our inspection activities have a tangible impact. The focus of interim inspections was refreshed in April 2015 taking into account the most frequent non compliances and this will ensure that our regulatory activities continue to be risk focussed.
- 4.4** That said, there is evidence of both persistent poor performance and some evidence of a culture that does not value learning or embedding a service robustly founded on quality.
- 4.5** We now have a substantial body of evidence from inspections, from the risk tool analysis (particularly in relation to multiple birth minimisation effectiveness) and from adverse incidents and legal parenthood failings – to better identify those clinics that may be coasting or struggling to comply. We have seen the limitations in clinics’ own systems for identifying errors and learning from them in a robust way.
- 4.6** This must prompt us to think about what we need to do to have an effect on that culture. To that end, we are:
- Trying to get upstream of the problem - embarking on a series of workshops geared towards individual clinics, as we have seen some evidence (from our recent experience of taking clinics through root cause analysis training, for example) that this leads to fewer reported incidents alongside a better appreciation of what drives quality.
 - Making a clearer link between clinic quality and performance - ready to apply proportionate steps, for example recommendations relating to licence lengths that are likely to better demonstrate to patients a clinic’s performance in providing high quality care.

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- Adjusting to new business models - starting to work alongside clinics working under a 'group' structure to better understand the risks at the group and clinic level and looking for trends and disparities. In doing so we will adopt a 'risk based approach' looking to see how the group's overall quality system performs in relation to the evidence we see in each inspection of a clinic within the group. We can also apply this approach to the incident reporting system.
 - Examining the data we hold more effectively - carrying out more frequent analysis of incidents, at four month intervals, again exploring trends and more actively addressing the common occurrences to resolve the majority of problems. We will provide workshops to clinics providing some training on root cause analysis techniques. We will take proven methodologies from other industries, disseminating the knowledge within the team and in turn to the sector. Moreover, we will look towards sectors such as aviation and aerospace to explore how human factors can be adapted in the sector.
 - Improving clinics' capacity for self-improvement - issuing a root cause analysis template has been designed that sets out the stages of an investigation in a methodical way. This is available to all clinics that require assistance.

Annex

Inspection Findings.

Chart 1

The number of critical and major non compliances found on inspection, 2014/15 and 2015/16

