Authority Agenda

Wednesday 8 July 2015
Meeting to be held at
ETC Venues, Hatton Garden, 51-53 Hatton Garden, London EC1N 8HN

1.	**Welcome, apologies and declaration of interests**	**(1.00pm)**
2.	**Minutes of 13 May 2015** HFEA (08/07/2015) 757 **Decision**	**(1.05pm)**
3.	**Chair's report** (verbal)	**(1.10pm)**
4.	**Chief Executive's report** (verbal)	**(1.20pm)**
5.	**Committee chairs' updates** (verbal) **Information**	**(1.30pm)**
6.	**Strategic performance report** HFEA (08/07/2015) 758 **Information**	**(1.40pm)**
7.	**Strategic risk register** HFEA (08/07/2015) 759 **Information**	**(1.55pm)**
8.	**Multiple births annual update** Presentation **Information**	**(2.05pm)**
9.	**Opening the Register update** HFEA (08/07/2015) 760 **Information**	**(2.30pm)**
	Break	**(2.50pm)**
10.	**Information for Quality update** HFEA (08/07/2015) 761 **Information**	**(3.00pm)**
11.	**Choose a Fertility Clinic** HFEA (08/07/2015) 762 **Information**	**(3.20pm)**
12.	**Any other business**	**(3.50pm)**

Close **3.55pm**

Next meeting **Wednesday 16 September, 2015**

Authority paper

Strategic delivery	Setting standards	☑	Increasing and informing choice	☑	Demonstrating efficiency, economy and value	☑
Paper title	Minutes of Authority meeting 13 May 2015					
Agenda item	**2**					
Paper number	HFEA (08-07-2015) 757					
Meeting date	8 July 2015					
Author	Charlotte Keen, Information and Access Policy Manager					
For information or decision?	Decision					
Recommendation	Members are asked to confirm the minutes as a true and accurate record of the meeting					

Minutes of the Authority meeting on 13 May 2015 held at ETC Venues, Hatton Garden, 51-53 Hatton Garden, London, EC1N 8HN

Members
There were 10 members at the meeting, 6 lay members and 4 professional members.

Members present
Sally Cheshire (Chair)
Dr Susan Price
Professor David Archard
Dr Andy Greenfield
Anthony Rutherford
Dr Alan Thornhill
Kate Brian
Margaret Gilmore
Yacoub Khalaf
Anita Bharucha

Apologies
Bishop Lee Rayfield
Rebekah Dundas

Observers
Ted Webb (DH)
Steve Pugh (DH)

Staff in attendance
Peter Thompson
Nick Jones
Juliet Tizzard
Sue Gallone
Catherine Drennan
Hannah Verdin
Joanne Anton
Siobhain Kelly
Anjeli Kara
Charlotte Keen

1. Welcome, apologies and declaration of interests

1.1. The Chair opened the meeting by welcoming Authority members, in particular Margaret Gilmore, Yacoub Khalaf and Anita Bharucha who were attending their first Authority meeting as members. The Chair also welcomed members of the public, including attendees from Scotland and New Zealand.

1.2. As with previous meetings, it was being audio-recorded and the recording would be made available on the HFEA website to enable interested members of the public who were not able to attend the meeting to listen to the HFEA's deliberations. This was part of the HFEA's drive to increase transparency about how the Authority goes about its business.

1.1. Apologies were received from Bishop Lee Rayfield and Rebekah Dundas.

1.2. Declarations of interest were made by:

- Anthony Rutherford (Consultant in Reproductive Medicine and Gynaecological Surgery at a licensed centre)
- Kate Brian (Regional organiser for London and the South East for Infertility Network UK)
- Yacoub Khalaf (Person Responsible at a licensed centre)
- Dr Alan Thornhill (for item 10 only)

2. Minutes of Authority meeting held on 11 March 2015

2.1. Members agreed the minutes of the meeting held on 11 March subject to minor amendments. The Chair agreed to sign the minutes as amended.

3. Chair's report

3.1. The Chair informed members that, since the last Authority meeting, she had attended a range of events with organisations in the IVF sector and the wider health and care system, although fewer events than usual due to the period of purdah before the general election.

3.2. On 17 March, the HFEA held their second Annual Conference, which was a great success, and the Chair expressed her thanks to everyone who took time to attend the event, with a special thank you to all the speakers and the HFEA staff who helped put the conference together.

3.3. The Chair, together with the Chief Executive, the Directors and the Chief Inspector, had indicated an interest in visiting clinics outside of the regular inspection schedule in order to hear what clinics felt about their performance and where they thought improvement was needed. These visits would then enable the HFEA, as the regulator, to consider how to help improve the quality of care. The Chair and the Chief Inspector had already visited St Mary's in Manchester and visits to Leeds and Guy's and St Thomas' were scheduled, with others to follow.

3.4. Looking ahead, the Chair advised members that she had been invited to speak at the Northern Fertility Nurses Conference in Leeds on 29 May.

3.5. Finally, the Chair advised members that she, together with the Chief Executive, had their annual accountability meeting with the Department of Health on 27 May to review the HFEA's performance over the 2014/15 business year and to identify key priorities for 2015/16.

4. Chief Executive's report

4.1. The Chief Executive advised members that he had attended the Audit and Governance Committee (AGC) on 18 March and would also be attending AGC in June for the end year accounts and annual governance statement sign-off.

4.2. On 20 April, the Chief Executive met the CEO of the Health and Social Care Information Centre (HSCIC) to discuss ways in which the HFEA and the HSCIC could work more closely together.

4.3. The Chief Executive advised members that the Welsh Language Commissioner had written to inform him of the intention to carry out a standards investigation. The investigation would determine whether, as an organisation which provides services in Wales, the HFEA should have to comply with the Welsh language commission standards. The investigation would begin on 25 May and last for 12 weeks. If the HFEA was required to do more following that investigation, this would be expected in March 2016. The Chief Executive advised members that he would keep them informed of developments.

4.4. Press Coverage: the Chief Executive summarised press coverage since the last Authority meeting, details of which had been circulated to members. He emphasised that purdah not only impacted on the amount of public work which could be carried out, but also on the extent to which the organisation could be as active in commenting on stories during that period. However, there were two stories which had cut through the election coverage and made the headlines.

4.5. CRISPR (Clustered Regularly Interspaced Short Palindromic Repeats): there had been considerable coverage of research in China on "genome-editing", where the Crispr technique had been used for the first time on human embryos. In terms of treatment possibilities, this technique was illegal in the UK, although it was legal in research, of which there was none at present.

4.6. The HFEA had received a number of press enquiries on this topic, although purdah had prevented the Executive from commenting in detail. Professor Robin Lovell-Badge had, however, spoken on the Today programme on Radio 4 and had provided a balanced account of the possibilities and potential problems with the treatment. He had advised that he could see its value in research but was less convinced as to any advantage it might offer over established procedures such as preimplantation genetic diagnosis (PGD) in treatment. Professor Lovell-Badge had also spoken very highly of the HFEA and the regulatory regime in the UK.

4.7. Another issue involving the HFEA during this period was a judicial review in the High Court of a decision taken by the HFEA's Statutory Approvals Committee (SAC) about the export of gametes to the USA. There were strict reporting restrictions around the case. However the judge would reach a verdict shortly.

4.8. Finally, the Chief Executive advised members that the HFEA's Director of Strategy and Corporate Affairs, together with an Authority member, had recently participated in a Progress Educational Trust (PET) debate on the HFEA's plans to introduce a patient feedback mechanism on the HFEA website. The British Medical Journal (BMJ) was planning to publish a piece on the debate in mid-May.

5. Strategic performance report

5.1. The Director of Finance and Resources advised members that she would be providing an update on the HFEA's current financial position and would then focus on part of the strategy and how the HFEA was doing in terms of delivery.

5.2. For the 2014/15 financial year, the Director of Finance and Resources advised members that there was a deficit of £186k which reflected the reduction in treatment fee income and unexpected expenses in relation to legal advice.

5.3. The Director of Finance and Resources advised members that the 2014/15 financial accounts were currently being audited and the following was therefore a pre-audit summary.

5.4. Before receiving the £920k grant-in-aid (GIA) from the Department of Health, the deficit in the financial accounts was £1,644k. With GIA the shortfall was £724k. However, the planned spend on IfQ from reserves (£565k) had to be taken into account and the true shortfall in the accounts was therefore £159k, as expected. The reserves were therefore reduced to £2,590k (from £3,314k).

5.5. In terms of signing off the annual report and accounts, the Director of Finance and Resources advised members that the report had been scaled down to the statutory requirements, primarily consisting of the strategic report, Directors' report, the remuneration report and the annual governance statement. The new report was based on an in-house style review which had helped to streamline the process. There was also far less information about Authority and Committee members within the annual report, although the full information which would continue to be available on the HFEA website.

5.6. The Director of Finance and Resources advised members that the annual report and accounts would be presented to the AGC on 10 June. The full document would then be circulated to Authority members for clearance, by exception, by 15 June. The annual report and accounts would then be signed off and laid before Parliament by the National Audit Office by the end of June.

5.7. The Director of Finance and Resources advised members that, for the 2015/16 financial year, budgets had been set with the assumption of a similar level of treatment fee income to the 2014/15 financial year. The GIA revenue had been confirmed by the Department of Health, with the same level of administrative GIA as for 2014/15, along with a small amount of programme GIA which would help offset the discount offered for elective single embryo transfer (eSET). The Director of Finance and Resources advised members that she was still awaiting confirmation for a small amount of capital funding for a refresh of the HFEA's IT equipment. The budget was very tight for the coming year, with some uncertainties around legal costs and future accommodation costs. There are spare reserves of just over £1m, allocated primarily to the IfQ programme.

5.8. The Director of Finance and Resources provided an overview to members on how the HFEA was delivering in relation to the 'efficiency, economy and value for money' part of the strategy. This part of the strategy consisted of two main streams:

- The reduced effort and costs for centres being regulated, and
- Keeping costs to a minimum and increasing value.

5.9. The Director of Finance and Resources reminded members that the objective was "ensuring the HFEA remains demonstrably good value for the public, sector and Government by ensuring we are easy to deal with and that we offer a professional and cost-effective service in all that we do."

5.10. The component parts of this, listed below, were set out in the strategy:

- Prioritising efforts and the application of resources in accordance with the strategy

- Continuing to engage with clinics on fees
- Ensuring the HFEA's governance tools underpinning decisions were in place
- Facilitating access to information and fulfilling Government requests
- Sharing with other organisations
- Internally provided services running smoothly.

5.11. The HFEA was delivering this part of the strategy so far through the following actions:

- Engagement and accountability through the Fees group, with two meetings held so far
- No increase in fee levels paid by clinics since 2006
- Cost control (2014/15 performance and 2015/16 budgets)
- Benefits, and challenges, of shared finance resources
- Efficiencies through co-location with the CQC
- Efficient facilities services largely led through the CQC
- Planning for the future move of offices, making best use of the Crown Estate
- Professional relationships with the Department of Health and auditors
- An effective Audit and Governance Committee (AGC).

5.12. The Director of Finance and Resources also reminded members of the other aspects of efficiency, economy and value, which were:

- Meeting legal and Parliamentary requirements
- Delivery of the people strategy
- Regulatory efficiency
- Evidence based decision making
- The IfQ programme.

5.13. The Director of Finance and Resources concluded that, at this stage, the HFEA was on course to deliver the strategy, although there were inevitable challenges which had been reflected in the strategic risks. The Director of Finance and Resources emphasised, however, that the HFEA was fully equipped to deliver and meet those challenges.

5.14. The Director of Strategy and Corporate Affairs updated members on the feedback from the HFEA Annual Conference on 17 March. The conference had been an opportunity to educate and train sector staff on a number of issues, as well as demonstrate how the HFEA had been delivering its strategy over the past year. Members noted a high proportion of the audience were attending an HFEA conference for the first time and tended to be more junior clinic staff. The conference had also attracted a larger audience than before with well over 200 in attendance.

5.15. The Director of Strategy and Corporate Affairs informed members that the HFEA would shortly select suppliers to carry out the design and development work around the new website and other systems. The Executive was also giving further consideration to how the patient feedback section of the website could be presented in a way that was meaningful and representative but equally engaging

and encouraging. The Director of Strategy and Corporate Affairs advised members that she would provide them with an update at their July meeting.

5.16. Following a discussion, members noted the latest Strategic Performance Report and also noted that the design of the document and the dashboard indicators was still a work in progress, with ongoing improvements to ensure that the report assisted the organisation in tracking delivery of its strategy.

6. Committee Chairs' update

6.1. The Chair of the Statutory Approvals Committee (SAC) reported that the committee had met on 26 March and 30 April. There had been three PGD applications and three Special Directions in March to consider, all of which were approved. There had been seven PGD applications and one Special Direction at the meeting in April, all of which were approved.

6.2. The Chair of the Licence Committee advised members that the committee had met on 12 March, 20 April and 7 May. On 12 March, the committee considered two initial treatment and storage licences, one of which was granted and one adjourned. The committee also considered a renewal for a treatment and storage licence (granted), a change of a Person Responsible (approved), a Grade A incident report and a number of other reports which the committee noted. At the meeting in April, the committee considered an initial research application which was granted and in May, the minutes of which had not yet been published, the committee considered two research licence renewals, an executive update and an update on the Grade A incident initially reported at the March meeting.

6.3. In the absence of the Chair of AGC, the Director of Finance and Resources advised members that the committee had met on 18 March and had received reports on:

- Risks and shared finance resources
- Financial policies (including the updated counter-fraud policy)
- An IfQ update from the Director of Compliance and Information
- The strategic risk register from the Head of Business Planning
- Interim feedback from the National Audit Office
- A progress report from DH Internal Audit
- The annual report and accounts.

6.4. The Scientific and Clinical Advances Advisory Committee (SCAAC) met outside the normal committee schedule on 1 April to consider new technologies for embryo testing.

6.5. A member requested that, for future Authority meetings, updates from the Executive Licensing Panel (ELP) be included in the committee updates item. The Chair explained that ELP was an internal committee at the HFEA which dealt with the less controversial and less novel aspects of licensing that were not required to go to a formal Licence Committee. The Chair of ELP agreed to provide a report on the committee's business as part of the committee update agenda item from the next Authority meeting onwards.

7. Information for quality: update and data dictionary

7.1. The Director of Compliance and Information explained that the IfQ programme was a comprehensive review of the information that the HFEA held, the systems

that governed the submission of data, the uses to which it was put and the way in which the information was published.

7.2. The Director of Compliance and Information explained that IfQ was a critical component of the HFEA's strategy and encompassed:

- The redesign of the HFEA's website and Choose a Fertility Clinic (CaFC)
- The redesign of the 'Clinic Portal' and combining it with data submission functionality that was currently provided in the HFEA's separate Electronic Data Interchange (EDI) system
- A revised dataset and data dictionary approved by the Standardisation Committee for Care Information (SCCI)
- A revised Register to include the migration of historical data contained within the existing Register
- The redesign of the HFEA's internal IT systems.

7.3. The Director of Compliance and Information reminded members that, in order to proceed with the programme, approval had been required by both the Department of Health and the Government Digital Service. As reported at the last Authority meeting, there had been a delay in the approval process, and this inevitably had resulted in some financial and implementation consequences in terms of expenditure in the next financial year and the time-line of the programme. However the business case, which had originally been submitted on 18 December 2014, was approved on 28 April 2015 for both the infrastructure and the public facing digital aspects of the programme. However, the digital approval was conditional in nature in the sense that proceeding to implementation would require the HFEA to seek further approval. At the point of the first stage – 'alpha' production – an assessment would be made by the Department of Health who in turn would have to satisfy the Government Digital Service standards.

7.4. The Director of Compliance and Information advised members that this process could potentially introduce substantial financial risk if there were any further delays. However, steps had been taken with the Department of Health and the Government Digital Service to clarify and confirm respective roles and accountability in order to minimise negative impacts.

7.5. The Director of Compliance and Information advised members that the Executive had spent considerable time thinking about risks, risk assurance and managing any identified risks, including the following activities:

- Continued DH Internal Audit engagement
- The IfQ programme risks had been integrated into the organisational risk framework and were monitored carefully
- A Government Gateway Review – part of the Office for Government Commerce approach relating to major projects – was commissioned in 2014:
    - The findings were reported to the HFEA on 1 April and were broadly positive
    - The programme was awarded an amber rating
    - Key issues identified included the impact of the programme on the organisation as it moved from technological change to organisational change.

7.6. The Director of Compliance and Information advised members that, although there was a strong internal technical team working on the programme, it had always been recognised that external supplier involvement was vital to the programme's success. A procurement exercise had therefore been carried out and overseen by the Crown Commercial Service. The closing date for tenders was 6 May 2015 with an encouraging volume of interest from external suppliers.

7.7. Work on the data dictionary was also progressing with meetings held with professional groups and discussions with researchers. There had been positive preparation for migrating data to a new register system, a key risk being diligently managed within the programme, and until all milestones had been met no migration would take place.

7.8. Following a discussion, Authority members noted:

- The approval received for the IT elements of the IfQ Programme by the Department of Health and the conditional approval received from the Government Digital Service in April 2015
- The procurement process had commenced with a tender return date of 6 May 2015
- The broadly positive report of the Government Gateway review
- Progress as regards the collection of data relating to specific research-related aspects of assisted reproduction treatment and progress relating to the migration of historic data to the new Register.