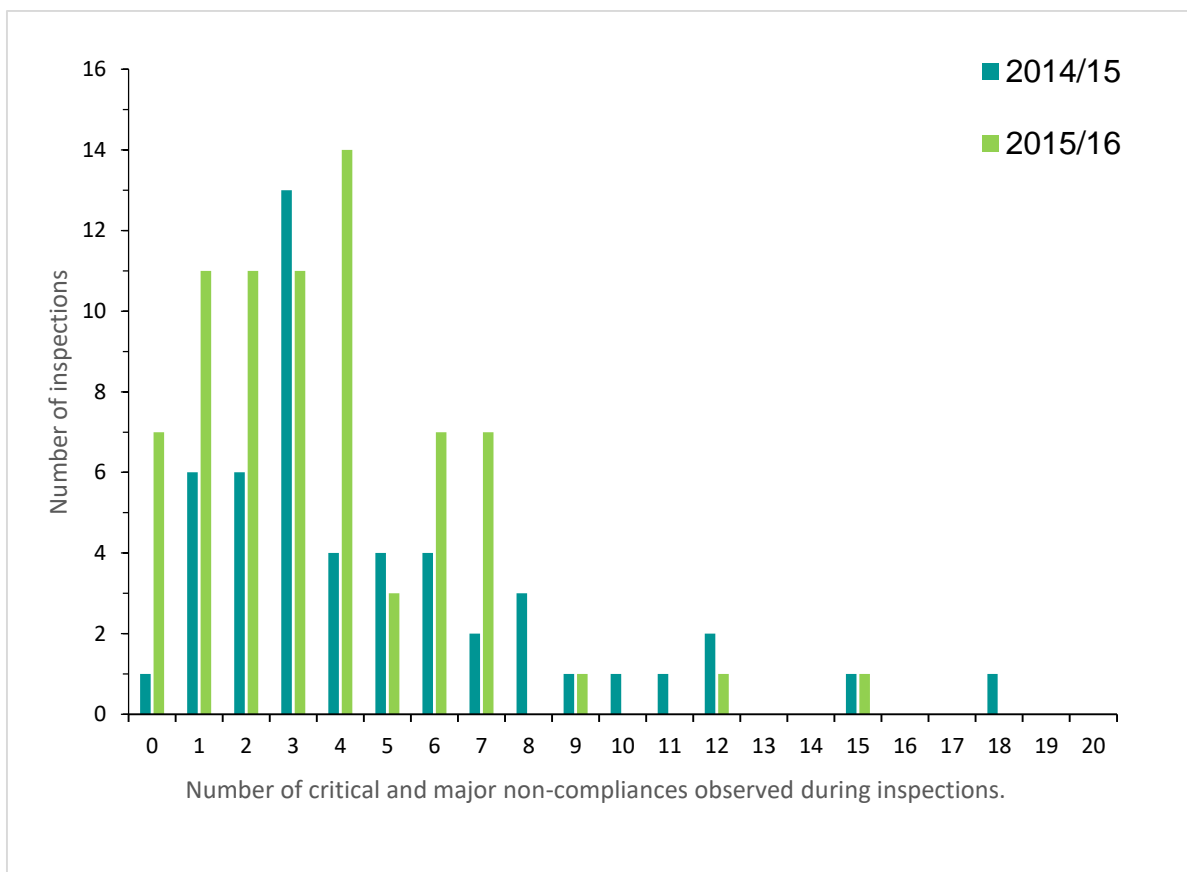


Chart 2

The number per inspection in 2015/16 of non-compliances of differing severity by centre activity/size

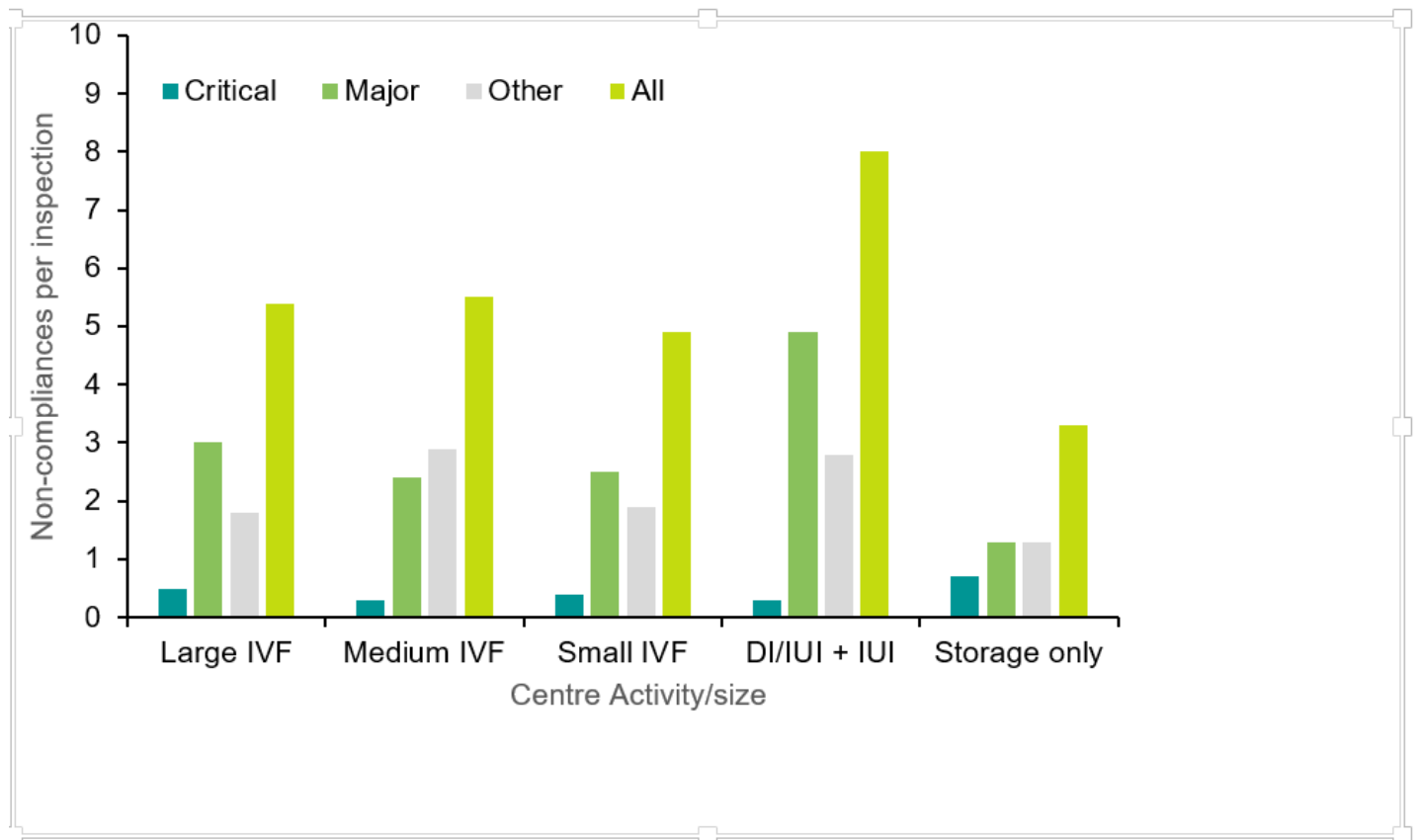


Chart 3

The number per inspection in 2015/16 of non-compliances of differing severity by inspection type.

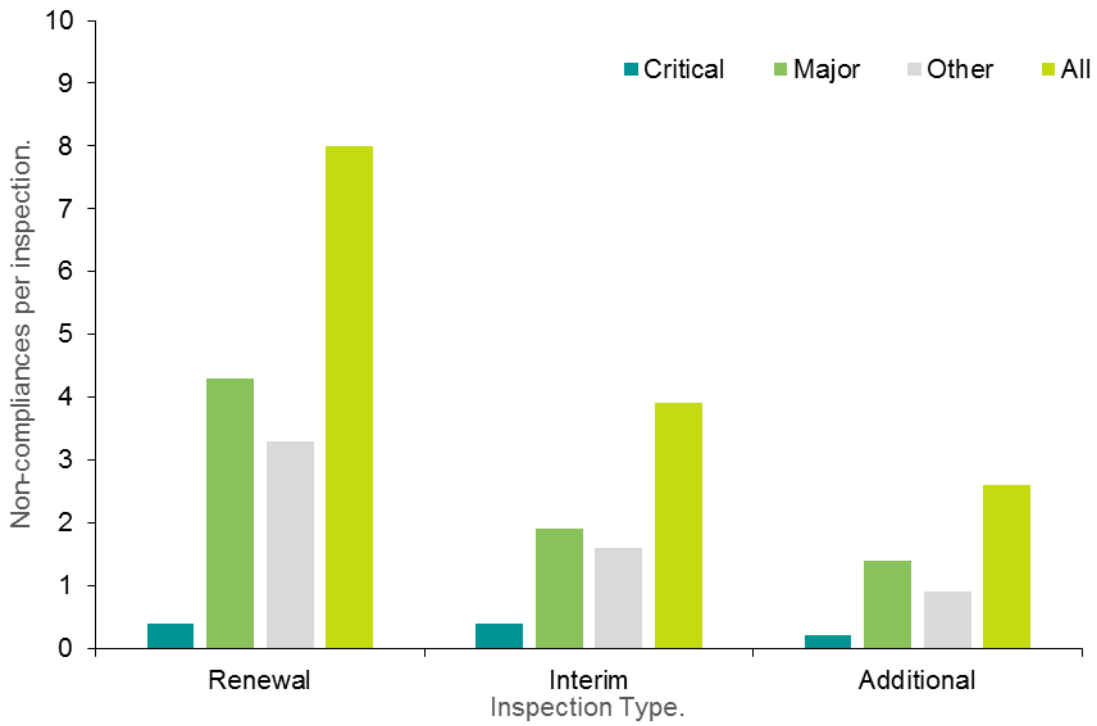


Chart 4

Frequently observed critical and major non-compliance types by clinic size and activity 2015/16