8. Equality Act update

8.1. The Authority and Committee Business Manager provided members with a brief overview of the Equality Act 2010. The Act came into force in 2010 and the purpose was to consolidate and extend previous anti-discrimination legislation. The Act established nine 'protected characteristics' and prohibited certain kinds of conduct in respect of people having these characteristics.

8.2. The HFEA was not a named 'public authority' for the purposes of the Act and was not therefore subject to the specific duties (publishing equality information and setting equality objectives). The Equality and Human Rights Commission guidance states that implementation of the Equality Act should be appropriate to the size of the organisation and its functions.

8.3. The Act, however, does set out a general public sector equality duty (PSED) and the HFEA was subject to this general duty. The general duty came into force in April 2011 and required public bodies to have due regard to the need to:

- Eliminate discrimination, harassment and victimisation
- Advance equality of opportunity between people from different groups
- Foster good relations between people from different groups.

8.4. The Authority and Committee Business Manager advised members that, following the change of government in 2010, the coalition had launched the 'Red Tape Challenge', the aim of which was to reduce regulations on organisations and companies and equalities was a theme of this piece of work.

8.5. As a result of this, a PSED review was carried out to establish if it was operating as intended. The review was announced in May 2012 and promised to assess the effectiveness of the PSED specific duties and be extended to include the general duties. The report of the steering group was published in September 2013. The

report made it clear that the Equality and Human Rights Commission (EHRC) needed to provide better guidance for public bodies on how to comply with the Equality Act. The report, whilst acknowledging the importance of the Act and the good work shown by organisations in adhering to the duty, stated that public bodies needed to take a proportionate approach to compliance and not seek to 'gold plate'. The report also specified that regulators had an important role to play in implementation and the principles of the PSED should be embedded in core functions. It was agreed that there should be a full evaluation of the PSED in 2016 when the general duty had been in force for five years.

8.6. In line with the recommendations from the PSED review, pressure on resources and in adherence with the strategic aim of the HFEA, the 2015 update had been approached as a 'health check' on where the Authority was now in terms of its requirements under the Act. The Authority and Committee Business Manager advised members that the HFEA currently maintained a good level of compliance and in some areas had made improvements. The table at Annex A of the paper showed the standing at the last review, which had been carried out in 2010, a review of progress in 2015 and an updated risk rating. In addition to the specific actions identified, members were advised that the IfQ programme would provide further benefits with accessibility being at the heart of the website development.

8.7. The Authority and Committee Business Manager recommended to members that a full review was carried out following the outcome of the government review in 2016. However, since the HFEA's Equality Champion had stepped down, having come to the end of her term, the Authority should now appoint a new board level Equality Champion.

Decision

8.8. Following a discussion, Authority members:

- Noted the progress set out in Annex A of the paper and supported the actions set out in Annex B
- Agreed to a full review and report back to the Authority in 2017 following the outcome of the government review in 2016
- Agreed to the appointment of a new Board Level Equality Champion.

8.9. The Chair confirmed that Kate Brian had agreed to take on the role of the HFEA's Equality Champion.

9. Draft licensing process and guidance for regulating mitochondrial donation

9.1. The Policy Manager provided members with a brief overview of the position relating to the Human Fertilisation and Embryology (Mitochondrial Donation) Regulations 2015 ('the Regulations'). Parliament had approved the Regulations to permit the use of Maternal Spindle Transfer (MST) and Pronuclear Transfer (PST) to avoid serious mitochondrial disease. The Regulations would come into force on 29 October 2015. The HFEA had until this date to design and launch a system for the regulation and licensing of mitochondrial donation, so that it was ready to receive applications from clinics who wished to carry out these treatments as soon as the Regulations came into force. The regulatory framework would reflect, and take into account, the extensive work carried out over the past four years, including:

- A public dialogue exercise which explored the ethical aspects and practical implications of allowing such techniques within regulation
- Three reviews on the safety and efficacy of methods to avoid mitochondrial disease.

9.2. The Policy Manager advised members it was important to note that, although the treatments themselves were novel, there were already existing regulatory frameworks within which the HFEA could operate.

9.3. **Safety and efficacy**: the Policy Manager reminded members that the scientific expert panel concluded there had been no evidence to date to suggest that the new mitochondrial donation techniques were unsafe. The expert panel did, however, recommend that further safety and efficacy tests should take place before treatment was offered and it was expected that such research would support the conclusions the panel had reached so far.

9.4. Three of these further tests were deemed by the panel to be essential before MST or PNT were used in treatment. Before the first clinical application of MST or PNT was considered, it was therefore appropriate, and expected by Parliament and stakeholders, that a further assessment would be made on the outcomes of the three tests. On present plans, once the Authority had been made aware that these tests had been completed, it would convene an expert panel to make that assessment and the panel's report would then be presented to the Authority.

9.5. **Licensing and authorisation**: the Policy Manager advised members that, in terms of licensing and authorisation, the Regulations envisaged a two stage process.

9.6. Stage one would cover the licensing of the clinic to undertake mitochondrial donation and would include the following steps:

- The clinic applying to vary its existing treatment licence
- The Inspectorate assessing the competence of the clinic and the suitability of its premises
- The Licence Committee considering the application and (if successful) varying the clinic's licence to perform PNT and/or MST.

9.7. Stage two would involve the authorisation to undertake the treatment on a case-by-case basis. This would include the following steps:

- The clinic would submit a patient application form
- The Statutory Approvals Committee (SAC) would assess the application on the basis of:
    - The particular risk of that patient passing on mitochondrial disease
    - The significance of the risk to a patient's child, and
    - The seriousness of the resulting disease.

9.8. The Policy Manager advised members that the paper set out a list of key questions that the HFEA proposed asking in the case-by-case application form. The questions were based on what was required by the Regulations, the current understanding of the biology involved, and careful scrutiny of the expert panel's scientific reviews. The Executive had also worked with members who had genetics expertise and would be seeking further views from relevant stakeholders.

9.9. **Regulatory framework**: the Policy Manager advised members that the Executive had reviewed the Code of Practice, the various reports on public attitude, safety and efficacy and regulatory considerations in order to identify areas where guidance or requirements pertaining to mitochondrial donation would need to be added or amended. The main policy issues would include :

- Clinic staff expertise, skills and experience to ensure that the staff involved had sufficient competence in the embryological techniques
- Ensuring the appropriate equipment and environment were in place
- Mitochondrial donor screening and selecting mitochondrial donors
- Donor compensation and the ten family limit
- Follow-up study requirements
- Consent and information provision.

9.10. **Register information**: the Policy Manager advised members that the paper set out the information the HFEA was required to collect for mitochondrial donation treatments. Clinics wishing to carry out mitochondrial donation would need to submit information to the HFEA about:

- The mitochondrial donor
- The patient being treated
- The sperm provider(s), and
- Treatment details, including:
    - The date
    - How many embryos were created
    - Which techniques were used
    - The fate of any embryos created
    - The outcome where embryos were transferred.

9.11. The Policy Manager advised members that, throughout June 2015, the Executive would seek focused stakeholder feedback on key areas to ensure that the HFEA had gathered the relevant expertise. The proposed questions set out in the paper concentrated mainly on the technical and operational issues.

9.12. The Policy Manager provided members with a summary of next steps. As mentioned, in June 2015 the Executive would be seeking stakeholder views. A further update would be presented to the Authority at its meeting in July 2015 with an Authority decision in September 2015 for the Regulations to be ready to come into force on 29 October 2015.

9.13. **Discussion points:** it was important to emphasise the provisional nature of the discussion, that it did not represent a settled policy decision and was very much a work in progress.

9.14. **Safety and efficacy:** members agreed with the approach set out in the paper and noted that it was not yet clear when the results of the further tests would be available. The Chief Executive pointed out that the HFEA had delegated the assessment of safety and efficacy to an expert panel, given the highly technical nature of the work. If the panel was of the view that, once the tests had taken place, that both MST and PNT techniques were safe and effective, that would be the most practical way of proceeding and the HFEA would be guided by the panel's expertise.

9.15. **Licensing and authorisation:** the Chair of SAC emphasised that it was important to note that PGD was very different to mitochondrial donation in terms of the understanding of 'significant risk' and that mitochondrial donation would be dealt with on a case-by-case basis whereas PGD was a condition-by-condition basis. It would therefore present challenges in terms of authorising and licensing mitochondrial donation. It would be important to consider further what kind of evidence the committee received and how that evidence would be interpreted. The committee would have to adopt a holistic approach. The Chair of SAC suggested that, since it was only a short time until October when the Regulations would come into force, it was very important to prepare both in terms of keeping clinics informed about what they would have to do to present their applications and also ensuring SAC members were equipped to consider applications. It would therefore be helpful to have exercises for committee members to engage in before November in order to allow them to be fully prepared.

9.16. Members noted that the Regulations required the Authority to license mitochondrial replacement on a case-by-case basis and agreed in principle the two stage approach of licensing and authorisation.

9.17. **Regulatory framework:** a member emphasised that staff competencies and skills should encompass not just the medical competencies but also counselling competencies. In relation to donor information and screening, the Head of Regulatory Policy advised members that the age limit of the mitochondrial donor was an area the Executive wanted to seek expert views on in June.

9.18. Members noted that, in relation to follow-up studies, this aspect of the process was not covered in the Regulations, and the Chair advised members that this was something which required careful consideration. The Chief Executive emphasised that, although follow-up studies were a good idea, it would clearly be unethical to require any follow-up.

Decision

9.19. Following the discussion, Authority members:

- Approved in principle the draft licensing processes and policy proposals set out in the paper
- Agreed the proposed questions for stakeholder feedback in June 2015 subject to members' comments following the meeting.

10. Embryo testing: testing for more than one condition or abnormality at a time

10.1. The Regulatory Policy Manager provided members with a background to embryo testing technologies. Preimplantation genetic diagnosis (PGD) and preimplantation genetic screening (PGS) had been available for many years. Technologies used in PGD were used to identify embryos at risk of being affected by an inherited genetic or chromosomal condition. PGS was used to screen embryos for common chromosomal abnormalities that could cause miscarriage or IVF failure.

10.2. The Regulatory Policy Manager advised members that, in recent years, significant advances had occurred in embryo testing technologies. The latest developments meant that it was now possible to simultaneously screen embryos under PGD and PGS at the same time. New technologies had also presented the ability to generate additional genetic information about conditions/abnormalities not being specifically tested for.

10.3. The Regulatory Policy Manager informed members that the Executive had sight of the advances in embryo testing technologies through the HFEA's annual horizon scanning process and they had been discussed by both the Scientific and Clinical Advances Advisory Committee (SCAAC) and the Ethics and Standards Committee (ESC). ESC, at its meeting in June 2014, had recommended that the Executive seek both legal advice and the views of key stakeholders. The Executive had discussed the issues with stakeholders at its annual embryo testing workshop in December 2014 and through correspondence with a number of professional bodies.

10.4. The Regulatory Policy Manager advised members that the latest developments in embryo testing technologies now gave rise to two potential scenarios:

- That patients may wish to have both PGS and PGD at the same time
- That patients may wish to use PGD to test for more than one genetic condition at a time.

10.5. The Regulatory Policy Manager advised members that this, in turn, gave rise to the following questions:

- If a patient satisfied the criteria for PGS, could PGD also be carried out at the same time using the same embryo biopsy sample and vice versa?
- If a patient satisfied the criteria for PGD for testing one condition, could PGD for another condition also be carried out and would those additional conditions need to meet any other criteria?

10.6. Both legal advice and stakeholder views supported the use of these technologies in practice and the idea of testing for more than one disease at a time. If Authority members were minded to allow testing for more than one disease at a time, they would need to consider how the information generated by the tests would be handled.

10.7. Taking into account the legal advice and views of stakeholders, the Regulatory Policy Manager asked members to consider the three options set out in section five of the paper:

- Option one: to prohibit the use of PGD to test for more than one genetic condition (the new technologies may be used, but areas of the test must be blocked out)
- Option two: to allow testing of more than one genetic condition, but withhold from patients the information that was generated
- Option three: to allow testing of more than one genetic condition, making sure that patients consented to receive (or not receive) the information generated.

10.8. In discussion, some members expressed misgivings about which patients were currently being offered PGS by clinics and how able PGS centres were to interpret complex test results. Members felt that it would be best to review this aspect before considering the policy questions in the paper.

10.9. The Regulatory Policy Manager advised members that SCAAC would consider the use of PGS at its forthcoming meeting in June. A member noted that delaying a decision in relation to the recommendations put to the Authority would not affect patients and, following a discussion, it was agreed that the Executive should bring this issue back to a later Authority meeting. Members, however, were in agreement that option two was not an appropriate approach.

11. Any Other Business

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

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

Chair _____

Date

Authority paper

Strategic delivery	**Setting standards**	☐	**Increasing and informing choice**	☐	**Demonstrating efficiency, economy and value**	☑
Paper title	**Strategic performance report**					
Agenda item	**6**					
Paper number	HFEA (08/07/2015) 758					
Meeting date	8 July 2015					
Author	Paula Robinson, Head of Business Planning					
For information or decision?	Information					
Recommendation	The Authority is asked to note and comment on the latest strategic performance report.					
Resource implications	In budget.					
Implementation	Measurement of most indicators is on a monthly basis.					
Communication	CMG reviews performance in advance of each Authority meeting. The Department of Health reviews our performance at each DH Update meeting. The Authority will receive this summary paper at each meeting, enhanced by additional reporting from Directors.					
Organisational risk	Medium, given limited resources and a challenging strategy and workplan.					
Annexes	A: Strategic Performance Report					

HUMAN FERTILISATION & EMBRYOLOGY AUTHORITY

1. Introduction

1.1. The attached paper summarises the main performance indicators up to the end of April 2015, following discussion by the Corporate Management Group (CMG) at its June performance meeting.

1.2. Overall performance is good, with very few performance measures in the red, and good progress towards our strategic aims.

2. Recommendation

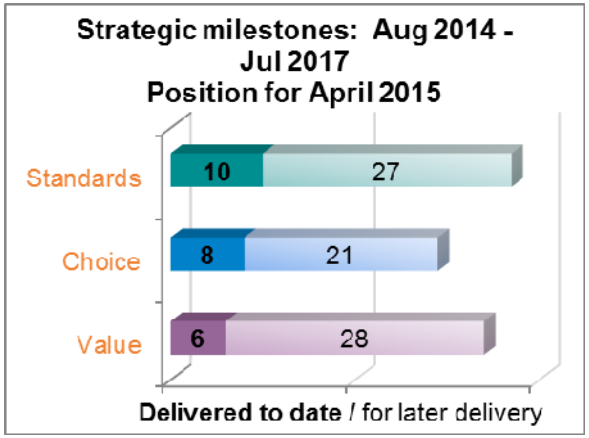
2.1. The Authority is asked to note the latest Strategic Performance Report.

HFEA performance scorecard

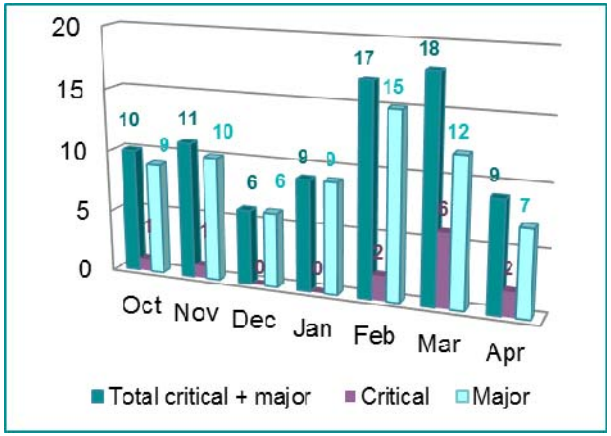
Summary section

Dashboard

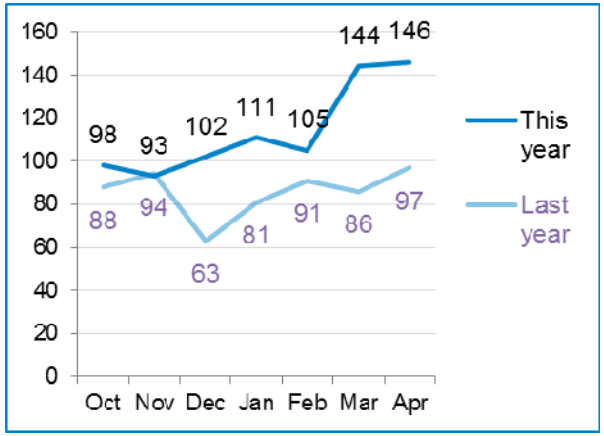
Strategic delivery totaliser
(see commentary for more detail)



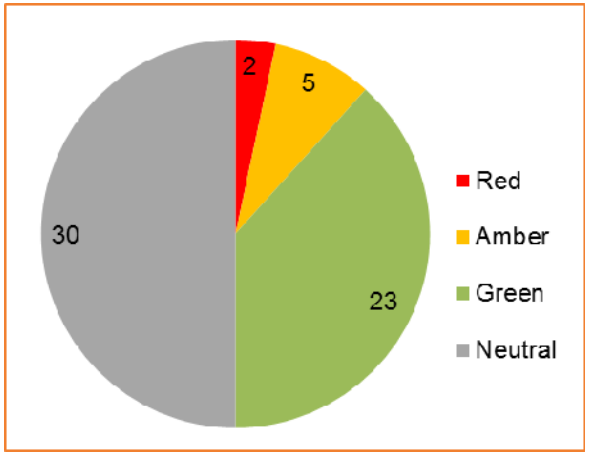
Setting standards:
critical / major recommendations on inspection