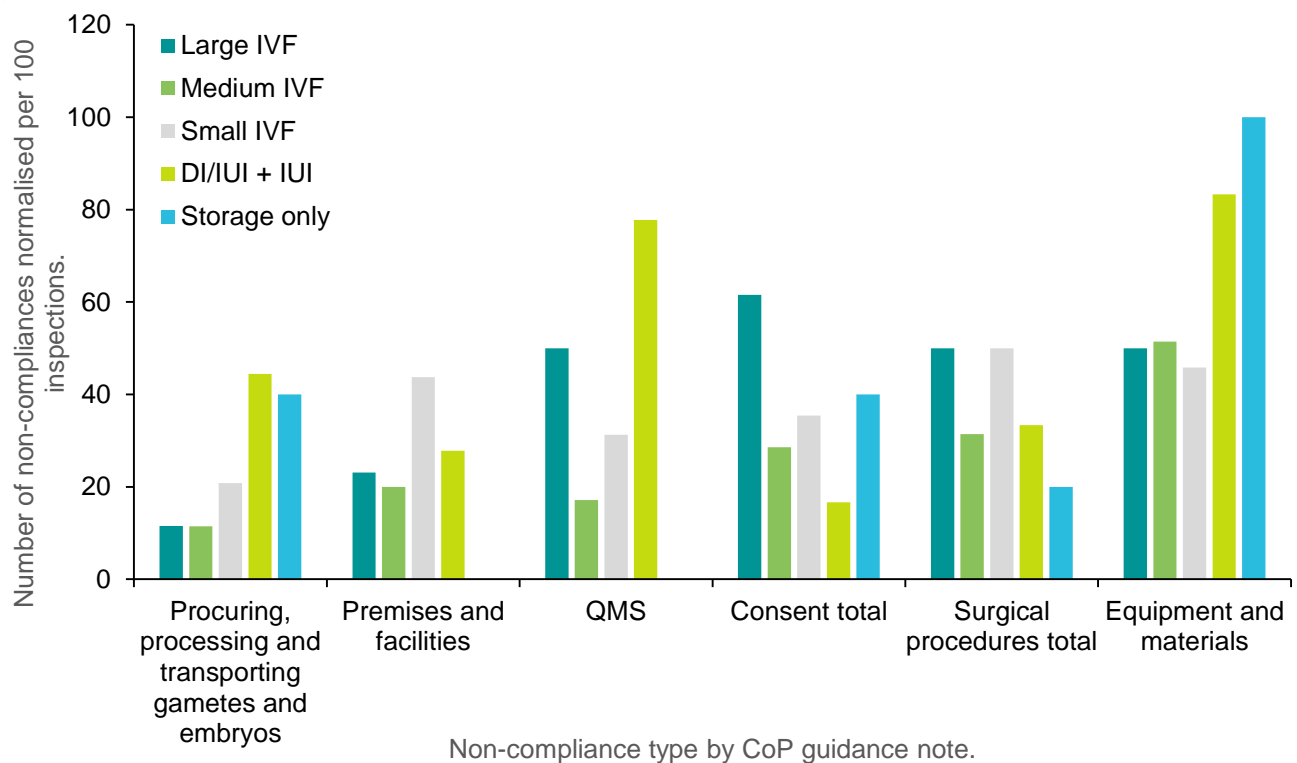


Chart 5

The number of non-compliances by guidance note and severity 2015/16

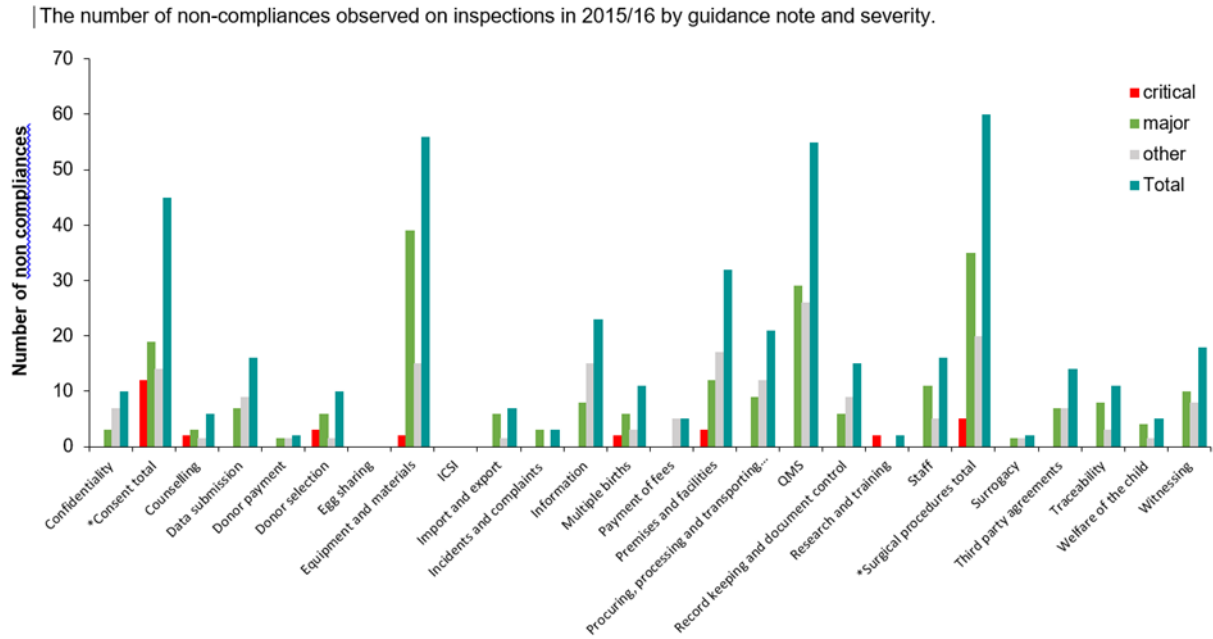


Table 1**Non-compliances grouped by severity**

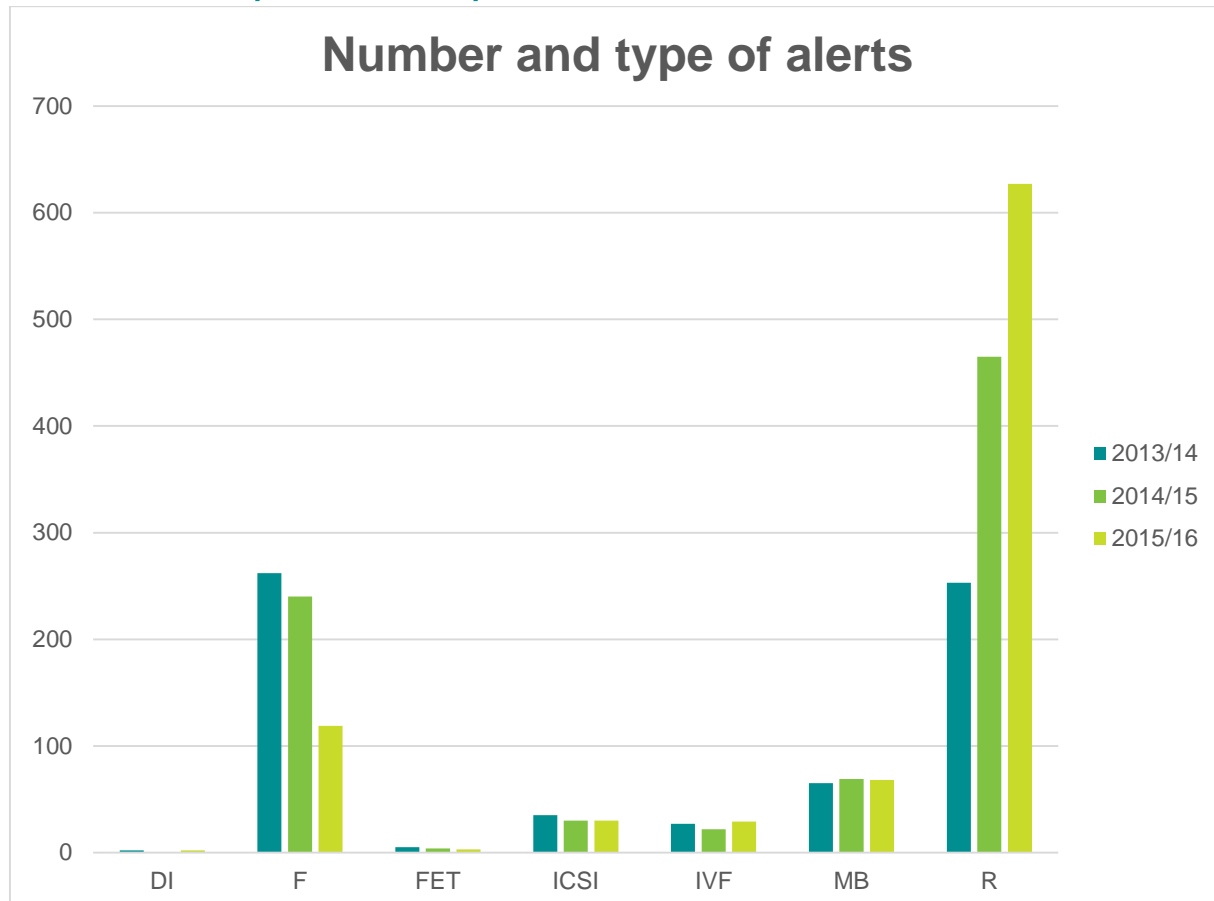
Non-compliances grouped by severity - critical (C), major (M), other (O) - identified on renewal and interim inspections, and on all inspections to clinics of varying size and activities in 2014/15 and 2015/16. Non-compliance detection rates per inspection are also shown. Notable decreases (Green) in non-compliance detection rates in 2015/16 versus 2014/15 are highlighted.

2014/15									
	Non-compliances found					Number per inspection			
<u>Inspection type</u>	C	M	O	All	Inspections	C	M	O	All
Renewal	15	139	138	292	27	0.6	5.1	5.1	10.8
Interim	9	49	23	81	16	0.6	3.1	1.4	5.1
Additional	8	22	5	35	9	0.9	2.4	0.6	3.9
<u>Clinic size/activity</u>									
Large IVF	6	48	53	107	13	0.5	3.7	4.1	8.2
Medium IVF	6	45	42	93	15	0.4	3.0	2.8	6.2
Small IVF	18	91	55	164	17	1.1	5.4	3.2	9.6
DI/IUI + IUI	2	20	11	33	5	0.4	4.0	2.2	6.6
Storage only	0	6	5	11	2	0.0	3.0	2.5	5.5
Grand Total	32	210	166	408	52	0.6	4.0	3.2	7.8
2015/16									
	Non-compliance found					Number per inspection			
<u>Inspection type</u>	C	M	O	All	Inspections	C	M	O	All
Renewal	15	151	114	280	35	0.4	4.3	3.3	8.0
Interim	14	69	59	142	36	0.4	1.9	1.6	3.9
Additional	2	13	8	23	9*	0.2	1.4	0.9	2.6
<u>Clinic size/activity</u>									
Large IVF	7	39	24	70	13*	0.5	3.0	1.8	5.4
Medium IVF	6	47	57	110	20	0.3	2.4	2.9	5.5
Small IVF	12	79	60	151	31*	0.4	2.5	1.9	4.9
DI/IUI + IUI	4	64	36	104	13	0.3	4.9	2.8	8.0
Storage only	2	4	4	10	3	0.7	1.3	1.3	3.3
Grand Total	31	233	181	445	80*	0.4	2.9	2.3	5.6

*Four additional inspections (to two large and two small clinics) were amalgamated with the inspections which precipitated them (two interim and two renewal).

Chart 6

Risk tool: Analysis of alerts between April 2015 and March 2016 and compared with data from 2014/15 and 2013/14.



F, Finance; the sum of all alerts related to delay or non-payment of invoices

R, Register; the sum of all alerts related to errors in reporting of treatments involving donor gametes

MB, Multiple births; the sum of all alerts related to trends in clinical multiple pregnancy rates as measured against the 10% multiple birth rate target

ICSI; the sum of all alerts related to trends in clinical pregnancy rates following ICSI treatments

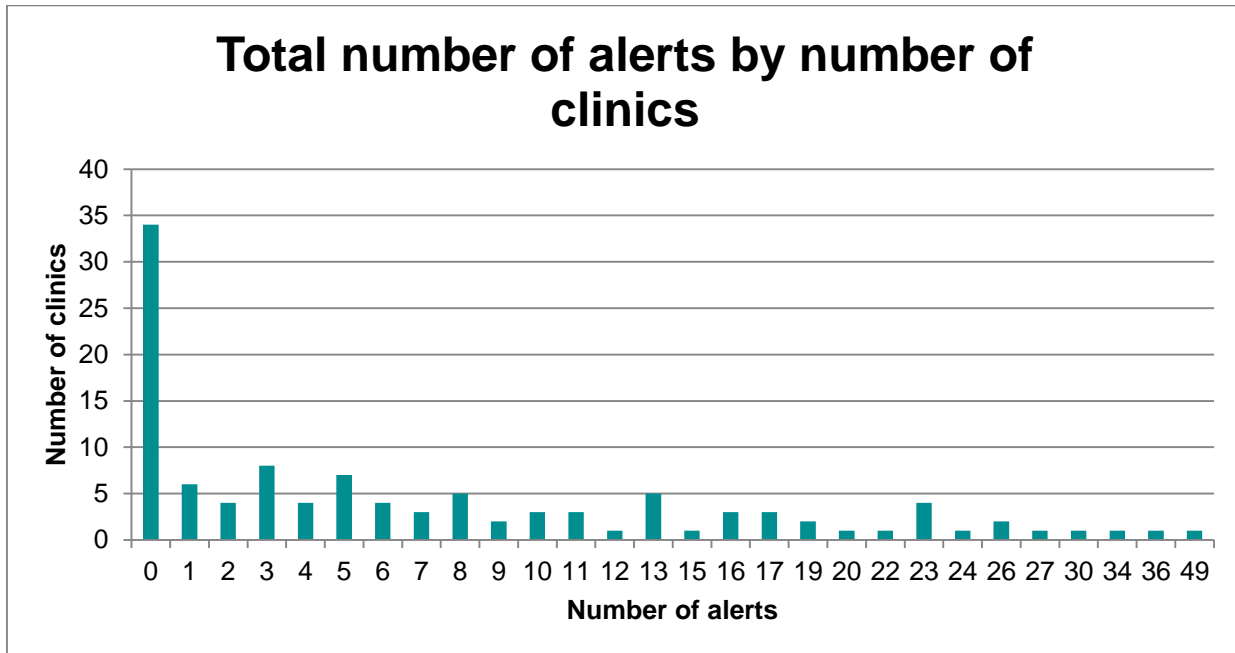
IVF; the sum of all alerts related to trends in clinical pregnancy rates following IVF treatments

DI; the sum of all alerts related to trends in clinical pregnancy rates following DI treatments

FET; the sum of all alerts related to trends in clinical pregnancy rates following frozen treatment cycles (IVF and ICSI).