Increasing and informing choice:
public enquiries received (email)

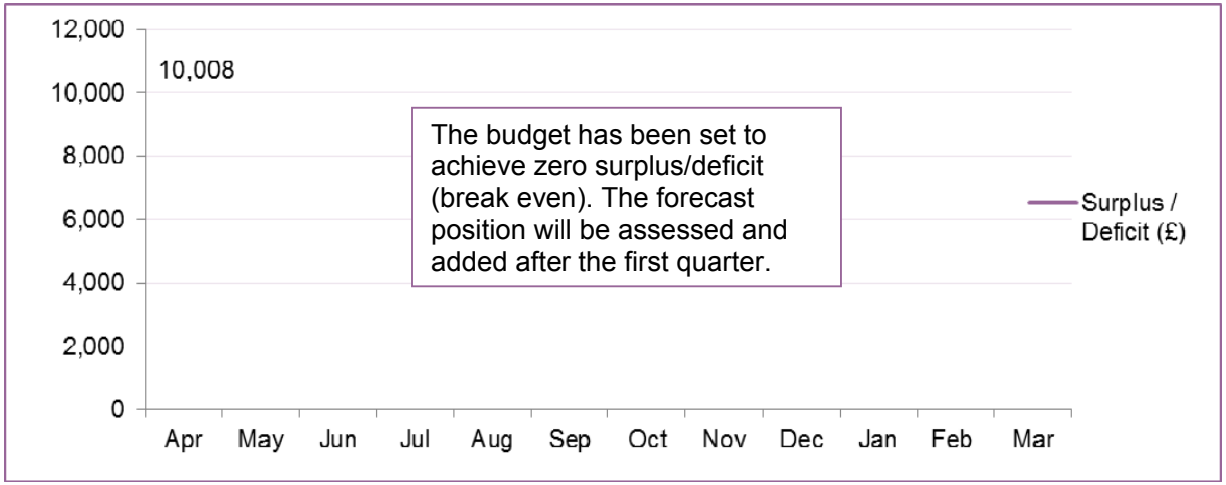


Overall status - performance indicators:



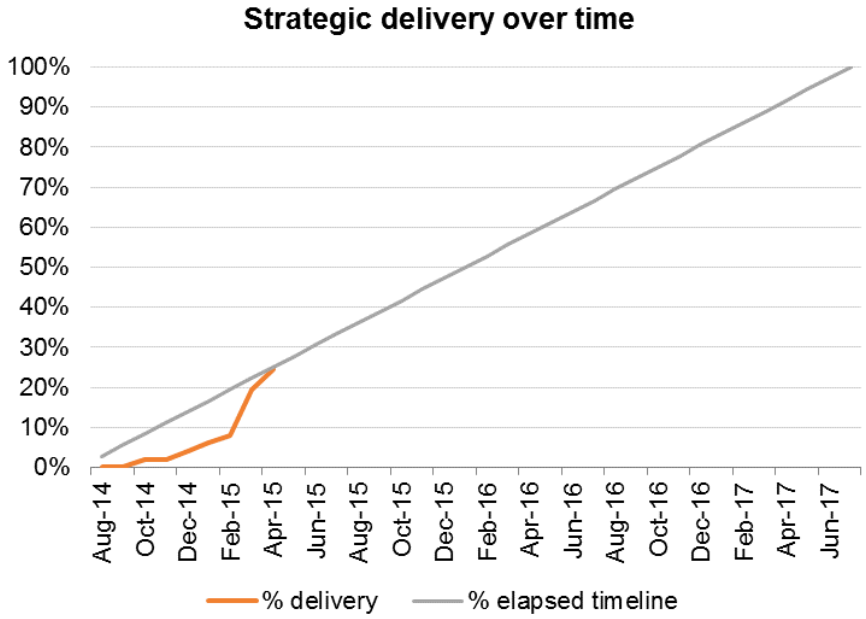
(See commentary for more detail.)

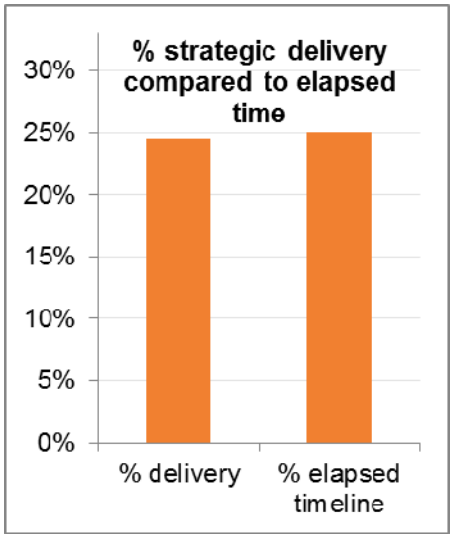
Efficiency, economy and value: Budget status: cumulative surplus/(deficit)



Dashboard Commentary

Strategic delivery – summary:





We are broadly on track, with just under 25% of items completed at one quarter of the way through the three year strategic period. The calendar of deliverables will be reviewed thoroughly following the first phase of Information for Quality (IfQ) programme delivery.

Setting standards

With the aim of ensuring high quality safe care, we have completed a range of advisory work on mitochondrial replacement techniques, and are currently creating new licensing processes, in preparation for an implementation date for the new regulations of 29 October. We have assured standards and safety by delivering our full year's programme of inspection and licensing, with a particular focus on quality and safety of care and on learning from incidents and adverse events in the sector, and by participating in EU competent authorities meetings. We have made process improvements to make the patient experience a more explicit consideration in our assessment of clinics' performance. This has been partially delivered through our approach to unannounced inspections, which incorporates more patient feedback. There will be further developments through the planned IfQ work on the presentation of Choose a Fertility Clinic (the majority of which is for delivery by the end of 2015/16).

We have continued to engage with patient and donor organisations so as to inform our future work and drive up quality. Recent engagement events have included a Lifecycle group meeting in February, attendance at the Association of Fertility Patient Organisations (AFPO) conference in April, and collaborative work with the sector on a range of strategy topics at our own Licensed Centre Panel and Professional Stakeholders Group meetings in April.

With the aim of increasing the awareness by clinics of their role and obligations with respect to donation, we have done work to ensure that clinics prepare patients adequately for donation, and that they understand their important lifelong role as a provider of accurate information about past donation treatments. We have also established, through our IfQ programme consultation, what the HFEA might do in collaboration with stakeholders and professional organisations regarding information about the availability of donor eggs and sperm (gametes), so that an accurate picture of the UK position can be established.

We considered whether we could perhaps work with professional groups in some way so as to optimise success rates. We subsequently concluded that the HFEA could not itself drive any increase in success rates. Instead we will continue to focus on ways in which we can constructively feed back to the sector the information that we hold about performance, quality and safety, with the aim of encouraging improved quality of care for patients (not only with respect to success rates).

June saw the start-up of our counselling support service pilot, improving the availability of counselling support for donor-conceived people wishing to access information held on the HFEA Register. The start-up was delayed by two months, owing to initial difficulties in identifying a supplier who could deliver the contract within our budget. The success of the three year pilot will be gauged at annual intervals.

Increasing and informing choice

We enhanced our provision of information to the public and feedback on performance to the sector by publishing our 6-monthly udpates of CaFC information in both October and April, and published ‘Fertility treatment in 2013’ in December. We also published our statistical report on donation and donor conception in October, and ran a successful Annual Conference in March.

We have been working to ensure that patient views and needs are better incorporated into our work, by increasing our dialogue with patients in relation to policy developments and decisions. There will be more emphasis on creating improved channels for more effective dialogue through our IfQ delivery.

Our ultimate goal is to increase and inform patients’ choices, by improving the presentation of information on CaFC, ensuring other information on our website is relevant and of high quality, and adding new information to the redeveloped website about available treatments, scientific research and other fertility subjects. To this end, we have started to explore how CaFC could be made easier to use, and identified a range of improvements which have formed the basis of the IfQ business case and tendering requirements. We are also now able to commence the first phase of redevelopment our website, which will allow for better patient feedback, improved transparency, and more interactive dialogue with our audiences.

Receiving the various required IfQ programme approvals from the Department of Health and the Government Digital Service took significantly longer than anticipated (over 4 months). In the end, approval for the systems element was obtained at the end of April, along with partial approval for the

digitial element (redevelopment of the website and associated actions). Further approvals will need to be sought after the initial phase of the digital work, which may lead to further delays. We are working to avoid this scenario by putting various mitigations in place, including ongoing dialogue with GDS throughout the initial (approved) phase of the work. The approval delay means that we have not yet begun to redevelop our website, and so this action is behind schedule.

Alongside all of these new and future developments, we have also continued to maintain the Register of treatments and outcomes, and continued to support clinics in reporting the important data it holds.

Efficiency, economy and value

We have met our aim of delivering good value to stakeholders by ensuring that set-up and planning work on IfQ projects went ahead efficiently during the 4 month period while we were awaiting the required approvals to start the substantive work. This ensured we made best use of the time and were prepared to go ahead with tendering as soon as the approvals were received. A detailed plan for the information systems project was produced in February, and a data migration strategy was agreed in March. The required approval, originally due in December, was obtained at the end of April.

A key aim of the IfQ programme is to modernise, and make more efficient, our Register function and processes. We furthered this aim through completing the main elements of the data dictionary project (by March, with some ongoing work throughout the current 2015/16 business year), and through early work to determine the scope for recalibrating the current data validation and correction regime (also completed in March).

We also continued to evidence our value to the sector by engaging openly with clinics about fees. A meeting of the fees group was held in April so as to ensure appropriate continued accountability for, and dialogue about, fee rates.

Red/amber/green status of performance indicators

The two red indicators shown in the ‘overall status - performance indicators’ pie chart on the dashboard are as follows:

The average number of working days from the day of inspection to the day the draft report is sent to the PR decreased to only 16 working days, but only 43% of the seven reports due during the month of April were sent to the clinic within 20 working days (compared to a target of 90%). This means that four reports went to clinics later than target. However none of the four took longer than 25 working days, and in all four cases this was because of a particular issue that was complex to resolve, and not because of any intrinsic or consistent issue with our processes or capability.

The annualised rolling figure for the processing of HLA applications continues to be affected by delays in obtaining needed information from centres during the processing period. Our target is to process 90% of applications to committee stage within 30 working days of receipt. We are currently performing at an annualised rate of 40%, with the average time taken being 41 working days. In April, two applications were delayed awaiting information, which is now expected to be received in June. These types of delays will continue to affect the annualised picture significantly, due to the very small number of HLA applications we receive (because each individual application constitutes a high percentage of the total).

Quality and safety of care

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

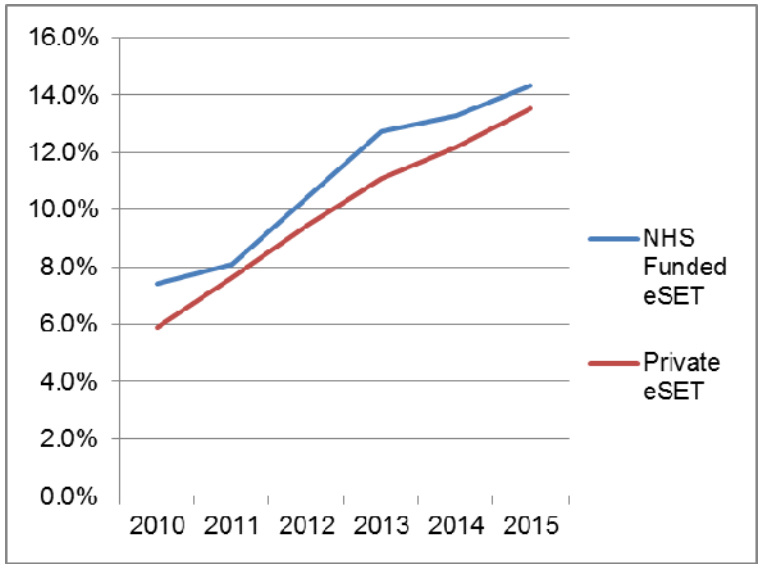
- No. of risk tool alerts (and themes)
- Common non-compliances (by type)
- Incidents report (and themes)

In addition, we have developed the items below as quality and safety of care proxies. The figures below were run on 5 June 2015 (in readiness for the CMG performance meeting).

ESET split by private/NHS:

Funding	Year					
	2010	2011	2012	2013	2014	2015
NHS Funded eSET	4292	4902	6262	7867	8433	3749
Private eSET	3422	4629	5695	6853	7715	3547
Funding	**Year**					
	2010	**2011**	**2012**	**2013**	**2014**	**2015**
NHS Funded eSET	7.4%	8.1%	10.4%	12.7%	13.3%	14.3%
Not recorded as eSET	33%	32%	30%	29%	28%	27%
Private eSET	5.9%	7.6%	9.5%	11.1%	12.2%	13.5%
Not recorded as eSET	53%	52%	50%	48%	46%	45%

Graph: eSet % trends NHS/private:



Explanatory text:

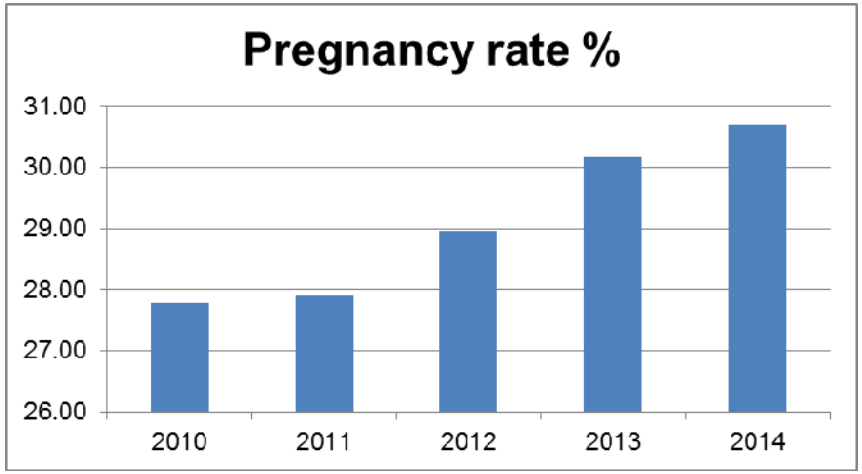
Looking at all IVF treatment forms; counting those records that the centres recorded as eSET.

2015 figures are (obviously) only partial.

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

Years	All cycles	Pregnancies	Pregnancy rate
2010	58015	16116	27.78
2011	60569	16895	27.89
2012	60227	17453	28.98
2013	61825	18648	30.16
2014	63444	19577	30.86

Graph showing the pregnancy rate over recent years:

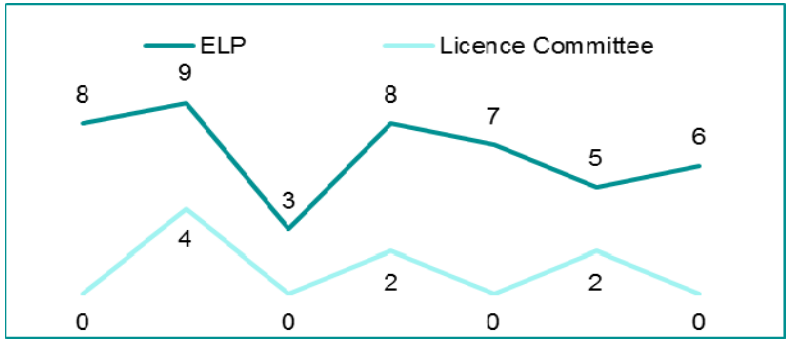
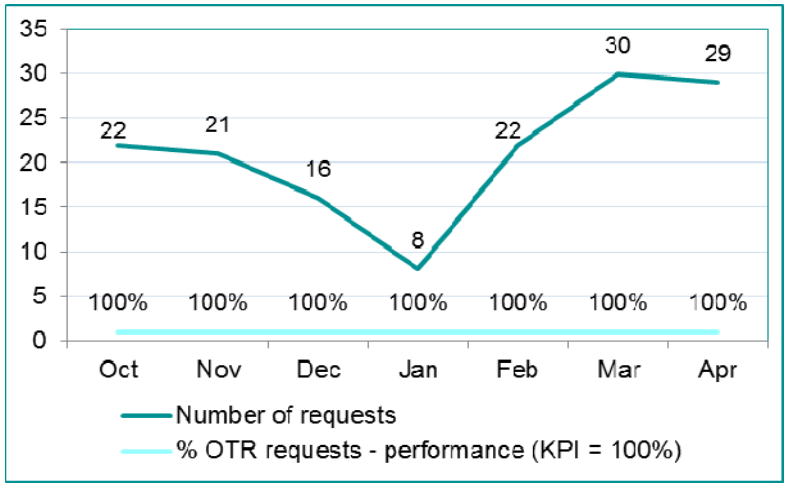


Explanatory text:

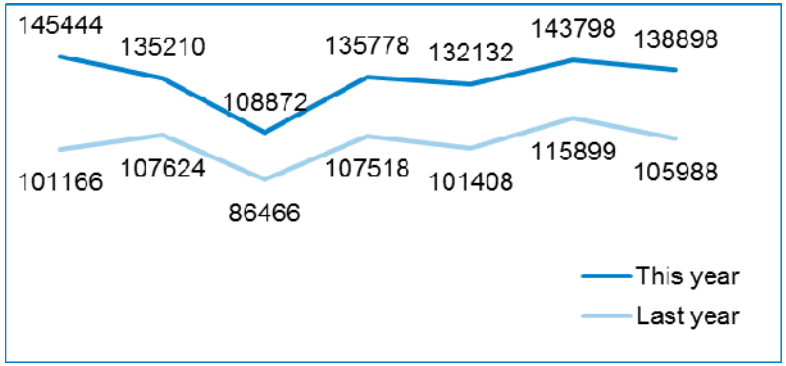
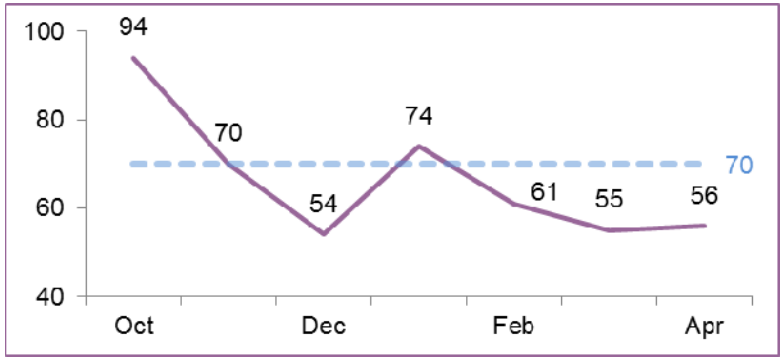
Looking at all IVF treatment forms

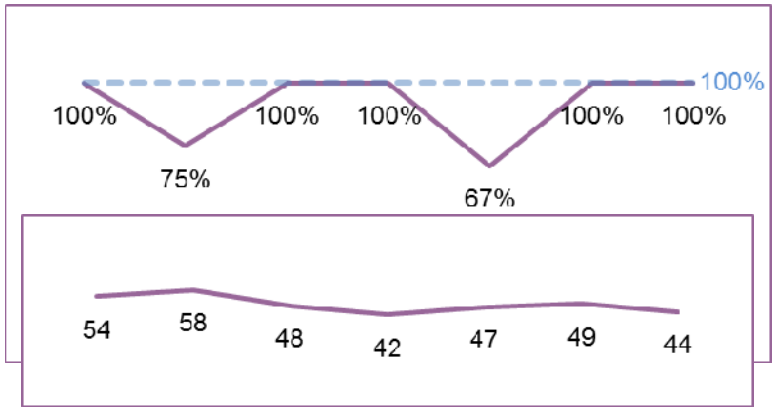
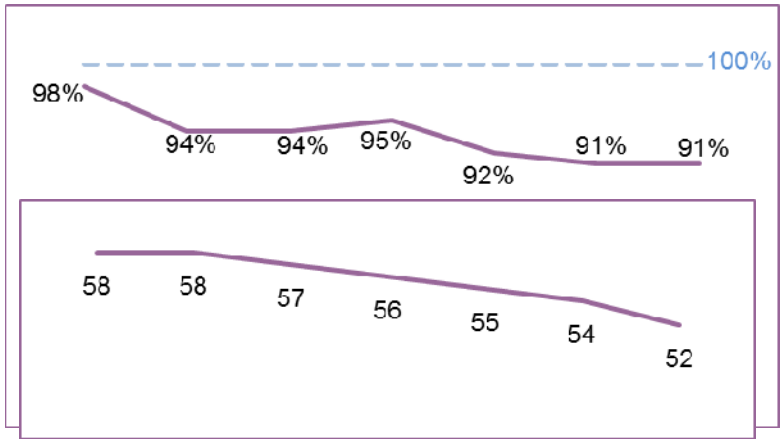
Providing a count of pregnancies - as recorded on the early outcome form. 2015 data is not complete enough to be included, as yet, owing to reporting lag on pregnancies.

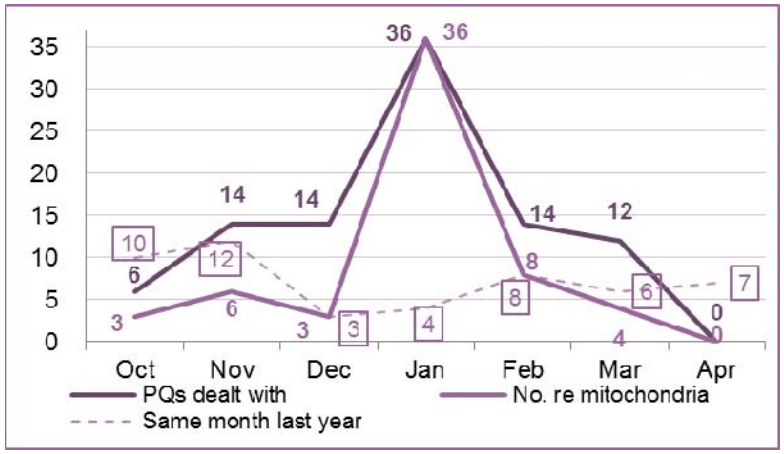
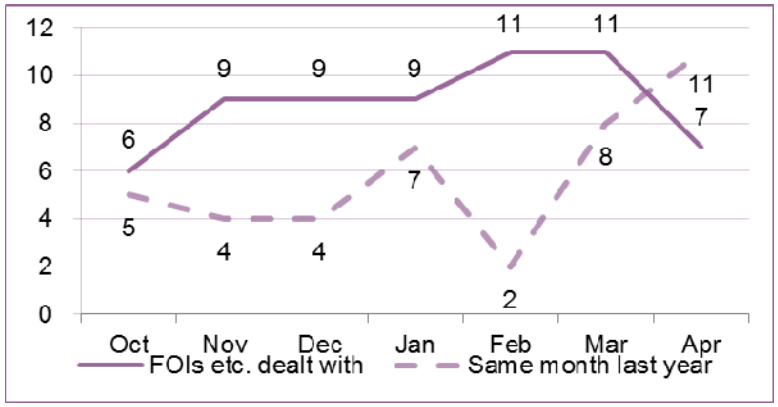
Key performance and volume indicators – April:

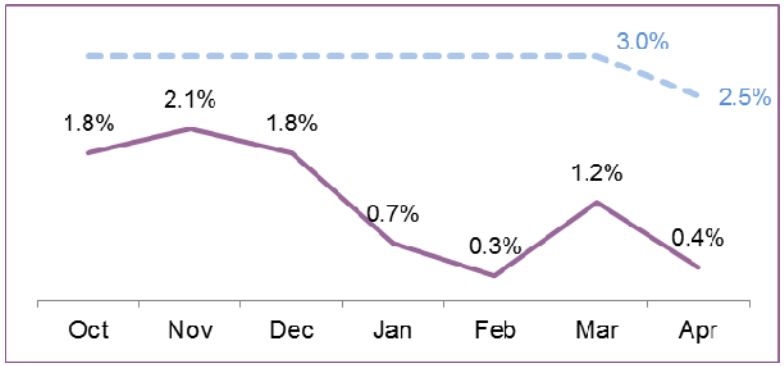
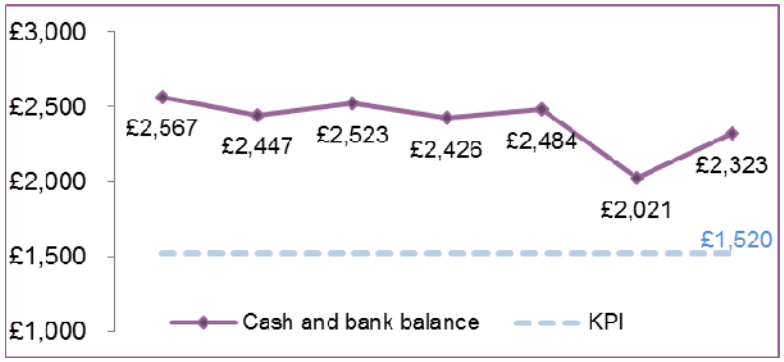
Indicator	Performance	RAG	Recent trend[1]	Aim[2]	Notes
Setting standards: improving the quality and safety of care through our regulatory activities.					
Licensing decisions made: - **By ELP** - **By Licence Committee**	6 0	⇩		No KPI – tracked for workload monitoring purposes	Volume indicator (no KPI target).
Setting standards: improving the lifelong experience for donors, donor-conceived people, patients using donor conception, and their wider families.					
Percentage of Opening the Register requests responded to within 20 working days	100% (29)	★		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 – above.		
Increasing and informing choice: ensuring that patients have access to high quality meaningful information.					
Number of visits to the HFEA website (cw previous year)	138,898 105,988	⇩		No KPI – tracked for general monitoring purposes.	Volume indicator showing general website traffic compared to the same period in previous year. Measured on the basis of 'unique visitors'.
Efficiency, economy and value: ensuring the HFEA remains demonstrably good value for the public, the sector and Government.					
Average number of working days taken for the whole licensing process, from the day of inspection to the decision being communicated to the centre.	55 working days	★		 Maintain at 70wd or less	KPI: Less than or equal to 70 working days.

Indicator	Performance	RAG	Recent trend[1]	Aim[2]	Notes
Monthly percentage of PGD applications processed within three months (66 working days). **Average number of working days taken.**	100% 44	★		Reach and maintain 100% ↑	New KPI: 100% processed (i.e. considered by LC/ELP) within three months (66 working days) of receipt of completed application.
Annualised (rolling year) percentage of PGD applications processed within three months (66 working days) **Average number of working days taken.**	91% 52	⇔		Reach and maintain 100% ↑	KPI: As above. (Annualised score). Performance has reached target, but the annualised figure is still being adversely affected by complex multi-type applications received during the rolling year, which take longer to process.

Indicator	Performance	RAG	Recent trend[1]	Aim[2]	Notes
Number of requests for contributions to Parliamentary questions	April: total = 0 (owing to the General Election)	⇩		No KPI – tracked for general monitoring purposes.	Volume indicator (a KPI focusing on turn-around times is also tracked – not shown in this graph). The number received in January 2015 was nine times that received in January 2014.
Number of Freedom of Information (FOI), Environmental Information Regulations (EIR) requests and Data Protection Act (DPA) requests	7	⇩		No KPI – tracked for general monitoring purposes.	Volume indicator (a KPI focusing on turn-around times is also tracked – not shown in this graph).

Indicator	Performance	RAG	Recent trend[1]	Aim[2]	Notes
Staff sickness absence rate (%) per month.	0.4%	★		Maintain 2.5% or less	KPI: Absence rate of ≤ 2.5%. Public sector sickness absence rate average is eight days lost per person per year (3.0%).
Cash and bank balance	£2,323k	⇧		Reduce	KPI: To move closer to minimum £1,520k cash reserves (figure agreed with DH).

Indicator	Performance	RAG	Recent trend[1]	Aim[2]	Notes
Management accounts:					

Income & Expenditure Account — Apr-2015

Accounting Period
Cost Centre Name
Department Name

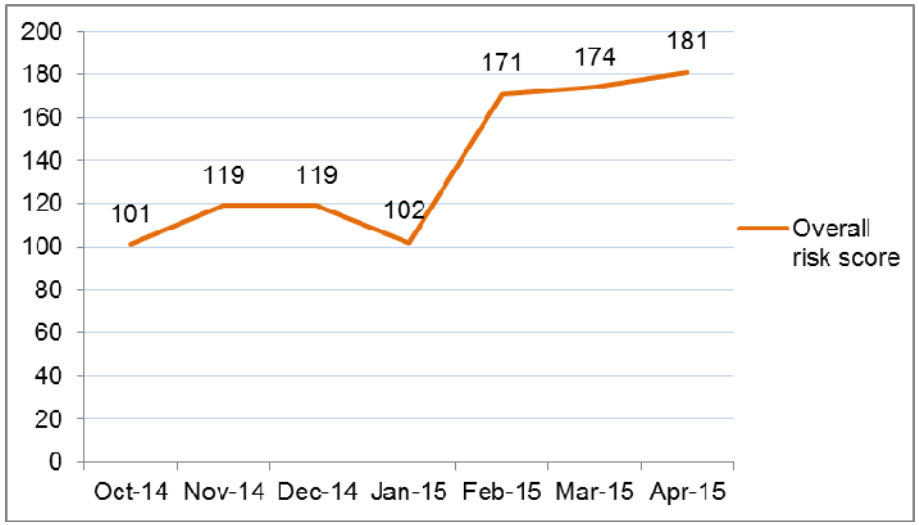
	Year to Date			Full Year		
	Actual YTD £	Budget YTD £	Variance YTD £	Forecast £	Budget £	Variance £
Income						
Grant-in-aid	-	-	-	1,120	1,120	-
Licence Fees	384	393	-10	4,110	4,120	-10
Other Income	50	1	50	56	6	50
Total Income	434	394	40	5,286	5,246	40
Revenue costs - Charged to Expenditure						
Salaries (excluding Authority)	208	224	16	2,744	2,744	-
Shared Services	8	8	-	91	91	-
Employer's NI Contributions	17	20	3	247	247	-
Employer's Pension Contribution	45	47	2	579	579	-
Authority salaries inc. NI Contributions	12	12	-0	146	146	-
Temporary Staff costs	-	-	-	-	-	-
Other Staff costs	23	15	-8	265	258	7
Authority/Committee costs	7	11	4	162	166	-4
Other Compliance costs	7	3	-4	43	39	3
Other Strategy costs	4	19	14	161	175	-14
Facilities costs incl non-cash	27	30	3	352	355	-3
IT costs costs	11	9	-2	108	106	2
Legal costs	62	84	22	318	340	-22
Professional Fees	-6	6	12	56	68	-12
Total Revenue costs	424	487	63	5,272	5,314	-43
Total Surplus/(Deficit) before Capital & Project costs	10	-93	-22	14	-69	83
IFQ & Other Project costs - Reserves funded	29	31	2	1,118	1,120	-2
Other Capital costs	-	-	-	-	-	-
TOTAL NET ACTIVITY	-19	-124	-24	-1,104	-1,189	85

Indicator	Performance	RAG	Recent trend[1]	Aim[2]	Notes
Commentary:	April 2015 Income for the month of April was approximately 40% more than budgeted. This was due to interest received from one clinic for delays in paying our treatment invoices. Treatment fees were 3% down on the same period last year. Costs for April were 13% down on budget. April is the beginning of the financial year and no significant issues have been identified.				

IfQ indicators: (NB The majority of IfQ indicators are pending full start-up of the programme)

Frequency / trigger point	Metric	Purpose	Latest status:
At programme set-up / major reorganisation / new tranche	MSP health check overall score achieved / maximum score as a %	Is the programme set up to deliver?	**April:** Annual health check score not yet available.
Monthly	Timescales: burndown chart showing remaining estimate of work.	Is there scope creep/over-run?	**April:** Measure to follow once plans are fully in place to measure against.
Monthly	Cost: earned value (% complete * estimated spend at completion)	Is the spend in line with milestone delivery?	There are four things we can attribute value to: websites and CaFC; Clinic Portal; Register and internal systems; defined dataset, discovery, stakeholder engagement etc. Currently, 25% of the value of the 1.8M programme cost at completion has been attributed to each project. We will re-baseline this measure shortly, when delivery starts. For the present position, as at the end of a defined dataset and discovery: Due to extended approval delays, the programme spend to date has increased without anything further being delivered since the last period. (In July, subject to the successful appointment of suppliers, delivery should be able to commence.) Meanwhile, our current estimate of earned value to date is shown below.

<table>
<tr><td></td><td></td><td></td><td>Earned value
<table>
<tr><th>Project</th><th>Dec-14</th><th>Jan-15</th><th>Feb-15</th><th>Mar-15</th><th>Apr-15</th></tr>
<tr><td>Websites and CaFC</td><td>0</td><td>0.25%</td><td>0.25%</td><td>0.25%</td><td>0.25%</td></tr>
<tr><td>Clinic Portal</td><td>0</td><td>0.25%</td><td>0.25%</td><td>0.25%</td><td>0.25%</td></tr>
<tr><td>Register and internal systems</td><td>0</td><td>0.25%</td><td>0.25%</td><td>0.25%</td><td>0.50%</td></tr>
<tr><td>Discovery</td><td>24%</td><td>24.5%</td><td>24.5%</td><td>25.00%</td><td>25.00%</td></tr>
<tr><td>IfQ Total earned value</td><td>24%</td><td>25.3%</td><td>25.3%</td><td>25.75%</td><td>26.00%</td></tr>
<tr><td>% of spend to date</td><td>35%</td><td>36%</td><td>38%</td><td>41.25%</td><td>68.95%</td></tr>
</table></td></tr>
<tr><td>Monthly</td><td>Quality: category A requirements dropped or postponed during this period</td><td>Are key requirements being lost from the programme which could trigger a change in the business case?</td><td>April:
To be worked up once suppliers are in place.</td></tr>
<tr><td>Monthly</td><td>Stakeholder engagement: combined stakeholder engagement score</td><td>Are we keeping stakeholders with us? Is it getting better or worse?</td><td>April:
Discussion within the Programme is needed as to how to measure this now that the initial stakeholder consultation period to inform the business case has come to an end. A method for capturing this will need to be built into stakeholder plans for each project – might need to report quarterly.</td></tr>
</table>

Monthly	Risks: sum of risk scores (L x I)	Is overall risk getting worse or better (could identify death by a thousand cuts)?	 **April:** Risk score from end of April = 181
Monthly	Software: burndown chart	Shows new items added and estimated delivery of the product backlog (or items marked for delivery)	**April:** To be worked up once the product backlog is in place (during the early period of delivery, following full approval and completion of tendering).
Quarterly	Benefits: value (£) of tangible benefits planned to the delivered by the programme	Is the value of the benefits increasing or decreasing – could trigger a review of the business case?	**April:** No figure available at this stage - to be worked up post-approval and completion of tendering.

Authority paper

Strategic delivery	**Setting standards**	☐	**Increasing and informing choice**	☐	**Demonstrating efficiency, economy and value**	☑
Paper title	**Strategic Risk Register**					
Agenda item	**7**					
Paper number	HFEA (08/07/2015) 759					
Meeting date	11 March 2015					
Author	Paula Robinson, Head of Business Planning					
For information or decision?	Information					
Recommendation	The Authority is asked to note and comment on the latest edition of the strategic risk register.					
Resource implications	In budget					
Implementation	Throughout 2015/16.					
Communication	AGC reviewed the risk register at its meeting on 10 June.					
Organisational risk	Low.					
Annexes	A: Strategic Risk Register					

HUMAN FERTILISATION & EMBRYOLOGY AUTHORITY

1. Strategic Risk Register – CMG review May 2015

1.1. CMG reviewed the new Strategic Risk Register (SRR) on 20 May at its quarterly risk meeting. Five of the twelve risks are currently above tolerance. CMG reviewed all risks, controls and scores. CMG's specific comments are contained in the SRR at Annex A.

1.2. The risk register was also discussed at AGC on 10 June. No changes were proposed. AGC also discussed progress with developing our approach to risk assurance (a new activity), coupled with recent work to refresh the way in which we identify and record operational risks.

2. Recommendations

2.1. The Authority is invited to note the June edition of the strategic risk register.

Annex A

HFEA Strategic Risk Register 2015/16

Risk Summary: High to Low Residual Risks

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

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

Recent review points: CMG February 2015 ⇨ AGC and Authority March 2015 ⇨ CMG 20 May 2015 ⇨ AGC 10 June 2015 (latest review).

[1] Strategic objectives 2014-2017:
Setting standards: improving the quality and safety of care through our regulatory activities. (Setting standards – quality and safety)
Setting standards: improving the lifelong experience for donors, donor-conceived people, patients using donor conception, and their wider families. (Setting standards – donor conception)
Increasing and informing choice: using the data in the register of treatments to improve outcomes and research. (Increasing and informing choice – Register data)
Increasing and informing choice: ensuring that patients have access to high quality meaningful information. (Increasing and informing choice – information)
Efficiency, economy and value: ensuring the HFEA remains demonstrably good value for the public, the sector and Government. (Efficiency, economy and value)

CMG and AGC Overview

20 May CMG Risk meeting:

- CMG updated the controls and the scores throughout.
- CMG noted AGC's discussion in March about the capability risk (C1) and its interaction with capacity (in the context of turnover and induction/probation periods for new staff members). CMG agreed that although the current period of high turnover seems to be coming to an end, this risk could recur, and should therefore be retained. AGC had specifically requested that the tolerance level for this risk (set low, at 6) should be reviewed by CMG. The reduction in overall staffing numbers over the past few years has left us with little resilience, particularly in specialist and small functions, and so turnover could affect capability more in some instances, with possible impacts on strategic delivery. Therefore, CMG agreed that our tolerance for the capability risk needs to remain low, even though the risk level is now reducing.

10 June AGC meeting:

- AGC noted that some risks are controlled by good records management practices including occasional TRIM refresher (or induction) training. The Senior Management Team (SMT) has begun to discuss how best to maintain good records management practices and learning in the organisation.
- Members of AGC were supportive of our intention to ensure that records management remains of good quality, especially in light of the fact that we expect clinics to perform well on records management, and inspect them on that basis. They also accepted that good practice is already largely in place, and that it is not straightforward to assign such duties in an organisation with few staff. SMT will give this further thought in the near future.
- AGC also heard (under other substantive items) about current risks/controls with respect to the new people strategy and current IfQ developments. It was acknowledged that the IfQ risks would need a thorough update once sprint zero was under way (July). It was also agreed that the risks relating to IfQ needed to include reference to maximising the benefits at the end of the programme of work, ie, culturally embracing and embedding the changes and new ways of working. Another risk factor was identified relating to the probable office move in or around April 2016, in that this could potentially coincide with a critical delivery period. There is general awareness of this issue across IfQ, and work-arounds will be decided well ahead of time, as soon as a firm date is announced for the HFEA's move.

Criteria for Inclusion of Risks:

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

Rank:

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

Risk Trend:

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

Risk Scoring System:

See last page.

Assessing Inherent Risk:

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

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

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

Causes/sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Inspection/reporting failure.	Inspections are scheduled for the whole year, using licence information held on Epicentre, and items are also scheduled to committees well in advance.	In place – Debra Bloor	Below tolerance for the time being, following recent recruitment and new staffing model.
	Audit of Epicentre to reveal any data errors.	Due for completion June 2015 – Sam Hartley	
	Inspector training, competency-based recruitment, induction process, SOPs, QMS, and quality assurance all robust.	In place – Debra Bloor	
Monitoring failure.	Outstanding recommendations from inspection reports are tracked and followed up by the team.	In place – Debra Bloor	
Unresponsiveness to or mishandling of non-compliances or grade A incidents.	Update planned to compliance and enforcement policy. Authority workshop took place in March 2015. More work to follow, including input from Committee Chairs and revised policy to September Authority alongside a set of other related Compliance team updates.	Partly complete – revision will go to September 2015 Authority – Debra Bloor	
	Staffing model changed to increase resilience in inspection team for such events – dealing with high-impact cases, additional incident inspections, etc..	In place – Debra Bloor – May 2015	

Insufficient inspectors or licensing staff	Inspection team up to complement following several recruitments.	In place – Debra Bloor	
	Licensing team up to complement following recruitment.	In place – Sam Hartley	
Recruitment difficulties and/or high turnover/churn in various areas; resource gaps and resource diversion into recruitment and induction, with impacts felt across all teams.	So far recruitment rounds for inspectors and support staff have yielded sufficient candidates, although this has required going beyond the initial ALB pool to external recruitment in some cases.	Managed as the situation evolves – Debra Bloor	
	NHS Jobs account changed in May 2015 so that vacancies now appear under an HFEA identity rather than a CQC identity (with CQC continuing to administer), so as to address the cause of misunderstandings by many job candidates.	In place – Rachel Hopkins	
	Additional temporary resources available during periods of vacancy and transition.	In place – Rachel Hopkins	
	Group induction sessions put in place where possible.	In place – Debra Bloor	
Resource strain itself can lead to increased turnover, exacerbating the resource strain.	Operational performance, risk and resourcing oversight through CMG, with deprioritisation or rescheduling of work an option.	In place – Paula Robinson	
Unexpected fluctuations in workload (arising from eg, very high level of PGD applications received, including complex applications involving multiple types of a condition; high levels of non-compliances either generally or in relation to a particular issue).	Staffing model developed (May 2015), to release an extra inspector post out of the previous establishment. This increased general resilience so as to enable more flex when there is an especially high inspection/report writing/application processing workload (as there is, in 2015).	In place – Debra Bloor	
	PGD workshop annually with the sector to increase their insight into our PGD application handling processes and decision-making steps; coupled with our increased processing times from efficiency improvements made in 2013 (acknowledged by the sector).	In place and annual – Debra Bloor	
Some unanticipated event occurs that has a big diversionary impact on key resources, eg, several major Grade A incidents occur at once.	Addressed by revised staffing model.	In place – Debra Bloor	
	Compliance and enforcement policy review (see above) will improve handling processes for incidents and non-compliance.	Partly complete – revision will go to September 2015 Authority – Debra Bloor	

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

Causes/sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Failures or weaknesses in decision making processes.	Keeping up to date the standard operating procedures (SOPs) for licensing, representations and appeals.	In place – Sam Hartley	At tolerance.
	Learning from recent representations experience incorporated into processes.	In place – Sam Hartley	
	Appeals Committee membership maintained – vacancy filled.	In place – Sam Hartley	
	Staffing structure for sufficient committee support.	In place – Sam Hartley	
	Decision trees; legal advisers familiar.	In place – Sam Hartley	
	Proactive management of quoracy for meetings.	In place – Sam Hartley	
	New T&S licences delegated to ELP and now in place. Licensing Officer due to become live.	Delegation to be returned to, in 2016 review of SOs. Licensing Officer role to take decisions from ELP – implementation due end June 2015.	
Failing to demonstrate competence as a regulator	Review of compliance and enforcement policy (in progress).	Partly complete – revision will go to September 2015 Authority – Debra Bloor	
	Inspector training, competency-based recruitment, induction process, SOPs, quality management system (QMS) and quality assurance all robust.	In place – Debra Bloor	

Effect of publicised grade A incidents.	Staffing model changed (May 2015) to build resilience in inspection team for such events – dealing with high-impact cases, additional incident inspections, etc.	In place – Debra Bloor	
	SOPs and protocols with Communications team.	In place – Debra Bloor	
	Fairness and transparency in licensing committee information.	In place – Debra Bloor	
	Dedicated section on website, so that the public can openly see our activities in the broader context.	In place – Debra Bloor	
Administrative or information security failure, eg, document management, risk and incident management, data security.	Staff have annual information security training (and on induction).	In place – Dave Moysen (next round is due in Q1 of 2015/16)	
	TRIM training and guidance/induction in records management in place.	Internal ownership of this function will be decided by SMT in the near future – end July 2015	
	The IfQ website management project will be reviewing the retention schedule.	By December 2015 – Juliet Tizzard	
	Guidance/induction in handling FOI requests, available to all staff.	In place – Sam Hartley	
	Further work to be planned on records management in parallel with IT strategy	Linked to IT strategy work – in progress – Dave Moysen/Sam Hartley	
Negative media or criticism from the sector in connection with legally disputed issues or major adverse events at clinics.	HFEA approach is only to go into cases on the basis of clarifying legal principles or upholding the standards of care by challenging poor practice. This is more likely to be perceived as proportionate, rational and necessary (and impersonal), and is in keeping with our strategic vision.	In place - Peter Thompson	
HFEA process failings that create or contribute to legal challenges, or which weaken cases that are otherwise sound.	Licensing SOPs, committee decision trees in place. Mitochondria tools in development.	Existing tools in place; mitochondria tools due by October 2015 – Sam Hartley	
	Review of compliance and enforcement policy (in progress).	Partly complete – revision will go to September 2015 Authority – Debra Bloor	
	QMS and quality assurance in place in inspection team.	In place – Debra Bloor	

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

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

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

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

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

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

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

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

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

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

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

Causes/sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Complex and controversial area.	Panel of legal advisors from various firms at our disposal for advice, as well as in-house Head of Legal.	In place – Peter Thompson	Above tolerance. One case is awaiting judgment as at the end of June 2015. We hope that this can be resolved shortly.
	Evidence-based policy decision-making and horizon scanning for new techniques.	In place – Hannah Verdin	
	Robust and transparent processes in place for seeking expert opinion – eg, external expert advisers, transparent process for gathering evidence, meetings minuted, papers available online.	In place – Hannah Verdin/Sam Hartley	
Lack of clarity in HFE Act and regulations, leading to the possibility of there being differing legal opinions from different legal advisers, that then have to be decided by a court.	Panel in place, as above, to get the best possible advice.	In place – Peter Thompson	
Decisions and actions of the HFEA and its committees may be contested.	Panel in place, as above.	In place – Peter Thompson	
	Maintaining, keeping up to date and publishing licensing SOPs, committee decision trees etc. Standard licensing pack completely refreshed and distributed to members/advisers April 2015.	In place – Sam Hartley	

	More work planned on enhancing committee tools to incorporate recent lessons learned.	In progress as at May 2015 – Catherine Drennan / Sam Hartley	
Subjectivity of judgments means the HFEA often cannot know in advance which way a ruling will go, and the extent to which costs and other resource demands may result from a case.	Scenario planning is undertaken at the initiation of likely action.	In place – Peter Thompson	
HFEA could face unexpected high legal costs or damages which it could not fund.	Discussion with the Department of Health would need to take place regarding possible cover for any extraordinary costs, since it is not possible for the HFEA to insure itself against such an eventuality, and not reasonable for the HFEA's small budget to include a large legal contingency.	In place – Peter Thompson	
Legal proceedings can be lengthy and resource draining.	Panel in place, as above, enabling us to outsource some elements of the work.	In place – Peter Thompson	
	Internal mechanisms (such as the Corporate Management Group, CMG) in place to reprioritise work should this become necessary.	In place – Peter Thompson	
Adverse judgments requiring us to alter or intensify our processes, sometimes more than once.	Licensing SOPs, committee decision trees in place.	In place – Sam Hartley.	
	Work planned to explore other relevant processes in light of lessons learned following a recent judicial review judgment.	In progress as at May 2015 – Catherine Drennan / Sam Hartley	

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

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

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

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

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

Answers in Hansard may not always reflect advice from HFEA.	The PQ team attempts to catch any changes to drafted wording that may unwittingly have changed the meaning. This, and ongoing issues with the very high volume being received at present, will be raised with DH when the framework agreement is next reviewed. HFEA's suggested answer and DH's final submission both to be captured in new PQ log.	In place – Sam Hartley / Peter Thompson Date of next review to be confirmed shortly – Peter Thompson	
Insufficient understanding of underlying system abilities and limitations, and/or of the topic or question, leading to data being misinterpreted or wrong data being elicited.	As above – expert staff with the appropriate knowledge and understanding in place.	In place – Juliet Tizzard / Nick Jones	

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

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

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

Causes/ sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Lack of counselling availability for applicants.	Counselling service pilot being established with external contractor.	Set-up in progress – Nick Jones – Jun 2015	At tolerance. The pilot counselling service will be in place from June onwards, and we will make a further assessment shortly based on early uptake and the delivery experience.
Insufficient Register team resource to deal properly with OTR enquiries and associated conversations.	Additional member of staff dedicated to handling such enquiries.	In place – Nick Jones	
Risk of inadequate handling of a request.	Trained staff, SOPs and quality assurance in place.	In place – Nick Jones	
	SOPs being reviewed by Register staff, CMG and PAC-UK, as part of the pilot set-up. Contract signed with PAC-UK for pilot delivery.	Done (May 2015) – In June the management of the Pilot will transfer to Rosetta Wotton.	

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

Causes/ sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Fee regime makes us dependent on sector activity levels.	Activity levels are tracked and change is discussed at CMG, who would consider what work to deprioritise and reduce expenditure.	Monthly (on-going) – Sue Gallone	Above tolerance, but 2014/15 overspend was able to be met from reserves.
	Fees Group created enabling dialogue with sector about fee levels.	In place. First meeting 29-10-14; and Apr and Oct each year, ongoing – Sue Gallone	
GIA funding could be reduced due to changes in Government/policy	A good relationship with DH Sponsors, who are well informed about our work and our funding model.	Quarterly meetings (on-going) – Sue Gallone	
	Annual budget agreed with DH Finance team alongside draft business plan submission.	December annually – Sue Gallone	
	Budget confirmation for 2015/16 obtained. Capital allocation is outstanding as at 27 May 2015.	In place – Sue Gallone Being actively sought from DH – Sue Gallone	
Budget setting process is poor due to lack of information from directorates	Quarterly meetings with directorates flags any short-fall or further funding requirements.	Quarterly meetings (on-going) – Morounke Akingbola	
Unforeseen increase in costs eg, legal, IfQ or extra in-year work required	Use of reserves, up to contingency level available. DH kept abreast of current situation and are a final source of additional funding if required. IfQ Programme Board regularly reviews the budget and costs.	Monthly – Sue Gallone Monthly – IfQ Programme Board	

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

<table>
<tr><th>Risk area</th><th>Description and impact</th><th>Strategic objective linkage</th><th>Risk scores</th><th>Recent trend</th><th>Risk owner</th></tr>
<tr><td rowspan="2">Capability

C 1: Knowledge and capability</td><td rowspan="2">There is a risk that the HFEA experiences unforeseen knowledge and capability gaps, threatening delivery of the strategy.</td><td rowspan="2">Efficiency, economy and value: ensuring the HFEA remains demonstrably good value for the public, the sector and Government.</td><td>Inherent risk level:
Likelihood: 4 | Impact: 4 | Inherent risk: 16 High
Residual risk level:
Likelihood: 3 | Impact: 3 | Residual risk: 9 Medium
Tolerance threshold: 6 Medium</td><td>⇔ ⇔ ⇩ ⇔</td><td>Peter Thompson</td></tr>
<tr><td colspan="2"></td></tr>
<tr><th>Causes/ sources</th><th colspan="2">Mitigations</th><th>Timescale and ownership of mitigations</th><th colspan="2">Effectiveness – commentary</th></tr>
<tr><td rowspan="3">High turnover, sick leave etc. leading to temporary knowledge loss and capability gaps.</td><td colspan="2">People strategy will partially mitigate. Mixed approach of retention, staff development, and effective management of vacancies and recruitment processes.</td><td>Done – May 2015 – Rachel Hopkins</td><td colspan="2" rowspan="3">Above tolerance.

This risk and the set of controls currently focuses on capability, rather than capacity. There are obviously some linkages, since managing turnover and churn also means managing fluctuations in capability and ensuring knowledge and skills are successfully nurtured and/or handed over.

Now that the period of highest turnover appears to be ending, CMG has reduced (slightly) the likelihood of this risk, but still decided to retain it, given that high turnover could recur.

CMG also reviewed the tolerance level for this risk, and agreed it should remain at 6. Since the HFEA has become a much smaller organisation over the past few years, leaving less</td></tr>
<tr><td colspan="2">A programme of development work is planned to ensure staff have the skills needed, so as to ensure they and the organisation are equipped under any future model, maximising our resilience and flexibility as much as possible. Staff can access civil service learning (CSL); organisational standard is five working days per year of learning and development for each member of staff.</td><td>In place – Rachel Hopkins</td></tr>
<tr><td colspan="2">Organisational knowledge captured via records management (TRIM), case manager software, project records, handovers and induction notes, and manager engagement.</td><td>In place – Rachel Hopkins</td></tr>
</table>

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

	There is a degree of flexibility within our resources, and increasing resilience is a key consideration whenever a post becomes vacant. Staff are encouraged to identify personal development opportunities with their manager, through the PDP process, making good use of Civil Service Learning.	In place – Peter Thompson	
Regarding the current work on licensing mitochondrial replacement techniques, there is a possible future risk, beyond October 2015, that we will need to increase both capability and capacity in this area, depending on uptake (this is not yet certain).	Future needs (capability and capacity) relating to mitochondrial replacement techniques and licensing applications are starting to be considered now, but will not be known for sure until later. No controls can yet be put in place, but the potential issue is on our radar.	New issue for consideration – Juliet Tizzard	

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

LIKELIHOOD: 1=Very unlikely 2=Unlikely 3=Possible 4=Likely 5=Almost certain

IMPACT: 1=Insignificant 2=Minor 3=Moderate 4=Major 5=Catastrophic

RISK MANAGEMENT SCORING MATRIX

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

Risk Score = Impact x Likelihood

Authority paper

Strategic delivery	**Setting standards**	☑	**Increasing and informing choice**	☑	**Demonstrating efficiency, economy and value**	☑
Paper title	Opening the Register Update					
Agenda item	**9**					
Paper number	HFEA (08/07/2015) 760					
Meeting date	8 July 2015					
Author	Rosetta Wotton, Donor Information Manager					
For information or decision?	Information					
Recommendation	Note developments to the Opening the Register service					
Resource implications	In budget					
Implementation	OTR service ongoing					
Communication	OTR service on website					
Organisational risk	Low					
Annexes	Annex A – Opening the Register Questionnaire Responses					

1. Introduction

1.1. This paper brings the Authority up to date on developments in the Opening the Register (OTR) service over the last three years, particularly in the areas of policy, number of applications and feedback received on the service.

2. Background

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

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

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

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

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

2.4. Applications by donor-conceived individuals, donors and parents for Register information are known as Opening the Register (OTR). Applicants submit the relevant application form with proof of identity and address by post to us. We

return their identity documents within 5 working days and respond to their application within 20 working days – both by special delivery post. We retain a copy of their identity documents for 5 years to enable applicants who wish to re-apply for updated information at a later date to do so with more ease.

2.5. The OTR service is provided primarily by the Donor Information Manager and a recently recruited Donor Information Officer, with some additional support provided by two other members of the Register Team. All OTR staff have completed a 30-hour Introduction to Counselling Skills course. The Donor Information Manager has worked in the OTR team for 4 years and, in addition to counselling skills training, she has completed an accredited mediation course and Samaritans training on handling challenging contacts. She has also attended BICA study days and numerous Donor Conception Network conferences.

3. HFEA strategy 2014-2017

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

Vision: High quality care for everyone affected by assisted reproduction

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

What we will do:

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

How we will work:

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

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

4. Policy developments

4.1. Since the last substantive update to the Authority on the OTR service several significant policy and process developments have taken place:

Operational issues

4.2. In June 2012 the Authority provided a steer on key operational issues. Further to Committee deliberations and legal advice, the Authority determined we could

- provide applicants with donor information in the donors own handwriting
- translate foreign language in donor information
- disclose messages containing concerning content
- disclose details of the donor's family history.

Redaction framework

4.3. We also developed a redaction framework to support OTR staff in making more confident decisions on what donor information to redact to protect donor anonymity whilst also retaining as much information as possible to the applicant.

Information on donor re-registration for past applicants

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

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

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

Improving the sharing, quality and disclosure of donor information

4.7. Following a workshop held at the HFEA Annual conference in 2014, we developed a guidance pack for clinics to support their disclosure of non-identifying donor information, including goodwill messages and pen portraits, with patients.

4.8. This pack was available to clinics in March this year along with the redaction framework and a good practice case study.

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

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

Support and intermediary service

4.11. Support for Register applicants was identified as a high priority by a group of key stakeholders in June 2013. This followed the Nuffield Council on Bioethics report 'Donor conception: ethical aspects of information sharing' published in April 2013, which made recommendations relating to donor information and support for applicants to the Register, and the McCracken review of the HFEA in 2013 which also recognised the importance of this work.

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

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

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

- adult donor-conceived people who have or are considering applying for identifying information about their donor; or are considering joining Donor Sibling Link and making contact with their donor-conceived sibling(s)

- donor-conceived people over the age of 16 who have or are considering applying for non-identifying information about their donor
- donors considering re-registering to be an identifiable donor
- donors who are aware that an adult person conceived from their donation has applied for their identifying information.

5. Performance

5.1. We have seen a steady rise year-on-year in the number of OTR applications handled, with a 20% increase in 2014 compared to the previous year (see table below).

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

5.2. In addition, and since launching in 2010, 79 donor-conceived individuals have joined Donor Sibling Link (DSL). This is our voluntary contact register, whereby registrants agree to us sharing their name and contact details with any of their donor-conceived genetic siblings who have also joined. Numbers registering are still small - 11 per year in 2011 and 2012 but increasing to 21 per year in 2013 and 2014 – but will likely grow significantly in the coming years.

5.3. We have also received 149 applications from anonymous donors (those who donated after the HFEA was set up but before 1 April 2005) to remove their anonymity. Over the last 3 years there have been slight increases year-on-year in such applications; however numbers are disappointingly low with only 12 doing so in 2014.

5.4. In 2013 a first application for identifying information from an adult donor-conceived individual with an identifiable donor was received. In total six applications of this nature have been received; two each year so far, and earlier this year we made the first DSL match.

5.5. In each case we offered and coordinated (where desired) support and intermediary assistance to the donor-conceived individuals and donors concerned.

Future policy

5.6. The Opening the Register domain is an ever changing and fluid area with

complex issues coming to light on a regular basis. New issues for consideration include: disclosing identifying information for safeguarding purposes; and our responsibilities where a donor or donor-conceived genetic sibling has died or is mentally incapacitated.

5.7. We also want to ensure the smooth running of the new support service together with evaluating quantitative and qualitative feedback from PAC-UK and the users of the service.

6. Questionnaire feedback

6.1. As part of the OTR service, applicants are provided with a link to an online confidential feedback questionnaire. Annex A sets out the responses received over the last 3 years - a summary is shown here.

- The majority of respondents discovered they could apply for information from the HFEA through our website, with others finding out through sources such as their clinic.
- Only a quarter of respondents said they had spoken to someone at the HFEA prior to applying, however 100% of these rated this experience as helpful or very helpful.
- A third of respondents stated they had discussed their decision to apply with someone external to the HFEA in advance and the majority had not considered using a formal counsellor first.
- Where the ease of finding the information on our website and the clarity of it were concerned, 89% and 93% of respondents respectively rated these as very good or excellent. Similarly 91% rated the clarity of the instructions on the application form just as highly.
- Our speed of response to applications was also rated well by respondents, with 89% considering it very good or excellent, and 82% also rated the format of the response letter just as highly.
- Expectations among respondents varied in terms of the amount of information they received from us; 58% considered it adequate, 26% didn't have any expectations, 16% expected to receive more and only 2% expected to receive less information.

6.2. Respondents were also invited to add any further comments they had on the letter or the process and the majority stated that they found the process straightforward, efficient and speedy, and are grateful for both the existence of the OTR service and the high level of service received.

7. Recommendation

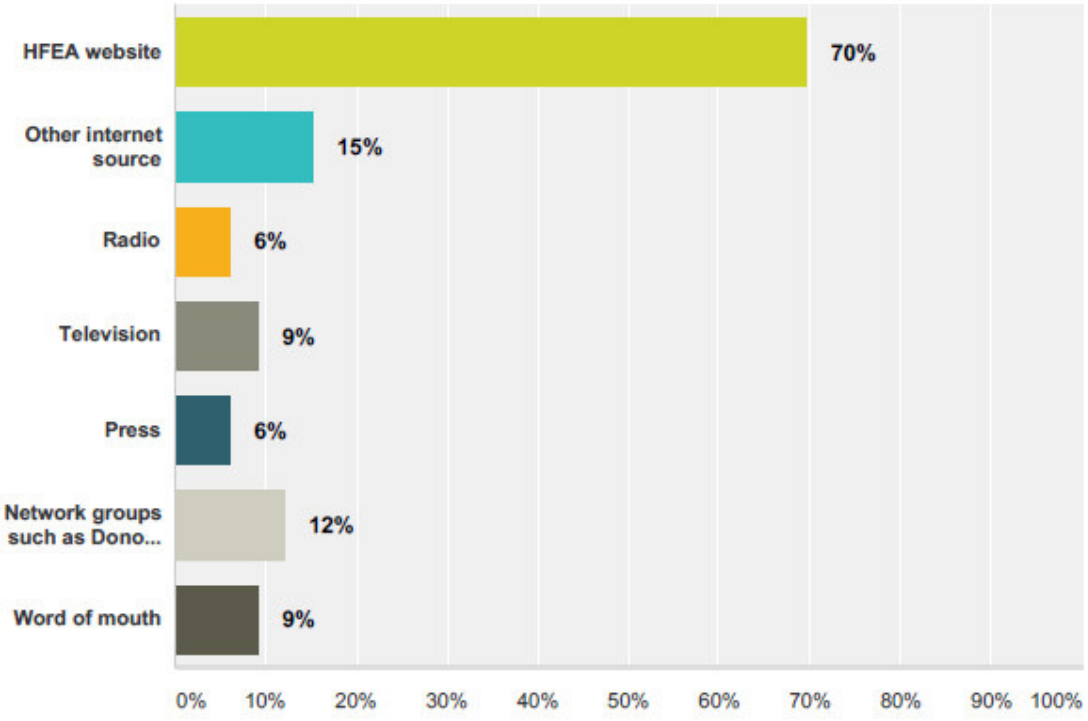
7.1. The Authority is asked to:

- Note the significant policy and process developments over the last 3 years to Opening the Register, which are in line with delivering the HFEA 2014-2017 strategy.
- Note the trend showing increases in the number of applications, timely and sensitive way in which they are handled.
- Note the positive feedback we have received about the Opening the Register service provided by the HFEA.

Opening the Register Questionnaire

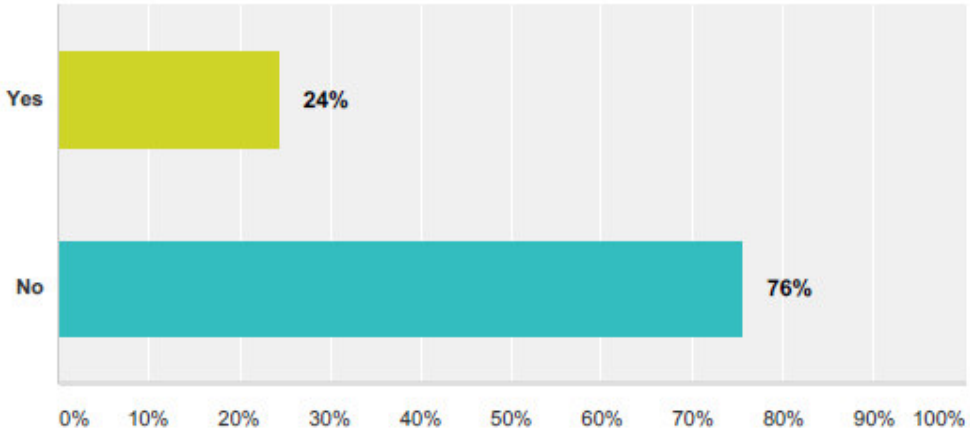
Q1 Where did you hear that you could apply for information from the HFEA register?

Answered: 33 Skipped: 13



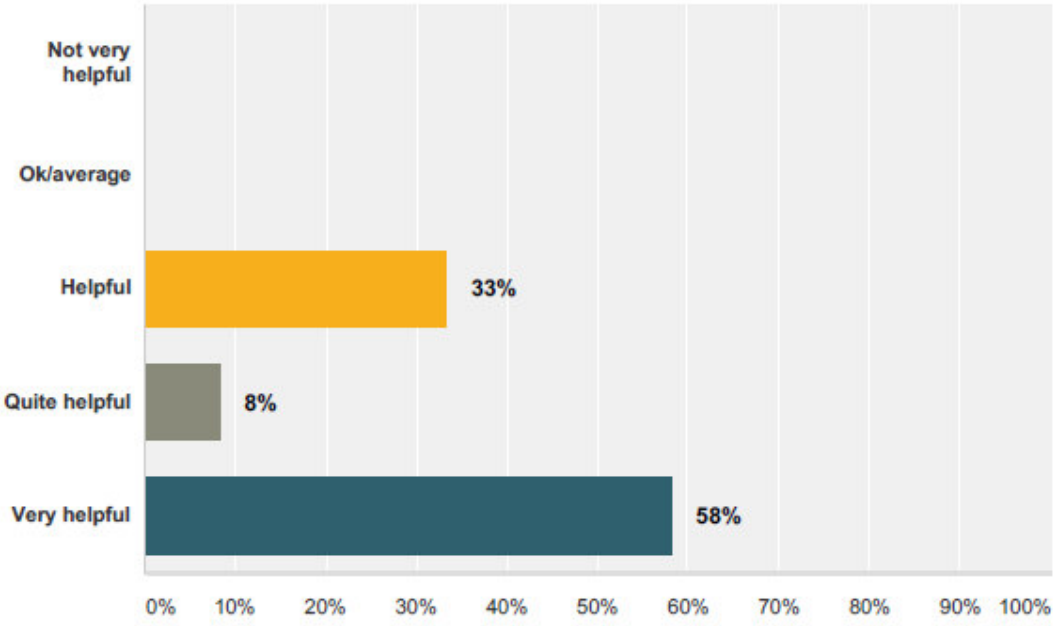
Q2 Did you speak to someone at the HFEA prior to applying for information from the HFEA register?

Answered: 45 Skipped: 1



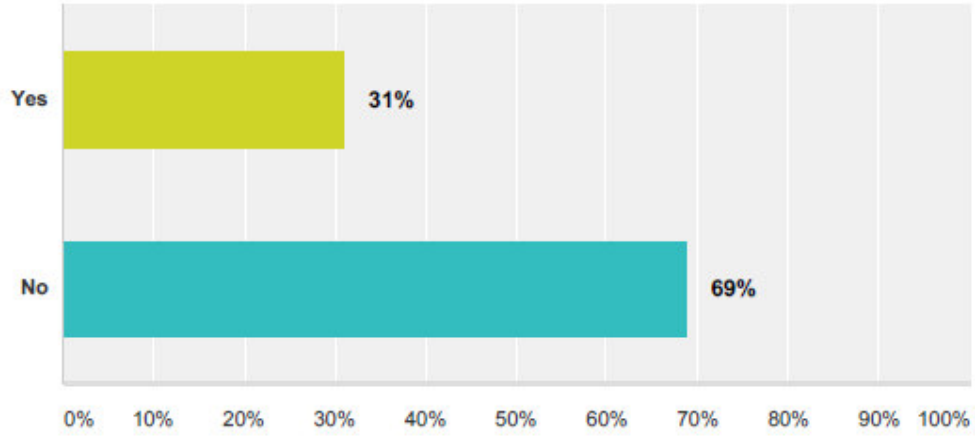
Q3 If you answered yes to the previous question, how would you rate the response ?

Answered: 12 Skipped: 34



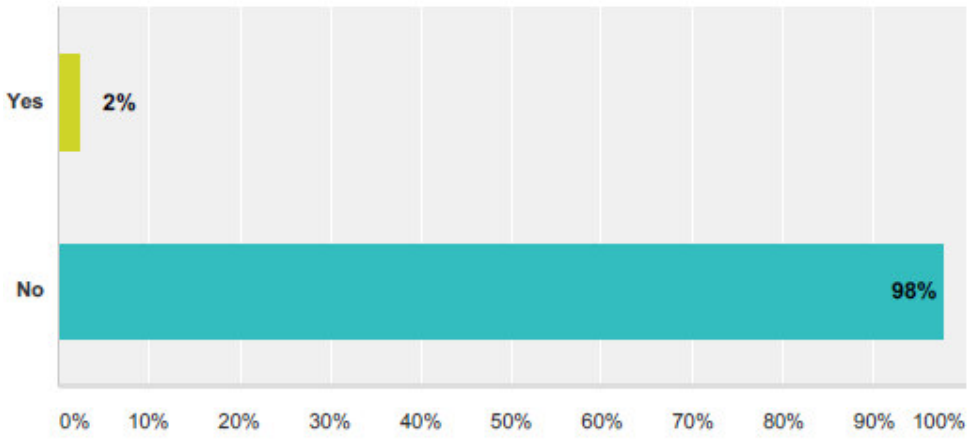
Q4 Did you discuss your decision to apply with someone external to the HFEA in advance ?

Answered: 45 Skipped: 1



Q5 Did you consider using a formal counsellor before applying for information from the HFEA register ?

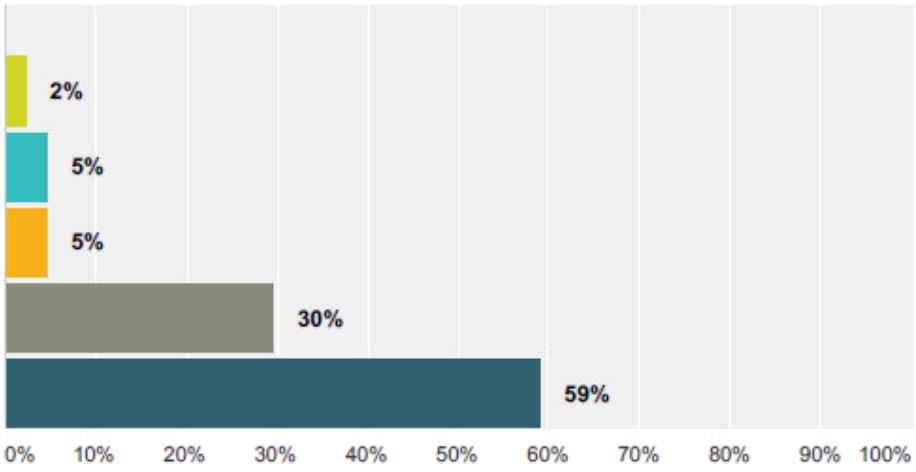
Answered: 45 Skipped: 1



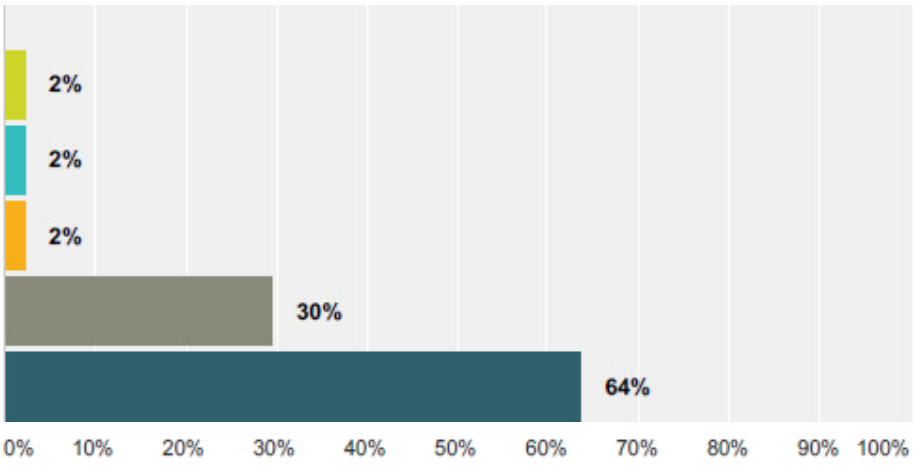
Q6 Thinking about the process to apply. How would you rate the following (1 being poor, 5 being excellent):

Answered: 44 Skipped: 2

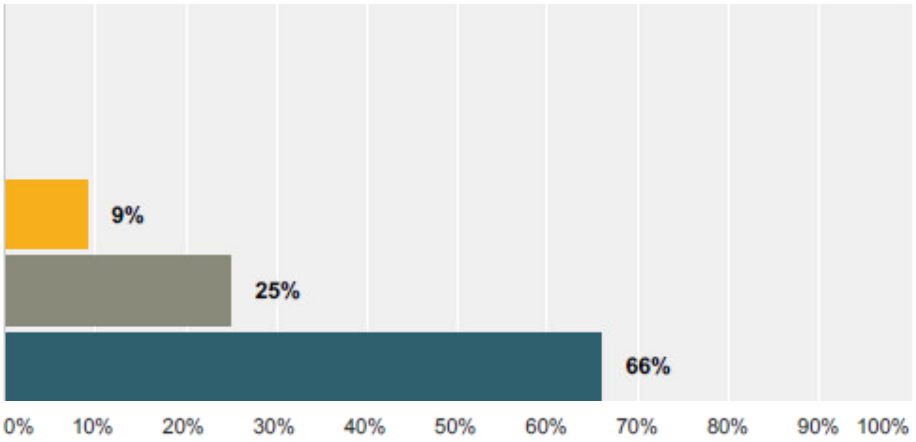
How easy was it to find the information you were looking for? (1-5 on ease)



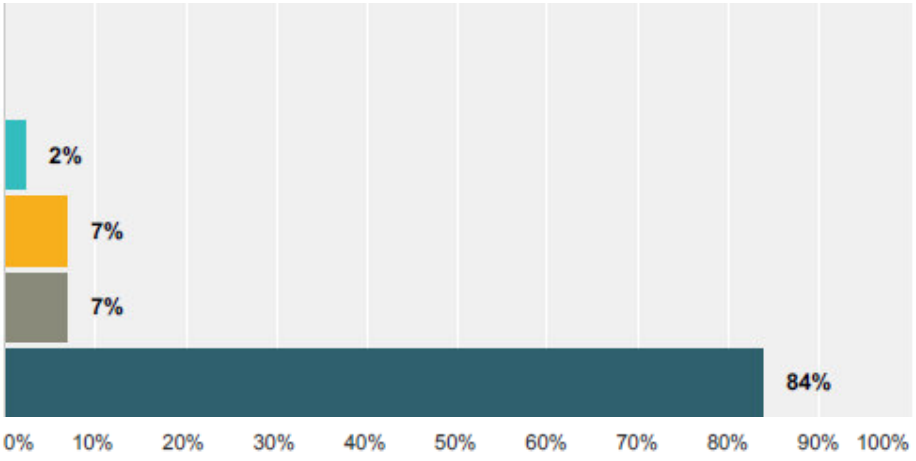
How clear was the information on the site? (1-5 on clarity)



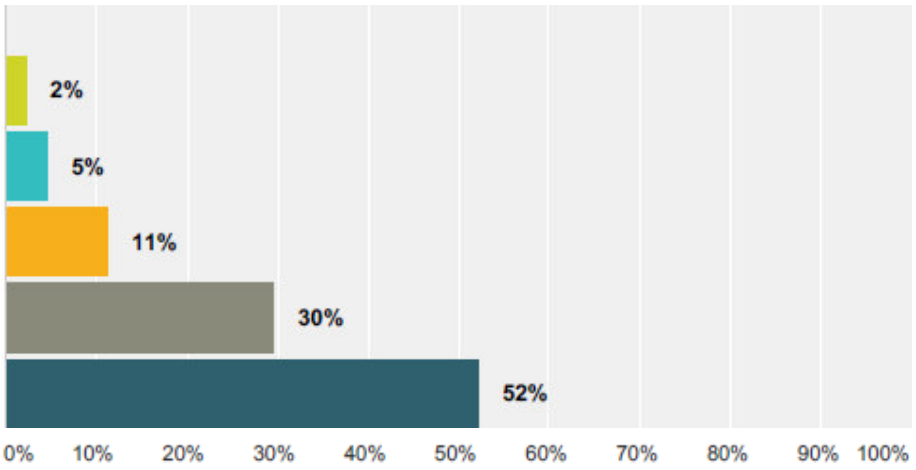
How clear were the instructions on the application form? (1-5 on clarity)



How would you rate the speed of the response? (1-5 as expected, better etc.)

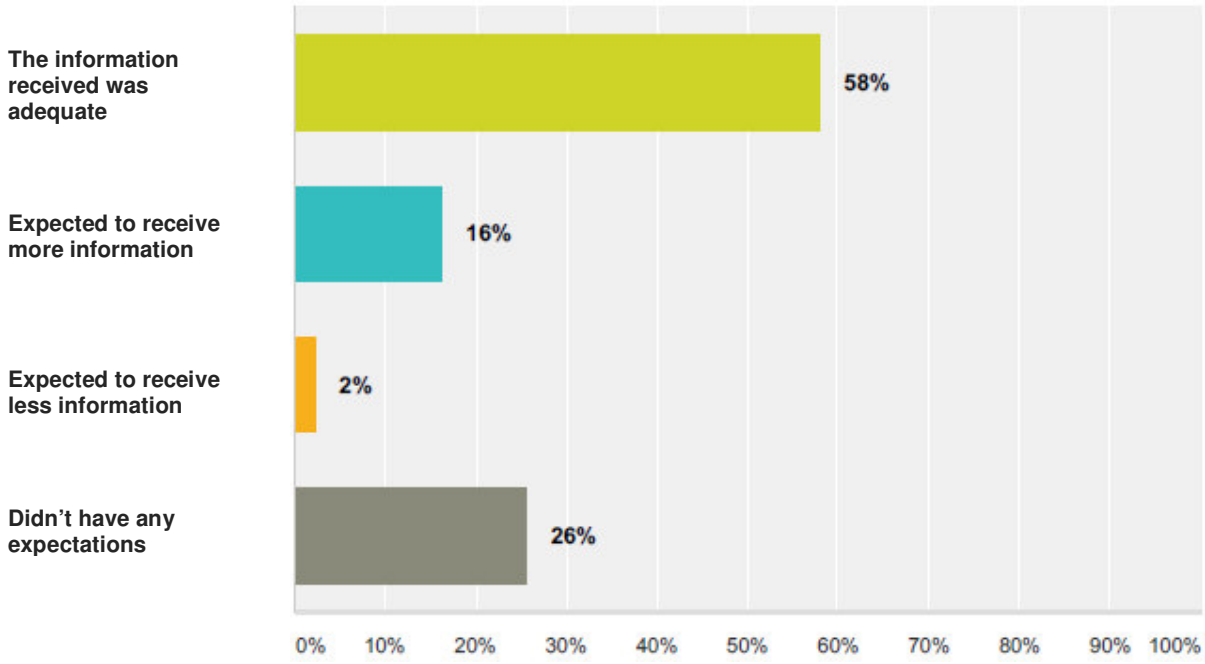


How would you rate the format of the letter you received ? (1-5)



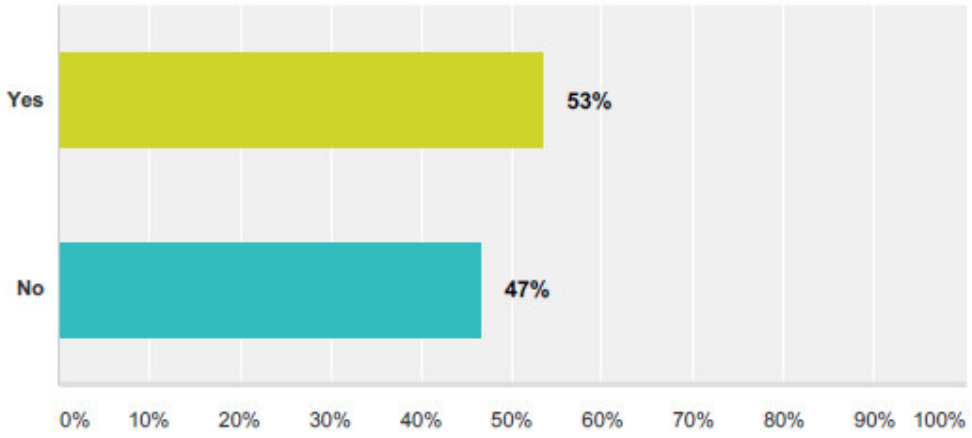
Q7 What were your expectations regarding the level of information you received from the HFEA?

Answered: 43 Skipped: 3



Q8 Are you aware of the Donor Sibling Link (DSL)?

Answered: 43 Skipped: 3



Authority paper

Strategic delivery	**Setting standards**	☑	**Increasing and informing choice**	☑	**Demonstrating efficiency, economy and value**	☑
Paper title	**Information for Quality: update**					
Agenda item	**10**					
Paper number	HFEA (08/07/2015) 761					
Meeting date	8 July 2015					
Author	Nick Jones, Director of Compliance and Information					
For information or decision?	Decision and Information					
Recommendation	• Comment on, and approve, the vision for change which will guide our work • Note the progress as regards procurement of third party suppliers in line with corporate approval process, and associated costs; • Note that progression from Alpha stage is dependent on external approval (with an update report provided to Members at that point); • Comment on the arrangements informing organisational change resulting from the realisation of the IfQ Programme.					
Resource implications	Significant - within approved IfQ budget.					
Implementation	During 2015/16 business year					
Communication	Regular throughout 2015/16					
Organisational risk	High					
Annexes	N/a					

HUMAN FERTILISATION & EMBRYOLOGY AUTHORITY

1. Background

1.1. The IfQ programme encompasses:

- The redesign of our website and Choose a Fertility Clinic (CaFC) function. Recommended changes to CaFC will be presented at this meeting by the Director of Strategy and Corporate Affairs
- The redesign of the 'Clinic Portal' (used for interacting with clinics) and combining it with data submission functionality that is currently provided in our separate EDI (Electronic Data Interchange) system (used by clinics to submit treatment data to the HFEA)
- A revised dataset and data dictionary which will be approved by the Standardisation Committee for Care Information (SCCI)
- A revised Register, which will include the migration of historical data contained within the existing Register
- The redesign of our main internal systems that comprise the Authority's Register and supporting IT processes.

1.2. Given the importance of the programme to the Authority's strategy, updates on progress are provided to each meeting of the Authority and approval for direction and actions sought. This update, in particular, introduces the concept of a clear vision or 'offer' to guide us, addresses progress in procuring technical services and considers consequences for organisational change. We welcome comment, challenge and, as appropriate, endorsement of direction of travel.

2. Our vision for change

2.1. As the programme has evolved – from our initial thinking; engaging with stakeholders through a consultation exercise; establishing a business case; specifying contract requirements - we have established a set of objectives and expectations captured in various ways.

2.2. The Authority has been instrumental in that and informed it along the way (and will continue to do so, for example on the CaFC item later). The Authority has made a series of decisions about the shape of the IfQ programme. Those decisions are not simply technical in nature, they also embody the kind of information provider the Authority wants to be.

2.3. Other aspects are more operational – for example information technology architecture and detailed clinic portal development that the Authority will expect to be carried out carefully but would not expect to be across in the same way. The teams involved in the Programme see it as a whole and it's important that we establish a clear vision, or blueprint, for the change we (all) want to see.

2.4. The remainder of this section attempts to summarise those decisions into one easy to read description of our information offer to patients and clinics (and to our own way of working – particularly in relation to internal systems description) once IfQ is complete.

Website

2.5. This is our window to the world and will represent who we are – our personality, style, tone. It will embody our refreshed brand, not just visually but in our tone of voice. It will be fresh and current, with dynamic content - 'something new every day.' It will link to HFEA social media channels, giving a more human, active feel.

2.6. The website will be aimed at patients and the public, written in an upbeat,

personable style. Patient information will be organised along a typical patient or donor journey. Nothing old and out of date – with content owners defined and prompted to renew. This will be applied strictly – with incentives and sanctions in place. The site architecture will be designed so that content is easy to find and nothing is more than a few clicks away. The search will need to be used much less but, where it is used, the findings will be presented more clearly. Information will be presented as a mixture of infographics, charts, video and images as well as short, crisp text. It will be maintained with less text content than currently.

Choose a Fertility Clinic

2.7. The transition from website to CaFC will be seamless with all the website design principles applied. It will be a source of authoritative, trusted information – which will draw patients away from statistics on clinics' own websites. It will only be so if it is accessible and therefore consumed. Complex information will be presented clearly and unnecessary layers of detail will not appear. Success rates will not be privileged over other information such as inspection findings and patient feedback, but will be presented, in a comparable way, so that patients can make a choice based on different aspects of quality.

Clinic Portal

2.8. The clinic portal will be the key window to the HFEA by clinics – and there will be a seamless (if password-protected) transition from the public website to the portal. It will be attractive and intuitive to use – picking up corporate branding and functionality of the website. It will provide useful information about requirements placed on licensed clinics and their key staff. It will have the risk tool; other useful publications; and enable clinics to access information about their own performance and in comparison with all their peers or a selection – so they can improve their own performance.

2.9. Clinics' experience in submitting data to us will be easier and more pleasant. It will be an intuitive experience and users can adapt the system around their work rather than their processes being determined by our system. It will prevent simple errors by having a real-time verification facility. It will handle all transactions with us – clinics will make applications based on a simple interface that recognises who the clinic is with their core information already visible, only specific, new information will need to be inputted.

2.10. Like any good transactional system it will be intuitive and instructions will be helpful, provided at a few levels such as on-screen and videos or FAQs available on the portal that they use to submit data. Whether or not integrated systems are in place at a clinic we should work hard to ensure that the experience of users of such systems is similar. We will have a very clear data submission policy linked to Direction 0005, and a transparent approach for amending the data dictionary (with significant changes approved by the Authority). We may not be able to completely design out user input error – there will always be a need for checking and ultimately verifying - but this will be a much simpler time saving process than now. And we will look to get CaFC refreshed on a monthly basis, with data being more contemporary than now.

Internal Systems

2.11. We will implement an information technology strategy that supports all the IfQ developments and which provides economic and efficient hosting and storage arrangements, utilising the benefits of the 'cloud' (as appropriate); to provide business continuity and appropriate security; and desktop services meeting high service standards. All the 'business tools' the HFEA needs to operate whether

provided internally or externally function well - and based on simplicity and agile development principles. Once the development phase of IfQ is complete we will move to different ways of working. Contracts with suppliers may be in place to allow for minor improvements, and maintenance including bug fixes – but preclude improvements of a significant nature. Business leads will understand from their knowledge of user feedback what improvements to systems are needed and will bid for resource accordingly using business case approach.

3. Procurement

3.1. All design work will be provided by external suppliers. For development, we are adopting a mixed model - supplementing internal capacity with specific expertise further to a procurement exercise conducted on our behalf by the Crown Commercial Service.

3.2. The procurement process by way of competitive tender is almost complete. Nine suppliers were invited to make presentations to us. On the whole we were impressed by the quality of bids and presentations. Since the end of the evaluation period we have selected two preferred suppliers to enter in to further negotiations and agree contractual terms. One supplier was successful in five outward facing contracts relating to website and portal design and development (with some economies of scale secured as a consequence); and a further supplier in the delivery of 'internal systems' – that is the Register modernisation and technical architecture to enable the external systems to function efficiently and securely within the HFEA information technology framework. Contractual formalities need to be completed but we expect work to have started on-site week commencing 6 July 2015.

3.3. As regards costs, the Authority has approved an overall budget of £1.134m for 2015-16. This provides the overall approval and the Authority Standing Orders allow for subsequent approval at appropriate levels, Contract sums for the outward facing and internal systems work are c£500,000 and c£200,000 including VAT, respectively. It is important to note that the Authority's contractual position is protected. Payment at this level is made on the basis of the delivery of all requirements - with those requirements set out each phase (Alpha, Beta, Live). Of course, our expectation is a successful progression from one stage to the next but our overall exposure is protected. At this stage, the HFEA Chief Executive has approved the overall approach to the contract(s) and a financial commitment not exceeding £60,000 broadly aligned to the first part of the Alpha stage. The Chief Executive will subsequently approve progress to Alpha, Beta and Live on the basis of a recommendation from the IfQ Programme Board. In addition the Board will recommend approval to stages of expenditure within these phases and expenditure signed off by the Director of Compliance and Information and the Director of Finance These approvals will be reported to the Audit and Governance Committee on a post-hoc basis.

3.4. A substantial contingency is also available, c.20% of budget which is prudent as well as being considered good practice. The balance supports programme costs and 'backfill' for key personnel.

3.5. The Authority is reminded that 'approval' risks remain. That is, Department of Health and Government Digital Service must approve progression from Alpha to Beta stage. These relate to 18 measures (all of which must be met) such that the development of public service digital interface meet key standards including the appropriate involvement of users; appropriate agile methodologies are used for development and so on (https://www.gov.uk/service-manual/digital-by-default). To some extent our financial risks are mitigated given contractual protections set

out in 3.3 above. Moreover, our focus has been and remains on being very clear about our objectives and how those will meet 'digital by default expectations.

4. Organisational change

4.1. The aspects set out in section 3 above are the culmination of much work - in reviewing our extant systems and evaluating their fitness; undertaking substantial engagement with stakeholders and users; researching and establishing our requirements; specifying those to secure proposals from third parties and so on. We have now reached a significant milestone in moving from preparation to development.

4.2. The Gateway Review (highlighted in the previous meeting of the Authority) told us that we need to have increasing regard to the consequences for HFEA ways of working, and in turn the implications on our teams as we move from development to implementation. We agree, and having secured an affordable programme with the potential to transform how we and others who interact with us work, our attention can turn to the opportunities and challenges presented by change.

4.3. It is worth setting out a few key themes that will inform our approach to this over the next few months.

- Given the 'agile' nature of development we expect the first few weeks of the programme of development to discuss and finalise a detailed and resourced plan for the remainder of the year. That said, we expect the period between now and October/November 2015 to be intensive and focused on development activity. Those involved in the programme will in turn be energised, stretched, challenged in this period. As we go through these months and beyond we and our teams begin to appreciate the changes and potential for change that are emerging. In other words, it's a joint and shared experience.
- The period beyond that will be no less pressured but focused more towards refinement, preparation for implementation and delivery. This will be when teams will be starting to develop plans for new ways of working as a consequence of those changes.
- Beyond that we must hold in our minds that the ways of working we are adopting for this programme of change will become a way of working more generally. Agile development encourages us to move away from thinking we build a new set of systems and go back to normal. Instead, we must adopt a way of working that evaluates user experience, determines what changes are necessary and affordable, before building and testing out those changes, and then moves to implementation and so on. Clearly this will not be as intense as currently, but signals a new way of working.
- We will need to keep our stakeholders involved and informed with activities taking place between now and April 2016 - and subsequently as we return to more business as usual activities;
- The business case for the programme anticipated modest financial savings. That said we expect a change of focus in some teams and this will impact on some roles. Any such changes – expected to come into effect in the next financial year - will be accompanied by discussion and consultation with directly affected staff.
- Finally, our approach will be guided by our vision for the change set out in section 2 above.

5. Recommendation

5.1. The Authority is asked to:

- Comment on, and approve, the vision for change which will guide our work
- Note the progress as regards procurement of third party suppliers in line with corporate approval process, and associated costs;
- Note that progression from Alpha stage is dependent on external approval (with an update report provided to Members at that point);
- Comment on the arrangements informing organisational change resulting from the realisation of the IfQ Programme.

Authority paper

Strategic delivery	**Setting standards**	☐	**Increasing and informing choice**	☑	**Demonstrating efficiency, economy and value**	☐
Paper title	**Choose a Fertility Clinic**					
Agenda item	**11**					
Paper number	HFEA (08/07/2015) 762					
Meeting date	8 July 2015					
Author	Juliet Tizzard, Director of Strategy and Corporate Affairs					
For information or decision?	Information					
Recommendation	To comment on the progress on the Choose a Fertility Clinic review					
Resource implications	Within approved IfQ budget					
Implementation	During 2015/16 business year					
Communication	Regular throughout 2015/16					
Organisational risk	High					
Annexes	None					

HUMAN FERTILISATION & EMBRYOLOGY AUTHORITY

1. Background

1.1. Our patient information about treatments and clinics has changed significantly over the years. From 1996 onwards, we published 'The patients' guide to DI and IVF', which consisted of information about treatment options and success rates (see annex A), making us trailblazers in publishing outcome data. With increasing use of the web, in 2005 we launched an online version of the guide, which was relaunched in 2009 as Choose a Fertility Clinic.

1.2. Six years on, the design of Choose a Fertility Clinic is looking a little old and tired. We've always suspected that the statistics on the site were hard to understand, but our user research rammed the message home. Patients were confused – to the extent that some lost trust in the data and looked elsewhere.

1.3. So the design and the presentation of statistics need a refresh. But we've also been clear that we want Choose a Fertility Clinic to do much more than present success rates. We want it to be a tool that can help patients select the best clinic for them. To do that, they need to know what services the clinic offers, but they also to get a feel for the quality of those services.

1.4. We came to the Authority in January 2015 with recommendations from the Information for Quality (IfQ) advisory group about the website, Choose a Fertility Clinic and the clinic portal. At that meeting, members agreed that the quality of a clinic should be measured in a multi-dimensional way: through patient feedback, inspection findings *and* success rates.

1.5. Wider developments in the IfQ programme are reported in a separate paper from the Director of Compliance and Information. This paper updates members on our progress on the review of Choose a Fertility Clinic. We would welcome members' views and comments to make sure that we are going in the right direction.

2. What we've already decided

2.1. Taking most of the recommendations from the IfQ Advisory Group on board, the Authority agreed in January that it wanted Choose a Fertility Clinic to offer:

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

2.2. Members asked the executive to think about how this could work in practice.

3. What we've done since January 2015

3.1. We set up two work streams, one on statistical information and one on non-statistical information, to take this work forward. The two groups have drafted a comprehensive set of recommendations which have recently been approved by the IfQ programme board. Here we present the key issues.

Statistics: cumulative birth rates

3.2. The IfQ advisory group recommended that, after births per embryo transferred, the second success rate should be births per egg collection (or cumulative birth rates). Births per *embryo transferred* enables patients to understand how good the clinic's success rates are across all services (IVF, ICSI, PGD, fresh and frozen cycles), getting above patient case-mix to an extent. Births per *egg collection* shows how likely patients at the clinic are to conceive over a full cycle of treatment – ie, one egg collection and all fresh and frozen embryo transfers which follow.

3.3. Our statisticians and analysts recommend that once a patient is successful, any further transfers from the same egg collection are excluded from the analysis, so that they are not double counted.

Statistics: sample sizes

3.4. One big issue with clinic-by-clinic data is that some clinics carry out very few cycles of treatment each year. That alone makes the statistics we present less reliable. Once the data tables are split into age band, the numbers (or sample size) get even lower and the statistical reliability decreases further.

3.5. To date, we have tried to overcome this problem by showing data in ranges (see the middle column below) and showing how the clinic's rates compare with the national average (right hand column). But, as you can see, the smaller the sample size, the more meaningless the ranges are.

Age	Live births per treatment cycle	Predicted chance of an average patient having a live birth Why this range?	How does this clinic compare to the national average? What does this mean?
Under 35	44 out of 213	Predicted chance between: **13% - 30%** most likely around: 20.7%	Below national average live birth rate of 32.5%
35-37	15 out of 112	Predicted chance between: **6% - 26%** most likely around: 13.4%	Below national average live birth rate of 28.5%
38-39	7 out of 75	Predicted chance between: **3% - 24%** most likely around: 9.3%	Consistent with national average live birth rate of 21.1%
40-42	3 out of 41	Predicted chance between: **2% - 29%** most likely around: 7.3%	Consistent with national average live birth rate of 14.0%
43-44	0 out of 11	Predicted chance between: **0% - 46%** most likely around: 0.0%	Consistent with national average live birth rate of 6.0%
Over 44	0 out of 3	Predicted chance between: **0% - 76%** most likely around: 0.0%	Consistent with national average live birth rate of 1.7%

3.6. One way of addressing this is to increase the sample sizes. This could be done by presenting data over more than one year or for a minimum number of cycles. This, however, would be difficult to achieve and potentially confusing for users.

3.7. Instead, we recommend that we change the age bands from the six we currently have to two: under 38 years and 38 years and over. This would give us a larger sample size: in the example above, this would mean a sample size of 325 for the under 38s and 130 for the 38 and over. The national data, because it aggregates all clinics should continue to display in six age bands and it will be easy for patients to see that data.

3.8. We chose 38 as the cut-off point because this is already a threshold between two age bands and it marks the point where the success rate declines more significantly. This banding would have the effect of greatly increasing the size and therefore the reliability of the sample, without significantly impacting on the accuracy of the results. And, with the births per embryo transferred calculation including fresh and frozen transfers, the sample sizes will be even bigger and more reliable.

Statistics: ranges

3.9. We have also reconsidered using ranges to convey statistical reliability. In our user testing, people found them confusing, partly because we call them 'predicted chance…' and also because a very small sample size results in a range so wide as to be meaningless.

3.10. By the same token, abandoning ranges altogether in favour of a single percentage point could be equally misleading, as the following example shows:

- Clinic A carries out 50 cycles a year resulting in 25 births, and has a 50% birth rate. But if they'd got just 5 more or 5 fewer births, the birth rate would be 60% or 40%.
- Clinic B carries out 2000 cycles a year resulting in 1000 births, and also has a 50% birth rate. But 5 more or 5 fewer births for this clinic would have a negligible impact on their birth rate: 50.25% or 49.75%.

3.11. Bad luck or good luck for Clinic A dramatically changes their result, so relying on a single percentage point is unwise. However, Clinic B's results are much more reliable.

3.12. So, single percentage points are easy to understand but ranges are more statistically reliable. Given the need to balance understanding and accuracy, we think this should come down to what works best for users, knowing a better visual design will help enormously. We have come up with three approaches to test on users:

- Stick with the ranges but improve the design (using visual rather than typographic display) and the data explanations (with simple text or an animation, video or suchlike)
- Show clinic-specific statistics, unless the sample size is below a particular threshold, in which case we would show the national data
- Show a single percentage point with percentage increase or decrease on either side, for example: 25% (+/- 10%). This could be done graphically.

Patient reviews: ratings

3.13. The Authority has already decided that we should not allow free-text feedback. We have considered ways of seeking more structured feedback and think that a

1-5 rating is the best approach.

3.14. We considered using the friends and family test question to generate an overall score: 'Would you recommend this clinic to a friend of family member who needed it?'. We could then have five further questions to give more detail., the downside of the friends and family test is that it is very general. The advantage is that it is used across the health service and is therefore recognisable.

3.15. We think that the best approach is to ask five questions covering customer service, decision-making, emotional support, information and transparency of costs (for self-funded patients). We would display the 1-5 rating for each question and then an overall average score for that clinic, derived from the five questions. However, we recommend testing out both approaches on users.

Patient reviews: honesty and representativeness

3.16. Some clinic staff have a legitimate concern about patient feedback: that it won't be representative of patient views at that clinic. They worry that:

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

3.17. One way of addressing false reviews is to make reviewers identify themselves by registering – even cross-checking to our register. Setting aside the potentially insurmountable confidentiality issues, our research shows that this will deter patients from giving feedback. They need anonymity to be frank.

3.18. One way of achieving a more representative set of views is to ask the clinic to contact a sample of patients and ask them to submit a review or forward their details to us for follow-up contact. There are confidentiality concerns with this approach, but the anonymity point bites here too: our research shows that patients don't feel able to be frank if their clinic is involved in review process. The administration needed might be prohibitive too.

3.19. We think we can address these in the follow ways:

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

3.20. With a free-text option, patients may feel frustrated that they can't say more. We will obviously point them to the complaints channel if they have that kind of problem with the service they received at the clinic. But we will also give reviewers the chance to click through to the fuller survey that inspectors use to assess patient satisfaction, letting them know they can give more expansive feedback that will be seen by the inspector and the clinic only.

Availability of donated eggs, sperm or embryos

3.21. In January, the Authority asked the executive to look further at this feature. We think it should be possible clinics to say whether they have egg, sperm or embryo donors available within broad timeframes (ie, immediately available, one to six months, more than six months). We have yet to test this concept on clinic representatives, but will do so in the next month with the formation of a stakeholder group which will meet for the first time in July.

Comparisons

3.22. Patients want to compare clinics. As we saw in our research, when thwarted from doing so on our current website, they simply create multiple tabs in their web browser to do it. IfQ advisory group members had misgivings about facilitating comparisons, largely because they think comparing success rates can be misleading. We agree. We think a better approach would be to allow users to short-list clinics, then display them in a table showing inspection findings, patient feedback *and* success rates. A carefully designed layout will discourage users from relying on one factor on its own.

4. Recommendation

4.1. We would welcome members' views and comments on the progress with Choose a Fertility to make sure that we are going in the right direction.

Annex A: Excerpt from 'Patients' guide to DI and IVF'

Centre0024
University of Bristol IVF Service

Address

UNIVERSITY OF BRISTOL IVF SERVICE
BUPA HOSPITAL
REDLAND HILL
DURDHAM DOWN
BRISTOL
AVON
BS6 7JJ

Telephone

0117 973 2562 ext 247

Licensed for

In Vitro Fertilisation - Donor Insemination - Storage of Sperm - Storage of Embryos - Egg Donation

In Vitro Fertilisation Treatment

(For treatments carried out during the period 1.4.93 to 31.3.94)

Number of patients	360
Number of cycles	448
Number of stimulated cycles	389
Number of unstimulated cycles	0
Number of frozen embryo transfers	57
Adjusted live birth rate	13.5% (+/- 4%)
(Unadjusted live birth rate 15.5%)	
Multiple birth rate	28.6%
Triplet birth rate	4.3%
Abandoned cycles	36

Donor Insemination Treatments

(For treatments carried out during the period 1.4.93 to 31.3.94)

Number of patients	15
Number of cycles	23
Number of stimulated cycles	23
Number of unstimulated cycles	0
Adjusted live birth rate	42.6% (+/-22%)
(Unadjusted live birth rate 26.1%)	
Multiple birth rate	50.0%
Triplet birth rate	12.5%

Centre0032
Southmead General Hospital

Address

DEPARTMENT OF INFERTILITY
SOUTHMEAD GENERAL HOSPITAL
WESTBURY-ON-TRYM
BRISTOL
AVON
BS10 5NB

Telephone

0117 959 5102

Licensed for

In Vitro Fertilisation - Donor Insemination - Storage of Sperm - Storage of Embryos - Egg Donation

In Vitro Fertilisation Treatments

(For treatments carried out during the period 1.4.93 to 31.3.94)

Number of patients	49
Number of cycles	74
Number of stimulated cycles	67
Number of unstimulated cycles	5
Number of frozen embryo transfers	2
Adjusted live birth rate	16.8% (+/- 10%)
(Unadjusted live birth rate 17.6%)	
Multiple birth rate	23.1%
Triplet birth rate	7.7%
Abandoned cycles	16

Donor Insemination Treatments

(For treatments carried out during the period 1.4.93 to 31.3.94)

Number of patients	56
Number of cycles	263
Number of stimulated cycles	180
Number of unstimulated cycles	83
Adjusted live birth rate	3.2% (+/- 3%)
(Unadjusted live birth rate 3.4%)	
Multiple birth rate	10.0%
Triplet birth rate	0.0%

6