This chart shows that the sector as a whole received more alerts relating to late payment of fees and accurate reporting of treatments involving donor gametes than relating to success rates. This is unchanged from the previous two reporting years. The chart does however show a significant decrease in the number of finance alerts sent to clinics as compared to the previous years. The number of alerts related to trends in success rates following IVF, ICSI and FET have not changed significantly.

Chart 7



In 2015/16, 34 of the 112 clinics included in the analysis received no alerts; a further 29 had between 1 and 5 alerts; 17 clinics had between 6 and 10 alerts and 32 clinics had >10 alerts.

The number of clinics receiving >10 alerts in 2015/16 has increased from that in 2014/15 by 5.

It should be noted that clinics that provide basic partner services or storage only do not pay monthly fees, do not provide treatment with donor gametes and make only a single annual data submission to the HFEA recording their success rates (this means that success rates and multiple pregnancy rates are not continuously monitored through the risk tool for these clinics). These clinics represent the majority of those receiving no or very few alerts.

Adverse incidents in fertility clinics

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

Details:

Meeting Authority

Agenda item 10

Paper number HFEA (14/09/2016) 810

Meeting date 14 September 2016

Author Paula Nolan, Clinical Governance Lead

Output:

For information or decision? For information

Recommendation To note the actions we are taking to improve clinics capacity to report, and learn from, incidents in Sections 3 and 4

Resource implications In budget

Implementation date Through ongoing compliance activities

Communication(s) The annual adverse incident report will be published as part of a campaign utilising the Clinic Portal and Clinic Focus – as a ‘call for action’.

Organisational risk Low Medium High

Annex 1: HFEA incident investigation template

Annex 2: annual incident report (draft – not for publication)

1. Background

- 1.1. Incidents happen in all healthcare settings. In recent years there has been considerable effort across different healthcare settings to learn from, and adopt techniques developed in, other industries where the mitigation of risk is crucial. And the HFEA has played its part in this process, since 2013 it has made public the reported incidents in the fertility sector and it has sought to encourage a culture of openness and learning. This paper summarises the incidents reported to the HFEA by clinics in 2015 and sets out the actions we propose to take to ensure that the sector continues to improve in reporting, reducing and, crucially, acting on any incidents.
- 1.2. The HFE Act provides a statutory framework in which incidents must be reported and analysed. The Person Responsible (PR) for an HFEA licensed clinic has a duty to report and analyse the causes of incidents¹. Similarly, the Authority has a duty² to investigate and take appropriate control measures in relation to reported incidents³.
- 1.3. The primary reason for reporting and investigating incidents is to improve safety for patients, embryos and clinic staff. Reporting an incident is not enough on its own: to be effective, learning should be extracted from each and every incident to minimise the risk of it happening again.
- 1.4. The HFEA has a national role in gathering information on incidents, identifying patterns and disseminating learning across the sector so that clinics can learn from the mistakes of others.
- 1.5. As noted above, in 2013 the Authority published for the first time information about incidents with the aim of promoting shared learning across the sector. In July 2014 we followed this up with a summary of incidents reported by clinics between 1 January 2010 and 31 December 2012⁴. The third annual report for incidents reported in 2015 will be published this month. Taken together, we have now five years of data on incidents in the fertility sector in the public domain and we need to decide what interventions will best drive further improvement.

2. What we have learnt

- 2.1. The number and type of incidents reported in 2015 is not significantly different from previous years. It is notable that no “A” grade incidents (the most serious) were reported in 2015.
- 2.2. However, the number of incidents by category suggests that too many in the sector are failing to learn from past errors, although it is not entirely clear why this is so. It may be that this is because clinics simply more need time to absorb the recommendations and “lessons learnt” included in previous incident reports, but that can be no excuse for failing to embed learning as quickly or effectively as we would like. There is evidence that the same type of incidents are occurring less at the clinic that reported them. In other words, where a clinic has direct experience of an incident it responds and changes its practice. Conversely, where a clinic’s experience of a problem is

¹ An incident is a serious adverse event or reaction as defined at 27.2 and 27.3 of the Code of Practice.

² S.15A of the Act.

³ Further information on our approach to incident handling can be found at <http://www.hfea.gov.uk/6678.html>

⁴ http://www.hfea.gov.uk/docs/Adverse_incidents_in_fertility_clinics_2010-2012_-_lessons_to_learn.pdf

indirect, through for example reading a report, some clinics may be taking the view that 'it couldn't happen here.' This is misplaced.

- 2.3.** As a first response, we will repeat our call to clinics to study this and previous reports with care. Changes in the reporting and investigation culture will not happen overnight and it might be several years before real changes are identified.
- 2.4.** We observe some lack of rigour in clinics undertaking root cause analysis – getting to the core of what failed. It is too easy to cite 'human error.' Rarely if ever is this the case – there will always be contributory factors.
- 2.5.** We often observe the corrective actions implemented by clinics following incidents tend to impose additional administrative steps (checking, documenting, double and triple checking) which may be impractical to adhere to and ineffective in preventing recurrence of incidents. Again, if clinics fully engage with incident investigations to identify the root causes, using human factors⁵ where appropriate, and implement corrective actions this is more likely to be effective.
- 2.6.** We must adapt our response to have a greater impact on clinics' incident systems such that improvements flow. Section 3 sets out the steps we have instituted or will be taking.

3. Clinical governance developments in 2015/6

- 3.1.** The system we have to report and deal with incidents works well in the main but it needs to develop if we are to have the impact we desire. To this end, we will continue to provide support to clinics, recognising that the number of incidents in relation to the number of treatment cycles is very small, and balance this, where necessary, with a greater focus on trends and at inspection.
- 3.2.** Where clinics report a high number of administration incidents, especially breaches in patient confidentiality, we will continue to offer focused assistance by the Clinical Governance Lead. To date, this support has encouraged clinics to carry out in-depth analysis of the causes of incidents. (This endeavour was supported by a workshop provided by the Information Commissioner's Office on data protection at a well-attended session at the 2016 HFEA annual conference.) Several clinics have managed to reduce their administration incidents following a focussed site visit.
- 3.3.** We will continue to provide bespoke workshops to clinics to improve their incident investigations. The HFEA Chief Inspector and Clinic Governance Lead have provided such workshops to several clinics shifting the clinic's focus from human error to arrive at the true root cause (system errors resulting in incidents). Removing the focus around human error and to steer the investigation towards human factors. A flow chart has been designed to help clinics in this task.
- 3.4.** We will intensify our review of reports that clinics undertake of incidents and their subsequent investigation. We have developed a new incident investigation template (annex 1) to help clinics

⁵ *Human Factors* is a discipline that explains the underlying reasons for human errors. It applies to human capabilities, limitations and behaviour for the purpose of increasing human performance, personal situational awareness and organisational awareness to eliminate where possible - and to reduce the risk for human error - in safe, efficient & cost effective operations.

produce more focused incident investigation reports and to appreciate better the root causes. This investigation template, introduced recently, also includes explanations around each stage of the investigation in order to provide guidance to the investigation team. Investigators of the incident are encouraged to consider preventive action or *risk based thinking* where the incident has the potential to occur elsewhere.

- 3.5.** We will make better use of our data to carry out a body of work. We will assess the reporting culture of these clinics in seeking reassurance there is an open and transparent reporting culture. If we notice a trend of recurring incidents we will work with the clinic to try and resolve these issues. We will also shine a more focused light on clinics reporting a disproportionately low number of incidents in relation to the volume of activity undertaken.
- 3.6.** On inspection our inspectors look for evidence that clinics have learnt from incidents rather than focussing on clinics' processes for incident reporting. Moreover, where clinics seem to be struggling to recognise when an incident should be reported to the HFEA the Clinical Governance Lead provides bespoke incident training sessions to individual clinics. This support will continue in 2015/16, but we will go further: where a clinic is not able to demonstrate that it is learning from experience we will reflect this in the inspection report and the recommendations relating to the licence.
- 3.7.** We will also keep abreast of wider developments within the healthcare system. We aim to develop a collaborative working relationship with NHS Improvement which is establishing a new Independent Patient Safety Investigation Service to ensure that wider learning from colleagues working in patient safety in a healthcare setting feeds into our own ways of working. We will also explore how sectors such as the aviation industry deal with incidents.

4. Recommendation

- 4.1.** The Authority is asked to note this report. In summary:
- We are seeking to influence the culture in licensed clinics so they develop an embedded learning and safety culture.
 - We will ensure that our work on incident oversight reads across more comprehensively to our inspection activities.
 - We are publishing a national report on incidents shortly, and we will use channels such as Clinic Focus and the clinic portal to maximise its impact.

Preventative Action/Risk based thinking.

Preventative Action is a Pro-active process to prevent the potential for an incident occurring. This is '*Risk Based Thinking*' an approach to the management of potential incidents. The centre must determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions should be appropriate to the effects of the potential problems.

Owner:

Date Completed:

Annotate if no P/A required.

Monitoring:

Detail any actions that may be required to ensure any corrected actions are embedded.

Owner:

Date Completed:

Annotate if no monitoring is required.

Final Approval:

Person Responsible or delegated individual to close incident.

Owner:

Date Completed: