Human Fertilisation & Embryology Authority

Authority meeting - agenda

9 March 2016

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

Agenda item		Time
1.	Welcome, apologies and declaration of interests	1:00pm
2.	Minutes 20 January 2016 **HFEA (09/03/2016) 785**	1:05pm
3.	Chair's report (verbal)	1:10pm
4.	Chief Executive's report (verbal)	1:20pm
5.	Committee chairs' updates (verbal)	1:30pm
6.	Strategic performance report **HFEA (09/03/2016) 786** For information	1:45pm
7.	Information for Quality: update **HFEA (09/03/2016) 787** For information	2:05pm
8.	Compliance and enforcement policy **HFEA (09/03/2016) 788** For decision	2:35pm
	Break	**3:00pm**
9.	Governance and transparency **HFEA (09/03/2016) 789** For decision	3:10pm
10.	Strategic risk register **HFEA (09/03/2016) 790** For information	3:30pm
11.	Business plan 2016/17 **HFEA (09/03/2016) 791** For decision	3:45pm
12.	Any other business	4:05pm

Minutes of Authority meeting 20 January 2016

Strategic delivery:	☐ Setting standards	☐ Increasing and informing choice	☐ Demonstrating efficiency economy and value
Details:			
Meeting	Authority		
Agenda item	2		
Paper number	HFEA (09/03/2016) 785		
Meeting date	9 March 2016		
Author	Charlotte Keen, Information Access and Policy Manager		
Output:			
For information or decision?	For decision		
Recommendation	Members are asked to confirm the minutes as a true and accurate record of the meeting		
Resource implications			
Implementation date			
Communication(s)			
Organisational risk	☐ Low	☐ Medium	☐ High
Annexes			

Minutes of the Authority meeting on 20 January 2016 held at ETC Venues, Hatton Garden, 51-53 Hatton Garden, London, EC1N 8HN

Members present	Sally Cheshire (Chair) Dr Susan Price Professor David Archard Dr Andy Greenfield Kate Brian	Yacoub Khalaf Margaret Gilmore Anita Bharucha Ruth Wilde
Apologies	Anthony Rutherford Bishop Lee Rayfield	
Observers	Ted Webb (Department of Health)	
Staff in attendance	Peter Thompson Nick Jones Juliet Tizzard Sue Gallone Catherine Drennan	Suzanne Hodgson Anjeli Kara Joanne McAlpine Charlotte Keen

Members

There were 9 members at the meeting, 6 lay members and 3 professional members

1. Welcome, apologies and declarations of interest

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

1.2. Apologies were received from Anthony Rutherford and Bishop Lee Rayfield.

1.3. Declarations of interest were made by:

- Kate Brian (Regional organiser for London and the South East for Infertility Network UK)
- Yacoub Khalaf (Person Responsible at a licensed centre)
- Ruth Wilde (Senior Fertility Counsellor at a licensed centre)

2. Minutes of Authority meeting held on 11 November 2015

2.1. Members agreed the minutes of the meeting held on 11 November, subject to one minor amendment, for signature by the Chair of the meeting.

3. Chair's report

3.1. The Chair welcomed two new Authority members, Ruth Wilde – a senior fertility counsellor - and Dr Anne Lampe – a clinical geneticist who had previously provided expert advice to the Statutory Approvals Committee (SAC) – to the meeting. Ruth Wilde's appointment commenced on 1 January 2016 and Dr Anne Lampe, who was observing the meeting, would formally become a member on 1 February 2016.

3.2. The Chair informed members that this was Dr Sue Price's last board meeting for the HFEA, as her term of office would come to an end on 31 January 2016. The Chair thanked Dr Price on behalf of all the Authority members for her invaluable contribution to the work of the HFEA over many years, including her role as Chair of the Scientific and Clinical Advances Advisory Committee (SCAAC), and wished her well for the future.

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

3.4. On 19 November, the Chair attended the annual dinner for the Royal College of Obstetricians and Gynaecologists (RCOG). On 2 December the Chair, together with the Chief Executive, attended a productive meeting with Lord Winston to discuss some of the issues that both Lord Winston and the HFEA were concerned about in the sector and in clinics.

3.5. The Chair and the Chief Executive continued with their programme of visits to clinics outside of the regular inspection schedule, in order to hear what clinics felt about their performance and where they thought improvement was needed. The visits would then enable the HFEA, as the regulator, to consider how to help improve the quality of care. On 4 December, they visited the Newcastle Centre for Life where the research centre for mitochondrial donation was located. Future visits included the Bourn Hall clinic in Cambridge on 21 January.

3.6. On 8 December, the Chair attended the Department of Health's arm's length bodies (ALBs) Ministerial round table with Jane Ellison, the Minister for Public Health. The main focus of the meeting was the comprehensive spending review.

3.7. On 9 December, the Chair advised members that she had spoken at the Progress Educational Trust Conference on mitochondrial donation, where much of the day had focused on genome editing. The Chair joined a panel together with Professor Doug Turnbull from the University of Newcastle, and Viscount Matt Ridley from the House of Lords.

3.8. On 12 January the Chair, together with an Authority member, attended the Department of Health's ALBs Corporate Leadership seminar on regulation.

4. Chief Executive's report

4.1. The Chief Executive advised members that, on 24 November, he had participated in a seminar run by the Committee on Standards in Public Life as part of their investigation into ethical standards for regulators.

4.2. On 8 December, the Chief Executive attended the National Information Board (NIB) Leadership meeting. The Chief Executive reminded members that the NIB was an initiative led

by the Department of Health involving all of the health sector's ALBs to make significant changes to the way in which information was used within the health and care system. The HFEA's role was limited given its specialist remit although it was appropriate that it was involved.

4.3. On 9 December, the Chief Executive advised members that he attended the Audit and Governance Committee (AGC) and the Progress Educational Trust (PET) Conference to which the Chair had already referred.

4.4. On 8 January, the Chief Executive attended the British Fertility Society (BFS) Annual Conference where the Director of Strategy and Corporate Affairs presented a talk about consent which was well received.

4.5. On 19 January, the Chief Executive, together with the Director of Compliance and Information, had spoken to visitors from the Government of the United Arab Emirates, who were keen to learn about the regulation of assisted reproduction in the UK.

4.6. The Chief Executive advised members that, on 15 December, HFEA staff had participated in an all staff away day. This had been an opportunity to reflect on a very busy year, the progress made in terms of delivering the business plan, and a forward look to the future. A large part of the day had been spent on preparing for the forthcoming office move which would be discussed in more detail later in the meeting.

4.7. On 11 January, the Chief Executive, with the Director of Compliance and Information, sat on an interview panel to appoint a new Chief Inspector. The calibre of the candidates was very high and the appointment of the successful candidate would be formally announced shortly.

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

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

4.10. Genome Editing: the Chief Executive advised members that there had been considerable press coverage of the fact that HFEA had received a research application which involved the use of the genome editing technique Crispr-Cas9. The HFEA Licence Committee met to consider the application, although the decision would not be made public until the minutes of the meeting have been agreed. The Chief Executive reminded members that the genetic modification of embryos had been legal in a research context in the UK since 2009, although it remained illegal in treatment.

4.11. Unregulated sperm donation: an unregulated sperm donor, claiming to have fathered 800 children, had been interviewed on the Victoria Derbyshire programme. The Chief Executive, together with the Chief Executive of the National Gamete Donation Trust (NGDT) had also taken part in the discussion. The HFEA planned to provide more information on the new website as to the dangers of using such services. There had been a lot of press coverage both before and after the show.

4.12. London Sperm Bank: the Chief Executive advised members that it had been brought to the HFEA's attention by a national newspaper that the promotional material for the London Sperm Bank stated that it screened potential sperm donors for dyslexia, attention deficit hyperactivity disorder (ADHD), attention deficit disorder (ADD) and other conditions. When questioned, the clinic claimed that HFEA guidelines permitted such screening. The HFEA had made it clear to both the newspaper and the clinic that the HFEA did not, or ever had, endorsed or guided clinics to screen for such conditions. Following discussions with their HFEA inspector, the clinic's management had removed the claims from their promotional materials and would be producing updated guidance for clinic staff.

5. Committee chairs' updates

5.1. The Chair of the Statutory Approvals Committee (SAC) reported that the committee had met on 26 November and 17 December. There had been five preimplantation genetic diagnosis (PGD) applications in November, all of which were approved, and one request for Special Directions which was granted. At the December meeting, two PGD applications had been considered, one of which was approved and one rejected.

5.2. The Chair of the Licence Committee advised members that the committee had met on 14 January. The minutes had not yet been published. The committee had considered one research renewal application, an initial research licence application and a research project interim inspection.

5.3. The Chair of AGC advised members that the committee had met on 9 December, and had received reports on:

- The spending review, the HFEA's office move and resilience and business continuity management, from the Director of Finance and Resources
- Register and Compliance risks and an update on the IfQ Programme, from the Director of Compliance and Information
- Strategic risks, from the Head of Business Planning
- Updates from the Internal and External Audit teams
- The implementation of audit recommendations, from the Finance and Accounting Manager
- Licensing appeals, from the Chief Executive
- An annual review of AGC activities and effectiveness.

5.4. The Director of Strategy and Corporate Affairs advised members that the Executive Licensing Panel (ELP) had met four times since the last Authority meeting. At the first three meetings, the panel had considered four treatment and storage renewal applications, all of which were approved; three licence variations, all of which were approved; three interim inspection reports, where the licences had been continued; and two Special Directions, both of which were granted. At the meeting on 15 January, the minutes of which had not yet been published, the panel had considered three interim inspections, two licence variations, three treatment and storage renewal applications, and one progress report.

6. Strategic performance report

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

6.2. The Director of Strategy and Corporate Affairs provided members with a summary of activities within her Directorate in the last six months and an overview of the Directorate's contribution to the HFEA strategy.

6.3. Setting standards – improving quality of care and the lifelong experience of donor conception: the Director of Strategy and Corporate Affairs reminded members that a new process for regulating mitochondrial donation had been launched following the regulations coming into force on 29 October 2015. Work also continued on redesigning the Choose a Fertility Clinic (CaFC) website as part of the IfQ programme. It was felt that CaFC and the information on each of the clinics which the HFEA licensed had an equally important role in driving up standards in clinics as the formal regulatory policies.

6.4. Increasing and informing choice – using HFEA data to improve outcomes and ensuring patients have access to high quality information: the Director of Strategy and Corporate Affairs advised members that the HFEA had attended both the Fertility Show and the Alternative Parenting Show which was an opportunity to meet patients, prospective patients and donors. 600 copies of the HFEA's 'Getting Started' guide were handed out together with 100 donation and multiple births leaflets. Patient information on reproductive immunology on the HFEA's website had also been updated as a result of SCAAC having reviewed the evidence.

6.5. Efficiency, economy and value - ensuring the HFEA remains demonstrably good value: the Director of Strategy and Corporate Affairs advised members that staff resources would be focused on work which would achieve the HFEA strategy, and saving money by implementing the refreshed brand which had been achieved by cutting expenditure on design and print.

6.6. The Director of Strategy and Corporate Affairs provided members with an overview of the HFEA's website activity. The most popular device used to access the HFEA website was the mobile phone, with 48% of users, although these users were the ones spending the least amount of time on the website. This was followed by 41% using a desktop or laptop and 11% using a tablet. After the United Kingdom, at 48%, the most popular geographical location of website users was the United States at 16%, India at 13%, Australia at 3% and Canada at 2%. Popular pages on the HFEA website continued to be the intrauterine insemination (IUI), in vitro fertilisation (IVF) and Intracytoplasmic sperm injection (ICSI). However, surrogacy, although not regulated by the HFEA, was the second most visited page on the website.

6.7. The Director of Strategy and Corporate Affairs reminded members that the annual conference, scheduled to take place on 24 March, was mainly for professionals working in licensed clinics and laboratories. Registration for the conference would be launched on 1 February and members were asked to let the Executive Assistant to the Chair and Chief Executive know if they wished to attend.

6.8. The Director of Compliance and Information provided members with an update on legal parenthood since the last Authority meeting. From 6 April 2009, women, and the partners of

women treated with donor sperm, where the couple was neither married nor in a civil partnership, were required to give their consent in order to become the legal parent of any child born. Legal parenthood gave a lifelong connection between a parent and a child, and affected things like nationality, inheritance, contact and some aspects of financial responsibility.

6.9. In 2009, the HFEA had issued a suite of guidance and specific new forms to enable the obligations on clinics to be discharged appropriately on behalf of patients. At the time, the HFEA also ran a series of workshops and inspectors also began looking in some depth on this subject at each clinic they visited.

6.10. The Director of Compliance and Information advised members that in June 2013 two issues emerged. One related to an inspection where defects were found in a clinic in the documentation for 14 specific cases. In the same week, a judgement was made on a particular application made to the court by a separated couple, where the judge had to make a declaration in terms of parenthood. The HFEA felt that this was a significant development and there was a need to understand better the extent to which there might be a more widespread issue. Therefore, in autumn of the same year, the HFEA issued information to all clinics through Clinic Focus and asked a number of clinics to undertake a detailed audit, as part of a trial, in order to understand whether the problem was more extensive. The evidence subsequently suggested that it might be and the HFEA consequently required all clinics to undertake an audit which would then be checked at inspection. The Chief Executive issued a letter to all clinics reporting the results of that audit and intimating that there was more widespread poor practice.

6.11. Between February and September 2015, the Family Division of the High Court gave consideration to a number of cases, the outcome of which made it clear that there were defects in the records affecting eight couples. A declaration was made on seven of the couples and the judge was able to grant parenthood.

6.12. The Director of Compliance and Information advised members that the HFEA's approach was one of transparency and openness and clinics were expected to take the same approach. Regular reports had been provided both to Authority members and AGC. Throughout the process, there had been good cooperation from clinics, with most clinics being exemplary in terms of the communication with the HFEA. The HFEA wanted to seek assurance from clinics that their processes going forward were robust and that every step had been taken to minimise the potential for failures of consent taking place in the future. The responsibility for this was clearly placed on the Person Responsible (PR) of each clinic. It was emphasised that a clear expectation had been placed on the PR to support patients through the difficult process as far as possible.

6.13. The Director of Compliance and Information emphasised that legal parenthood would continue to be a focus of the HFEA's inspection and monitoring activity. He noted that clinics had provided assurances to the HFEA about their current practice. Of the 92 clinics that had provided such treatment since the law changed in 2009, 28 clinics had one or more anomaly, and fewer than five clinics were subject to ongoing inquiries. It was expected that, on the basis of the evidence that the HFEA had seen, there would be around 90 patients with some level of parenthood doubt. However, a proportion of those patients were unlikely to pursue the matter any further. Some seven cases had already been determined at the High Court with a further

nine cases currently under consideration. In most cases to date, the Department of Health had decided to intervene in the court proceedings, in order to try to ensure the determination was made in accordance with statute.

6.14. The Director of Compliance and Information provided members with a summary of lessons learned. When the new rules came into force in 2009, it was felt that the HFEA acted in a thoughtful and consultative manner when setting the expectations of clinics. However, it was acknowledged that the difficulty of the task faced by them may have been under-estimated.

6.15. In conclusion, the Director of Compliance and Information advised members that, going forward, it was fundamental there was a clear policy and a shared understanding of why adhering to a rigorous process was so important. The requirements were not just administrative in nature: they set out the basis of the legal relationship of the parent and child going forward. The use of multiple forms, the lack of checking, mistakes and quality assurance were suggestive of an absence of a clear understanding at all levels within a service.

6.16. Following a discussion, members noted the update on legal parenthood and that further communication to the sector would be forthcoming as regards lessons learned.

6.17. The Director of Finance and Resources provided an overview of financial performance and a summary of the position towards the end of the financial year. At the end of December, there was a surplus of £383k. The surplus was partly due to a lower spend on salaries and legal costs. The forecast for the end of the financial year was a surplus of just under £300k.

6.18. Turning to the 2016/17 financial year, the Director of Finance and Resources advised members that the changes to fees, which had been agreed at the last Authority meeting, had been announced to clinics in Clinic Focus at the beginning of January, although it was made clear that those changes were still subject to Treasury approval. The Treasury had considered the changes and there were a few outstanding queries to clarify with them.

6.19. The Director of Finance and Resources advised members that the Department of Health had confirmed the amount of grant-in aid for 2016-17, which was a small reduction from the current financial year.

6.20. In relation to the HFEA's office move, the Director of Finance and Resources confirmed that the HFEA would be sharing office space with the National Institute of Clinical Excellence (NICE). This would mean developing more flexible ways of working for staff and a 'ways of working' group had been set up which would play a key part in making sure that staff concerns were addressed. Visits to the new offices were also currently underway for all staff.

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

7. Information for Quality: update

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

- The redesign of the HFEA's website and Choose a Fertility Clinic (CaFC) function

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

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

- The approvals process to proceed to Beta phase
- The HFEA annual conference
- Data migration and the data dictionary
- Revisions to the programme timeline
- Arrangements for the management of the IfQ programme.

7.3. As members had been previously advised, the externally facing part of the programme could not formally proceed beyond 'Alpha' (proof-of-concept) stage until approvals in line with Government Digital Service (GDS) Standards had been granted by the Department of Health. The Director of Compliance and Information advised members that the first stage assessment, undertaken by the Department of Health Digital Projects team on 12 November, was passed to a high standard. The second stage assessment – undertaken by the Government Digital Service itself – had also been approved.

7.4. The Director of Compliance and Information advised members that, building on the proof-of-concept work presented to Authority members at the last meeting, the teams had made good progress on a working website and clinic portal. The HFEA conference to be held in March 2016 would provide an opportunity to showcase the progress made, and to generate anticipation for the roll-out of the 'beta' version of the products. It would also introduce the proposed data dictionary (the data required to be submitted to the HFEA relating to treatments and other activity) together with the plans for the data submission part of the clinic portal. Members were advised the clinic portal was scheduled for release in October 2016.

7.5. The Director of Compliance and Information advised members that substantial cleansing activity of Register data was being undertaken by the Information and IT teams at the HFEA, in order to effect a smooth transfer to the new Register in line with the HFEA data dictionary. Whilst this work had minimised data cleansing burden on clinics, input from clinics was required and this work was expected to take place over the next three to four months. The HFEA had communicated with clinics in order to prepare them for this next step, although it was unlikely to be a popular move, and the Executive noted that further communication with clinics was vital in order to work most effectively with them in the coming months.

7.6. Progress on exposing the data dictionary to stakeholders, and for accreditation by the Health and Social Care Information Centre (HSCIC), had been slower than hoped. Consequently, this part of the programme was becoming a risk to delivery. Members noted they would be asked to 'sign off' the data dictionary at the Authority meeting in March.

7.7. Principally as a consequence of the first stage approval delay, the Director of Compliance and Information advised members that there had been subsequent revisions to the programme timeline. The public beta for the website and clinic portal had now been pushed back approximately three months and two months respectively – with both now expected to be launched (for beta testing) in July 2016. The revised timeline had been discussed with stakeholders and, from feedback, it was clear that it was best to ensure complete confidence in the accuracy of the products before release, even if this resulted in a slight delay.

7.8. The Director of Compliance and Information advised members that the IfQ programme oversight had now been absorbed by the HFEA's Programme Management Office (PMO), further to the departure of the dedicated Programme Manager. Whilst in its early days, the arrangement was working well with the programme helped by having well- established project boards with continuing oversight of each of the projects making up the Programme.

7.9. Following a discussion, members noted the progress made on the IfQ programme and the slippage on timescales.

8. Applications to use Register data for epidemiology studies

8.1. The Researcher in Statistics and Epidemiology presented this item and advised members that the HFEA Register Research Panel (RRP) had been set up in 2010 after the law changed to allow the disclosure to external researchers of patients' identifying information. The Authority remained the statutory Oversight Committee and therefore had a duty to exercise oversight of the work of the RRP.

8.2. Since 2010, a total of eight studies had been approved, with three published papers and two presentations at international conferences (the European Society of Human Reproduction and Embryology (ESHRE) and the American Society for Reproductive Medicine (ASRM)).

8.3. Since the last report to Authority members in January 2015, the panel had received and approved one new application, with three other grant applications, one of which had already been approved. The number of new applications was disappointing. However, the excellent quality of work performed demonstrated the value of the Register and allowing researchers access to it. The studies helped to answer questions of significant patient and scientific interest, including the long term health of women and their babies, development of prognostic tools, and the effect of culture media.

8.4. The Researcher in Statistics and Epidemiology provided members with an update on ongoing studies. The HFEA was currently preparing data for two studies:

- Mortality and morbidity in children born after IVF (University College London) – the HFEA was in the process of extracting data for linkage at the HSCIC
- A culture media linkage study (University of Manchester) aiming to identify the impact of different culture media on subsequent live birth rates and birth weights – the HFEA was extracting data for linkage onsite.

8.5. The Researcher in Statistics and Epidemiology advised members of three studies, previously reported to them and due to be published later in the year:

- The Epihealth Outcomes Project (University of Manchester) in relation to the effect of maternal age, embryo cryopreservation and culture on perinatal outcomes and child health – researchers were still working on their analysis of the data that the HFEA had provided and planned to start writing up their findings in the coming months
- The development and validation of statistical models to predict pregnancy outcomes following IVF (University of Aberdeen) – researchers had completed their analysis, with one paper already published and one planned for publication later in the year
- The cancer risk and mortality in women after IVF (UCL) – the principal investigator, Professor Alastair Sutcliffe, presented the ovarian cancer results at the ASRM in October 2015. The remainder of the analysis should be published soon.

8.6. Following a discussion, Authority members noted the report provided to them by the RRP.

9. Embryo testing: testing for more than one condition at a time

9.1. 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.

9.2. The requirements for PGD and PGS were as follows. A centre was only permitted to carry out PGS in order to establish whether an embryo may have an abnormality that 'may affect its capacity to result in a live birth.' Centres were required to validate the use of PGS for each group of patients to whom they offered it. To carry out PGD, two requirements must be met: there must be a 'particular' risk (an existing known risk of a genetic disease in the family) and a 'significant' risk (the disease must be sufficiently serious and on the list of conditions authorised by the Authority for PGD).

9.3. 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.

9.4. The Regulatory Policy Manager reminded members of two potential scenarios which had arisen from the latest developments in embryo testing technologies, and the legal advice which had been sought by the Executive for both scenarios:

- Patients may wish to have both PGS and PGD at the same time – legal advice concluded that PGS and PGD should be considered separately and the requirements for each must be satisfied before testing was carried out. If a patient satisfied the requirements for PGD and PGS, both forms of embryo testing could be carried out at the same time.
- Patients may wish to use PGD to test for more than one genetic condition at a time - legal advice concluded that it was possible for an embryo that had satisfied the particular and significant risk requirements for PGD for one genetic condition, to be

tested for additional conditions at the same time, provided it satisfied the significant risk test.

9.5. Members had last considered this issue at its meeting in May 2015. At that meeting, members had expressed misgivings about the type of patients currently being offered PGS by clinics and how complex test results could be interpreted. It was therefore agreed that these comments should be further considered before a decision is made. The paper now presented to members addressed the Authority's comments before asking for a decision on whether it was appropriate to test for more than one condition or abnormality at a time. The Authority's choice would come down to where members wished to strike the balance between maximising patient choice and being concerned about the implications of handling and interpreting additional genetic information.

9.6. In line with the Authority's recommendations in May 2015, SCAAC considered the Code of Practice guidance note on PGS at their June meeting, and made the following recommendations:

- Based on the current level of evidence, the Authority should not recommend PGS for particular patient groups
- Guidance around information for patients should be updated to reflect the use of the latest embryo testing technologies
- Genetic information generated through embryo testing technologies should be interpreted by experts in genetics and embryo testing
- Patients should be offered access to both genetic and infertility counsellors, and given guidance on questions they should ask.

9.7. The Regulatory Policy Manager provided members with a summary of stakeholder views. In relation to handling and sharing information:

- Patients would want access to any information generated through embryo testing, however ambiguous the finding may be
- Patients should see an expert in interpreting genetic information and discuss their options in the light of the information generated
- Patients should be able to opt out of receiving any additional genetic information that embryo testing might find
- Genetic information which could not help select an optimal embryo for transfer should not be tested for.

9.8. In relation to counselling requirements and recording consent, stakeholder views were that:

- Any additional genetic information that could be obtained via embryo testing should be explained to the patient
- Patients should be offered access to both a genetic and infertility counsellor, before and after embryo testing
- Consent should be recorded for what is being tested for, and whether any additional information should be disclosed to the patient.

9.9. Taking into account the legal advice, the views of SCAAC and stakeholders, the Regulatory Policy Manager asked members to consider two possible policy options and for members to decide on the most appropriate approach:

- Option one: to prohibit the use of PGD to test for more than one genetic condition (where there is only a known risk of one condition)
- Option two: to allow testing of more than one genetic condition, making sure that patients consent to receive (or not receive) the information generated.

Decision

9.10. Following a discussion, members agreed that option two was the most appropriate because it best reflected the legal position and they could see no evidence for being more stringent than the law allowed. Members were reassured that this would not result in people requesting PGD for non-serious reasons. This was because in order to allow testing for a second genetic condition, patients would already have qualified for PGD and met the two requirements: that there must be a 'particular' risk (an existing known risk of a genetic disease in the family) and a 'significant' risk (the disease must be serious enough and on the list of conditions authorised by the Authority for PGD). The second disease must also be serious enough to be on the same list.

9.11. The Executive agreed to consider how to communicate the new guidance to clinics, and how best to let patients know about the options available to them and their implications.

10. Government initiatives around better regulation

10.1. Authority members accepted the following recommendations in relation to the Government initiatives around better regulation, subject only to comments and questions from members:

- The emerging proposals from Government
- The forthcoming consultation on bodies having a duty under the terms of the Enterprise Bill, and that the HFEA does not make a case for exemption
- The Executive's proposed approach to fulfilling these duties (when enacted)
- The Executive's proposed approach to continue to resist any duty to appoint a Small Business Appeals Champion.

11. Any other business

11.1. The Chair of the meeting confirmed that the next meeting would be held on 9 March at ETC Venues, Hatton Garden, 51-53 Hatton Garden, London, EC1N 8HN. Members were asked to confirm their attendance to the Executive Assistant to the Chair and Chief Executive as soon as possible.

12. Chair's signature

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

Signature

Chair

Date

Strategic performance report

Strategic delivery:	☒ Setting standards	☒ Increasing and informing choice	☒ Demonstrating efficiency economy and value
Details:			
Meeting	Authority		
Agenda item	6		
Paper number	HFEA (09/03/2016) 786		
Meeting date	9 March 2016		
Author	Paula Robinson, Head of Business Planning		
Output:			
For information or decision?	For information		
Recommendation	The Authority is asked to note and comment on the latest strategic performance report.		
Resource implications	In budget		
Implementation date	Ongoing – strategic period 2014-2017		
Communication(s)	CMG reviews performance in advance of each Authority meeting, and their comments are incorporated into this Authority paper. The Department of Health reviews our performance at each DH Update meeting (based on the CMG paper). The Authority receives this summary paper at each meeting, enhanced by additional reporting from Directors. Authority's views are fed back to the subsequent CMG performance meeting.		
Organisational risk	☐ Low	☒ Medium	☐ High
Annexes	Annex 1: Strategic performance report		

1. Introduction

1.1. The attached paper summarises the main performance indicators, following discussion by the Corporate Management Group (CMG) at its 17 February performance meeting.

1.2. The majority of the data relates to the position at the end of December 2015. Some of the financial data also includes the position at the end of January 2016.

1.3. Overall performance is good, and we are making good progress towards our strategic aims.

2. Recommendation

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

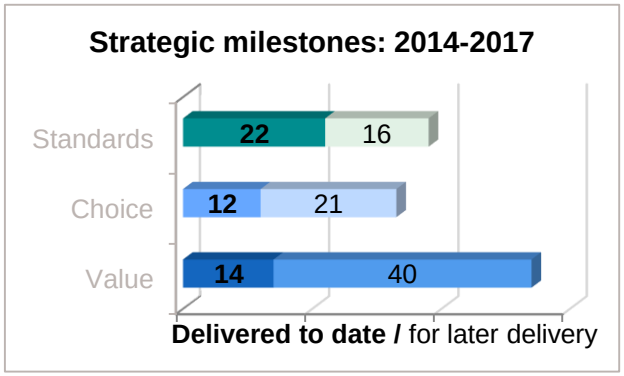
Annex A - HFEA strategic performance scorecard

1. Summary section

Dashboard – December data

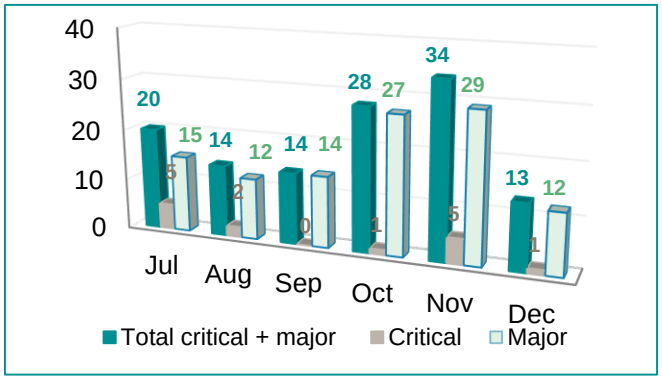
Strategic delivery totaliser

(see overleaf for more detail)



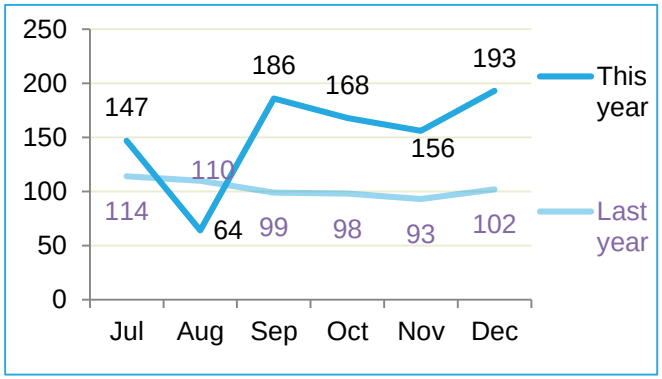
Setting standards:

critical and major recommendations on inspection

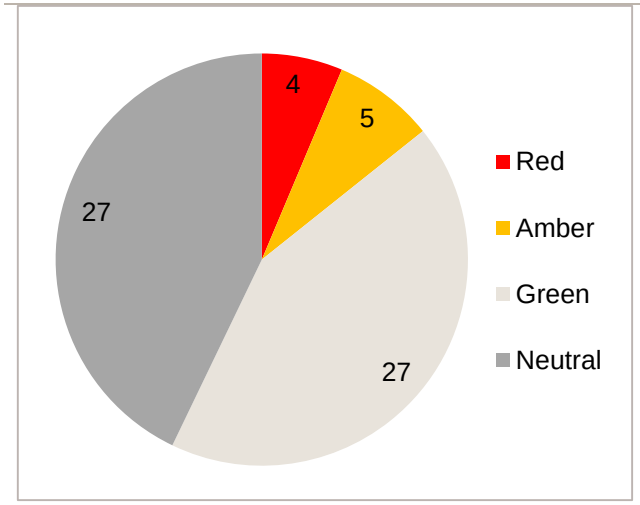


Increasing and informing choice:

public enquiries received (email)



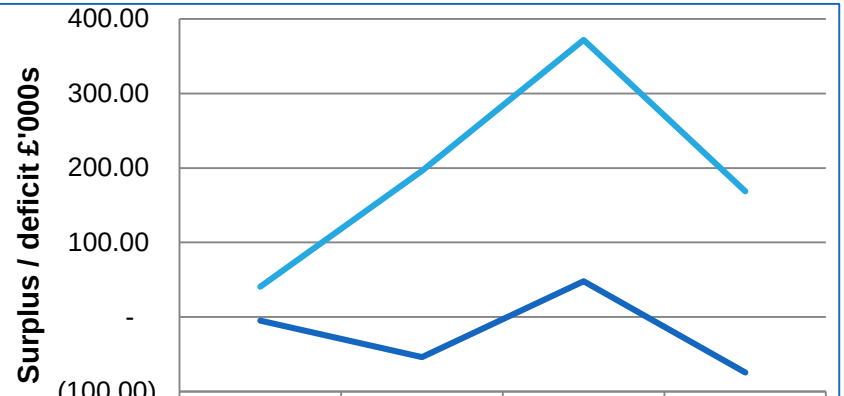
Overall performance - all indicators:



(See RAG status section for detail.)

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

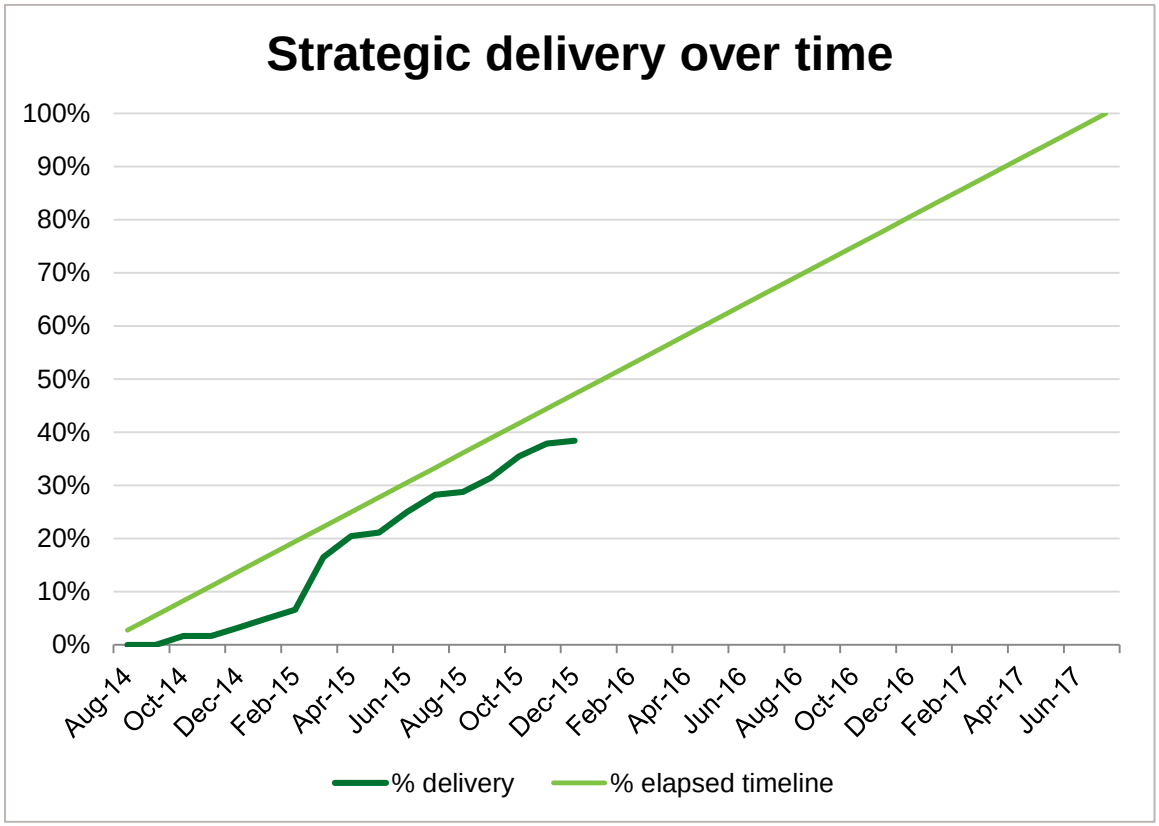
This graph details our net actual position as at end quarter 3 (month 9 – December 2015) and our forecast position at that time for 31 March 2016. The graph shows the expected deficit did not arise ie we are forecasting a surplus for the year. The components making up the surplus/deficit is shown later by two other graphs (income and expenditure).

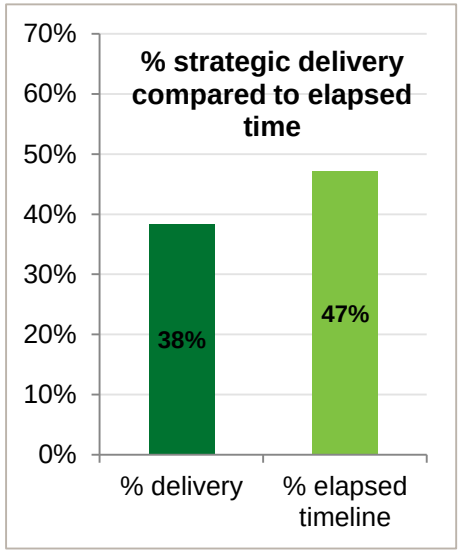


	Q1-Jun-15	Q2-Sep-15	Q3-Dec-15	Q4-Mar-16
Budgeted surplus/deficit	(5.04)	(53.98)	47.94	(74.36)
Forecast surplus/deficit	40.79	196.01	372.06	168.62

Dashboard - Commentary

Strategic delivery (to end of December) – summary:





The totaliser data was significantly updated in December, to add all the IfQ work planned for delivery during beta phase. This work has started. There are a large number of key milestones that will be reached in the coming year. Owing to the major investment made to date in planning, arriving at various proofs of concept (in the alpha phase), and seeking various approvals, we are now in a position to build products (at the time of reporting this was at risk, since we were awaiting formal GDS approval; this was then received in January). This re-casting of the timeline data has made us appear 'behind' on the above graph. However now that real product development has commenced, we should expect to see the delivery line start to converge with the elapsed timeline over the coming months.

Strategic delivery for September to December

Setting standards

In September, the compliance reports on risk tool alerts and themes, common non-compliances and incidents were all delivered on time to the Authority meeting, focusing on analysing current quality and safety issues in clinics, helping clinics to improve outcomes and reduce risks, and disseminating learning. Our annual publication reporting on clinical incidents (in 2014) was also published, containing information about learning points from incidents and adverse events, to inform both the clinics themselves and our future inspections. A multiple births stakeholder group meeting was also held as planned. We had originally planned to commission an external review of our inspection regime, to report in September, but a decision was taken to defer this work, pending the outcomes of our Triennial Review (which may include relevant recommendations).

In October, we completed the mitochondrial donation project, getting new application and licensing processes in place in time for implementation of the new legislation on 29 October. In addition we collaborated and engaged with others, through our own Licensed Centres Panel meeting and attendance of the AFPO conference held by patient and donor organisations.

Increasing and informing choice

Our six-monthly Choose a Fertility Clinic (CaFC) data was published on time in October, providing updated information (up to the end of quarter two of 2015 for pregnancy data) to the public and feedback on performance to the sector.

The annual report on clinical incidents and alerts was also published on time, in November.

Efficiency, economy and value

In September, work continued on the IfQ website and clinic portal projects. The alpha phase of work (proofs of concept) was subsequently completed in November, with approval to proceed obtained in principle following a very positive DH assessment. GDS approval was expected in December, but in the event was not received until January 2016. Meanwhile we took the decision to proceed with the beta phase at risk, since otherwise we would have needed to stand down our suppliers. Detailed beta phase planning has been completed, setting out the products and user stories that will be built and tested in each sprint. The Authority continues to receive regular reports on IfQ progress.

In October, our regular fees engagement with clinics took place. This meeting provides accountability and transparency on fee rates to the sector.

Red/amber/green status of performance indicators as at December 2015

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

The number of working days from the day of inspection to the day the draft report is sent to the PR has a target of 90% in 20 working days. In December performance was at 50%, with two out of four reports being sent at 27 working days. In one case this was because of unexpected additional workload, and in the other case the report took longer to refine since it was a template for future transport centre reports. There was also one report outstanding from November, which was sent 39 days after inspection. This was due to practical issues in obtaining a suitable peer review.

The total number of outstanding errors in the system taking into account the eight weeks centres are given to resolve rose by 16% in December, to 2,240. We attribute this to two main factors. Less proactive chasing is being undertaken since the team are prioritising correcting egg thaw treatment data to ensure correct linkage to freezing events and other important IfQ related work (an investment in improving accuracy in the future). There are also a number of new clinics with high error rates.

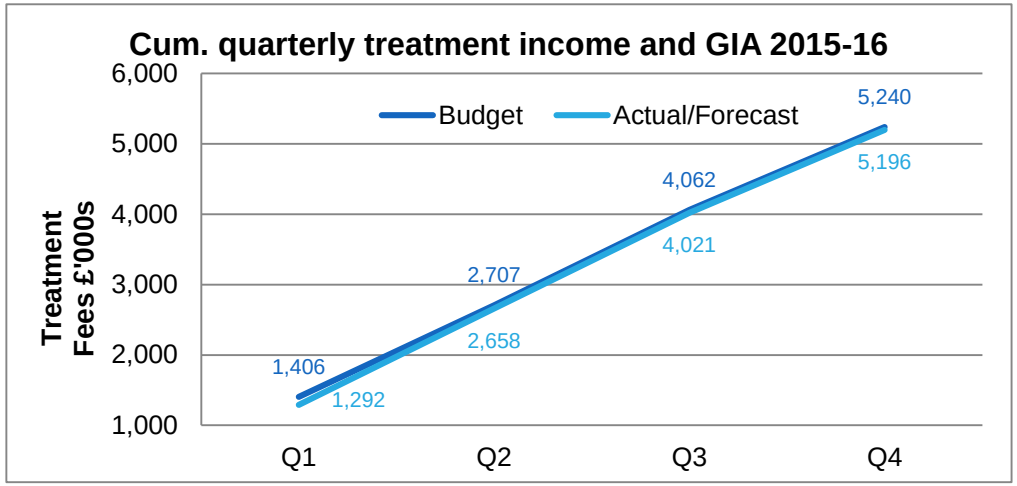
Two projects were on a red risk rating in December.

The Fertility Trends report project requires data for analysis, some of which (on egg freezing) requires cleansing before it can be used. This cleansing needs to be performed by the same staff who are currently cleansing the data for the IfQ-related data migration, and has had to be prioritised over that work. In addition, the report needs to be published at our Annual Conference on 24 March 2016, so the timeline is tight. Since December, the data cleansing required has progressed well, and the risk rating has been reduced to amber.

The Office Move project was also on a red risk rating in December, pending the resolution of some technical issues regarding our new internet connection (critical for business continuity). This has since been resolved, and the risk rating has accordingly been reduced to amber.

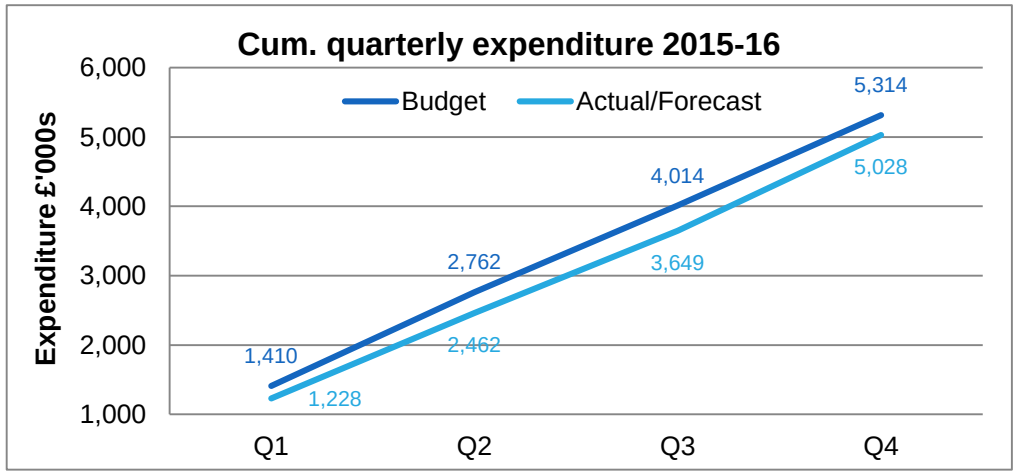
Budget status – January data

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



This graph shows our budgeted (planned) licence fee income and grant-in-aid (GIA) compared to what is actually happening.

As of month 10 (31 Jan-16) we are not far off our budget (a shortfall of only £44k). Treatment fees are the most variable of our income stream and will therefore continue to be monitored.



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

Year to date we are under spending against budget (£317k) which is relative to our reduced income. The underspend has been added to by inclusion of receipts from legal cases where we were awarded costs. Our year end forecast is showing an under spend of £286k up from £177k reported at the end of Q3. This position may change as more information is known and on-going pieces of work are completed.

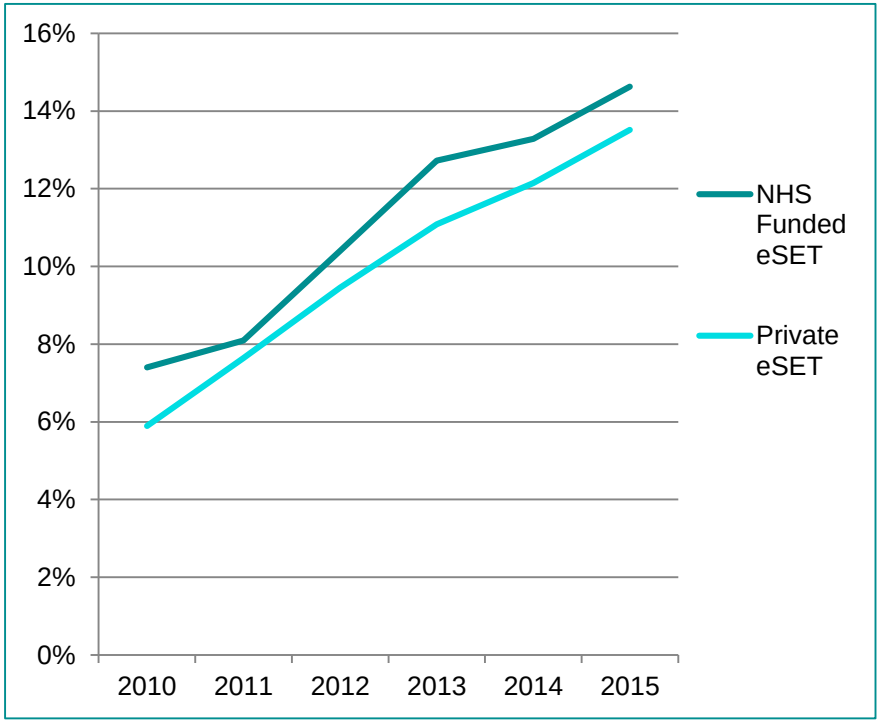
Quality and safety of care

The following figures and graphs were run on 28 January 2016.

ESET split by private/NHS:

Funding	Year						
	2010	2011	2012	2013	2014	2015	2016*
NHS Funded:							
Recorded as eSET	4294	4903	6264	7867	8443	9689	447
	7%	8%	10%	13%	13%	15%	19%
Not recorded as eSET	19283	19491	17869	17723	17837	16843	561
	33%	32%	30%	29%	28%	26%	24%
Private:							
Recorded as eSET	3422	4629	5698	6857	7732	9256	402
	6%	8%	9%	11%	12%	14%	17%
Not recorded as eSET	31019	31546	30400	29388	29558	29289	964
	53%	52%	50%	48%	46%	45%	41%

Graph: eSet % trends NHS/private:



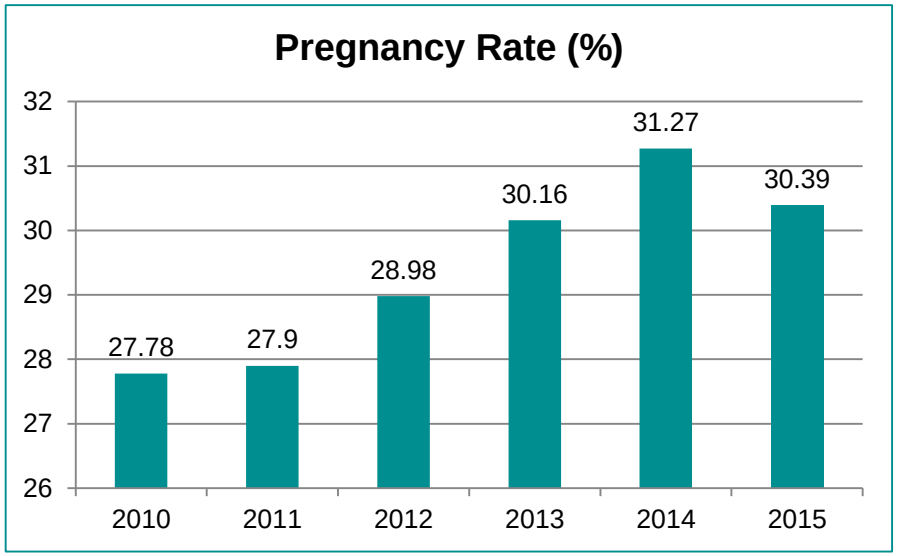
Explanatory text: Looking at all IVF treatment forms; counting those records that the clinics recorded as eSET.

* Very early 2016 data is provided for interest only, since it is too early in the year to draw any conclusions from it. This data is not included in the graph.

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

Years	All cycles	Pregnancies	Pregnancy rate %
2010	58018	16116	27.78
2011	60569	16896	27.89
2012	60231	17452	28.98
2013	61835	18648	30.16
2014	63570	19876	31.27
2015	65077	19776	30.39
2016	2374	1	0.04

Graph showing the pregnancy rate over recent years:



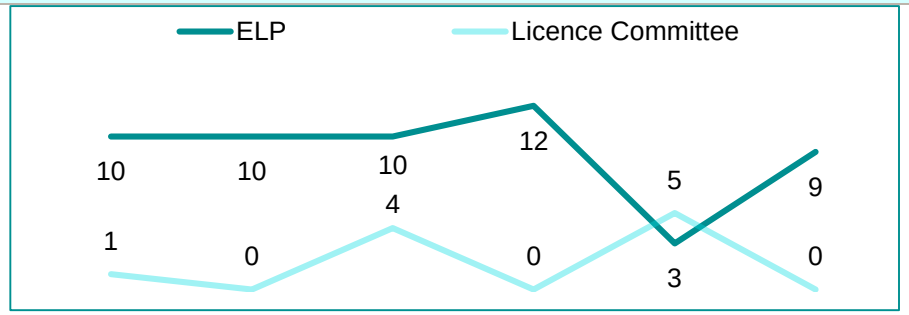
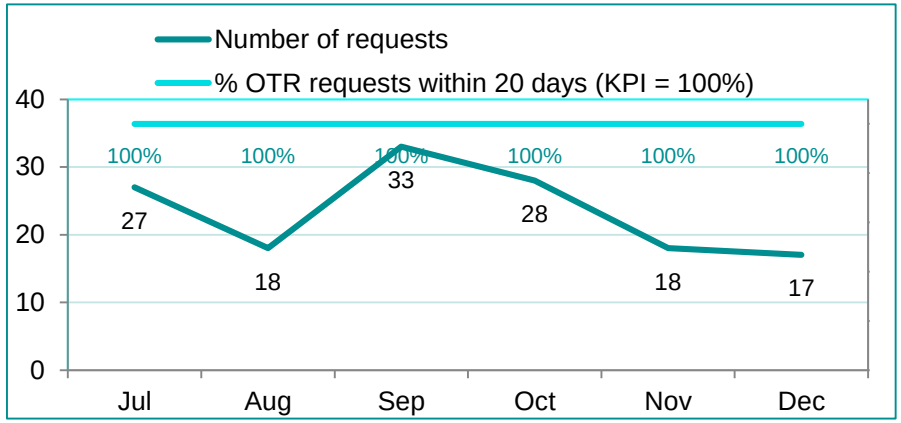
Explanatory text: Looking at all IVF treatment forms, and providing a count of pregnancies - as recorded on the early outcome form.

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

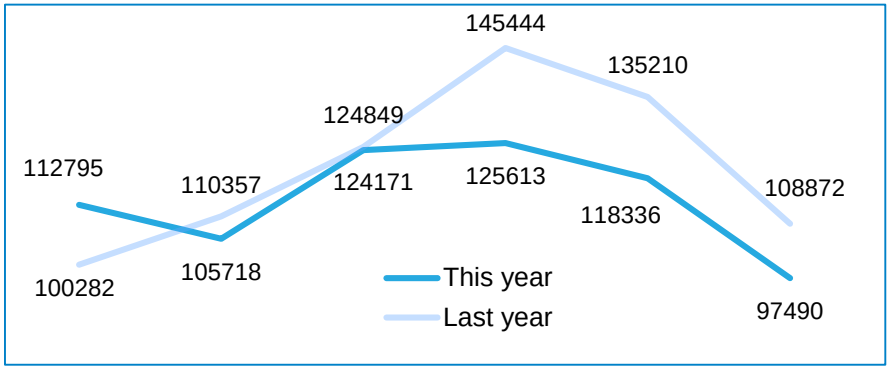
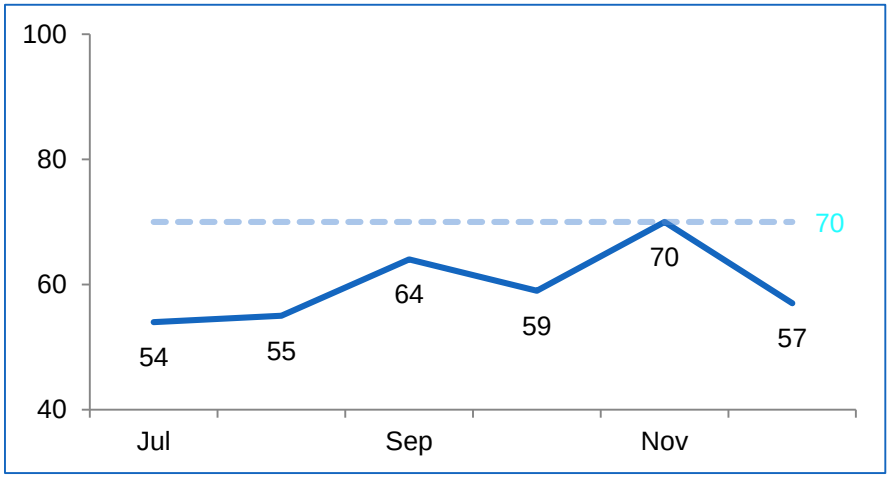
- number of risk tool alerts (and themes)
- common non-compliances (by type)
- incidents report (and themes).

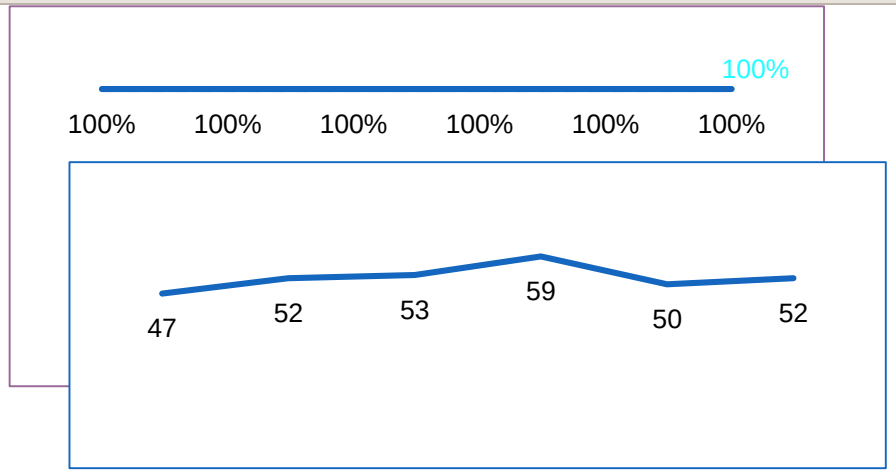
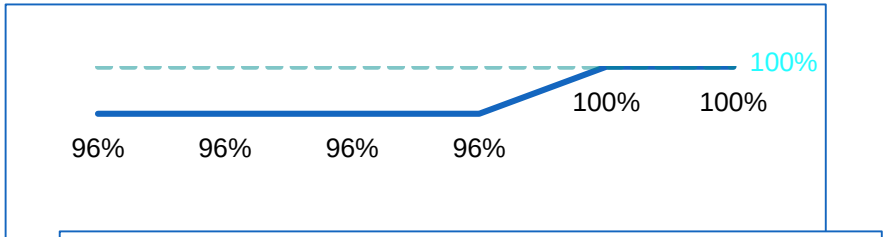
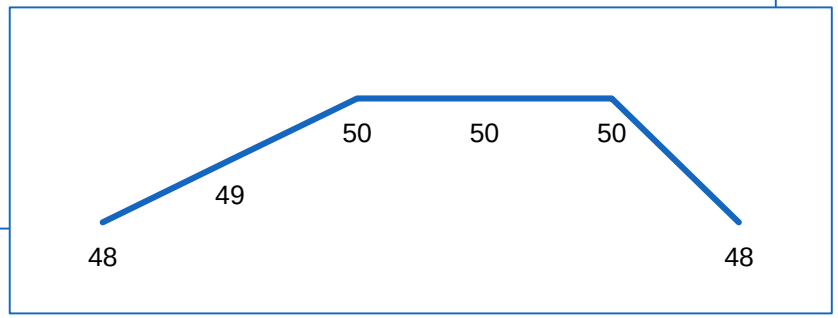
2. Indicator section

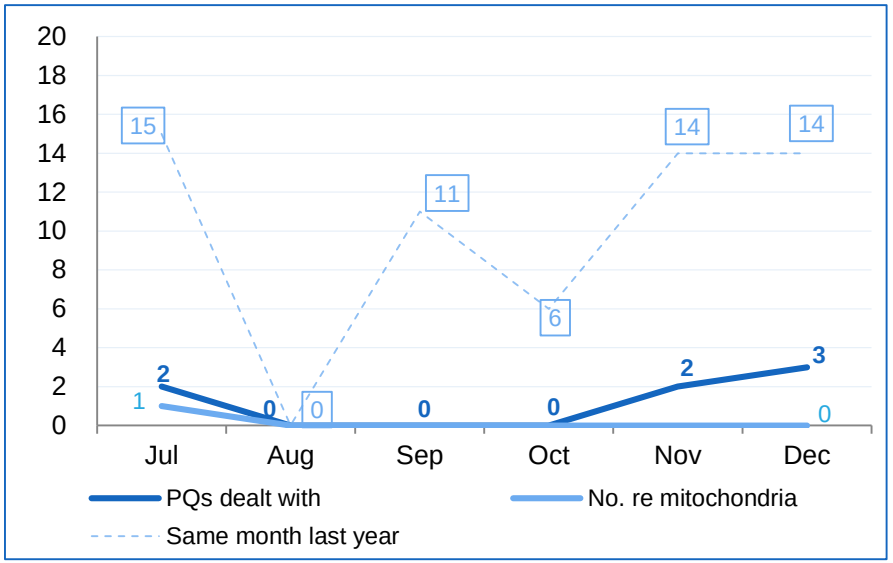
Key performance and volume indicators – December data:

Indicator	Performance	RAG	Recent trend[1]	Aim[2]	Notes
Setting standards: improving the quality and safety of care through our regulatory activities.					
Licensing decisions made: - **By ELP** - **By Licence Committee**	9 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% (17)	★		Maintain at 100% ↑	KPI: 100% of complete OTR requests to be responded to within 20 working days (excluding counselling time) The dip in August reflects the summer holiday period.

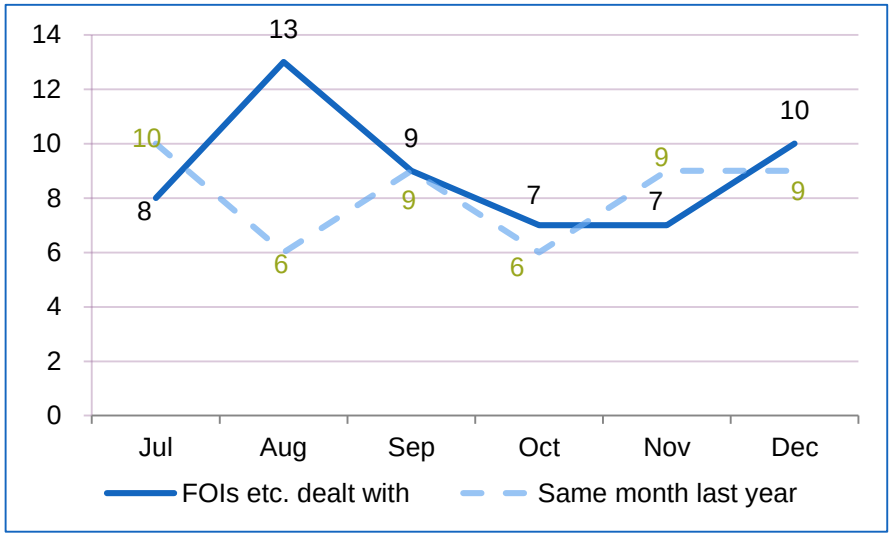
[1] Blue dashed line in graphs = KPI target level. This line may be invisible when performance and target are identical (eg, 100%).
[2] Direction in which we are trying to drive performance. (Are we aiming to exceed, equal, or stay beneath this particular KPI target?)

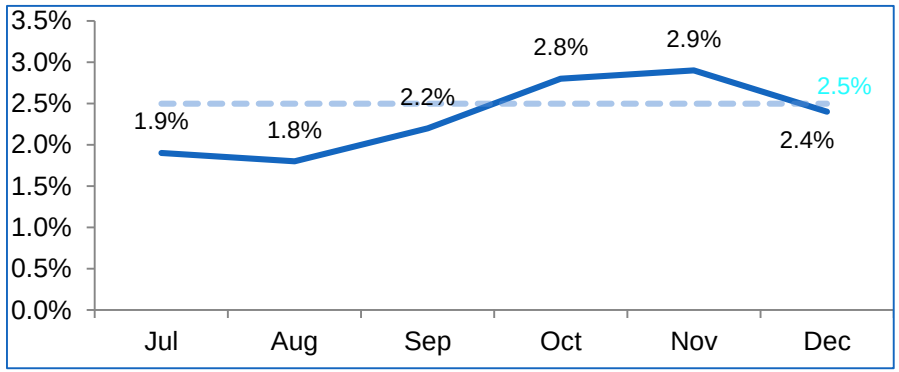
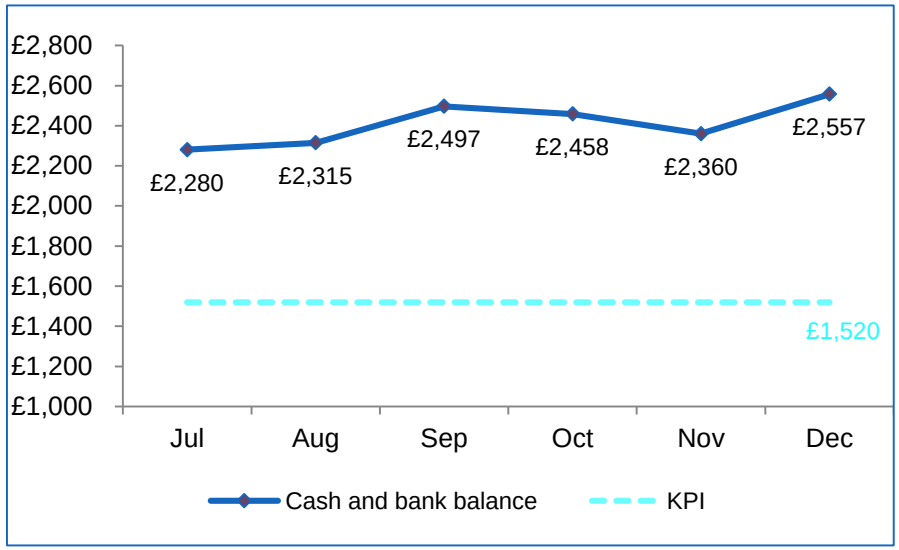
Indicator	Performance	RAG	Recent trend[1]	Aim[2]	Notes
Increasing and informing choice: using the data in the Register of Treatments to improve outcomes and research.					
			See graphs focused on quality of outcomes – after dashboard page.		
Increasing and informing choice: ensuring that patients have access to high quality meaningful information.					
Number of visits to the HFEA website (cw previous year) (trend arrow indicates movement since previous month)	97,490 (108,872)	⇩		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'.
Note: This indicator was discussed at performance CMG in February. We noted that a dip is typical for December, but that there is still a downward trend, over all. The web team has done some analysis, which shows that our web pages are still well used and viewed. Our twitter following is rising, and there may be a correlation between the two trends. An annual review of our Communications Strategy will be presented to the Authority later this year, and will address this area.					
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.	57 working days	★		Maintain at 70wd or less	KPI: Less than or equal to 70 working days.

Indicator	Performance	RAG	Recent trend[1]	Aim[2]	Notes
Monthly percentage of PGD applications processed within three months (66 working days).	100%	★		Maintain 100%	KPI: 100% processed (i.e. considered by LC/ELP) within three months (66 working days) of receipt of completed application.
Average number of working days taken.	52	★			
Annualised (rolling year) percentage of PGD applications processed within three months (66 working days)	100%	★		Maintain 100%	KPI: As above. (Annualised score). Performance has reached target, and the annualised figure, which earlier was adversely affected by some complex multi-type applications received during the rolling year, has attained 100%.
Average number of working days taken.	48	★			

Indicator	Performance	RAG	Recent trend[1]	Aim[2]	Notes
Number of requests for contributions to Parliamentary questions	Total = 3	⇧		No KPI – tracked for general monitoring purposes.	Volume indicator.

Note: Last year's numbers were notably high. Many of those PQs related to the work we were then doing on mitochondria. However, figures are increasing markedly again in 2016 (January's figure is 18). However these are about a range of subjects, and none have been about mitochondria.

Number of Freedom of Information (FOI), Environmental Information Regulations (EIR) requests and Data Protection Act (DPA) requests	10	⇧		No KPI – tracked for general monitoring purposes.	Volume indicator. There does not appear to be any trend or predictability in the volume or focus of our FOI (and other) requests.

Indicator	Performance	RAG	Recent trend[1]	Aim[2]	Notes
Staff sickness absence rate (%) per month.	2.4%	★		 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	£2,557k	⇧		 Reduce	KPI: To move closer to minimum £1,520k cash reserves (figure agreed with DH).

Note: January's balance is approximately 15% below December's levels - £2,185k – helped by payment of December bills.

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

Management accounts:

January 2016 accounts:

Income & Expenditure Account — Jan-2016

Accounting Period
Cost Centre Name
Department Name

	Year to Date			Full Year		
	Actual YTD £	Budget YTD £	Variance YTD £	Forecast £	Budget £	Variance £
Income						
Grant-in-aid	840	840	-	1,120	1,120	-
Licence Fees	3,419	3,513	-94	4,025	4,120	-94
Other Income	55	5	50	56	6	50
Total Income	**4,314**	**4,358**	**-44**	**5,201**	**5,246**	**-44**
Revenue costs - Charged to Expenditure						
Salaries	3,006	3,167	-161	3,611	3,807	-196
Other Staff costs	192	218	-26	228	258	-30
Authority/Committee costs	115	143	-27	154	166	-12
Other Compliance costs	46	33	13	62	39	23
Other Strategy costs	66	129	-63	164	175	-11
Facilities costs incl non-cash	277	296	-19	339	355	-16
IT costs costs	82	88	-7	96	106	-10
Legal costs	220	312	-92	296	340	-44
Professional Fees	66	55	11	78	68	10
Total Revenue costs	4,070	4,441	-371	5,028	5,314	-287
Total Surplus/(Deficit) before Capital & Project costs	**244**	**-83**	**327**	**174**	**-69**	**243**
Capital & Project - Reserves funded						
IFQ	537	864	-327	945	1,135	-190
Donor Support	8	16	-8	8	20	-12
Other Capital costs	74	-	74	100	100	-
TOTAL NET ACTIVITY	**619**	**879**	**-261**	**1,053**	**1,255**	**-202**

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

Commentary:

Summarised management accounts – commentary for January 2016:

Income

Treatment fee income for the year to date is 3% down against budget and 2% below the same period in 2014-15.

We are forecasting a short fall of 2% compared to budget. The shortfall reflects the trend we have experienced over the last twelve months. We continue to keep a close eye on this.

Other income excluding interest on legal fees is 8% up on budget and we are expecting this to remain until year end.

Expenditure

Year to date non pay expenditure is 16% below budget at the end of January 2016.

There are underspends across directorates relating to publications, stakeholder relations, media and administration and legal costs (where we have been reimbursed some costs). These are offset by over spends on external inspection costs, and PGD application review fees which were not budgeted for.

Staff costs for the year to date are under budget by 5% and this has been affected by vacancies during the year.

A further review was conducted in early February. Before spend on IfQ, we are forecasting overall expenditure to be 8% lower than what we have budgeted. Subject to there being no surprises, it is likely that this will be maintained until year-end.

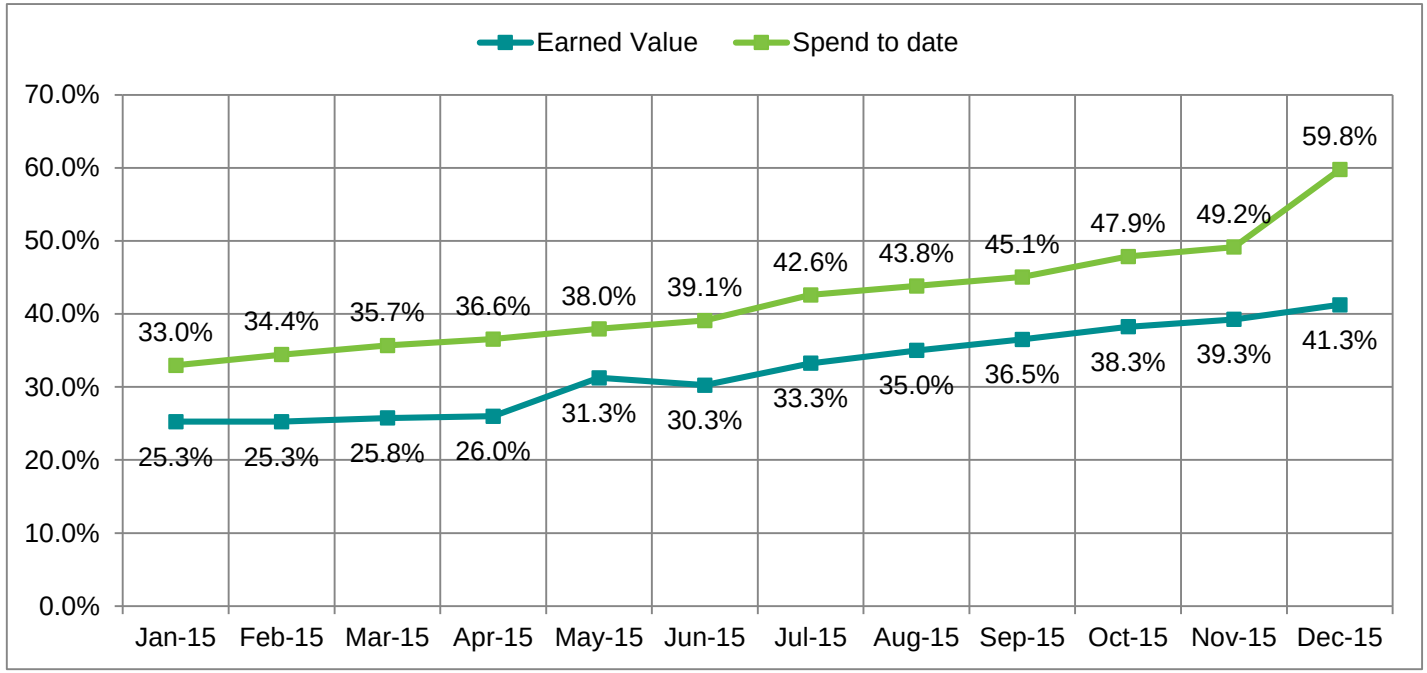
IfQ and other project costs

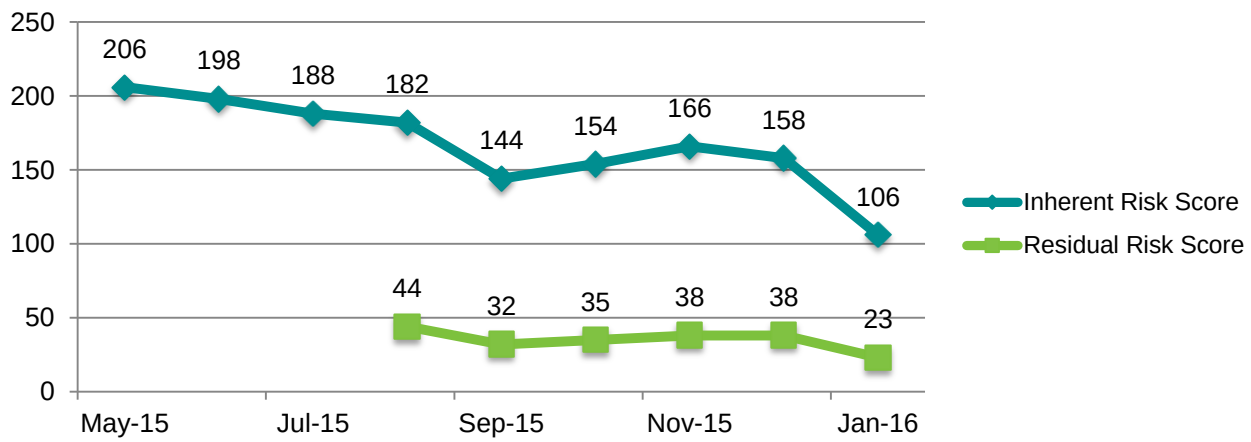
The pace of spend increased slightly in January (cumulative spend now at £537k compared to budget of £864k), with the year to date underspend increasing to 38%.

Our forecast at year end has been reviewed. We expect that £945k of our original total budget (£1,135k) will now be spent. There will be some carry-over to 2016/17 which may be in the region of £200k.

IfQ indicators: December update for Beta project phase

Frequency / trigger point	Metric	Purpose	Latest status:
At programme set-up / major reorganisation / new tranche	MSP health check overall score achieved / maximum score as a %	Is the programme set up to deliver?	The annual health check has been postponed until February. This piece of work has been delayed by IfQ handover work, including significant workload associated with updating the budget, contract sign-off for beta, sprint re-planning for beta, and daily project support activities.
Monthly	Timescales: burndown chart showing remaining estimate of work.	Is there scope creep/over-run?	In beta sprint two (in January) half of the assigned tasks were completed. The remaining tasks were either not started or part-completed, with outstanding actions reallocated to beta sprint three. We purposely over-allocated the first sprints of beta in order to give flexibility in the event of any blockage. Nonetheless, if the above trend were to continue this would have an impact on the timeline. Scope creep is being contained, however, and the beta deliverables have been confined to the minimum viable products (MVPs) identified in the product backlogs.
Monthly	Resource usage: The total number of days Reading Room are contracted to provide, vs the number of days consumed to date.	To monitor the rate of resource usage.	The external resources utilisation figures for beta (sprints 1 and 2) were provided by RR on 1 February 2015. This showed an above pro-rata consumption of the resource days in the first two sprints of beta. However we anticipate that in the last four sprints of beta the requirement for RR resources will be decreasing due to the GDS/DH planned downtime. This will continue to be monitored.

Freq-uency / trigger point	Metric	Purpose	Latest status:
Monthly	Cost: earned value (% complete * estimated spend at completion)	Is the spend in line with milestone delivery?	There are four things we can attribute value to: websites and CaFC; Clinic Portal; the Register and internal systems; defined dataset, discovery, stakeholder engagement etc. 25% of the value of the 1.8M programme cost at completion has been attributed to each project. The graph below shows earned value versus spend, to date. However, in practice, our main spend (payments to the main contractor, Reading Room), occurs only at the end of each phase of work, ie, not monthly. Our first major payment (for alpha phase work) was made in December, which causes the spend figure to jump upwards at that point. Now that we are in beta, and building products, we expect the earned value gradually to catch up with spend. The earned value only increased by two percent in December due to the majority of effort that month being invested into detailed beta planning and readjustment of the current timeline. The programme completed an important milestone when the DH GDS gateway assessment was successfully passed in January. 

Freq-uency / trigger point	Metric	Purpose	Latest status:
Monthly	Stakeholder engagement: combined stakeholder engagement score (internal plus external stakeholder events)	Are we keeping stakeholders with us? Is it getting better or worse?	There are monthly 'show and tell' sessions in place for staff. There was also an information giving session on IfQ at our all staff conference in December. We are holding external IfQ stakeholder group meetings monthly. In addition we are including articles about the IfQ programme in Clinic Focus and stakeholder publications. Total combined score (December) = 4.
Monthly	Risks: sum of risk scores (L x I)	Is overall risk getting worse or better (could identify death by a thousand cuts)?	The below line graph represents the overall IfQ risk score, which combines the perceived impact and likelihood of the current risks on hand each month. The overall risk score for the IfQ Programme has decreased as previous risks have been mitigated and closed. The largest proportions of our risk score are associated with resources, quality and development. More information is available in the risk log regarding severity and rating. In January, a thorough comb of the risk log was done, resulting in the closure of some risks – this can be seen in the graph below. 

Freq-uency / trigger point	Metric	Purpose	Latest status:
Quart-erly	Benefits: value (£) of tangible benefits planned to be delivered by the programme	Is the value of the benefits increasing or decreasing – could trigger a review of the business case?	The benefits realisation value should be reviewed based on the business case; this will be looked at during the next IfQ Programme Board meeting. No issues have been raised regarding benefits realisation to date.

Information for Quality programme: update

Strategic delivery:	☒ Setting standards	☒ Increasing and informing choice	☒ Demonstrating efficiency economy and value
Details:			
Meeting	Authority		
Agenda item	7		
Paper number	HFEA (09/03/2016) 787		
Meeting date	09 March 2016		
Author	Nick Jones, Director of Compliance and Information Cathy Hodgson, Register Information and data dictionary lead		
Output:			
For information or decision?	For information		
Recommendation	The Authority is asked to: • Note the progress made on the programme.		
Resource implications	Nil		
Implementation date	During 2015–16 and 2016–17 business years		
Communication(s)	Regular, range of mechanisms		
Organisational risk	☐ Low	☐ Medium	☒ High
Annexes	Annex 1 Data Dictionary background Annex 2 Data Dictionary		

1. Background

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

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

1.2. Given the importance of the programme to the achievement of the Authority's strategy, updates on progress are provided to each meeting of the Authority and approval for direction and actions sought.

1.3. This brief paper updates Members on:

- Update on approvals process to proceed to 'beta' phase
- The HFEA annual conference
- Data migration
- progress regarding the data dictionary, see annexes 1 and 2
- Programme timelines and budget implications

2. Update on approval to proceed to 'beta' phase

2.1. As members have been previously advised, the externally facing part of the programme could not formally proceed beyond 'alpha' (proof-of-concept) stage until approvals in line with Government Digital Service Standards had been granted by the Department of Health (DH).

2.2. The first, Alpha, stage assessment – undertaken by the Department of Health Digital Projects team was passed to a high standard. The second stage assessment – to be undertaken by the Government Digital Service (essentially a check on the first stage Departmental process) has now also been passed.

2.3. In early May 2016, both the website and Clinic portal will be again require assessment, and subject to the associated approvals from DH and GDS, both products will be released to 'public beta'.

3. Beta progress

3.1. The Programme is currently half way through the beta phase of *Release 1* development, and is producing tangible components of the new website, Choose a fertility clinic and Clinic portal. Despite some delays reported to the previous meeting of the Authority related to progressing design work, and balancing external resources, the programme remains on track to meet reported deadlines and for the beta DH assessment deadline.

3.2. For CaFC, significant work has been completed on the search tool and profile pages, with both nearing completion for beta. The CaFC search design and CaFC profile prototype were shared with a recent stakeholder group meeting and feedback will be incorporated in the next iteration of the pages.

3.3. The new website is now well progressed, with the team having completed templates for key landing and content pages. Revised content is now being migrated to the beta version of the new website, following consultation with internal HFEA teams, Authority members and external stakeholders.

3.4. For Clinic portal, design work is also making good progress. Designs for the new Clinic portal are also well progressed, with the team are nearing completion on the dashboard and a searchable knowledge base page.

3.5. The Internal Systems team have now completed a majority of the work required to support the updated functionality of the website, CaFC and Clinic portal beta phase builds. Shortly, the team will be commencing foundational work on the key functionality required in Release 2, notably, the new Register and EDI.

4. The HFEA annual conference

4.1. As previously advised, a centre-piece of the HFEA annual conference will be showcasing the progress made and generating a sense of anticipation for the roll-out of the beta version of the updated website, CaFC and clinic portal. This demonstration is anticipated to include aspects of the search tool and the clinic portal knowledge base and dashboard.

5. Data migration

5.1. As previously advised, we have now finalised the extent to which data in the current Register needs to be cleansed (that is with input necessary from clinic staff) such that we can effect a smooth transfer to the new Register (with a different data structure), in line with the HFEA data dictionary.

5.2. The Information and IT teams are carrying out substantial cleansing activity and the burden placed on clinics to undertake this work has been minimalised. However, the quantum of effort required by some clinics will be material. We are focusing on the work which must be done to enable the migration to take

place, and expect this work to start soon after the HFEA conference, which provides a useful opportunity to 'warm up' clinics to the task.

5.3. In order to form a clearer idea of the amount of time clinics will need to conduct cleansing, a selected number of clinics have been identified to undertake a pilot of cleansing activity this month.

5.4. More broadly, we have been communicating with clinics preparing them for the coming requirement to cleanse data, and we are hopeful that the prospective benefits offered by the new system will act as an incentive. Equally we are realistic about the potential for this not being a popular move.

6. Data dictionary

6.1. A significant part of the Information for Quality programme (IfQ) is about restructuring the HFEA Register. Both what and how we collect information and how we hold it in the future is changing. A background paper is attached at annex 1, detailing the progress that has been made.

6.2. In addition, the full details of the new proposed data dictionary are attached at Annex B. Whilst this is relatively dense it will be useful and interesting for clinic staff to see – so by publishing this paper the data dictionary goes in to the public domain. The changes are all about details as the fundamentals of what is required for the HFEA Register has not varied. As such, it is expected that not all Members will wish to engage with the document but there is an audience who will wish to engage in some detail.

6.3. In any event, we will continue to collect information on each IVF treatment (including ICSI) and donor insemination treatment; registration information to uniquely identify each patient, partner, intended parents or donors involved in treatments; the outcome of treatments and movement of eggs, embryos or donor sperm.

7. Programme timelines and budget implications

7.1. A revised IfQ programme plan was finalised and signed off by the IfQ Programme Board in January 2016, in line with the overall £1.134m agreed by Authority.

7.2. As previously advised, the changes to the timeline meant that the public beta for the website and Clinic portal were pushed back approximately three months and two months respectively – with both now expected to be launched (for beta testing) in July 2016.

7.3. Whilst the overall budget for IfQ remains unchanged at £1.134m, this revised timeline does extend work that was expected to be completed this financial year, in to the next. This will result in circa £450,000 being carried from this financial year to next financial year within the IfQ budget. Despite invoices for

beta work not expected from our primary supplier until July 2016, the Finance team will work closely with DH and the NAO to capitalise work completed during beta as accrued costs incurred in this financial year to minimise the impact of this underspend.

7.4. As part of reviewing HFEA's overall budget position at the end of this financial year, the Finance team is also considering the establishment costs of IfQ on the HFEA. These are primarily comprised of the non-IfQ dedicated staff costs of managing the programme, and the associated impacts to de-prioritised business-as-usual work.

8. Recommendation

8.1. The Authority is asked to

- Note the progress made on the IfQ programme.
- Note and comment on annex 1, background to the data dictionary
- Note and comment on annex 2, the data dictionary and endorse the work carried out so far and approve of continuation

Human Fertilisation & Embryology Authority

Information for Quality programme: update

Annex 1 - Background to the data dictionary

1. Background

1.1. Licensed fertility clinics submit information about each cycle of treatment they carry out, such as patient and donor details, the treatment provided and its outcome. This information is held on a database called the Register. The requirement to keep a Register of Treatments stems from the Human Fertilisation and Embryology Act 1990 (as amended) (the Act).

1.2. The Register is an extremely valuable asset to both us and our stakeholders. We use it to:

- securely hold information about donors and their donations
- ensure traceability of gametes and embryos
- provide patient information on success rates
- monitor clinic performance, and
- facilitate research into the safety of treatments.

2. Re-statement of purpose

2.1. In January 2015 the Authority received a report from the Authority's IfQ Advisory Group which made a range of recommendations based on our public consultation in late 2014. The Advisory Group noted that the HFEA has not in the past been explicit about why information is required for the Register and how it is then used. Furthermore, that without an agreed structure to justify the submission of data, we could:

- collect more information than necessary without a clear purpose for its use and thus increase the burden on clinics, or
- collect less information than necessary with the effect that we would not have the required information to allow us to use the Register effectively for our stakeholders.

2.2. The Authority agreed that data should only be collected if it meets at least one of the following criteria:

- because it is required by law, in particular to enable us to provide donors, donor-conceived people and their parents with the information they are entitled to
- to provide prospective and current patients and donors with sufficient, accessible and up-to-date information in order to allow them to make informed decisions
- to provide information that enables the HFEA to assess compliance of individual clinics against agreed standards
- to provide information that enables the HFEA to alert clinics of performance changes

- to obtain information about current practice that is considered by the professional groups and other relevant stakeholders to be useful and beneficial
- to provide identifying information that enables linkage studies about children conceived as a result of licensed treatment
- to enable ethically and scientifically approved research.

2.3. It was also agreed the HFEA

- Should establish a dedicated standing group to assess any future requests for additions (or deletions) to the dataset, using agreed criteria
- Information required for the Register should only be submitted if it meets at least one of the justifications (in 2.2 above)
- Only data that is clearly defined and that can be validated or verified should be submitted to ensure only accurate and meaningful information is held on the Register
- NHS number should be a mandatory data requirement. Where unavailable, the passport number or unique ID number relevant to the patient's citizenship should be the preferred unique identifier.

2.4. The team have been working since then on finalising the data items, further to the consultation taking into account the need to ensure the criteria at 2.2 are met. The principal changes to the current dataset are set out below.

3. Data elements removed from data collected

3.1. A number of data elements have been removed because they could be inferred from other data and didn't need to be collected as specific items. These are:

- Date donor gametes first supplied will now be inferred from donor usage
- Whether donor sperm or eggs is imported will now be derived from donor registration
- Whether patient has partner will be inferred from presence of partner record.

3.2. Some data elements have been removed because they were very rarely used or provided detail which wasn't considered useful:

- Whether assisted hatching technique used
- Multiple dates for donor insemination – only first date.
- Type of insemination
- Thawed for research and found not viable
- Reason for removing eggs/ embryos or donor sperm from storage and allowing to perish.

3.3. 'Causes of infertility' has been removed because of concerns about accuracy and completeness of the data given the often complicated nature of fertility problems and particularly the possibility that since data is collected at

registration it is not updated as further patient or partner investigations adds information.

3.4. Reason for termination of pregnancy, reason for embryo reduction, reason for lost to follow-up and abandoned cycle reason have all been removed. The information has not been used in analysis and so not required in the revised Register.

3.5. Collecting both the number of eggs fertilised normally and number of embryos developed was felt to be duplication. Initially we were only going to collect the number of eggs fertilised normally but after further consideration this has changed to only collecting the number of embryos developed to ensure clearer embryo accounting.

3.6. 'Sperm procurement' fields are not required as recording at use or times of movement would meet requirements.

3.7. Congenital abnormalities observed in the baby (currently collected as - Yes/No/Maybe) will not be recorded since the information is known to be incomplete because of the large number of anomalies which would not be identified at birth or immediate perinatal period potentially giving false outcome information.

4. Data elements added or amended in the data collected

4.1. When the HFEA issued new guidance around surrogacy treatments in clinic it was recognised that those involved should not always be recorded as donors but the changes required for The following elements have been added:

- New role of 'intended parent'
- Is donor known to patient on treatment
- IVM as treatment option
- Details of treatment carried out at a primary clinic's satellite or transport centre.
- Number of embryos re-frozen
- Embryo & egg storage now recording if slow freeze or vitrification used
- BMI at time of treatment
- Number of embryos remaining in storage
- NHS status indicator and identification type
- Items required for collection of mitochondrial donation treatments, including mitochondrial donor, PNT only sperm donor and additional treatment fields when MRT treatments occur. They have been included in the data dictionary but kept separate as possible so that clinics which aren't doing MRT, nor plan to, do not need to consider them when reviewing the data dictionary.

- Confirmation flags for some fields to replace confirmation that currently takes place at verification.
- Extra fields on for Single European Code (SEC) – the new European Directive requirements being introduced in 2017
- The current 'screening type' list is replaced with shorter list under 'embryo biopsy'

5. Standardisation Committee for Care Information (SCCI)

5.1. SCCI was setup by the National Information Board (NIB) to ensure common standards in data collection. It does so by reviewing the details of collections and issuing Information Standards Notices (ISNs). The Health and Social Care Information Centre (HSCIC) supports applicants to prepare papers so that applications are consistent with HSCIC standards and provide sufficient detail for SCCI to make a decision.

5.2. HFEA staff have been working with HSCIC staff to enable the HFEA Register Data submission to become an official ISN. It will be called UK ART Data Set. There are number of stages to the process and we have passed the 'need' stage and working towards moving from 'need' to 'requirement'. This is currently planned for May 2016 SCCI board. There is a subsequent stage from 'requirement' to 'full' which we would hope to accomplish in July 2016.

5.3. Some of the changes described above have been driven by wanting to ensure compatibility of data standards with those set at national level. This applies to both the data and submission mechanism.

6. The data submission system

6.1. The changes to the data collected should be seen alongside the planned improvements in the data *collection* method. The IfQ aim to reduce the burden for centres has always been firmly based on changing the collection method.

6.2. The changes in method of data entry are being developed, and will include:

- Improve accuracy of inputting information by using more on screen prompts and guidance on what needs recording and access to data descriptions while inputting
- More incentives to improve the quality of information by the use of flagging and more real-time error information so that issues can be readily understood and problems fixed on the spot.
- Saving time and improving quality by having no opportunity for clinics to enter duplicate information and consequent issues with identifying and deleting previous or copy records.

- Minimising the burden of clinics undertaking periodic verification work by confirming information as it is the data is entered when notes are readily available for checking.

Annex 2 (Proposed Data Dictionary)

Information for Quality programme: update
Annex 2 (Proposed Data Dictionary)

The details below are of the proposed data dictionary for HFEA Register data submission. This presentation is a limited version of the data dictionary which will be submitted to SCCI board as UK ART Data set. There will be version available soon with additional fields available, showing links to existing NHS data dictionary elements where they exist, whether fields are mandatory and data validation rules.

Note: the data below has been grouped into tables to clearly define what centres are expected to collect for inclusion on the HFEA Register the re-development of the data collection system may use differently structured tables for the collection process. In particular the information that needs to be collected for patients, partners and intended parents has considerable overall around personal details but is included in each table here.

Summary of tables

Table name	Overview
Patient Details table	This table should include a record for each patient being treated. The patient is the woman who is undergoing egg collection and/or will receive embryos. The patient number is assigned by the centre and must be unique within the centre.
Partner Details table	This table should include a record for each partner. A partner (male or female) of the woman who is undergoing treatment to become pregnant and where that partner intends to be the legal parent of any child born as a result of treatment. Partner information does not need to be supplied if the woman is a gestational surrogate. The partner record is linked to the patient by inclusion on the partner record of the patient number.
Intended Parent Details table	This table should include a record for each intended parent. An intended parent is person (usually as part of a couple) who is providing gametes for the use in treatment and is intending to be the parent of any children born from the treatment but is not undergoing the treatment.
Donor Registrations	This table should include a record for each egg or sperm donor registered.
Donor re-registrations	This table should include a record for each donor re-registration. Those who donated before 1/4/2005 and are currently anonymous to the recipients of their donation can re-register to be identifiable with via the centre where they donated or HFEA.
Mitochondrial Donor Registration details	This table should include a record for each mitochondrial donor. Since the information for a mitochondrial donor differs to that collected for egg donors a person who is both should have a donor record and a mitochondrial.
PNT only sperm donor details	This table should include a record for each PNT only sperm donor. This is a man who provides sperm solely for the fertilisation of mitochondrial donated eggs as part of the PNT (pro-nuclear transfer) mitochondrial treatment of a patient.
Treatment type for the patient	This table should include a record for each patient treatment,
Donor Inseminations	This table should include a record for each donor insemination
Start of stimulation to collect eggs	This table should include a record for each stimulation with the intention of collecting eggs.
Egg Collection	This table should include a record for each egg collection
Mixing of eggs and sperm	This table should include a record for each mixing of eggs from an identifiable person with the sperm from an identifiable person. Separate records need to be created where the eggs from one person are mixed with sperm from 2 different men. This includes the record of transfer or storage of embryos created from the mixing.
Frozen embryo transfers	This table should include a record for each time frozen embryos are thawed for transfer. It also records where embryos are

	thawed and then re-frozen.
Early Outcome	This table should include a record for each embryo transfer event
Outcome of pregnancy	This table should include a record for the outcome of each embryo transfer event that resulted in a pregnancy and holds information that would be common to several fetal outcomes. The detailed outcome from each fetal heart should be included on fetal outcomes table.
Individual fetal outcomes of pregnancy	This table should have a record for every fetal heartbeat indicated on early outcome form for the treatment. Information common to the fetal outcomes, e.g. country of birth is included on outcome.
Transfer out	This table should have a record for each transfer out of eggs or embryos or donor sperm.
Transfer in	This table should have a record for each transfer in of eggs or embryos or donor sperm.
Consent variation	This table should have a record when a patient wished to vary their consent from the originally submitted. The consent covered in this table is the consent to use of their identifying information in contact or non-contact research.

Contents

Patient details table

Data Item Name	Access Name	Definition	Format	Codes	Value Descriptions
UK ART Centre Number	CentreCode	This is HFEA assigned centre number for licenced UK centre.	an4		0001 - 9999
Local Patient Identifier	PATIENTNO	This is the number given to the patient by the centre. This is allocated by the centre, unique within the centre and used by the centre.	an13		
Patient Forenames	Forename	The forenames of the female patient who will receive embryo transfer or insemination with intention of giving birth to a child. This will be as written on their NHS number/ID.	an50		Free text
Patient Surname	Surname	The surname of the female patient who gave birth to the child. This will be as written on their NHS number/ID.	an50		Free text
Patient Date of birth	DoB	Date of birth of the patient	Date		
Unusual DoB confirmation	UnusualDOB	This is for centres to provide confirmation on dates of birth which show the patient is under 18 or over 49 at the time of registration or treatment. Centre will be prompted to confirm the DoB is correct when a patient's calculated age at registration or treatment is under 18 or over 50.	a1	Y	Should be set to Y when asked and DoB is correct.
Patient Surname at birth	surnameAtBirth	Surname of patient at birth (if different from current)	an50		Free text
Patient Town or district of birth	BirthTownDistrict	Town or district of birth of the patient	an50		Free text
Patient Country of birth	birthCountry	Country of birth of the patient	a3		ISO codes
				ZZZ	Not stated
				EEE	England
				WWW	Wales
				SSS	Scotland
				NNN	Northern Ireland
IDENTIFIER TYPE	IDType	Indicates what sort of identifier the patient has supplied. It is expected that patients will provide NHS / CHI / HCN numbers but where if not this shows reason and what number was provided instead. Only NHS numbers can be traced by HSCIC.	an1	1	NHS number has been provided
				2	CHI - Community Health Index (Scotland) provided.
				3	HCN - Health Care Number (Northern Ireland) provided
				4	Travelled from abroad for treatment - passport number provided
				5	UK resident unable to provide NHS/CHI/HCN number - passport provided instead

Data Item Name	Access Name	Definition	Format	Codes	Value Descriptions
				6	UK resident where neither NHS/CHI/HCN or passport number supplied but another identifier, e.g. driving licence
NHS / CHI / HCN NUMBER	NHSCHIHCN NO	This is the NHS / CHI / HCN number of the patient.	n10		
NHS NUMBER STATUS INDICATOR CODE	NHSNOStatus	Where NHS number has been given this Indicates the status of the NHS Code	an2	01	Number present and verified
				02	Number present but not traced
				03	Trace required
				04	Trace attempted - No match or multiple match found
				05	Trace needs to be resolved - (NHS Number or PATIENT detail conflict)
				06	Trace in progress
				07	Number not present and trace not required
				08	Trace postponed (baby under six weeks old)
PassportNo	PassportNo	Passport number of patient provided for identification purposes	an20		
Passport country of issue	PassportCount ry	Country of issue of passport whose number has been entered in passport number field	a3		ISO 3 character country codes
Patient Ethnic Category Code	ETHNIC	The ethnicity of a PATIENT, as specified by the PATIENT. The first character of the value must be from the list below.	an2	**White**	
				A	British
				B	Irish
				C	Any other White background
				Mixed	
				D	White and Black Caribbean
				E	White and Black African
				F	White and Asian
				G	Any other mixed background
				Asian or Asian British	
				H	Indian
				J	Pakistani
				K	Bangladeshi
				L	Any other Asian background
				Black or Black British	
				M	Caribbean
				N	African
				P	Any other Black background

Data Item Name	Access Name	Definition	Format	Codes	Value Descriptions
				Other Ethnic Groups	
				R	Chinese
				S	Any other ethnic group
				Z	Not Stated
Is the patient disabled	Disabled	Records whether the patient is disabled. This is self-declared by the patient and does not have to be registered disability.	an1	Y	Patient has indicated that they have a disability
				N	Patient has indicated that they have NO disability
Number of previous natural or DI pregnancies	previousNaturalDIPregnancies	A pregnancy is said to have occurred if a test on a sample of urine or blood to detect pregnancy hormone (βhCG) is positive or an ultrasound scan confirms a gestation at any site. This will include a pregnancy reported by the patient even if it was not confirmed in a clinic/GP. It includes pregnancies to any partner.	n2		
Number of natural or DI live births	NaturalDILive Births	The number of live birth events that result from a conception that did not involve IVF(including ICSI). This will be as reported by the patient. It includes pregnancies to any partner. It includes conception involving donor insemination.	n2		
Number of previous IVF	PreviousIVFPregnancies	The number of IVF treatments previously started in which stimulation medication was taken or treatment was intended in a natural ovarian cycle. This information is reported as given by the patient at the start of treatment. It includes pregnancies to any partner.	n2		
Number of IVF live births	IVFLiveBirths	The number of live birth events from a conception that involved IVF(including ICSI) and frozen/thawed embryos. This information is reported as given by the patient at the start of the treatment. It includes pregnancies to any partner.	n2		
Date that intercourse without contraception started.	DateInfertilityStart	From this date, the duration of Infertility can be calculated. This will be approximate date in most cases. Where month is known 15 should be used as day, where only year is known use 1 July, e.g. 01/07/2013. It indicates the date at which the couple stopped using contraception with the assumption that it would then be possible to conceive. If there has been no chance of pregnancy i.e. the partner has had a vasectomy or same sex couple this should be left blank. If the patient has had a previous live birth, this date relates to the period after that pregnancy.	an10		
Height in metres	HeightM	The height in metres of the patient at the time of registration.	n1. max n2		
Weight in kilograms	WeightKGS	The weight in kilograms of the patient at the time of registration	n3.max n3		
Body Mass Index (BMI)	BMI	Body mass index of patient at time of registration. This will be calculated for the centre if height and weight are provided.	n2.n1		

Data Item Name	Access Name	Definition	Format	Codes	Value Descriptions
Consent to non-contact research	ConsentNonContactResearch	This is taken from the CD form completed by the patient in 'Disclosing your identifying information ..' section. This records whether they agreed or not to non-contact research.	an1	Y	Yes
				N	No
Consent to contact research	ConsentContactResearch	This is taken from the CD form completed by the patient in 'Disclosing your identifying information ..' section. This records whether they agreed or not to contact research.	an1	Y	Yes
				N	No
Comments on any part of the patients details	Comments	This is to allow the clinic to add any relevant comments that they wish as free text.	an250		
Date comment added	CommentDate	This is the date the comment was added.	Date		

Partner details table

Data Item Name	Access Name	Definition	Format	Codes	Value Descriptions
UK ART Centre Number	CentreCode	This is HFEA assigned centre number for licenced UK centre.	an4		
Local Patient Identifier	PARTNERNO	This is the number given to the partner by the centre. This is unique within the centre, allocated and used by the centre.	an13		
Link to patient	PATIENTNO	This is unique number of the patient who is linked to this partner. This provides link between partner and patient records.	an13		
Forenames	Forename	The forenames of the partner. This will be as written on their NHS number/ID.	an50		Free text
Surname	Surname	The surname of the partner. This will be as written on their NHS number/ID.	an50		Free text
Date of birth	DoB	Date of birth of this individual	Date		
Surname at birth	surnameAtBirth	Surname of partner at birth (if different to current surname)	an50		
Gender of the partner	PartnerGender	This is the sex of the partner, if they are a gamete provider within a treatment cycle this should define their role of either egg or sperm source. Thus a transsexual male to female whose sperm was being used in treatment should be recorded as male.	an1	1	Male
				2	Female
Town or district of birth	BirthTownDistrict	Town or district of birth of the partner	an50		
Partner Country of birth	BirthCountry	Country of birth of the partner	a3		ISO country codes
				ZZZ	Not stated
				EEE	England
				WWW	Wales
				SSS	Scotland

Data Item Name	Access Name	Definition	Format	Codes	Value Descriptions
				NNN	Northern Ireland
IDENTIFIER TYPE	IDType	Indicates what sort of identifier the partner has supplied. It is expected that partners will provide NHS / CHI / HCN numbers but where this is not possible this shows reason and what number was provided instead. Only NHS numbers can be traced by HSCIC.	an1	1	NHS number has been provided
				2	CHI - Community Health Index (Scotland) provided.
				3	HCN - Health Care Number (Northern Ireland) provided
				4	Travelled from abroad for treatment - passport number provided
				5	UK resident unable to provide NHS/CHI/HCN number - passport provided instead
				6	UK resident where neither NHS/CHI/HCN or passport number supplied but another identifier, e.g., driving licence
NHS / CHI / HCN NUMBER	NHSCHIHCN NO	This is the NHS / CHI / HCN number of the partner	n10		
NHS NUMBER STATUS INDICATOR CODE	NHSNOStatus	Indicates the status of the NHS Code	an2	01	Number present and verified
				02	Number present but not traced
				03	Trace required
				04	Trace attempted - No match or multiple match found
				05	Trace needs to be resolved - (NHS Number or PATIENT detail conflict)
				06	Trace in progress
				07	Number not present and trace not required
				08	Trace postponed (baby under six weeks old)
PassportNo	PassportNo	Passport number of partner provided for identification purposes	an20		
Passport country of issue	PassportCount ry	Country of issue of passport whose number has been entered in passport number field	a3		
Ethnic Category	ETHNIC	The ethnicity of a PARTNER as specified by the PARTNER. The first character of the value must be from the list below.	an2	**White**	
				A	British
				B	Irish
				C	Any other White background

Data Item Name	Access Name	Definition	Format	Codes	Value Descriptions
				Mixed	
				D	White and Black Caribbean
				E	White and Black African
				F	White and Asian
				G	Any other mixed background
				Asian or Asian British	
				H	Indian
				J	Pakistani
				K	Bangladeshi
				L	Any other Asian background
				Black or Black British	
				M	Caribbean
				N	African
				P	Any other Black background
				Other Ethnic Groups	
				R	Chinese
				S	Any other ethnic group
				Z	Not Stated
Consent to non-contact research	consentNonContactResearch	This is taken from the CD form completed by the person in 'Disclosing your identifying information ..' section. This records whether they agreed or not to non-contact research.	an1	Y	Yes
				N	No
Consent to contact research	consentContactResearch	This is taken from the CD form completed by the person in 'Disclosing your identifying information ..' section. This records whether they agreed or not to contact research.	an1	Y	Yes
				N	No
Comments on any part of the partner details	Comments	This is to allow the clinic to add any relevant comments that they wish as free text.	an250		
Date comment added	CommentDate	This is the date that the comment was added.	Date		

Intended Parent details table

Data Item Name	Access Name	Definition	Format	Codes	Value Descriptions
UK ART Centre Number	CentreCode	This is HFEA assigned centre number for licenced UK centre.	an4		
Local Patient Identifier	IntendParentNo	This is the number given to the intended parent by the centre. This is unique within the centre and used by the centre.	an13		
Forenames	forename	The forenames of the intended parent. This will be as written on their NHS number/ID.	an50		
Surname	surname	The surname of the intended parent who gave birth to the child. This will be as written on their NHS number/ID.	an50		

Data Item Name	Access Name	Definition	Format	Codes	Value Descriptions
Date of birth	DoB	Date of birth of this of the intended parent	Date		
Surname at birth	surnameAtBirth	Surname of intended parent at birth	an50		
Gender of the intended parent	gender	This is the biological sex of the partner, if they are a gamete provider within a treatment cycle this should define their role of either egg or sperm source. Thus a transsexual male to female whose sperm was being used in treatment should be recorded as male.	an1	1	Male
				2	Female
Town or district of birth	birthTown/district	Town or district of birth of the intended parent	an30		
Intended parent Country of birth	birthCountry	Country of birth of the intended parent	a3		ISO codes
				ZZZ	Not stated
				EEE	England
				WWW	Wales
				SSS	Scotland
				NNN	Northern Ireland
IDENTIFIER TYPE	IDType	Indicates what sort of identifier the intended parent has supplied. It is expected that intended parents will provide NHS / CHI / HCN numbers but where if not this shows reason and what number was provided instead. Only NHS numbers can be traced by HSCIC.	an1	1	NHS number has been provided
				2	CHI - Community Health Index (Scotland) provided.
				3	HCN - Health Care Number (Northern Ireland) provided
				4	Travelled from abroad for treatment - passport number provided
				5	UK resident unable to provide NHS/CHI/HCN number - passport provided instead
				6	UK resident where neither NHS/CHI/HCN or passport number supplied but another identifier, e.g., driving licence
NHS / CHI / HCN NUMBER	NHSCHIHCNNO	This is the NHS/CHI/HCN number of the intended parent.	n10		
NHS NUMBER STATUS INDICATOR CODE	NHSNOStatus	Indicates the status of the NHS Code	an2	01	Number present and verified
				02	Number present but not traced
				03	Trace required
				04	Trace attempted - No match or multiple match found

Data Item Name	Access Name	Definition	Format	Codes	Value Descriptions
				05	Trace needs to be resolved - (NHS Number or PATIENT detail conflict)
				06	Trace in progress
				07	Number not present and trace not required
				08	Trace postponed (baby under six weeks old)
PassportNo	PassportNo	Passport number of intended parent provided for identification purposes	an20		
Passport country of issue	PassportCountry	Country of issue of passport whose number has been entered in passport number field	a3	ISO Codes	
Ethnic Category	ETHNIC	The ethnicity of an intended parent as specified by the intended parent. The first character of the value must be from the list below.	an2	**White**	
				A	British
				B	Irish
				C	Any other White background
				Mixed	
				D	White and Black Caribbean
				E	White and Black African
				F	White and Asian
				G	Any other mixed background
				Asian or Asian British	
				H	Indian
				J	Pakistani
				K	Bangladeshi
				L	Any other Asian background
				Black or Black British	
				M	Caribbean
				N	African
				P	Any other Black background
				Other Ethnic Groups	
				R	Chinese
				S	Any other ethnic group
				Z	Not Stated
Last UK centre if treatment elsewhere	lastUKTreatmentClinic	If intended parent has been treated elsewhere this is centre code of last UK treatment.	an4		
Consent to non-contact research	consentNonContactResearch	This is taken from the CD form completed by the intended parent in 'Disclosing your identifying information ..' section. This records whether they agreed or not to non-contact research.	an1	Y	Yes
				N	No
Consent to contact research	consentContactResearch	This is taken from the CD form completed by the intended parent in 'Disclosing your identifying information ..' section. This	an1	Y	Yes
				N	No

Data Item Name	Access Name	Definition	Format	Codes	Value Descriptions
		records whether they agreed or not to contact research.			
Comments on any part of the intended parent details	Comments	This is to allow the clinic to add any relevant comments that they wish as free text.	an250		
Date comment added	CommentDate	This is the date that the comment was added.	Date		

Donor details table

Data Item Name	Access Name	Definition	Format	Codes	Value Descriptions
UK ART Centre Number	CentreCode	This is HFEA assigned centre number for licenced UK centre.	an4		0001 - 9999
NUMBER OF DONOR	DONORNO	This is the unique number given to the donor in the clinic when gametes are collected and stored. If the donor has been imported from outside the UK the centre will register the donor and the first 2 characters should represent the country where the donor lived at time of donation.	an13		
Donor current surname	Surname	The current surname of the donor as written on their NHS number/ID.	an50		
Donor forenames	ForeName	The current forenames of the donor as written on their NHS number or ID.	an50		
Donor surname at birth (if different)	SurnameAtBirth	The surname of the donor at birth	an50		
Donor forenames at birth (if different)	ForeNameAtBirth	Any previously used forenames	an50		
Date of birth of donor	DoB	Date of birth of the donor	an10		
Town or district of birth	birthTown/district	Town of District of birth of the donor	an30		
Donor Country of birth	BirthCountry	The country of birth of the donor	a3		ISO 3 character country codes
				ZZZ	Not stated
				EEE	England
				WWW	Wales
				SSS	Scotland
				NNN	Northern Ireland
IDENTIFIER TYPE	IDType	Indicates what sort of identifier the donor has supplied. It is expected that donor will provide NHS / CHI / HCN numbers but where if not this shows reason and what number was provided instead. Only NHS numbers can be traced by HSCIC.	an1	1	NHS number has been provided
				2	CHI - Community Health Index (Scotland) provided.
				3	HCN - Health Care Number

Data Item Name	Access Name	Definition	Format	Codes	Value Descriptions
					(Northern Ireland) provided
				4	Travelled from abroad for treatment - passport number provided
				5	UK resident unable to provide NHS/CHI/HCN number - passport provided instead
				6	UK resident where neither NHS/CHI/HCN or passport number supplied but another identifier, e.g., driving licence
NHS / CHI / HCN NUMBER	NHSCHIHCN NO	This is the NHS/CHI/HCN number of the donor.	n10		
NHS NUMBER STATUS INDICATOR CODE	NHSNOStatus	Indicates the status of the NHS Code	an2	01	Number present and verified
				02	Number present but not traced
				03	Trace required
				04	Trace attempted - No match or multiple match found
				05	Trace needs to be resolved - (NHS Number or PATIENT detail conflict)
				06	Trace in progress
				07	Number not present and trace not required
				08	Trace postponed (baby under six weeks old)
PassportNo	PassportNo	Passport number of patient provided for identification purposes	an15		
Passport country of issue	PassportCountry	Country of issue of passport whose number has been entered in passport number field	a3		ISO 3 character country codes
Current address	BS7666Address	The address of the donor at the time of donation			
Donor phone	DonorPhone	This is the contact phone number provided by the donor.	an20		
Donor email	DonorEmail	This is the email provided by the donor.	an100		
Person marital status	MaritalStatus	An indicator to identify the legal marital status of a DONOR.	an1	S	Single
				M	Married / In Civil Partnership
				D	Divorced/Person whose Civil Partnership has been dissolved

Data Item Name	Access Name	Definition	Format	Codes	Value Descriptions
				W	Widowed/Surviving Civil Partner
				P	Separated
				N	Not Disclosed
Does donor have own biological children?	OwnBiological Children	This asks if the donor has their own biological children and should be answered Y/N. If yes the number of boys and girls needs to be completed	an1	Y	Yes
				N	No
Number of own boys	OwnChildrenBoys	This is the number of male children born to this donor at the time of donation..	n2		
Number of own girls	OwnChildrenGirls	This is the number of female children born to this donor at the time of donation.	n2		
Height in metres	HeightM	The height in metres of the donor at the time of donation.	n1. max n2		
Weight in Kilograms	WeightKGS	The weight in kilograms of the donor at the time of donation	n3.max n3		
Eye colour of donor	EyeColourLookUpID	The eye colour of the donor.	an2	01	Blue
				02	Brown
				03	Green
				04	Grey
				05	Hazel
				06	Green/brown
				07	Blue/Grey
				08	Blue/Green
				09	Green/Grey
				10	Green/Hazel
				11	Black
				12	Blue/Green/Grey
				13	Dark Brown
Natural Hair colour of donor	HairColourID	The natural hair colour of the donor.	an2	01	Black
				02	Blonde dark
				03	Blonde light
				04	Brown dark
				05	Brown light
				06	Red
Skin colour of donor	SkinColourID	The skin colour of the donor.	an2	01	Light/Fair
				02	Medium
				03	Dark
				04	Freckles
				05	Olive
Last UK centre if donated previously	lastUKTreatmentClinic	If donor has donated elsewhere this is centre code of last UK donation treatment. If the donor is known to have also donated	an4		

Data Item Name	Access Name	Definition	Format	Codes	Value Descriptions
		outside the centres should enter 9005			
Was the donor adopted?	adopted	If the donor knows that they were adopted, this is recorded as 'yes'.	an1	Y	Yes
				N	No
Was the donor conceived by donation?	conceivedByDonation	If the donor knows that they were donor-conceived, this is recorded as 'yes'.	an1	Y	Yes
				N	No
Ethnic category of donor	ETHNIC	The ethnicity of a DONOR, as specified by the DONOR. The first character of the value must be from the list below.	an1	**White**	
				A	British
				B	Irish
				C	Any other White background
				Mixed	
				D	White and Black Caribbean
				E	White and Black African
				F	White and Asian
				G	Any other mixed background
				Asian or Asian British	
				H	Indian
				J	Pakistani
				K	Bangladeshi
				L	Any other Asian background
				Black or Black British	
				M	Caribbean
				N	African
				P	Any other Black background
				Other Ethnic Groups	
				R	Chinese
				S	Any other ethnic group
				Z	Not Stated
Ethnic group of donor's mother	mothersEthnicity	The ethnicity of the mother of the DONOR, as specified by the DONOR. The first character of the value must be from the list below.	an1	**White**	
				A	British
				B	Irish
				C	Any other White background
				Mixed	
				D	White and Black Caribbean
				E	White and Black African
				F	White and Asian
				G	Any other mixed background
				Asian or Asian British	
				H	Indian
				J	Pakistani
				K	Bangladeshi

Data Item Name	Access Name	Definition	Format	Codes	Value Descriptions
				L	Any other Asian background
				Black or Black British	
				M	Caribbean
				N	African
				P	Any other Black background
				Other Ethnic Groups	
				R	Chinese
				S	Any other ethnic group
				Z	Not Stated
Ethnic group of donor's father	FathersEthnicity	The ethnicity of the father of the DONOR, as specified by the DONOR. The first character of the value must be from the list below.	an1	**White**	
				A	British
				B	Irish
				C	Any other White background
				Mixed	
				D	White and Black Caribbean
				E	White and Black African
				F	White and Asian
				G	Any other mixed background
				Asian or Asian British	
				H	Indian
				J	Pakistani
				K	Bangladeshi
				L	Any other Asian background
				Black or Black British	
				M	Caribbean
				N	African
				P	Any other Black background
				Other Ethnic Groups	
				R	Chinese
				S	Any other ethnic group
				Z	Not Stated
How many families has the donor consented to?	LimitFamilyNo	This is the information that is recorded in the clinical records about the decision made by the donor in relation to the maximum number of family units that they wish to result from their donation. This value can't be more than 10.	n2		
Consent to non-contact research	consentNonContactResearch	This is taken from the CD form completed by the donor in 'Disclosing your identifying information ..' section. This records whether they agreed or not to non-contact research.	an1	Y	Yes
				N	No
Consent to contact research	consentContactResearch	This is taken from the CD form completed by the donor in 'Disclosing your identifying information ..' section. This records whether they agreed or not to contact research.	an1	Y	Yes
				N	No

Data Item Name	Access Name	Definition	Format	Codes	Value Descriptions
Comments on any part of the intended parent details	Comments	This is to allow the clinic to add any relevant comments that they wish as free text.	an250		
Date comment added	CommentDate	This is the date that the comment was added.	Date		

Donor Re-registration table

Data Item Name	Access Name	Definition	Format	Codes	Value Descriptions
UK ART Centre Number	CentreCode	This is HFEA assigned centre number for licenced UK centre. This is the centre where donor was registered.	an4		
Local Donor Identifier	DONORNO	This is the donor number given to the donor by the centre, This will be a unique reference number within the centre and will be the number by which the centre have recorded details of the donor. Centres need to register donors which they have recruited or imported from outside the UK.	an13		
Donor current surname	surname	The current surname of the donor as written on their NHS number/ID.	an50		
Donor forenames	foreName	The current forename of the donor as written on their NHS number/ID.	an50		
Donor surname at birth (if different)	surnameAtBirth	The surname of the donor at birth	an50		
Donor forenames at birth (if different)	foreNameAtBirth	Any previously used forenames	an50		
Date of birth of donor	DoB	Date of birth of the donor	Date		
Town or district of birth	birthTown/district	Town of District of birth of the donor	an50		
Donor Country of birth	birthCountry	The country of birth of the donor	a3		ISO codes
				ZZZ	Not stated
				EEE	England
				WWW	Wales
				SSS	Scotland
				NNN	Northern Ireland
IDENTIFIER TYPE	IDType	Indicates what sort of identifier the donor has supplied. It is expected that donor will provide NHS / CHI / HCN numbers but where if not this shows reason and what number was provided instead. Only NHS numbers can be traced by HSCIC.	an1	1	NHS number has been provided
				2	CHI - Community Health Index (Scotland) provided.
				3	HCN - Health Care Number (Northern Ireland) provided

Data Item Name	Access Name	Definition	Format	Codes	Value Descriptions
				4	Travelled from abroad for treatment - passport number provided
				5	UK resident unable to provide NHS/CHI/HCN number - passport provided instead
				6	UK resident where neither NHS/CHI/HCN or passport number supplied but another identifier, e.g., driving licence
NHS / CHI / HCN NUMBER	NHSCHIHCNNO	This is the NHS/CHI/HCN number of the donor.	n10		
NHS NUMBER STATUS INDICATOR CODE	NHSNOStatus	Indicates the status of the NHS Code	an2	01	Number present and verified
				02	Number present but not traced
				03	Trace required
				04	Trace attempted - No match or multiple match found
				05	Trace needs to be resolved - (NHS Number or PATIENT detail conflict)
				06	Trace in progress
				07	Number not present and trace not required
				08	Trace postponed (baby under six weeks old)
PassportNo	PassportNo	Passport number of patient provided for identification purposes	an15		
Passport country of issue	PassportCountry	Country of issue of passport whose number has been entered in passport number field	a3		ISO country codes
Current address	BS7666Address	The address of the donor at the time of donation			
Gender of the donor	gender	This is the gender as provided on the donor re-registration application of the individual.	an1	1	Male
				2	Female
Donor phone	DonorPhone	This is the contact phone number provided by the re-registering donor.	an20		
Donor email	DonorEmail	This is the email provided by the re-registering donor.	an100		
Comments on any part of the donor re-registration details	Comments	This is to allow the clinic to add any relevant comments that they wish as free text.	an250		
Date comment added	CommentDate	This is the date that the comment was added.	Date		

Mitochondrial Donor table

Data Item Name	Access Name	Definition	Format	Codes	Value Descriptions
UK ART Centre Number	CentreCode	This is HFEA assigned centre number for licenced UK centre.	an4		
Local Patient Identifier	DONORNO	This is the number given to the mitochondrial donor by the centre. This is unique within the centre and used by the centre	an13		
Forenames	forename	The forenames of the mitochondrial donor. This will be as written on their NHS number/ID.	an50		
Surname	surname	The surname of the mitochondrial donor who gave birth to the child. This will be as written on their NHS number/ID.	an50		
Date of birth	DoB	Date of birth of Donor	an10		
Surname at birth	surnameAtBirth	Surname of mitochondrial donor at birth	an50		
Town or district of birth	birthTown/district	Town or district of birth of the mitochondrial donor	an30		
Donor Country of birth	birthCountry	Country of birth of the mitochondrial donor	a3		ISO country codes
				ZZZ	Not stated
				EEE	England
				WWW	Wales
				SSS	Scotland
				NNN	Northern Ireland
IDENTIFIER TYPE	IDType	Indicates what sort of identifier the donor has supplied. It is expected that donor will provide NHS / CHI / HCN numbers but where if not this shows reason and what number was provided instead. Only NHS numbers can be traced by HSCIC.	an1	1	NHS number has been provided
				2	CHI - Community Health Index (Scotland) provided.
				3	HCN - Health Care Number (Northern Ireland) provided
				4	Travelled from abroad for treatment - passport number provided
				5	UK resident unable to provide NHS/CHI/HCN number - passport provided instead
				6	UK resident where neither NHS/CHI/HCN or passport number supplied but another identifier, e.g., driving licence
NHS / CHI / HCN NUMBER	NHSCHIHCNNO	This is the NHS/CHI/HCN number of the donor.	n10		
NHS NUMBER STATUS INDICATOR CODE	NHSNOStatus	Indicates the status of the NHS Code	an2	01	Number present and verified
				02	Number present but not traced

Data Item Name	Access Name	Definition	Format	Codes	Value Descriptions
				03	Trace required
				04	Trace attempted - No match or multiple match found
				05	Trace needs to be resolved - (NHS Number or PATIENT detail conflict)
				06	Trace in progress
				07	Number not present and trace not required
				08	Trace postponed (baby under six weeks old)
PassportNo	PassportNo	Passport number of mitochondrial donor provided for identification purposes	an20		
Passport country of issue	PassportCountry	Country of issue of passport whose number has been entered in passport number field	a3		ISO codes
Ethnic Category	ETHNIC	The ethnicity of a mitochondrial donor as specified by the mitochondrial donor. The first character of the value must be from the list below.	an2	**White**	
				A	British
				B	Irish
				C	Any other White background
				Mixed	
				D	White and Black Caribbean
				E	White and Black African
				F	White and Asian
				G	Any other mixed background
				Asian or Asian British	
				H	Indian
				J	Pakistani
				K	Bangladeshi
				L	Any other Asian background
				Black or Black British	
				M	Caribbean
				N	African
				P	Any other Black background
				Other Ethnic Groups	
				R	Chinese
				S	Any other ethnic group
				Z	Not Stated
Last UK centre if treatment elsewhere	lastUKTreatmentClinic	If mitochondrial donor has been treated elsewhere this is centre code of last UK donation.	an4		
Consent to non-contact research	consentNonContactResearch	This is taken from the CD form completed by the mitochondrial donor in 'Disclosing your identifying information ..' section. This	an1	Y	Yes
				N	No

Data Item Name	Access Name	Definition	Format	Codes	Value Descriptions
		records whether they agreed or not to non-contact research.			
Consent to contact research	consentContactResearch	This is taken from the CD form completed by the mitochondrial donor in 'Disclosing your identifying information ..' section. This records whether they agreed or not to contact research.	an1	Y	Yes
				N	No
Comments on any part of the mitochondrial donor details	Comments	This is to allow the clinic to add any relevant comments that they wish as free text.	an250		
Date comment added	CommentDate	This is the date that the comment was added.	Date		

PNT only sperm donor details table

Data Item Name	Access Name	Definition	Format	Codes	Value Descriptions
UK ART Centre Number	CentreCode	This is HFEA assigned centre number for licenced UK centre.	an4		
NUMBER OF DONOR	DONORNO	This is the unique number given to the donor in the clinic when gametes are collected and stored.	an13		
Donor current surname	surname	The current surname of the donor as written on their NHS number/ID.	an50		
Donor forenames	foreName	The current forenames of the donor as written on their NHS number or ID.	an50		
Donor surname at birth (if different)	surnameAtBirth	The surname of the donor at birth	an50		
Donor forenames at birth (if different)	foreNameAtBirth	Any previously used forenames	an50		
Date of birth of donor	DoB	Date of birth of the donor	an10		
Town or district of birth	birthTown/district	Town of District of birth of the donor	an50		
Donor Country of birth	birthCountry	The country of birth of the donor	a3		ISO country codes
				ZZZ	Not stated
				EEE	England
				WWW	Wales
				SSS	Scotland
				NNN	Northern Ireland
IDENTIFIER TYPE	IDType	Indicates what sort of identifier the donor has supplied. It is expected that donor will provide NHS / CHI / HCN numbers but where if not this shows reason and what number was provided instead. Only NHS numbers can be traced by HSCIC.	an1	1	NHS number has been provided
				2	CHI - Community Health Index (Scotland) provided.

Data Item Name	Access Name	Definition	Format	Codes	Value Descriptions
				3	HCN - Health Care Number (Northern Ireland) provided
				4	Travelled from abroad for treatment - passport number provided
				5	UK resident unable to provide NHS/CHI/HCN number - passport provided instead
				6	UK resident where neither NHS/CHI/HCN or passport number supplied but another identifier, e.g., driving licence
NHS / CHI / HCN NUMBER	NHSCHIHCN NO	This is the NHS/CHI/HCN number of the donor.	n10		
NHS NUMBER STATUS INDICATOR CODE	NHSNOStatus	Indicates the status of the NHS Code	an2	01	Number present and verified
				02	Number present but not traced
				03	Trace required
				04	Trace attempted - No match or multiple match found
				05	Trace needs to be resolved - (NHS Number or PATIENT detail conflict)
				06	Trace in progress
				07	Number not present and trace not required
				08	Trace postponed (baby under six weeks old)
PassportNo	PassportNo	Passport number of patient provided for identification purposes	an15		
Passport country of issue	PassportCountry	Country of issue of passport whose number has been entered in passport number field	a3		ISO codes
Ethnic Category	ETHNIC	The ethnicity of a PNT only sperm donor as specified by the PNT only sperm donor. The first character of the value must be from the list below.	an2	**White**	
				A	British
				B	Irish
				C	Any other White background
				Mixed	
				D	White and Black Caribbean
				E	White and Black African
				F	White and Asian
				G	Any other mixed background

Data Item Name	Access Name	Definition	Format	Codes	Value Descriptions
				Asian or Asian British	
				H	Indian
				J	Pakistani
				K	Bangladeshi
				L	Any other Asian background
				Black or Black British	
				M	Caribbean
				N	African
				P	Any other Black background
				Other Ethnic Groups	
				R	Chinese
				S	Any other ethnic group
				Z	Not Stated
Consent to non-contact research	consentNonContactResearch	This is taken from the CD form completed by the PNT only sperm donor in 'Disclosing your identifying information ..' section. This records whether they agreed or not to non-contact research.	an1	Y	Yes
				N	No
Consent to contact research	consentContactResearch	This is taken from the CD form completed by the PNT only sperm donor in 'Disclosing your identifying information ..' section. This records whether they agreed or not to contact research.	an1	Y	Yes
				N	No
Comments on any part of the PNT only sperm donor details	Comments	This is to allow the clinic to add any relevant comments that they wish as free text.	an250		
Date comment added	CommentDate	This is the date the comment was added.	Date		

Treatment type table

Data Item Name	Access Name	Definition	Format	Codes	Value Descriptions
UK ART Centre Number	CentreCode	This is HFEA assigned centre number for licenced UK centre.	an4		
Local Patient Identifier	PATIENTNO	This is the number given to the patient or egg donor by the centre. This is unique within the centre and used by the centre. If this patient or donor number doesn't exist the centre will be prompted to enter basic registration details.	an13		
Main treatment type	MainTreatType	This is the intended primary treatment that is required to be reported under the HFE Act i.e. the creation of a human embryo in vitro or the use of donated gametes for fertility treatment. Multi-	an9	87600016	SNOMED Code - In vitro fertilization - the removal of oocyte(s) from a woman's body which are then placed in culture with a defined population of motile spermatozoa to

Data Item Name	Access Name	Definition	Format	Codes	Value Descriptions
		options are possible,			assist fertilisation and the formation of a diploid zygote. The zygote then undergoes pre-implantation development 'in vitro' and, if appropriate, is returned to a synchronous uterus.
				338482017	SNOMED Code - ICSI - Intracytoplasmic sperm injection - the removal of oocyte(s) from a woman's body which are then each injected with a single spermatozoa to assist fertilisation and the formation of a diploid zygote. The zygote then undergoes pre-implantation development 'in vitro' and, if appropriate, is returned to a synchronous uterus.
				236896006	SNOMED code - Artificial insemination by donor - The placing of spermatozoa from a man who is not her partner and does not intend to be the father of the child, directly into a woman's uterus with the purpose of fertilising oocytes 'in vivo'.
				441369004	SNOMED code - Thawing of cryopreserved embryo (procedure) -Planned replacement of thawed embryos created in a previous treatment
				440645004	SNOMED code - cryopreservation of oocyte. This is recorded where intention at the start of the stimulation procedure is to store eggs and not to create embryos within that treatment procedure e.g. eggs are to be frozen prior to an oncology treatment.
				236912008	SNOMED Code - Gamete Intrafallopian Transfer - GIFT - This is a rarely performed procedure that should be recorded via data submission.
				MRT	SNOMED code yet to be available - Mitochondrial Replacement Therapy
Secondary treatment type	SecondTreatType	These are additional procedures that are required to be submitted under Directions. Multiple options may be included. Further fields may be required and, it appropriate, these may be separated into clinical, embryology or socio-demographic subtitles.	an2	01	Freeze all / storage of embryos - recorded if there is no intention at the start of the stimulation procedure to transfer embryos to the uterus within that treatment procedure e.g. embryos are to be frozen prior for later transfer or long term storage

Data Item Name	Access Name	Definition	Format	Codes	Value Descriptions
					due to an oncology treatment
				02	Screening - Whether any screening will be done on one or all embryos. Screening covers pre- implantation genetic diagnosis (PGD) is the removal of polar bodies, or cell (s) during pre-implantation development 'in vitro' for genetic profiling of the pre-implantation embryo for any other reason.
				03	Use of surgically retrieved sperm – The use of spermatozoa obtained by surgical means directly from the testis or the epididymis for the purpose ICSI in males for whom sperm cannot be obtained by ejaculation.
				04	Thawed eggs used. The thawing of oocytes that have been previously cryopreserved which are then injected with a single spermatozoa to assist fertilisation and the formation of a diploid zygote. The zygote then undergoes pre-implantation development 'in vitro' and is returned to a synchronous uterus.
				05	Surrogate - The woman patient who intends to become pregnant does not intent to be the woman who will care for the child as a parent.
				06	Eggs are collected that are not at metaphase 2 and need development for more than 24 hours before insemination.
				07	Unstimulated / natural cycle - No drugs are given to stimulate the ovaries before treatment is provided e.g. clomifene, gondadotrophins, hCG.

Donor Insemination table

Data Item Name	Access Name	Definition	Format	Codes	Value Descriptions

Data Item Name	Access Name	Definition	Format	Codes	Value Descriptions
UK ART Centre Number	CentreCode	This is HFEA assigned centre number for licenced UK centre.	an4		
Local Patient Identifier	PATIENTNO	This is the number given to the patient by the centre. This is unique within the centre and used by the centre.	an13		
Donor Insemination ID	DonorInsemID	Unique number at centre identifying this DI treatment. This is generated for those submitting directly or supplied by EPRS submitter.	an12		
Sperm donor centre	donorSpermCentre	This is the centre number where the sperm donor is registered. This will be the centre which recruited and procured the donor sperm or imported the sperm from abroad.	an4		
Sperm donor code	spermDonorNumber	This is donor number allocated by the donor sperm centre and unique within the donor centre. If the donor has been imported this code will start with 2 digit country code indicating donor's country of residence at time of donation.	an13		
Stimulated or not	Stimulated	Whether the patient has been stimulated or not before the donor insemination treatment	an1	Y	Yes
				N	No
Date of insemination	DITreatmentDate	This is the first date of insemination. Only the first date of insemination needs to be recorded where the patient is inseminated with donor sperm on several consecutive days	an10		Date as YYYYMMDD
NHS funded treatment?	NHSFunded	States whether NHS funded treatment or not.	an1	Y	Yes
				N	No
Organisation funding treatment	commissioningOrg	The commissioning body where the cycle has been NHS funded - this could be CCG in England, health board in Scotland, Wales or Northern Ireland	an50		
Comments on any part of the donor insemination details	Comments	This is to allow the clinic to add any relevant comments that they wish as free text.	an250		
Date comment added	CommentDate	This is the date that the comment was added.	Date		

Egg stimulation details table

Data Item Name	Access Name	Definition	Format	Codes	Value Descriptions
UK ART Centre Number	CentreCode	This is HFEA assigned centre number for licenced UK centre.	an4		
Local Patient Identifier	PATIENTNO	This is the number given to the patient by the centre. This is unique within the centre and used by the centre.	an13		

Data Item Name	Access Name	Definition	Format	Codes	Value Descriptions
Stimulation date	Stimdate	This is the date stimulation was started for the egg collection process	an10		Date as YYYYMMDD
Stimulation organiser	StimOrganiser	If the stimulation will not or was not done at the centre reporting the subsequent egg collection and mixing or storage then this field records the type of organisation who did organise stimulation for the patient.	an1	1	All stages of treatment completed at this centre.
				2	Stimulation and pre-stimulation patient care completed at satellite or transport centre.
Stimulation location	StimLocation	This will be the centre code or satellite or transport code where stimulation took place.	an8		
Comments on any part of the stimulation details	Comments	This is to allow the clinic to add any relevant comments that they wish as free text.	an250		
Date comment added	CommentDate	This is the date that the comment was added.	Date		

Egg collection details table

Data Item Name	Access Name	Definition	Format	Codes	Value Descriptions
UK ART Centre Number	CentreCode	This is HFEA assigned centre number for licenced UK centre.	an4		
Local Patient Identifier	PATIENTNO	This is the number given to the patient or egg donor by the centre. This is unique within the centre and used by the centre. If this patient or donor number doesn't exist the centre will be prompted to enter basic registration details.	an13		
Egg collection number	EggCollection Record	This is unique number identifying the egg collection	an12		
Egg collection organiser	EggCollOrganiser	If the egg collection was not done at the centre reporting the egg collection and mixing or storage then this field records the type of organisation who did egg collection for the patient.	an1	1	All stages of treatment completed at this centre.
				2	Egg collection, stimulation and pre-stimulation patient care completed at transport centre.
Egg collection location	EggCollLocation	This will be the centre code or satellite or transport centre code where stimulation took place.	an8		

Data Item Name	Access Name	Definition	Format	Codes	Value Descriptions
Egg collection/ abandonment/ thaw of eggs date/Freeze date	EggDate	This is date that the eggs are collected or the date that the decision is made to abandon a planned IVF or ICSI treatment after the stimulation of the ovaries has started but the egg collection has not taken place. If thawed eggs are used, this is the date of the thawing of the eggs. If any eggs collected are frozen this is the date of freezing.	an10		
EggDate indicator	EggDateFlag	This flags whether the eggdate refers to a collection date or a cycle abandoned date or an egg thaw date.	an1	1	Fresh egg collection date
				2	Egg collection abandoned date - when no egg collection was attempted
				3	Egg thaw date
Total number of eggs collected from patient	TotalEggsCollected	Total number of eggs collected from patient	n3		
Unusual egg number confirmation	Unusualeggnumbers	This is for centres to provide confirmation egg numbers if they are unusual in the context of the egg collection. This will apply if egg collection is unstimulated but not IVM and more than 2 eggs are collected or if more than 40 eggs are collected.	a1	Y	Should be set to Y when asked and data is correct.
Number of eggs mixed IVF		This is the number of eggs to which sperm were added by conventional insemination	n2		
Number of eggs injected with sperm ICSI		This is the number of eggs injected using the technique of ICSI	n2		
Number of eggs donated fresh	EggsDonatedFresh	Number of eggs donated for use by egg recipient fresh	n2		
Number of eggs donated for mitochondria donation treatment only	EggMitoDonated	Number of eggs donated for use in mitochondrial donation treatment	n2		
Number donated for research	EggsResearch	Number of eggs donated for research	n2		
Number of eggs stored for patient	EggsFrozen	Number of eggs stored for future use by patient	n2		
Number of eggs donated frozen	EggsDonatedFrozen	Number of eggs donated which have been stored for future recipient	n2		
Method of egg freezing	EggFreezeMethod	Method of egg freezing. Where eggs have been stored for future use of patient or donated for future use is defined the method of freezing.	an1	1	Frozen via vitrification method
				2	Frozen using slow freeze method

Data Item Name	Access Name	Definition	Format	Codes	Value Descriptions
Number of eggs discarded	EggsDiscarded	Number of eggs discarded, those which are not suitable for fresh mixing, donation or frozen	n2		
Comments on any part of the donor insemination details	Comments	This is to allow the clinic to add any relevant comments that they wish as free text.	an250		
Date comment added	CommentDate	This is the date that the comment was added.	Date		

Mixing details of an individual woman's eggs with an individual man's sperm

Data Item Name	Access Name	Definition	Format	Codes	Value Descriptions
UK ART Centre Number	CentreCode	This is HFEA assigned centre number for licenced UK centre.	an4		
Local Patient Identifier	PATIENTNO	This is the number given to the patient by the centre. This is unique within the centre and used by the centre. This is the female who	an13		
MixingID	MixingID	This is unique number identifying generated by the centre for this mixing event	an12		
Gamete source	Gamete source	Gamete source. Each mixing can only have one egg provider (either patient's own eggs or donated eggs) and one sperm provided (either from the patients' partner or from a donor)	an1	1	Patient eggs and partner sperm
				2	Patient eggs and donor sperm
				3	Donor eggs and patient's partners sperm
				4	Donor eggs and donor sperm
Egg collection number	EggCollectionRecord	This is the record number of the egg collection which is the source of the eggs being mixed. When the mixing event is using donated eggs this is the egg collection number which records the donated eggs collection or transfer file number import for imported donor eggs	an12		
Partner number	PartnerNo	The number of the patient's partner whose sperm is being used in the creation of embryos	an13		
Sperm donor centre	SpermDonorCentre	This is the centre number where the sperm donor is registered. This will be the centre which recruited and procured the donor sperm or imported the sperm from abroad.	an4		

Data Item Name	Access Name	Definition	Format	Codes	Value Descriptions
Sperm donor code	SpermDonorNumber	This is donor number allocated to the sperm donor by the sperm donor centre and unique within the centre who have registered the donor.	an13		
Egg donor centre	EggDonorCentre	This is the centre number where the egg donor is registered. This will be the centre which recruited and procured the donor eggs or imported the eggs from outside UK.	an4		
Egg donor code	EggDonorNumber	This is donor number allocated by the egg donor centre and unique within the egg donor centre.	an13		
Egg and sperm mixing date	MixingDate	This is the date of egg and sperm mixing where different to the egg collection date	an10		
Number of embryos developed after IVF.	IVFembryos	This is the number of inseminated eggs that developed into embryos.	n2		
Number of embryos developed after ICSI.	ICSIembryos	This is the number of injected eggs that developed into embryos	n2		
Embryo biopsy	EmbryoBiopsy	This records if embryo biopsy has occurred and which types.	an1	0	NONE
				1	PGD
				2	PGS
				3	HLA
				4	OTHER
Date of embryo transfer	EmbryoTransferDate	This is the date the embryo transfer occurred.	an10		
No. of embryo's transferred	EmbryoTransferNumber	This is the number of embryos transferred.	n1		
Elective single embryo transfer	eSET	Elective single embryo transfers are those where a single embryo, rather than 2 or more embryos, is transferred by choice, when more than one suitable embryo is available	an1	Y	
Date of embryo storage	EmbryoStorageDate	This is the date the embryo storage occurred if not on same date as transfer.	an10		
No. of embryos stored for patient	EmbryosStoredPatient	This is the number of embryos that were cryopreserved for the woman's own use.	n2		
No. of embryos stored for donation using slow freeze	Number of embryos stored slow freeze	This is the number of embryos that were cryopreserved by the slow freeze method for the donation only.	n2		
No. of embryos stored for donation	NumberEmbryoStoredDonated	This is the number of embryos that were cryopreserved for donation only.	n2		
Method of embryo freezing	EmbryoFreezeMethod	Method of embryo freezing. Where embryos have been stored for future use of patient or donated for future use this defines the method of freezing.	an1	1	Frozen via vitrification method
				2	Frozen using slow freeze method

Data Item Name	Access Name	Definition	Format	Codes	Value Descriptions
No. of embryo's donated fresh	NumberEmbryoDonatedFresh	This is the number of fresh embryos that were donated to a recipient(s)	n2		
No. of embryos donated fresh to research	NumberEmbryoDonatedResearch	This is the number of embryos that were donated to a licensed research project	n2		
No. of embryo's discarded	NumberEmbryoDiscarded	This is the number of embryos discarded from those created in this treatment	n2		
Number of embryos remaining in storage.	NumberEmbryosRemainStored.	See calculation from linked date under heading 'Linked forced entry with another field'.	n2		
Reason if embryo's created but none transferred	ReasonNoneTransferred	Reason if embryo's created but none transferred	an1	1	OHSS Risk
				2	No suitable embryos after biopsy
				3	Social reasons
				4	Other
Comments on any part of the patient details	Comments	This is to allow the clinic to add any relevant comments that they wish as free text.	an250		
Date comment added	CommentDate	This is the date that the comment was added.	Date		

Mitochondrial Donation Treatments

Data Item Name	Access Name	Definition	Format	Codes	Value Descriptions
UK ART Centre Number	CentreCode	This is HFEA assigned centre number for licenced UK centre.	an4		
Local Patient Identifier	PATIENTNO	This is the number given to the patient by the centre. This is unique within the centre and used by the centre. This is the patient number of the person receiving the mitochondrial donation.	an13		
Treatment number	TreatmentID	Unique treatment identifier	an12		
Mitochondrial application reference		This is reference number of the MDT application which has been approved by HFEA licence committee	an15		
Mitochondrial donor centre	MitoDonorCentre	The centre number where the mitochondrial donor is registered for mitochondrial donation.	an4		
Mitochondrial donor code	MitoDonorNumber	The unique number within the donor centre given to the mitochondrial donor.	an13		
Patients Egg collection number	PatientEggCollectionRec	This is the record number of the egg collection which is the source of the patient's eggs which will be part of mitochondrial treatment..	an12		

Data Item Name	Access Name	Definition	Format	Codes	Value Descriptions
Mitochondrial donors Egg collection number	MitoEggCollectionRecord	This is the record number of the egg collection which is the source of the mitochondrial donor's eggs which will be part of mitochondrial treatment..	an12		
Sperm donor centre	donorSpermCentre	If donor sperm is used this is the centre number where the sperm donor is registered. This will be the centre which recruited and procured the donor sperm or imported the sperm from abroad.	an4		
Sperm donor code	spermDonorNumber	If donor sperm is used this is donor number allocated by the donor sperm centre and unique within the donor centre. If the donor has been imported this code will start with 2 digit country code indicating donor's country of residence at time of donation.	an13		
PNT only sperm donor centre	PNTonlyDonorCentre	The centre number where the PNT only donor is registered for PNT only sperm donation.	an4		
PNT only sperm donor code	PNTonlyDonorNumber	The unique number within the donor centre given to the PNT sperm donor.	an13		
PNT - number of patient's eggs mixed	PNTpatienteggsmixed	The number of patient's eggs mixed with partner or donor sperm to create embryos for PST treatment	n2		
PNT - number of embryos developed from patient's eggs	PNTpatientemrbyosDevelop	The number of embryos developed from patient's eggs mixed with partner or donor sperm for PNT treatment	n2		
PNT - number of mitochondrial donor's eggs mixed	PSTmitoDonoreggsmixed	The number of mitochondrial donor's eggs mixed with sperm to create embryos for PNT treatment	n2		
PNT - number of embryos developed from mitochondrial donor's eggs	PNTmitodonorembryosDevelop	The number of embryos developed from mitochondrial donor's eggs mixed with sperm for PNT treatment	n2		
PNT - number of embryos developed from mitochondrial donor's eggs	PNTmitodonorembryosDevelop	The number of embryos developed from mitochondrial donor's eggs mixed with sperm for PNT treatment	n2		
Number of PNT embryos created	PNTembryonumber	Number of PNT embryos created which contain the patient's nuclear DNA and donor mitochondria	n2		
MST Number of patients eggs used	MSTpatientsEggs	Number of patient eggs used in MST	n2		
MST Number of mitochondrial donors eggs used	MSTmitodonorEggs	Number of mitochondrial donors eggs used in MST	n2		
Number of MST eggs created	MSTeggscreated	Number of MST eggs created which contain the patient's nuclear DNA and donor mitochondria	n2		
Number of MST	MSTembryonumber	Number of MST embryos created which contain the patient's	n2		

Data Item Name	Access Name	Definition	Format	Codes	Value Descriptions
embryos created		nuclear DNA and donor mitochondria			
Number of PNT embryos transferred	PNTtransfernumber	Number of embryos created via PNT transferred to the patient	n2		
Number of MST embryos transferred	MSTtransfernumber	Number of embryos created via MST transferred to the patient	n2		
Date of embryo transfer	EmbryoTransferDate	This is the date the embryo transfer occurred.	an10		
Date of embryo storage	EmbryoStorageDate	This is the date the embryo storage occurred, .if not on same date as transfer.	an10		
Number of PNT embryos stored for patient use	PNTembryosStored	Number of PNT embryos stored for future use of patient	n2		
Number of PNT embryos stored for patient use	PNTembryosStored	Number of PNT embryos stored for future use of patient	n2		
Number of MST embryos stored for patient use	MSTembryosStored	Number of MST embryos stored for future use of patient	n2		
Number of PNT embryos donated to research	PNTembryosStored	Number of PNT embryos donated to research	n2		
Number of MST embryos donated to research	MSTembryosStored	Number of MST embryos donated to research	n2		
Number of PNT embryos discarded	PNTembryosStored	Number of PNT embryos discarded	n2		
Number of MST embryos discarded	MSTembryosStored	Number of MST embryos discarded	n2		
Comments on any part of the mitochondrial replacement treatment details	Comments	This is to allow the clinic to add any relevant comments that they wish as free text.	an250		
Date comment added	CommentDate	This is the date that the comment was added.	Date		

Frozen embryo treatments table

Data Item Name	Access Name	Definition	Format	Codes	Value Descriptions
UK ART Centre Number	CentreCode	This is HFEA assigned centre number for licenced UK centre.	an4		
Local Patient Identifier	PATIENTNO	This is the number given to the patient by the centre. This is unique within the centre and used by the centre.	an13		
Embryo creation treatment identifier	MixingID	This is the number of mixing event (mixingID) where the embryos being thawed were created.	an12		
Embryo thaw date	EmbryoThawDate	This is the date that the embryos are thawed/warmed.	an10		
Number of embryo's thawed	NumberEmbryosThawed	The number of embryos thawed/warmed this should be the number removed from cryostorage for the purpose of thawing	an2		
Number of viable embryo's following thawing	NumberViableEmbryos	Number of viable embryo's following thawing. The definition of viability is it with >50% cells apparently surviving immediately post thaw or re-expanding within 1.5h of the thaw (for blastocysts) / cleaving overnight (for cleavage stage embryos)?	an2		
Embryo Biopsy on thawed embryos	EmbryoBiopsyThawed	This records if embryo biopsy has occurred and which types. If the embryos had a biopsy before freezing it will show here. If the embryos undergo biopsy after thawing it should be recorded here.	an1	0	NONE
				1	PGD
				2	PGS
				3	HLA
				4	OTHER
Date of embryo transfer	EmbryoTransferDate	This is the date the embryo transfer occurred.	an10		
Number of thawed embryos transferred	NumberThawedEmbryoTransferred	This is the number of thawed/warmed embryos that are transferred.	an2		
Elective single embryo transfer	eSET	Elective single embryo transfers are those where a single embryo, rather than 2 or more embryos, is transferred by choice, when more than one suitable embryo is available	an1	Y	
Number of embryos refrozen	NumberEmbryoRefrozen	This is the number of embryos that are refrozen after thawing and returned to storage after thaw/warm.	an2		
Date of refreezing	DateEmbryoRefreezing	Date of refreezing of embryos if any have been refrozen	an10		
Number of thawed viable embryos discarded	NumberThawedEmbryosDiscarded	This is the number of embryos that are thawed/warmed and then discarded. This only includes those viable after thawing	an2		
Comments on any part of the outcome details	Comments	This is to allow the clinic to add any relevant comments that they wish as free text.	an250		
Date comment added	CommentDate	This is the date that the comment was added.	Date		

Early outcome table

Data Item Name	Access Name	Definition	Format	Codes	Value Descriptions
UK ART Centre Number	CentreCode	This is HFEA assigned centre number for licenced UK centre.	an4		
Local Patient Identifier	PATIENTNO	This is the number given to the patient by the centre. This is unique within the centre and used by the centre.	an13		
Treatment to early outcome refers	TreatmentID	Number of treatment that records transfer event that EO refers to. This links EO to embryo transfer activity	an12		
Number of fetal pulsations	Pregnant	A clinical pregnancy is an intrauterine gestation sac that contains a fetal pulsation. The number of fetal pulsations is given here. This information indicates that there is a viable fetus present and follow up data is required. If there is no intrauterine fetal pulse seen this is entered as zero e.g. there was a negative pregnancy test or a biochemical pregnancy or an ectopic pregnancy or a molar pregnancy.	n1		
Number of gestational sacs	numberOfGestationalSacs	This is the number of gestational sacs identified. It is used with number of fetal pulsations to identify a monozygotic twin pregnancy	n1		
Has centre been unable to obtain treatment outcome information?	NoOutcomeObtainable	This is when all attempts to trace the outcome of the treatment have failed either at pregnancy or birth - formerly recorded as 'lost to follow-up'	an1	Y	Yes
				N	No
Comments on any part of the early outcome details	Comments	This is to allow the clinic to add any relevant comments that they wish as free text.	an250		
Date comment added	CommentDate	This is the date that the comment was added.	Date		

Outcome table

Data Item Name	Access Name	Definition	Format	Codes	Value Descriptions
UK ART Centre Number	CentreCode	This is HFEA assigned centre number for licenced UK centre.	an4		
Local Patient Identifier	PATIENTNO	This is the number given to the patient by the centre. This is unique within the centre and used by the centre.	an13		
Outcome identifier	OutcomeID	Unique reference number for this outcome record	an12		
Treatment that outcome refers too	TreatmentID	Number of treatment that records DI or embryo transfer event that outcome refers to. This links outcome to embryo transfer or DI treatment	an12		
Pregnancy terminated	PregnancyTerm	This indicates that the pregnancy has been terminated by the patient. Note that selective embryo reduction should be recorded	an1	Y	

Data Item Name	Access Name	Definition	Format	Codes	Value Descriptions
		on fetal outcome			
Number of fetal outcomes	Total fetal outcomes	Number of fetal outcomes for this pregnancy. Should match number of fetal hearts on early outcome and same number of fetal outcomes records linked.	an1		1-9
Baby's town or district of birth	BabyBirthTownDist	This is the town or district in which the baby or babies were born.	an50		Free Text
Baby's country of birth	BabyBirthCountry	This is the country in which the baby or babies were born.	a3		ISO Country Codes
				ZZZ	Not stated
				EEE	England
				WWW	Wales
				SSS	Scotland
				NNN	Northern Ireland
Comments on any part of the outcome details	Comments	This is to allow the clinic to add any relevant comments that they wish as free text.	an250		Free Text
Date comment added	CommentDate	This is the date that the comment was added.	Date		

Fetal outcome table

Data Item Name	Access Name	Definition	Format	Codes	Value Descriptions
UK ART Centre Number	CentreCode	This is HFEA assigned centre number for licenced UK centre.	an4		
Local Patient Identifier	PATIENTNO	This is the number given to the patient by the centre. This is unique within the centre and used by the centre.	an13		
outcome ID		The outcome record number which this fetal is providing detail for.	an12		
Fetal number	Fetal number	The fetal number within this pregnancy outcome	n1		
Fetal outcome	Fetal outcome	The outcome of this fetus,		10	Live Birth. This is when a baby has been delivered after 24 weeks gestation and shows signs of life.
				20	Stillbirth. The baby is born dead after 24 weeks gestation
				30	Miscarriage. A miscarriage is the expulsion of the fetus from the uterus before 24 weeks gestation.
				70	Embryo reduction at less than 24 weeks.

Data Item Name	Access Name	Definition	Format	Codes	Value Descriptions
					This is when a procedure or intervention has been carried out to remove an embryo from a multiple gestation.
				80	Embryo reduction at equal to or greater than 24 weeks. This is when a procedure or intervention has been carried out to remove an embryo from a multiple gestation.
				XX	Other including vanishing/papyraceous twin, or ectopic
Baby weight	Babyweight	This is the birth weight of the baby in grams.	n4		
Baby's Gender	Babygender	This is the gender of the baby as assigned at birth.	n1	1	Male
				2	Female
				9	Indeterminate, i.e. unable to be classified as either male or female
Delivery date	DeliveryDate	Date that the baby was delivered for live birth or still births.	an10		
Indicator of Neonatal death	NeonatalDeathFlag	Neonatal death. This is an indicator that the baby born live died before 28 completed days after birth. http://www.perinatal.nhs.uk/pnm/definitions.htm	an1	Y	
Baby's NHS Number	NHSNO	This is the NHS/CHI/HCN number of the baby	n10		
Baby's NHS number Status Indicator Code	NHSNOStatus	Indicates the status of the NHS Code	an2	01	Number present and verified
				02	Number present but not traced
				03	Trace required
				04	Trace attempted - No match or multiple match found
				05	Trace needs to be resolved - (NHS Number or PATIENT detail conflict)
				06	Trace in progress
				07	Number not present and trace not required
				08	Trace postponed (baby under six weeks old)
Baby's forenames	BabyForename	The forenames of the baby. This will be as written on their NHS/CHI/HCN record.	an50		Free text
Baby's surname	BabySurname	The surname of the baby. This will be as written on their NHS/CHI/HCN record.	an50		Free text
Comments on any part	Comments	This is to allow the clinic to add any relevant comments	an250		Free text

Data Item Name	Access Name	Definition	Format	Codes	Value Descriptions
of the fetal outcome details		that they wish as free text.			
Date comment added	CommentDate	This is the date that the comment was added.	Date		

Transfer In of eggs, embryos and donor sperm table

Data Item Name	Access Name	Definition	Format	Codes	Value Descriptions
UK ART Centre Number	CentreCode	This is HFEA assigned centre number for licenced UK centre. This is the centre receiving the eggs or embryos or donor sperm	an4		
Local Patient Identifier	PERSONID	This is a number given to the egg, donor sperm or embryo provider by the centre. This is unique within the centre and used by the centre. For eggs or embryos this will be the patient they belong too. For a donor sperm being imported from outside the UK this will be donor code used for registration. For donor sperm transferred from another UK centre this will be the number allocated by the centre sending the donor sperm. For eggs or embryos this will be the patient they belong too.	an13		
Transfer type	TransferType	This defines whether the transfer record refers to eggs, embryos or donor sperm.	an1	1	Eggs
				2	Embryos
				3	Donor Sperm
Where imported from	ImportedFrom	Indicates if the transfer is from a UK centre or whether from outside the UK	an1	1	Transferred into the centre from another UK Licensed centre
				2	Transferred into the centre from outside the UK
Transferred from centre code	TransferFrom Centre	If from inside the UK the number of the UK centre which the eggs/embryos or donor sperm have been imported from.	an4		
Country imported from	ImportCountry Code	If from outside the UK country where eggs/sperm/embryos have been imported from	an3		ISO codes
Special directions	SpecialDirectio ns	If the import has been done under special directions this is the special directions number supplied by Licence committee.	an20		
Egg collection or Embryo creation treatment identifier	TreatmentID	Where eggs or embryos are being imported this contains either the egg collection or embryo creation treatment identifier so that eggs can be linked to egg collection or embryos linked to gamete source information form number to link embryos being thawed to their creation	an12		Could be multiple treatment reference numbers
Number of eggs	NumEggs	Number of eggs being transferred	n2		
Number of embryos	NumEmbryos	Number of embryos being transferred	n2		
Quantity of donor	QuantityDonor	Quantity of donor sperm samples being transferred.	n2		

Data Item Name	Access Name	Definition	Format	Codes	Value Descriptions
sperm	Sperm				
Measurement of donor sperm	MeasureSperm	Where a quantity of donor sperm has been submitted please complete the method of storage.	an1	1	Ampoules
				2	Straws
				3	Vials
Single European Code	SEC	The SEC will be attached to the movement of any donor eggs or sperm or embryos created using donor eggs or sperm. If this transfer has SEC attached it should be entered here.	an40		
Comments on any part of the fetal outcome details	Comments	This is to allow the clinic to add any relevant comments that they wish as free text.	an250		
Date comment added	CommentDate	This is the date that the comment was added.	Date		

Transfer out of eggs, embryos and donor sperm table

Data Item Name	Access Name	Definition	Format	Codes	Value Descriptions
UK ART Centre Number	CentreCode	This is HFEA assigned centre number for licenced UK centre. This is the centre sending the eggs, embryos or donor sperm.	an4		
Local Patient Identifier	PERSONID	This is the number given to the egg or sperm or embryo provider by the centre. This is unique within the centre and used by the centre to refer to the patient or donor. For a donor sperm being exported this will be donor code used for registration. For patients eggs this will refer to the patient number as used on egg collection record. For donor eggs this will refer to the egg donor code. For embryos either the patients whose eggs were used to create the embryos or in case of surrogacy one of the intended parents who contributed gametes.	an13		
Transfer type	TransferType	This defines whether the transfer record refers to eggs, embryos or donor sperm.	an1	1	Eggs
				2	Embryos
				3	Donor Sperm
Transfer Reason	TransferReason	This is the type of transfer that is occurring. Whether for use in another centre or abroad or to be destroyed, because of end of consent or storage period.	an1	1	Transferred out of the centre to another UK licenced centre
				2	Transferred out of the centre to outside of the UK.
				3	Donated to Research
				4	Destroyed because reached end of storage period or withdrawal of consent.
Transferred to UK	TransferToCe	If transferring within the UK the number of the UK centre which	an4		

Data Item Name	Access Name	Definition	Format	Codes	Value Descriptions
centre code	ntre	the eggs/embryos or donor sperm have been transferred too.			
Country exported too	ExportCountry Code	If transferring to outside the UK this records the country where eggs/sperm/embryos have been exported too.	a3		ISO country codes
Special directions	SpecialDirectio ns	If the export has been done under special directions this is the special directions number supplied by the Licence committee.	an12		
Transfer date	TransferDate	This is the date that the eggs/embryos or donor sperm left the centre which is sending them elsewhere	an10		
Egg collection or Embryo creation treatment identifier	TreatmentID	Where eggs or embryos are being imported this contains either the egg collection or embryo creation treatment identifier so that eggs can be linked to egg collection or embryos linked to gamete source information form number to link embryos being thawed to their creation	an12		Could be multiple treatment reference numbers
Number of eggs	NumEggs	Number of eggs being transferred	n2		
Number of embryos	NumEmbryos	Number of embryos being transferred	n2		
Quantity of donor sperm	QuantityDonor Sperm	Quantity of donor sperm samples being transferred.	n2		
Measurement of donor sperm	MeasureSper m	Where a quantity of donor sperm has been submitted please complete the method of storage.	an1	1	Ampoules
				2	Straws
				3	Vials
Donor consent expiry date	DonorConsent Expiry	Where donor gametes are being exported the donor consent expiry date needs to be included in transfer document since it is part of SEC.	an10		date in YYYYMMDD format
Single European Code	SEC	The SEC needs to be attached to the movement of any donor eggs or sperm or embryos created using donor eggs or sperm. This number will be generated from the information supplied above as UK country code + centre code + donor code (or patient for embryos) + transfer type + iteration number + expiry date.	an40		
Comments on any part of the fetal outcome details	Comments	This is to allow the clinic to add any relevant comments that they wish as free text.	an250		
Date comment added	CommentDate	This is the date that the comment was added.	Date		

Consent variation table

Data Item Name	Access Name	Definition	Format	Codes	Value Descriptions
UK ART Centre Number	CentreCode	This is HFEA assigned centre number for licenced UK centre. This is the centre where the patient, partner or donor was registered or where patient had treatment resulting in child whose consent is to be varied.	an4		0001 to 9999
Type of person whose consent is being varied.	CVType	This indicates the type of person to which the consent variation will apply. Whether it is for a patient or partner or donor or child. consent variation enables changes to the consent currently applied for that person with regard to identifying information for research purposes.	an1	1	Patient
				2	Partner
				3	Donor
				4	Child
Local patient/partner/donor identifier	CVID	This the patient/partner/donor number given to the patient, partner or donor by the centre, This will be a unique reference number within the centre and will be the number by which the centre have recorded details of the patient / partner / donor. Where the consent variation is for a child this will be the birth mothers patient number	an13		
Patient/partner/donor surname	Surname	This is the surname of the patient, partner or donor who want to change their consent. Where changing consent for a child this should be patient's surname	an50		
Child's DOB	ChildDOB	Where the CV form is for a child the child's DOB needs to be included here so the child can be identified	an10		
Consent to non-contact research	ConsentNonContactResearch	This is the new consent taken from the CD form completed by the patient/partner/donor in 'Disclosing your identifying information ..' section. This records whether they agreed or not to non-contact research.	an1	Y	Yes
				N	No
Consent to contact research	ConsentContactResearch	This is taken from the CD form completed by the patient in 'Disclosing your identifying information ..' section. This records whether they agreed or not to contact research.	an1	Y	Yes
				N	No
Comments on any part of the consent variation details	Comments	This is to allow the clinic to add any relevant comments that they wish as free text.	an250		
Date comment added	CommentDate	This is the date that the comment was added.	Date		

Compliance and enforcement policy

Strategic delivery:	☒ Setting standards	☐ Increasing and informing choice	☐ Demonstrating efficiency economy and value
Details:			
Meeting	Authority		
Agenda item	**8**		
Paper number	HFEA (09/03/2016) 788		
Meeting date	09 March 2016		
Author	Nick Jones, Director of Compliance and Information		
Output:			
For information or decision?	For decision		
Recommendation	It is recommended that the Authority agrees the revised Compliance and enforcement policy and 'Guidance on licensing'		
Resource implications	In budget		
Implementation date	1 April 2016		
Communication(s)	Publication through usual channels		
Organisational risk	☐ Low	☒ Medium	☐ High
Annexes	Annex 1: Compliance and enforcement policy Annex 2: Guidance on licensing		

1. Background

1.1. It is good practice that regulators set out in public their general approach in ensuring compliance with regulatory requirements. The regulated need to know what is expected of them to achieve compliance and the steps that the regulator might take if compliance is not evident. The HFEA has had such a Compliance and enforcement policy since 2009. The policy sets out, first, the routine actions by which the HFEA judges compliance, notably inspection and the licensing process; and, second, importantly, the steps we would take to escalate and manage concerns about regulatory compliance.

1.2. At its September 2015 meeting the Authority considered a proposed revised policy together with changes to two 'indicative' guidance documents provided to licensing committees[1]; the first regarding the length of licences granted[2] and the second regarding the potential sanctions that might be applied[3], where concerns relating to poor performance are evident.

1.3. The Authority agreed that the proposed documents should be subject to focused consultation – and piloting – which has now been undertaken. This paper presents the revised policy (at annex 1) and proposes a new single guidance document on licensing drawing together the two documents referred to above (at annex 2).

2. The compliance and enforcement policy

2.1. The compliance and enforcement policy aims to provide licensed centres and society with clear signals about the responses and standards they can expect from the Authority when it is dealing with non-compliance. The policy also guides the compliance team when there are difficult decisions to be made about whether non-compliance with regulatory requirements poses a significant risk such that suspension or revocation of a licence may be warranted.

2.2. The consultation exercise sought views through Clinic Focus and we also engaged members of the Licensed Centres Panel and principal professional stakeholders. There was a modest response, but all respondents were supportive and saw considerable sense in the proposals – on the basis that it provided greater clarity and certainty about the conduct of any review or investigation when performance concerns are evident.

2.3. The main proposed changes to the policy relate to the factors that govern the escalation of concerns and the arrangements for investigating them, and then the reporting of them to a licensing

[1] The HFEA Licence Committee, and the Executive Licensing Panel
[2] HFEA guidance on periods for which new or renewed licences should be granted
[3] HFEA indicative sanctions guidance for Licence Committees

committee. The aim throughout has been to provide greater clarity and transparency – to the licensed centre and to the HFEA team. The revised document is slightly different in style to that consulted on to make the policy clearer for centres and HFEA staff.

2.4. It is important to note the policy places no new or additional requirements on licensed centres. No material changes to the way we go about inspection and checking compliance at a routine level are expected. Greater clarity as to how we go about dealing with concerns is provided, but again these are not new or additional requirements.

2.5. Routine inspection findings, based on evidence and observations, are effective in highlighting where improvements are required. Usually there is no immediate and/or direct risk to patients, their gametes or embryos; and effective recommendations for improvement can be framed and implemented. These matters are set out in section 2 of the policy. For many centres most of the time this is the only element of the policy that they will need to be familiar with.

2.6. Where there is a possibility further to inspections, or from other information or activity, that more serious regulatory sanctions may need to be applied (due to the severity and nature of the non-compliance) further review of a clinic's practices is needed. The first step in doing so will be a management review. This is set out in section 3 of the policy. Such a review might be needed to determine whether a particular non-compliance (s), represent a one-off occurrence, a practice, or are indicative of other serious failings. Relations between the HFEA and the licensed centre can become strained at such times and there may be barriers to conducting further investigations for fear of accusations of harassment; and centre staff may feel or allege they are being treated differently and/or disproportionately.

2.7. The policy has been revised to clarify the action that may be appropriate in such circumstances. Such action might include further, potentially forensic, scrutiny of a centre's practices where there are, or may be, risks to the safety of patients or to their gametes or embryos, or where a serious breach of the Act is observed or suspected. The aim is to ensure that centres are only subject to such scrutiny if concerns are suitably serious, while empowering the compliance team in what may otherwise be challenging circumstances.

2.8. The revised policy also now sets out the circumstances in which a report of the findings of any investigation will be drafted and referred to a licensing committee. Where an investigation concludes that concerns have no foundation with no recommendations for improvement the policy states that no further action beyond documenting this finding in the management review record will be taken.

2.9. There are also amendments to the process by which a warrant might be sought. Such a serious decision, though very rare, requires a particular escalation process and for the first time, the revised policy sets out the

principles that should be applied in decided whether to make such an application.

3. Guidance on licensing

3.1. The proposals presented to the Authority in September 2015 also indicated a review of guidance relating to periods for which new or renewed licences should be granted, and guidance on indicative sanctions that may be applied.

3.2. The guidance has been substantially changed and consolidated within a single 'Guidance on licensing' document, at annex 2. This has been done to bring greater coherence and to reflect the fact that a decision on the length of a licence to be issued is a regulatory tool in itself; to see that as separate to guidance on sanctions is artificial. The principal changes are set out below:

The length of licence

3.3. Consideration of the centre's history will routinely include (but not be restricted to) consideration of the committee minutes from the time of the centre's last renewal or four years (whichever is more recent); implementation of recommendations made at the time of the last inspection; and co-operation with any alerts, advice and/or recommendations made in the intervening time.

3.4. In deciding the duration of a licence the committee should consider the scale of non-compliance; the PR's apparent understanding of the impact of the non-compliance; the PR's commitment (or otherwise) to implement corrective actions within agreed timescales; and the risks of non-compliance to safety of patients, their embryos or gametes, and/or the quality of service at the time that the decision is being made.

3.5. The committee should also consider the quality of service provided by the centre. To assure consistency and proportionality consideration of quality should be based on observation of the centre's success rate trends, clinical multiple pregnancy and birth rates and feedback provided by patients.

3.6. The guidance suggests that four year licences remain the norm for treatment centres; three year licences are considered where there are concerns where further focused inspection after one year might be useful; that two year licences are not routinely issued, except in respect of new centres with no licensing history; and one year licences are issued where concerns give rise to the need for a full inspection within one year.

3.7. Consideration is given to the issue of Special Directions, or a short-term licence, in exceptional circumstances, where a centre's licence is likely to expire before it can be demonstrated that substantive improvements have been effective.

3.8. For some time we have grappled with how we might provide a more public assessment of the performance of clinics within a range – for example in the way that Ofsted rate a school 'outstanding', 'good' or 'needing improvement'. As a licensing authority we can grant a licence or not – and there are legal and resource complications in making subjective assessments to promote consumer/patient awareness, comparison and so on.

3.9. However, given the limited range of 'incentives' available to us, we believe there are substantial advantages in better linking centres' relative performance and the length of licence granted – an evidence based judgment made by a licensing committee at the time the licence is granted.

3.10. Members will be aware that a range of options has been considered relating to the forthcoming new website and 'Choose a fertility clinic' tool – regarding the headline measures. Alongside outcome rates and patients' feedback we plan to use the length of licence to provide the 'what do inspectors say about this clinic?' input.

Sanctions

3.11. The changes retain the features of the current guidance particularly regarding the statutory basis for applying sanctions and seeks to closer align guidance with the sections of the Act that set out when the Authority may vary (for example, by adding a condition to a licence), suspend or revoke a licence. The guidance has been revised to emphasise the following as factors that a licensing committee might consider in reaching a decision:

3.12. The guidance also seeks to simplify and clarify the aggravating and mitigating features that a licensing committee may consider in any matters of non-compliance reported to it.

4. Recommendation

4.1. The Authority is to consider:

- the revised Compliance and enforcement policy.
- the new Guidance on licensing.

4.2. If the Authority is content with the documents, we will undertake style and format improvements to ensure that they convey the agreed information as clearly as possible.

Compliance and enforcement policy

1 About this policy

1.1 This Compliance and enforcement Policy (policy) sets out the broad approach that the Authority will take in dealing with non-compliance by licensed clinics and research centres.

1.2 The policy has two aims:

- to provide clarity for centres and society about how we will respond to non-compliance in the sector we regulate; and
- to provide HFEA inspectors and other staff with a clear framework for making regulatory decisions.

1.3 This policy has been produced in accordance with the Authority's powers and meets its statutory duties[1] to carry out its functions effectively, efficiently and economically and with due regard to the principles of best regulatory practice. Such practice is guided by the Regulators' Code[2] which sets out that regulators (such as the HFEA) should:

- carry out their activities in a way that supports those they regulate to comply and grow
- provide simple and straightforward ways to engage with those they regulate and hear their views
- should base their regulatory activities on risk
- should share information about compliance and risk
- should ensure clear information, guidance and advice is available to help those they regulate meet their responsibilities to comply
- should ensure that their approach to their regulatory activities is transparent.

1.4 The Authority manages compliance and enforcement through a range of mechanisms. Most non-compliances and performance are addressed through day-to-day contact between the centre and its inspector and through the scheduled statutory inspection and licensing process. This element of the regulatory regime is set out in section 2 below.

1.5 More serious areas of non-compliance or poor performance may be identified through scheduled inspections or from other information or activity. These non-compliances may require other regulatory mechanisms, including investigations, written warnings, referral to professional bodies or the police, or the application of a warrant to search licensed premises. The escalation and management of such serious concerns is set out in section 3 below.

1.6 This policy replaces all previous policies relating to these matters. It should be read alongside the Authority's Guidance on Licensing.

[1] Section 8ZA of the Human Fertilisation and Embryology Act 1990 (as amended)
[2] Better Regulation Delivery Office April 2014
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/300126/14-705-regulators-code.pdf

2 Inspections and licensing

2.1 The HFEA's regular interactions with centres is inspection. Centres must be inspected at intervals not exceeding two years. The purpose of an inspection is to:

(a) assess the extent to which centres comply with the requirements of the Human Fertilisation and Embryology Act 1990 (as amended) as set out in licence conditions, Directions, the Code of Practice and all applicable statutory provisions

(b) provide an independent and professional perspective on the running of the centre

(c) promote good practice so that centres can improve the quality of service they provide to patients and donors

(d) provide centres with a positive learning experience

(e) provide centres with the opportunity to feed back on their experience of the inspection process, in order to assist the Authority to continually improve its procedures

(f) give patients reliable information about a centre's compliance with statutory and other obligations and about the quality and safety of licensed activities undertaken at that centre.

2.2 All inspections are:

(a) Evidence-based, consistent, proportionate and open to scrutiny

(b) undertaken in a professional and courteous manner

(c) focused on risk; and

(d) aim to add value for centres and service users.

2.3 During the inspection, the inspection team may identify and require improvements to be made, taking into account any mitigating factors. The inspection team will give the Person Responsible (PR) reasons for making the recommendations.

2.4 After the inspection, the inspection team will prepare a report and show it to the PR in draft. The PR will be given a reasonable opportunity to comment on the findings and recommendations of the draft report.

2.5 The report will be sent to the Executive Licensing Panel or Licence Committee, which will then decide whether a licence should be granted, renewed or allowed to continue. Where there are concerns about the centre's compliance with regulatory requirements, the Executive Licensing Panel or Licence Committee can decide whether a licence should be varied (for example, adding a condition to the licence), revoked or suspended (see section 3).

2.6 After consideration by the Executive Licensing Panel or Licence Committee, inspection reports will normally be published on the Authority's website.

3 The management of centres with serious areas of non-compliance

3.1 Where the inspection team becomes aware of concerns about a centre's compliance or performance, a *management review* meeting will be held to evaluate the risk and determine a proportionate course of action. The review will usually include an inspector and at least one senior member of the team and any such other persons considered appropriate. A record of the management review meeting will be kept.

3.2 Following an evaluation of the quality of the service, in particular the actual or potential risks to the safety of patients, gametes and or embryos arising as a consequence of the concerns under investigation, the management review will consider the most appropriate action, which may include any or all of the following:

(a) implementation of a period of performance monitoring

(b) contacting and/or meeting with the PR and/or other key staff members to discuss concerns

(c) an investigation into the foundation, scope and/or scale of concerns. This may include commissioning a review by an expert

(d) an unannounced or scheduled inspection visit (depending on the nature of the concerns under investigation). Where there are concerns that non-compliance has posed or may pose a risk to the safety of patients, their gametes or embryos, or where a serious breach of the Act is suspected, the inspection may include detailed scrutiny of some or all of a centre's practices. The PR will usually be informed of the details of any concerns or allegations under investigation. Where it is necessary to protect the identity of a whistle-blower or information source the investigation or inspection may be initiated before the full details of any concerns or allegations are provided to the PR

(e) where investigation identifies areas for improvement, completion of a report of the findings of the investigation informing the PR of the required improvements and the timescales for their implementation

(f) where an investigation concludes that concerns have no foundation with no recommendations for improvement no further action beyond documenting this finding in the management review record will be taken

(g) sending a warning letter to the PR, informing them that enforcement will be undertaken if the identified improvements are not completed within a given time scale

(h) referring a report of the findings of an investigation to the Executive Licensing Panel or Licence Committee documenting the recommendations for improvement.

3.3 Where the management review judges that there are serious risks to the safety of patients, gametes and/or embryos, the following actions may be taken, with or without recourse to the actions described at 3.2 above:

(a) referring a report for consideration by the Executive Licensing Panel or Licence Committee with a recommendation that the licence should be varied (including by the imposition of additional conditions)

(b) referring a report for consideration by the Licence Committee with a recommendation that the licence should be revoked (or suspended)

(c) exercising powers under Section 39 of the Act (taking possession of material from licensed centres during an inspection)

(d) applying for a warrant in accordance with Section 40 of the Act

(e) where a criminal offence may have been committed, consideration given to referring the matter to the police for criminal investigation

(f) where professional codes of conduct may have been breached, referring the professional concerned to the relevant professional body

(g) where concerns may be relevant to another regulator, informing the relevant regulatory body.

3.4 In deciding whether to take any of the actions set out at 3.3 above the Executive should consider that one or more of the following tests are met:

(a) there are concerns about the ability of the PR to discharge his or her duties under Section 17 of the Act

(b) the centre has not completed, or does not appear likely to complete, any necessary recommendations for improvement within the stipulated time frame

(c) the centre has a previous history of non-compliance or failure to implement recommendations for improvement promptly or within required timeframes

(d) there is a risk to patients or service users, or to gametes and embryos

(e) there is evidence that a criminal offence may have been, or is being, committed.

3.5 In deciding what actions to take the Executive will use professional judgement, may take legal advice; and will act proportionately. The inspection team will not make a recommendation for the revocation (or suspension) of the licence unless one or more of the requirements of Section 18(1) or (2) of the Act are met.

3.6 A decision to refer a centre or an individual to an external body should only be made by agreement with the Chief Inspector and/or the Director of Compliance and Information. If it is judged that a matter should be referred to the police or that a warrant should be obtained, the recommendation will be brought to the attention of the Chief Executive.

3.7 Where the Authority has reasonable grounds for suspecting that an offence under the Act is being or has been committed on any premises, it may apply to a Justice of the Peace for a warrant to enter, search and seize materials from those premises.

3.8 Where the Chief Executive has been informed that the recommendation of the management review is that a warrant should be applied for, he or she will inform the Chair of the Authority of the recommendation and the reasons for it. In reaching a decision to seek a warrant, the following principles should be applied:

- the decision should be proportionate to any harm that might be caused
- patient safety should be compromised or at risk of being compromised

- any relevant ongoing licensing or regulatory action has been exhausted or there is a clear reason why acting outside of those actions would be justified
- the decision and the rationale for the decision is carefully and contemporaneously documented.

3.9 The Chair may consult the Deputy Chair and the Chair of the Audit and Governance Committee about the recommendation.

3.10 In the event of a disagreement amongst those consulted, the Chair may veto the recommendation. The decision to apply for the warrant shall otherwise be made by the Chief Executive.

1 April 2016

Guidance on licensing

1. About this guidance

1.1 This guidance sets out the range of factors that licensing committees of the Authority (the Licence Committee and the Executive Licensing Panel) may take into account when reaching a decision in respect of a licensed clinic or research centres.

1.2 The guidance has two aims:

- to provide clarity for centres and society about the factors which guide any licensing decision by the Authority; and
- to provide members of licensing committees of the Authority with a clear framework for making decisions about the length of a licence and what sanctions, if any, to apply.

1.3 The application of this guidance should ensure that any decision to apply or determine penalties is fair and consistent, although any decision on fairness can only be a matter for a licensing committee.

1.4 This guidance has been produced in accordance with the Authority's powers and meets its statutory duties[1] to carry out its functions effectively, efficiently and economically and with due regard to the principles of best regulatory practice. Such practice is guided by the Regulators' Code which sets out that regulators (such as the HFEA) should:

- carry out their activities in a way that supports those they regulate to comply and grow
- provide simple and straightforward ways to engage with those they regulate and hear their views
- base their regulatory activities on risk
- share information about compliance and risk
- ensure clear information, guidance and advice is available to help those they regulate meet their responsibilities to comply
- ensure that their approach to their regulatory activities is transparent.

1.5 Any centre wishing to offer assisted reproduction services or undertake research on human embryos in the UK can only do so under licence from the HFEA. The Authority has the power to decide what length of time to issue a licence and the factors which guide this decision are set out in section 2 below.

1.6 The Authority also has the power to apply a range of sanctions to a licence, including the power to vary, suspend or revoke the licence. In making such a decision a licensing committee is taking a serious decision with significant consequences for the centre. The factors which guide this decision are set out in section 3 below.

1.7 This guidance replaces all previous guidance relating to these matters[2]. It should be read alongside the Authority's compliance and enforcement policy.

[1] Section 8ZA of the Human Fertilisation and Embryology Act 1990 (as amended)
[2] The HFEA indicative sanctions guidance for licence committees and HFEA guidance on periods for which new or renewed licences should be granted

2. The length of a licence

2.1 A treatment or storage licence cannot be granted for more than five years and a licence for research cannot be granted for more than three years[3]. The Authority has decided that the length of licence granted is a reasonable measure of the quality of service provided by the centre.

2.2 The following are matters that a licensing committee may take into account when deciding the duration of a licence.

- **The centre's history of compliance**: consideration of the clinic history including (but not restricted to)
  - consideration of the committee minutes from the time of the clinic's last licence renewal
  - implementation of recommendations made at the time of the last inspection
  - co-operation with any alerts, advice and/or recommendations made since the last inspection.

  Where there is evidence of failure to implement recommendations for improvement and/or take appropriate action with respect to alerts, advice or guidance, then there may be good reason to undertake a focused site visit to a centre outside of the normal inspection cycle so that evidence of the implementation of effective corrective action can be reviewed. This approach is intended to encourage regulatory compliance.

- **Evidence of non-compliance with statutory requirements**: the licensing committee will consider the scale of non-compliance; the Person Responsible's (PR) apparent understanding of the impact of the non-compliance(s); the PR's commitment (or otherwise) to implement corrective actions within agreed timescales; and, most importantly, the risks to the safety of patients, their embryos or gametes, and/or the quality of service at the time that the licensing decision is made.

  This is to ensure proportionality. Where a report documents a large number of non-compliances, but there has been a prompt and effective response it is recognised that the risks associated with non-compliance are likely to have been mitigated. Where, however, the PR's response indicates a failure to commit to make improvements or a failure to appreciate the seriousness of the non-compliances, it may be appropriate to request a focused site visit within a specified period of time so that evidence of the implementation of effective corrective action can be reviewed. This approach is, again, intended to encourage regulatory compliance.

- **Quality of service provided:** the licensing committee will consider the quality of service provided by the centre. To assure consistency and proportionality consideration of quality is based on observation of the centre's success rate trends, clinical multiple pregnancy and birth rates, and feedback provided by patients.

2.3 In taking into account the factors above, the licensing committee will usually offer an appropriate length of licence based on the following circumstances:

[3] Schedule 2 of the Act

Annex 2

Length of licence	Anticipated circumstances of issue	Consequence
4 years	A four-year licence will usually be offered where: • a centre has taken appropriate and timely action in relation to any non-compliances identified as posing a risk to patients, their gametes or embryos • where the PR has given a commitment to implement all the required recommendations in relation to critical and major non compliances • the clinic's history suggests that the PR has previously implemented recommendations for improvement and/or advice and guidance • there are no serious concerns about the quality of service based on observation of success rates; multiple pregnancy and birth rates; and patient feedback.	A four-year licence minimises the regulatory burden for centres with an unannounced observation based interim inspection occurring at year two.
3 years	A three-year licence will usually be offered where: • there is a history that indicates a previous failure to implement recommendations for improvement in the time since the last licence renewal; • there are concerns related to quality of service; A three-year licence will also usually be offered where the application is for a licence for research.	A three-year licence would allow a centre to be subject to an interim inspection within one year (rather than the usual two) to review evidence of implementation of recommendations and/or to review quality of service. This could be scheduled or unannounced.
2 years	Two-year licences are only usually offered where the centre is new, and there is no licensing history to guide licensing decisions a two-year licence can be offered.	A newly-licensed centre can be offered a licence of any length but it is usual to offer a two year licence enabling an 'interim' (mid-point) inspection during the first year providing a useful indication of early performance and progress.
1 year	A one-year licence will usually be offered where concerns are more serious and there are doubts that improvement will be sustained but there is no immediate and/or direct risks to patients, their gametes or embryos.	A one-year licence has adverse administrative consequences for licensed centres but is necessary where there are serious wide ranging concerns and there is either a poor history of compliance or insufficient information to assure a committee that the required improvements will be made.
Adjournment and/or issue of Special Direction or short-term	Where there is a history that suggests serious concerns about a PR's ability to ensure regulatory compliance, a licensing committee could adjourn a decision (perhaps requiring issue of Special Directions or a short-term	A licence is only granted **after** the PR is able to demonstrate that the recommendations for improvement have been implemented and that they have been **effective** in

licence	licence) pending the submission of further evidence.	preventing recurrence of non-compliance.

3. Sanctions

3.1 Where a licensing committee considers it necessary to impose sanctions on a licence, this represents a serious step and will usually only be taken where there is significant non-compliance with the requirements of the Human Fertilisation and Embryology Act 1990 (as amended), licence conditions, Directions, the provisions of the Code of Practice or any other applicable statutory provisions.

3.2 The purpose of sanctions is to:

- promote compliance with the requirements of the Act and the Code of Practice issued by the Authority
- protect those using, or affected by, the services offered at centres licensed by the Authority; and
- maintain public confidence in the conduct of licensed activities within the United Kingdom.

3.3 In considering whether or not to apply a sanction, the licensing committee has to exercise a discretion, and will do so in a way that is fair and reasonable. This will require the licensing committee to take into account the interests of the licence holder or PR against the factors set out in paragraph 3.2, above.

3.4 The sanctions available to a licensing committee are limited by the Human Fertilisation and Embryology Act. The licensing committee can, vary, suspend or revoke a licence.

3.5 A licensing committee may vary a licence (for example, add conditions to a licence where it has the power to revoke a licence)[4]. In deciding whether to vary a licence, the committee may take into account whether:

- the non-compliance is capable of being remedied
- appropriate and realistic conditions can be formulated
- the Person Responsible (PR) has shown insight and is likely to comply with any conditions imposed.

3.6 A licensing committee may suspend a licence[5]where it:

- has reasonable grounds to suspect that there are grounds for revoking the licence; and
- is of the opinion that the licence should immediately be suspended.

3.7 It may, by notice, suspend the licence for up to three months as may be specified in the notice. The licensing committee may, by further notice, renew or further renew the original suspension.

3.8 In deciding to suspend a licence, the licensing committee may take into account the following:

- there is failure by the PR to ensure that suitable practices are used to ensure the safety of patients, their gametes or embryos and/or the quality of service

[4] S.18A (3)
[5] S19C (1) and (2)

- there is failure by the PR to ensure compliance with the conditions of the licence where this may carry a risk to the safety of patients, their gametes or embryos and/or the quality of service
- the PR ceases to be considered a suitable person by virtue of dishonesty and/or failure to cooperate with investigations particularly where this may have compromised the safety of patients, their gametes or embryos and/or the quality of service
- there is failure by the PR to ensure suitability of staff; that proper equipment is used or that premises are suitable, particularly where this has had an impact or may impact on the safety of patients, their gametes or embryos and/or the quality of service
- public confidence in the conduct of licensed activities requires immediate action
- no suitable person is available to act as PR
- conditions cannot be adequately framed and/or would be unworkable in practice
- there is evidence of previous breaches of conditions or Directions issued by the Authority
- there is evidence of a history of significant non-compliance
- there is a reasonable expectation that following a period of suspension performance can return to acceptable standards.

3.9 A licensing committee may revoke a licence[6] where:

- it is satisfied that any information given for the purposes of the application for the licence was in any material respect false or misleading
- it is satisfied that the PR has failed to discharge, or is unable because of incapacity to discharge, the duty under section 17
- it is satisfied that the PR has failed to comply with directions given in connection with any licence
- it ceases to be satisfied that the premises specified in the licence are suitable for the licensed activity
- it ceases to be satisfied that any premises which are relevant third party premises in relation to a licence are suitable for the activities entrusted to the third party by the person who holds the licence
- it ceases to be satisfied that the holder of the licence is a suitable person to hold the licence
- it ceases to be satisfied that the PR is a suitable person to supervise the licensed activity
- the person responsible dies or is convicted of an offence under this Act, or
- it is satisfied that there has been any other material change of circumstances since the licence was granted.

3.10 In deciding to revoke a licence, the Committee may take into account the following:

- there is failure by the PR to ensure that suitable practices are used to ensure the safety of patients their gametes or embryos and/or the quality of service
- there is failure by the PR to ensure compliance with the conditions of the licence where this may carry a risk to the safety of patients their gametes or embryos and/or the quality of service
- the PR ceases to be considered a suitable person by virtue of dishonesty and or failure to cooperate with investigations particularly where this may have compromised the safety of patients their gametes or embryos and/or the quality of service
- there is failure by the PR to ensure suitability of staff; that proper equipment is used or that premises are suitable particularly where this has had an impact or

[6] S.18 (2)

may impact on the safety of patients their gametes or embryos and/or the quality of service
- public confidence in the conduct of licensed activities requires immediate action
- no suitable person is available to act as PR
- conditions cannot be adequately framed and/or would be unworkable in practice
- there is evidence of previous breaches of conditions or Directions issued by the Authority
- there is evidence of a history of significant non-compliance.

3.11 In making a decision, the licensing committee shall also have regard to the range of sanctions available, and will seek to ensure that any sanction applied is proportionate in all circumstances of the case. When considering whether to impose a sanction and what sanction to impose, a committee may take into account the following aggravating and mitigating features:

Aggravating features	**Mitigating features**
Failure by the PR and centre staff to cooperate with any inspection or investigation undertaken by the executive, or attempts to frustrate any inspection or investigation by introducing delays such as failure to respond to correspondence and being unavailable for meetings and so on.	Full cooperation by the PR and centre staff with any inspection or investigation undertaken by the executive
Non-disclosure of material information that may assist with the inspection or investigation and may conceal relevant facts or evidence.	Full disclosure of material information with no attempt made to conceal facts or evidence
A lack of insight by the PR and centre staff in to the seriousness of the non-compliance and the action being taken by the executive.	Insight demonstrated by the PR and centre staff with regard to the nature and serious of non-compliance and an understanding of the reasons why the action is being taken by the executive
Failure by the PR and centre staff to take any or sufficient and sustained action in remedying non compliance	There is evidence that early and effective remedial action has been taken by the PR and centre staff.
There is limited or no evidence of good cooperation and productive working relationships between the PR and centre staff, such that little or no confidence that remedial action will be sustained can be drawn.	There is evidence of good cooperation and productive working relationships between the PR and centre staff, such that greater confidence that remedial action will be sustained can be drawn.
Failure to provide the Authority with information required to be included in the statutory register under section 31 of the Act, or with any other information required.	The provision of information to the Authority made promptly on request.

1 April 2016

Governance and transparency

Strategic delivery:	☐ Setting standards	☐ Increasing and informing choice	☒ Demonstrating efficiency economy and value
Details:			
Meeting	Authority		
Agenda item	9		
Paper number	HFEA (09/03/2016) 789		
Meeting date	9 March 2016		
Author	Juliet Tizzard, Director of Strategy and Corporate Affairs		
Output:			
For information or decision?	For decision and information		
Recommendation	The Authority is asked to: • note the committees' annual reviews; and • agree the changes to Standing Orders.		
Resource implications	Minimal		
Implementation date	1 April 2016		
Communication(s)	Via the website		
Organisational risk	☐ Low	☒ Medium	☐ High
Annexes	Annex A: Standing Orders		

1. Introduction

1.1. For the HFEA to be an effective and trusted regulator, we must have high quality decision making processes which are clear to clinics, patients and the wider public. To achieve that, we have a number of committees, with clear instructions from the Authority about how they should make decisions. These are in our Standing Orders and explained on our website.

1.2. This paper is an annual review of our governance structures, consisting of:

- the findings of the annual review of each committee's effectiveness; and
- a review of our Standing Orders.

2. Annual review of committee effectiveness

2.1. All committees have carried out the required annual review of their effectiveness. Generally, the feedback was positive and committees have done well to incorporate new Authority members.

2.2. The committees which make licensing and authorisation decisions have fewer concerns about succession planning and quoracy than in last year's review, although there are still a few technology issues to iron out to ensure remote attendance works smoothly.

2.3. The Scientific and Clinical Advances Advisory Committee is making good use of external speakers. It is spending much of its efforts feeding into patient information about new technologies and would like specific reference to patient information in its terms of reference (see below). It would also like to strengthen links between the committee and professional societies.

2.4. The table below summarises the feedback from each committee.

Committee	Positives	Areas for improvement
Licence Committee	The new members have settled in well. They have demonstrated excellent insight and raised important issues. The scientific expertise within the committee has enabled the committee to function without the attendance of external advisers. The committee has retained oversight of tougher licensing decisions. Successful feedback loop due to attendance of the Head of Governance and Licensing.	Technical problems with some aspects of the video conferencing which need to be addressed, as quoracy can be dependent on attendance via this channel. Member availability is still an issue which could affect quoracy and decision making capability. The committee noted on very rare occasions there are delays in receiving documents which results in tabled papers.
Statutory Approvals	The addition of external advisers has continued to be extremely valuable and	A possible evaluation of the use of Genetic Alliance opinions and exploring a

Committee	has greatly improved the quality of committee's deliberations. Effective chairing to manage differences of opinion whilst maintaining collective ownership of decisions. Successful feedback loop due to attendance of the Head of Governance and Licensing.	patient perspective as an alternative. Keeping the committee up to speed with new technologies and techniques and feedback from the sector via the inspection team. This could be achieved via a periodic workshop. A review of regulation and licensing of x-linked conditions and what conditions are appropriate for PGD testing.
Executive Licensing Panel	The committee functions well, takes consistent decisions despite having a frequently used deputy chair and the paperwork and minutes are well drafted. The volume of work and high frequency of meetings are manageable.	There have been some discussions between Licensing and the Inspectorate to improve the flow of paperwork, but this generally works well.
Audit and Governance Committee	The committee continues to benefit from having external members and the new members have integrated well. The relationships between the chair, committee and internal and external audit are well developed and function well. Recommendations from last year regarding annual reviews have been implemented and inspection observations are in progress. The committee has made suggestions such as the gateway review, which has been extremely helpful to IfQ.	Could challenge the executive even more robustly to get past the natural 'can do' attitude of the HFEA, to really delve in to the issues. Formal reporting to the Authority. This will be introduced from July 2016.
Scientific and Clinical Advances Advisory Committee	The committee has sufficient members with a broad range of views and the meetings are well attended. Successful use of a briefing document for external speakers to provide context on where their contribution fits in to the committee's work. The committee agreed that meetings were chaired well, follow up was effective and papers and minutes were high quality.	The committee felt that there should be greater clarity around the committee's function and what its primary audience should be. The committee could evaluate external speakers more formally. It was agreed that early sight of papers could facilitate expert input by committee members at the drafting stage. Relationships with specialist groups could be strengthened, and collaboration on patient information would be useful.
Remuneration, Appointments and Oversight committees	*Formal reviews not undertaken due to infrequency of meetings*	
Appeals	The committee has heard one appeal this year. The Audit and Governance Committee has had an early discussion of a review of the appeals process in the light of this appeal. This will be considered later in the 2016/17 business year.	

3. Review of Standing Orders

3.1. The Authority agreed, at its September 2015 meeting, to amend the Standing Orders to allow delegation of licensing and authorisation of mitochondrial donation. These changes are reflected (and highlighted) in the Standing Orders (Annex A).

3.2. We have made a number of small consequential amendments to reflect changes of job titles (from Head of Governance and Licensing to Head of Corporate Governance) and names of guidance documents for licensing (see separate paper on the Compliance and enforcement policy).

3.3. One further amendment has been made to the Scientific and Clinical Advances Advisory Committee's purpose. This is to reflect SCAAC's role regarding patient information and safety and efficacy (see page 37 of the Standing Orders).

Functions of the Scientific and Clinical Advances Advisory Committee

6.2 The functions of the Scientific and Clinical Advances Advisory Committee shall be to:

(a) make recommendations to the Authority on ~~policy implications arising out~~ the safety and efficacy of scientific and clinical developments (including research) in assisted conception, embryo research and related areas

(b) make recommendations to the Authority on patient information relating to those scientific and clinical developments

(c) advise the Authority on significant implications for licensing and regulation arising out of such developments, and

(d) where required, work with the Authority members to consider the social, ethical and legal implications arising out of such developments.

4. Recommendation

4.1. The Authority is asked to:

- note the committees' annual reviews; and
- agree the consequential changes to Standing Orders and those regarding SCAAC's remit.

Human Fertilisation & Embryology Authority

Standing Orders

Effective 1 April 2016

Version control

Reviewed and approved by Authority on 9 December 2009.

Amendments approved by Authority on 20 January 2010 and 12 May 2010.

Typographical corrections made on 4 August 2010

Reviewed and amendments approved by Authority via written resolution (issued 12 November 2010) and decision noted at Authority meeting on 8 December 2010.

Reviewed and amended in light of new equalities legislation and approved by Authority on 23 March 2011.

Reviewed, amended and approved by Authority on 7 December 2011.

Amendments approved by Authority on 12 September 2012.

Amendments approved by Authority on 23 January 2013.

Reviewed, amended and approved by Authority on 20 March 2013.

Amendments approved by Authority on 13 November 2013.

Reviewed, amended and approved by Authority on 5 March 2014.

Reviewed, amended and approved by Authority on 11 March 2015.

Reviewed, amended and approved by Authority on 17 September 2015.

Reviewed, amended and approved by Authority on 9 March 2016.

Contents

Foreword[1]

1. The Human Fertilisation and Embryology Authority (HFEA) is an executive non-departmental public body sponsored by the Department of Health. The HFEA is a body corporate, established by Section 5 of the Human Fertilisation and Embryology Act 1990 (as amended) (the Act). In accordance with Schedule 1 to that Act, the Chair and members of the Authority are appointed by the Secretary of State for Health.

2. The HFEA is the UK's independent regulator of treatment using eggs and sperm, and of treatment and research involving human embryos. The HFEA sets standards for, and issues licences to, centres. It provides authoritative information for the public, in particular for people seeking treatment, donor-conceived people and donors. The HFEA determines the policy framework for fertility issues, which are sometimes ethically and clinically complex.

3. The HFEA is committed to adopting best practice in corporate governance. These Standing Orders form part of the corporate governance framework with which the HFEA must comply, and which includes:

   - the Act
   - Regulations issued by the Secretary of State for Health or the HFEA
   - the framework agreement between the HFEA and the Department of Health, or any other memorandum of understanding (MoU) or other agreement
   - Standing Financial Instructions adopted by the HFEA, and
   - Financial procedures for procurement and payment of goods and services, budget management and travel and subsistence.

4. As a public body, the HFEA is also required to comply with applicable legislation including that relating to human rights, equalities, freedom of information, environment information and data protection; and with relevant government policies on information assurance and data security. In addition, the HFEA is expected to comply with the statutory code of practice for regulators (The Regulators' Code).

5. In accordance with the Act (under Section 8) the HFEA shall:

   (i) keep under review information about embryos and any subsequent development of embryos and about the provision of treatment services and activities governed by this act, and advise the Secretary of State, if he/she asks it to do so, about these matters

   (ii) publicise the services provided to the public by the HFEA or provided in pursuance of licences

   (iii) provide, to such extent as it considers appropriate, advice and information for persons to whom licences apply or who are receiving treatment services or providing gametes or embryos for use for the purpose of activities governed by the Act, or may wish to do so

[1] This foreword is not part of the Standing Orders

(iv) maintain a statement of the general principles which it considers should be followed in the carrying–on of activities governed by the Act, and in the carrying-out of its functions in relation to such activities

(v) promote, in relation to activities governed by this act, compliance with requirements imposed by or under this act, and the Code of Practice under Section 25 of the Act, and

(vi) perform such other functions as may be specified in regulations.

6. In accordance with the Act (under Section 8ZA) the HFEA must carry out its functions effectively, efficiently and economically and, so far as relevant, have regard to the principles of best regulatory practice.

7. These Standing Orders take account of the relevant Cabinet Office guidance for public bodies which is intended to secure the public service values of impartiality, integrity, objectivity, openness and accountability, and to ensure that value for money is optimised.

8. These Standing Orders primarily govern the procedures for meetings of the Authority and the committees established by the Authority.

9. In the conduct of operational activities, Authority members and employees are also expected to comply with the HFEA's published principles and policies approved by the Authority and employees of the HFEA are, in addition, expected to comply with the requirements set out in the employee handbook.

Standing Orders

Effective 1 April 2016

1. Use of Standing Orders

1.1. Power to make Standing Orders

1.1.1. These Standing Orders are made in accordance with the powers of the HFEA:

a) under paragraph 9 of Schedule 1 to the Act, to regulate its own proceedings and to make such arrangements as it considers appropriate for the discharge of its functions, and

b) under section 9A of the Act, to establish committees and to delegate functions to committees, Authority members and employees.

1.1.2. These Standing Orders shall govern the proceedings of the Authority and its committees and working groups.

1.2. Commencement

1.2.1. These Standing Orders were adopted by the Authority at its public meeting on 9 December 2009, and first came into force on 1 January 2010.

1.3. Variation and amendment of Standing Orders

1.3.1. These Standing Orders can be amended by the Authority, provided that:

- a notice of motion has been given, and
- no fewer than half of the Authority members vote in favour of amendment, and
- at least two-thirds of the Authority members are present, and
- the variation proposed does not contravene any statutory provision, or a direction made by the Secretary of State.

1.4. Standing Orders to be given to Authority members, committee members and officers

1.4.1. It shall be the duty of the Chief Executive to ensure that:

a) existing Authority members, committee members and officers and all new appointees are provided with a copy of these Standing Orders and informed of their obligation to comply with these Standing Orders; and

b) a copy of these Standing Orders is published on the Authority's website.

1.5. Non-compliance with Standing Orders

1.5.1. All Authority members, committee members, officers and employees shall have a duty to disclose any non-compliance with these Standing Orders to the Chair of the HFEA or Chief Executive.

1.5.2. If for any reason these Standing Orders are not complied with, details of the non-compliance and any justification for non-compliance shall be reported to the next formal meeting of the Authority for action or ratification.

1.6. Review of Standing Orders

1.6.1. These Standing Orders shall be reviewed at least annually by the Authority. The scope or extent of such a review can be agreed in advance by the Chair, with input from the executive and committee chairs, where relevant.

2. Interpretation

2.1. Role of Chair of the Authority

2.1.1. The Chair of the HFEA shall be the final authority on the interpretation of these Standing Orders.

2.2. Definition of terms

2.2.1. The following terms are used in these Standing Orders:

'the Act' means the Human and Fertilisation and Embryology Act 1990 (as amended)

'Adviser' means persons appointed to provide advice to the Authority, its committees or working groups

'Advisory group' means a group of persons appointed to provide advice to the Authority, its committees or working groups

'Chair of the HFEA' means the person appointed by the Secretary of State for Health to chair the HFEA and shall be deemed to include the Deputy Chair of the Authority, if the Chair is absent from the meeting or is otherwise unavailable

'Chief Executive' means the person appointed by the HFEA to act as Chief Officer and Accounting Officer of the Authority

'Committee' means a committee established by the HFEA (under s.9A(2)of the Act)

'Committee members' means persons formally appointed by the Chair of the HFEA to sit on or to chair specific committees

'Corporate Management Group' (CMG) means the executive management group established by the Chief Executive for effective management of the HFEA

'Deputy Chair of the HFEA' means the HFEA member appointed by the Secretary of State to take on the Chair's duties if the Chair of the HFEA is absent for any reason

'Lay member' means a member of the Authority, who is not, nor has been:

- a medical practitioner registered under the Medical Act 1983,
- concerned with keeping or using gametes or embryos outside the body, or
- directly concerned with commissioning or funding any research involving such keeping or use, or actively participated in any decision to do so

'Officer' means a member of the CMG

'Secretary of State' means the Secretary of State for Health

'Working group' means a non-standing committee of the HFEA, established and maintained for a specific purpose

'Working group members' means persons formally appointed by the Chair of the HFEA to sit on or to chair specific working groups.

3. The Authority

3.1. Responsibilities of Authority members

3.1.1. Authority members shall, at all times, act in accordance with the provisions of the Act and with the provisions of the Code of conduct for Authority members annexed to these Standing Orders.

3.1.2. Authority members shall not give the Chief Executive instructions which conflict with his/her duties as the Authority's accounting officer.

3.1.3. No Authority member shall solicit for any person any appointment as a member or employee of the Authority, or recommend any person for such appointment.

3.1.4. Authority members shall, as soon as possible, disclose to the Chief Executive any relationship between them and a candidate of whose candidature they become aware. It shall be the duty of the Chief Executive to report to the Authority any such disclosure made.

3.1.5. Authority members shall, in the conduct of Authority business, have regard to the functions and duties of the Authority set out in sections 8 and 8ZA of the Act.

3.1.6. Authority members shall, in the conduct of Authority business, comply with all relevant legislation applying to public bodies and with government policies on information assurance and data security. In addition, Authority members shall have proper regard to the principles set out in the statutory code of practice for regulators (The Regulators' Code).

3.1.7. Authority members shall ensure that the financial transactions of the Authority are carried out in accordance with the Standing Financial Instructions and other financial procedures adopted by the Authority.

3.1.8. The Authority shall appoint an Authority member to act as equality champion, who will promote compliance with equalities legislation and from time-to-time report to the Authority on it.

3.2. Responsibilities of Authority members, committee members and employees

3.2.1. In the conduct of operational activities, Authority members and employees shall comply with applicable policies approved by the HFEA.

3.2.2. Authority members, committee members and employees shall ensure compliance with the financial procedures for procurement and payment of goods and services, budget management and travel and subsistence adopted by the Authority.

3.3. Particular responsibilities of Chair of the Authority

3.3.1. The Chair of the HFEA shall in addition to the responsibilities shared by all Authority members have particular responsibility for:

a) approving the agenda for meetings of the Authority

b) chairing meetings of the Authority

c) signing minutes of Authority meetings

d) briefing Authority members

e) ensuring that these Standing Orders are complied with

f) the appraisal of Authority members

g) the appraisal of the Chief Executive

h) the appointment of members to committees or working groups

i) taking decisions on litigation

j) ensuring a log of whistle blowing incidents is maintained

k) liaison with the Secretary of State for Health and other relevant Ministers on behalf of the Authority

l) representing the HFEA to the public, and

m) issuing 'Chair's letters' to licensed centres setting out changes of policy, the issuing of new directions under the Act, or any other important messages.

3.3.2. The Chair of the HFEA may consult with two or more Authority members as appropriate before discharging the particular responsibilities set out above or before undertaking any action on behalf of the Authority.

3.4. Particular responsibilities of Deputy Chair of the Authority

3.4.1. Where the Chair of the HFEA has died or has ceased to hold office, or where he/she has been unable to perform his/her duties as Chair owing to illness, absence from the UK or any other cause, the Deputy Chair shall act as chair until a new Chair is appointed or the existing Chair resumes his/her duties, as the case may be; and reference to the Chair in these Standing Orders shall, so long as there is no Chair able to perform his/her duties, be taken to include references to the Deputy Chair.

3.5. Particular responsibilities of the Chief Executive

3.5.1. The Chief Executive is the HFEA's designated accounting officer and, as such, is accountable to Parliament and the Secretary of State for:

a) safeguarding the public funds for which he/she has been charged

b) handling those public funds, ensuring propriety and regularity when doing so

c) day-to-day operations and management of the HFEA.

3.5.2. The Chief Executive shall establish the Corporate Management Group to ensure:

d) effective management of the HFEA's business and operational activities

e) achievement of the HFEA's strategic and statutory objectives

f) continuous improvement within the HFEA, and

g) monitoring of compliance with applicable legislation, and oversight of executive working groups on particular subjects.

3.5.3. The Chief Executive shall determine the membership and terms of reference of the Corporate Management Group.

3.6. Registers of interests and hospitality

3.6.1. The HFEA shall maintain and publish a register of interests and a register of hospitality, formally to record declarations of Authority members and employees.

3.7. Declarations of interest and potential conflicts

3.7.1. At every meeting of the Authority or of a committee, members shall be required to declare any interests they may have.

3.7.2. Authority members and committee members shall identify any potential conflicts as soon as possible after receipt of papers in advance of any meeting of the Authority or of a committee.

3.7.3. Where a potential for a conflict of interests is identified, Authority members and committee members shall consult and follow the 'Guidance for Authority and committee members on handling conflicts of interest'.

3.8. Access to external legal advice by Authority members

3.8.1. All external legal advice must usually be commissioned through the Authority's legal advisers and no advice can be commissioned without the approval of the Chair of the HFEA or the Chief Executive.

3.9. Register of policies

3.9.1. The Authority shall maintain a register of all policies approved by it and relating to the effective running of the Authority, and shall review all such policies at regular intervals.

4. Meetings

4.1. Ordinary meetings

4.1.1. Members of the Authority shall usually meet as a full Authority no fewer than six times in each calendar year, and such meetings shall be held at such intervals and venues as the Chair may determine.

4.1.2. All ordinary meetings of the Authority will be open to members of the public to attend.

4.1.3. All ordinary meetings may begin with a private session of the Authority (which may, at the Chair's discretion, be attended by officers, advisers, auditors or Department of Health representatives), at which may normally be discussed:

a) the Authority's risk register

b) any legal update

c) any commercially sensitive matters, and

d) any other business that the Chair judges is reasonable to be conducted in private.

4.2. Extraordinary meetings

4.2.1. In addition to the fixed ordinary meetings, extraordinary meetings of the Authority may be called:

a) at any time by the Chair, and

b) subject to paragraph 4.2.2, at the request of any Authority member.

4.2.2. An extraordinary meeting requested by an Authority member shall only be held if:

a) the request is made in writing to the Chair of the Authority, specifying the item(s) to be considered at the meeting

b) the written request is signed by at least one-third of the Authority members, and

c) the written request sets out the need for an extraordinary meeting and the reason why the matters to be considered should not be considered at the next ordinary meeting of the Authority.

4.2.3. It will be for the Chair to decide whether the extraordinary meeting is held in public or in private.

4.3. Written resolutions

4.3.1. A written resolution shall be as valid and effectual as if it had been passed at a full meeting of the Authority provided that:

a) the resolution is circulated by email to all Authority members

b) Authority members shall have at least three days to respond to the resolution

c) no fewer than one-third of the Authority members respond, and

d) the majority of those responding are in favour of, and approve, the resolution.

4.4. Notice of meetings and written resolutions

4.4.1. Other than in exceptional circumstances, the Chair of the HFEA shall notify Authority members of the dates of the ordinary meetings of the Authority in any calendar year at least one month before the beginning of that year.

4.4.2. Failure to serve notice on any Authority member shall not affect the validity of an ordinary meeting.

4.4.3. The Chair of the HFEA shall notify Authority members of the date of an extraordinary meeting or written resolution to be considered by the Authority and shall provide Authority members with such notice as is reasonable in the circumstances.

4.5. Agendas

4.5.1. The Chair of the Authority, in consultation with the Chief Executive, shall determine the agenda for all meetings of the full Authority.

4.5.2. An Authority member desiring a matter to be included on an agenda shall make his/her request to the Chair at least 10 working days before the meeting, and should include appropriate supporting information. Requests made less than 10 days before a meeting may be included on the agenda at the discretion of the Chair.

4.5.3. Papers may be tabled at a meeting of the full Authority only with the permission of the Chair and no business other than that set out in the Agenda shall be considered at a meeting of the Authority, except where the Chair considers that the nature or urgency of the matter is such that it would be desirable to consider the matter at that meeting.

4.5.4. Agenda items which are not considered at a meeting may be carried forward for consideration at an appropriate later ordinary meeting, or at an extraordinary meeting.

4.6. Distribution of papers

4.6.1. The Chief Executive shall endeavour to ensure that agendas and supporting papers (where possible) are sent to Authority members in good time before an Authority meeting, and shall usually send out such papers five working days before the meeting.

4.6.2. Agendas and papers may be distributed by such method as the Chief Executive considers appropriate, including by email.

4.6.3. Agendas and papers for a meeting, including those sent by email, shall be deemed to have been received on the day following the day they were sent.

4.6.4. Provided that the agenda and/or papers for a meeting have been sent to Authority members in accordance with this standing order, their non-receipt by any Authority member shall not invalidate the business transacted at that meeting.

4.6.5. Papers for consideration by the full Authority or by a committee shall be presented in the standard template approved by the Chief Executive.

4.6.6. The papers considered by Authority members at a meeting of the Authority and the minutes of the meetings of the Authority shall be published in accordance with the HFEA's policy on the publication of Authority and committee papers and shall be made available to the public in accordance with the HFEA's publication scheme and the Freedom of Information Act 2000.

4.7. Chair of meeting

4.7.1. At any meeting of the Authority, the Chair, if present, shall preside. If the Chair is absent from the meeting, the Deputy Chair shall preside. If the Chair and Deputy Chair are absent, such Authority member as the Authority members present shall choose, shall preside.

4.7.2. If the Chair of the HFEA is absent temporarily or is disqualified from participating on the grounds of a declared conflict of interest, the Deputy Chair, if present, shall preside. If the Chair and Deputy Chair are absent, or are disqualified from participating, such Authority member as the Authority members present shall choose, shall preside.

4.7.3. The decision of the Chair of the meeting on questions of order, procedure, relevancy, regularity and any other matters shall be final.

4.8. Quorum

4.8.1. No business shall be transacted at a meeting unless at least one third of the Authority members are in attendance at that meeting.

4.8.2. At the discretion of the Chair, Authority members may attend meetings of the Authority by telephone or video-conferencing.

4.8.3. In determining whether or not there is a quorum, the Chair shall take into account the provisions of section 4 (4) of Schedule 1 of the Act regarding the composition of the Authority. If the quorum comprises a majority of non-lay Authority members, the Chair of the HFEA may decide that a particular vote or decision cannot be taken. The decision of the Chair on such matters is final.

4.8.4. Any Authority member (including the Chair of the Authority) who has been disqualified from participating in the discussion on any matter and/or from voting on any question by reason of the declaration of a conflict of interest shall no longer count towards the quorum. If a quorum is then not available for the discussion and/or the decision on any matter, that matter may not be discussed further or voted upon at that meeting. Such a position shall be recorded in the minutes of the meeting.

4.9. Voting

4.9.1. The Authority shall usually seek to achieve consensus on issues requiring a decision by the Authority members.

4.9.2. Where the Chair determines that a vote is necessary, the nature of that vote shall be at the discretion of the Chair, and may be by oral expression or show of hands or by paper ballot if a majority of the Authority members present so request.

4.9.3. Only those Authority members (including the Chair of the Authority) actually in attendance at the time that a vote is to be taken shall be entitled to vote. Voting by proxy is not permitted.

4.9.4. Where a vote is held, the issue shall be decided by a majority of the votes of the Authority members who are in attendance at the meeting (including the Chair of the Authority) and who have not been disqualified from participating in the decision by reason of any declared conflict of interest.

4.9.5. In the event of the number of votes for and against a motion being equal, the Chair of the meeting shall have a second or casting vote.

4.10. Minutes

4.10.1. The proceedings of every meeting of the Authority shall be formally recorded. The recording shall be made available on the Authority's website as soon as is reasonably practicable.

4.10.2. The Chief Executive shall ensure that an employee is present at every meeting of the Authority to act as secretary to that meeting and to produce the minutes of the meeting.

4.10.3. The names of the Chair and Authority members present at the meeting shall be recorded in the minutes.

4.10.4. The minutes shall not usually record:

a) the names of individual Authority members who made specific comments, contributions or suggestions at a meeting, or

b) the vote (or abstention) of individual Authority members.

4.10.5. If an Authority member so requests, his/her vote or the fact that he/she abstained from participating in a discussion or voting on any matter, shall be recorded in the minutes.

4.10.6. The draft minutes of the proceedings of a meeting of the Authority shall be drawn up and submitted for agreement by the Authority members at the next meeting, and the person chairing that meeting shall sign the minutes with any agreed amendments which may be necessary.

4.11. Attendance by officers and auditors

4.11.1. The following persons shall be entitled to attend all meetings of the Authority and to bring any matter to the attention of the Authority members:

a) Chief Executive

b) Corporate Management Group

c) internal auditors, and

d) external auditors.

4.12. Attendance of non-Authority members

4.12.1. Observers from the Department of Health and employees of the Authority may attend ordinary meetings of the Authority.

4.12.2. At any meeting of the Authority, the Chair may require persons who are not Authority members (including members of the public, officers, other observers, and employees) to withdraw for any part of a meeting, if the Chair considers it desirable for the Authority members to meet in private or in the absence of some of those present.

4.12.3. The Chair of the HFEA may require any person whose presence the Chair considers to be disruptive to the proceedings to withdraw from the meeting.

4.12.4. The Chair of the HFEA may invite such persons as he or she considers desirable to attend a meeting of the Authority and to advise the Authority members on any matter on the agenda for that meeting.

5. Reservation of powers to the Authority

5.1. List of reserved matters

5.1.1. The following matters shall be reserved to the Authority and shall not be delegated:

~~a)~~e) appointment of the Chief Executive, with the approval of the Secretary of State

~~b)~~a) disciplinary action against the Chief Executive

~~c)~~b) approval and amendments of Standing Orders

~~d)~~c) establishing of committees and working groups

~~e)~~d) agreement of the terms of reference and reporting arrangements of committees and working groups

~~f)~~e) receiving reports from committees, working groups and individual members

~~g)~~f) the appointment of HFEA representatives on external bodies

~~h)~~g) approving the strategic aims of the HFEA

~~i)~~h) approving the HFEA's corporate strategy or any equivalent documentation required by the Department of Health

~~j)~~i) approving the HFEA's annual business plan

~~k)~~j) approving the annual budget

~~l)~~k) approving the annual report and accounts

~~m)~~l) (in consultation with the Department of Health and the Treasury) approving the structure and level of fees levied on licence holders and applicants for licences

~~n)~~m) monitoring of the HFEA's performance against the annual plan and budget

~~o)~~n) determination of all policies relating to the performance of the HFEA's functions under Section 8 of the Act

~~p)~~o) approval of the annual update to the Code of Practice and General Directions

~~q)~~p) ratification of any urgent decisions taken by the Chair in accordance with section 5.2 of these Standing Orders.

5.2. Emergency powers of Chair and Chief Executive

5.2.1. The powers which the Authority has reserved to itself in paragraph 5.1 may, in an emergency, be exercised by the Chair of the HFEA and the Chief Executive.

5.2.2. An emergency is any situation in which decisions or actions are required and such decisions or actions cannot be postponed until the next ordinary meeting of the Authority.

5.2.3. The Chair of the HFEA shall, before exercising emergency powers under this section, make best endeavours to obtain the views of Authority members on the required decision or action.

5.2.4. The exercise of emergency powers by the Chair of the HFEA and the Chief Executive shall be reported to the next meeting of the Authority, and may be ratified by the Authority members.

6. Arrangements for the exercise of functions by delegation

6.1. Power to delegate

6.1.1. The matters below are delegated in accordance with section 9A of the Act.

6.2. Litigation

6.2.1. Decisions on litigation against or on behalf of the HFEA shall be delegated to the Chair of the HFEA.

6.2.2. Before making a decision on litigation, the Chair of the HFEA may consult with the Deputy Chair of the HFEA and the Chair of the Audit and Governance Committee, or where appropriate, with two other Authority members.

6.2.3. Subject to 6.2.4 below, the Chair of the HFEA shall ensure that Authority members are regularly updated on key decisions and stages reached, in respect of litigation affecting the HFEA.

6.2.4. Where the Chair of the HFEA considers that it would be inappropriate to update Authority members on litigation issues because there are associated matters that are yet to be determined by a committee of the HFEA, including licence applications, the Chair may defer updating Authority members until the associated matters are determined by the relevant committee.

6.3. Licensing functions

6.3.1. The HFEA shall establish the role of Licensing Officer. The HFEA delegates to the Licensing Officer (who shall be an HFEA employee, member of the Executive Licensing Panel and be appointed by the Chief Executive):

~~a)~~q) the exercise of certain administrative licensing functions, as set out in annex B to these Standing Orders and amended from time to time by the Authority.

6.3.2. The HFEA shall establish and maintain an Executive Licensing Panel. The HFEA delegates to the Executive Licensing Panel:

~~a)~~r) the exercise of certain routine licensing functions (including those delegated to the Licensing Officer), as set out in annex B to these Standing Orders and amended from time to time by the HFEA; and

~~b)~~s) the power to issue directions under sections 24(5A) to (5E) and section 24(13) of the Act.

6.3.3. The Executive Licensing Panel shall be constituted and shall operate in accordance with the Executive Licensing Panel protocol set out in annex C to these Standing Orders.

6.3.4. In accordance with Section 9A(2) of the Act, the HFEA shall establish and maintain a Licence Committee which will include Authority members and such additional committee members as the HFEA considers necessary.

6.3.5. The HFEA delegates to the Licence Committee:

a) the exercise of its complex or controversial licensing functions (but also including those delegated to the ELP and Licensing Officer), as set out in annex B to these Standing Orders as amended from time to time by the HFEA, and

b) the power to issue directions under sections 24(5A) to (5E) and section 24(13) of the Act.

6.3.6. Save when considering representations under Section 19(4) of the Act, the Licence Committee shall be constituted and shall operate in accordance with the Licence Committee protocol set out in annex D to these Standing Orders.

6.3.7. When considering representations under Section 19(4) of the Act, the Licence Committee shall be constituted and shall operate in accordance with the Human Fertilisation and Embryology (Procedure for Revocation, Variation or Refusal of Licences) Regulations 2009 (as amended).

6.4. Reconsideration of licensing decisions

6.4.1. In accordance with section 20A of the Act, the HFEA shall establish and maintain an Appeals Committee.

6.4.2. The HFEA delegates to the Appeals Committee the power to carry out its functions under section 20 of the Act.

6.4.3. The Appeals Committee shall be constituted and shall operate in accordance with the Human Fertilisation and Embryology (Appeals) Regulations 2009.

6.5. Disclosure of information for research purposes

6.5.1. The HFEA shall establish and maintain:

a) a Register Research Panel

b) a Register Research Review Panel, and

c) an Oversight Committee

to exercise the Authority's functions under the Human Fertilisation and Embryology (Disclosure of Information for Research Purposes) Regulations 2010.

6.5.2. The Authority delegates to the Register Research Panel, the power to:

a) authorise access to Register data for the purposes of medical or non-medical research, and

b) deny, suspend, revoke, vary or impose conditions upon authorisation to access Register data.

6.5.3. The Authority delegates to the Register Research Review Panel, the power to:

a) uphold or overturn the decisions of the Register Research Panel

b) authorise access to Register data for the purposes of medical or non-medical research, and

c) deny, suspend, revoke, vary or impose conditions upon authorisation to access Register data.

6.5.4. The membership, functions, and arrangement for meetings of the Register Research Panel; Register Research Review Panel; and the Oversight Committee, shall be as set out in annex A to these Standing Orders.

6.6. Delegation of amendments to the Code of Practice, General Directions and other guidance

6.6.1. The HFEA may agree from time to time to the delegation of revisions to the Code of Practice and General Directions.

6.6.2. The terms of reference of such delegations shall be approved by Authority members at meetings of the Authority, and the minutes of that meeting shall record the matters delegated by the HFEA.

6.7. Delegation to other committees, working groups and individual members

6.7.1. The HFEA may agree from time to time to the delegation of functions and powers to other committees, sub-committees, working groups, or individual members.

6.7.2. The constitution and terms of reference of these committees, sub-committees or working groups, and their specific delegated powers and those of any individual member shall be approved by Authority members at meetings of the Authority, and the minutes of that meeting shall record the matters delegated by the Authority.

6.8. Delegation to officers

6.8.1. Those functions of the Authority, which have not been reserved by the Authority or delegated to the Chair (in Section 5 of these Standing Orders); or delegated to a committee, working group, panel, or officer (in Section 6 of these Standing Orders), shall be exercised by the Chief Executive on behalf of the Authority.

6.8.2. The Chief Executive shall determine which functions he/she will perform personally and shall nominate officers or other employees, as appropriate, to undertake the remaining functions for which he/she will retain accountability to the Authority.

6.8.3. The Chief Executive shall report periodically to the Authority on the exercise of powers so delegated.

7. Committees, working groups and advisory groups

7.1. Power to establish committees and working groups

7.1.1. In accordance with section 9A(2) of the Act, the Authority shall establish and maintain the committees set out in annex A to these Standing Orders.

7.1.2. In accordance with paragraph 9 of schedule 1, the Authority may from time to time, establish working groups of Authority members and other members as deemed necessary by the Authority.

7.1.3. A proposal to establish a working group shall identify the purpose of the group, the likely budget and employee resources needed; the outputs required of the group, and the timeframe for which the group shall exist.

7.1.4. The Chief Executive shall ensure that a person is appointed to act as secretary to each Committee or working group and to take the minutes of each meeting.

7.2. Membership of committees and working groups

7.2.1. This paragraph does not apply to the Appeals Committee.

7.2.2. The Chair of the HFEA shall appoint the Chair of a Committee, committee members and the Chair and members of working groups established by the Authority.

7.2.3. The Chair of the HFEA shall only appoint persons who are not Authority members to a committee or working group where the Appointments Committee has agreed that such persons are suitable for appointment to a committee.

7.2.4. The remuneration for persons who are not Authority members but who have been appointed as a committee or working group member shall be as agreed from time to time with the Department of Health.

7.2.5. The terms of office for members of committees or working groups shall be decided by that committee or working group's Chair, but shall not normally be for more than three years.

7.3. Conduct of meetings of committees and working groups

7.3.1. This paragraph does not apply to meetings of the Licence Committee, Executive Licensing Panel or Appeals Committee.

7.3.2. Subject to paragraph 7.3.3 and 7.3.4 below, and in accordance with paragraph 9 of schedule 1 to the Act, committees and working groups established by the Authority may regulate their own proceedings.

7.3.3. The Chair of the committee or working group shall at each meeting:

~~a)~~d) inquire whether any committee or working group member has any interests to declare, and if so, ensure that such interests are recorded

~~b)~~e) where potential conflicts are identified, ensure that the committee or working group refers to and follows the 'Guidance for Authority and committee members on handling conflicts of interest'

~~c)~~f) where appropriate, sign the minutes of any previous meetings with any agreed amendments that may be necessary, and

~~d)~~g) ensure that the proceedings of the committee or working group comply with the terms of reference and delegated powers set out in Annex A to these Standing Orders or established by the Authority.

7.3.4. With the permission of the Chair of the committee or working group, committee members may participate in a meeting by the use of telephone- or video-conferencing facilities, or other appropriate means.

7.4. Distribution of agenda and papers

7.4.1. The committee secretary shall send the agenda and papers to all committee or working group members in good time before the meeting, and usually no less than five working days before the meeting.

7.4.2. Papers shall be distributed by such method as is determined by the committee Chair.

7.5. Minutes of meetings

7.5.1. Paragraph 4.10 of these Standing Orders shall apply with appropriate modifications.

7.6. Publication of papers

7.6.1. The minutes of the meetings of committees shall be published in accordance with the HFEA's Policy on the Publication of Authority and Committee Papers and shall be made available to the public in accordance with the HFEA's publication scheme and the Freedom of Information Act 2000.

7.7. Advisers and advisory groups

7.7.1. The Authority delegates to the Chief Executive and his/her Senior Management Team the power to appoint advisers or advisory groups to support committees or working groups, and to determine remuneration necessary (if any) for those appointees.

8. Sealing and execution of documents

8.1. Application of seal

8.1.1. The application of the Authority's seal shall be authenticated by the signature of the Chair or Deputy Chair of the Authority.

8.2. Signing of documents

8.2.1. The following Authority members and officers shall be authorised to sign deeds or other documents on behalf of the Authority:

~~a)~~h) Chair of the Authority

~~b)~~i) Deputy Chair of the Authority

~~c)~~j) Chief Executive, and

~~d)~~k) Members of the Corporate Management Group.

8.3. Signing of contracts

8.3.1. Officers and employees shall be authorised to sign contracts on behalf of the Authority in accordance with the authorised delegations for ordering goods and services set out in the financial procedures approved by the Authority.

Standing orders: Annex A

Standing committees and additional committees established by the Authority and their terms of reference

1. Standing committees of the Authority

1.1. The Authority shall maintain the following standing committees concerned with licensing:

~~a)~~l) Licence Committee, and

~~b)~~m) Appeals Committee.

1.2. The membership and procedures of the Licence Committee (other than when considering representations made under section 19(4) of the Human Fertilisation and Embryology Act 1990) are set out in the Protocol for the conduct of meetings of the Licence Committee (Annex D to the Authority's Standing Orders).

1.3. The membership and procedures of the Licence Committee when considering representations made under section 19(4) of the Human Fertilisation and Embryology Act 1990 are set out in the Human Fertilisation and Embryology (Procedure for Revocation, Variation or Refusal of Licences) Regulations 2009 (as amended).

1.4. The membership and procedures of the Appeals Committee are set out in the Human Fertilisation and Embryology (Appeals) Regulations 2009.

1.5. The Authority shall maintain the following additional committees:

~~a)~~n) Audit and Governance Committee

~~b)~~o) Statutory Approvals Committee

~~c)~~p) Remuneration Committee

~~d)~~q) Appointments Committee

~~e)~~r) Scientific and Clinical Advances Advisory Committee, and

~~f)~~s) Oversight Committee.

1.6. A report of the activities of the non-licensing standing committees shall be presented to every ordinary meeting of the Authority (if they have met since the last Authority meeting), and presentation of such reports shall be a standing item on the agenda for all ordinary Authority meetings.

1.7. All the Authority's additional standing committees may:

~~a)~~t) receive expert advice where the committee Chair considers that such advice would assist the committee in its deliberations, and

~~b)~~u) sit with a legal adviser in attendance and may allow the legal adviser to remain with the committee during any private deliberations.

1.8. Where an issue is considered by a committee across several meetings, the validity of the proceedings of that committee shall not be affected by reason only that members of that committee,

a) who were in attendance at a former meeting were not in attendance at a later meeting of the committee, or

b) who were not in attendance at a former meeting of the committee are in attendance at a later meeting.

1.9. The validity of the proceedings of any of the committees shall not be affected by reason only of:

~~a)~~c) a defect in the appointment of any committee member, or

~~b)~~d) a vacancy in the membership of that committee.

2. The Audit and Governance Committee

Purpose of the committee

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

Delegated powers and functions of the Audit and Governance Committee

2.2. The Authority delegates to the Audit and Governance Committee, the following powers:

~~a)~~e) approval of the internal audit programme, and

~~b)~~f) approval of the statement on internal control or equivalent annual governance statement included in the annual accounts.

2.3. The functions of the Audit and Governance Committee shall be to:

~~a)~~g) oversee the general corporate governance of the Authority (including supervision and review of the operational effectiveness of the Authority's internal control and risk management procedures)

~~b)~~h) ensure that the Authority complies with its statutory functions, and with the requirements of the regulators' code, requirements applicable to arm's length bodies, and the principles and best practice guidance issued by the Better Regulation Executive

~~c)~~i) meet regularly with the Authority's internal and external auditors to ensure that the Authority is complying with statutory requirements and best practice relating to internal control systems risk management, audit, and financial reporting requirements

~~d)~~j) review the annual financial statements before their submission to the Authority focusing particularly on changes in, and compliance with accounting policies and practices, and

~~e)~~k) review and manage the effectiveness of the Authority's whistle-blowing policy.

2.4. In particular, the Audit and Governance Committee shall:

a) review the adequacy of all risk and control related disclosure statements, together with any accompanying statement from the internal auditors, prior to endorsement by the Authority

b) review the adequacy of structures, processes and responsibilities for identifying and managing key risks facing the Authority

c) review the adequacy of internal audit policies to ensure compliance with the controls assurance standards and other relevant guidance

d) review the adequacy of policies and procedures for all work related to fraud and corruption as set out in the Secretary of State directions and as required by the National Health Service Counter Fraud Service

e) make recommendations to the Authority about the appointment (including renewal) and, where necessary, dismissal of the internal audit service and the audit fee payable

f) manage the relationship with the external auditor (the Comptroller and Auditor General), and ensure that any chargeable non-audit services provided do not compromise the auditors' independence or objectivity

g) review the planning, conduct and conclusions of the external audit process (including review of all reports and annual audit letters, together with the associated management responses)

h) receive reports from the Tender Panel established in accordance with the financial procedures approved by the Authority, and

i) receive reports about all consultancy contracts made by the Authority.

2.5. In pursuance of these functions, the Authority authorises the Audit and Governance Committee to:

~~a)~~i) require a review or investigation of any procedures and activities undertaken by the Authority that fall within its remit

~~b)~~k) obtain from any employee, such information as it considers relevant to the carrying out of its functions. (All employees are directed to co-operate with any request made by the Audit and Governance Committee)

~~c)~~l) obtain such external legal or other professional advice as it considers necessary to enable it to fulfil its functions, and

~~d)~~m) provide such advice or recommendations to the Chair, the Authority members and the Authority's Chief Executive, as it considers necessary or appropriate.

Membership of the Audit and Governance Committee

2.6. The Audit and Governance Committee shall consist of up to five members including:

~~a)~~n) a Committee Chair (who shall be an Authority member)

~~b)~~o) a Deputy Committee Chair (who shall be an Authority member)

~~c)~~p) two persons who shall not be Authority members and who have relevant legal, financial, public sector or other corporate governance expertise.

2.7. The Chair of the HFEA shall appoint the members of the Audit and Governance Committee.

2.8. Members of the Audit and Governance Committee shall usually be appointed for a term of three years.

Meetings of the Audit and Governance Committee

2.9. The quorum for a meeting of the Audit and Governance Committee shall be three, which shall include the Committee Chair or Deputy Committee Chair.

2.10. The Audit and Governance Committee shall usually meet no fewer than four times a year.

Attendance at meetings of the Audit and Governance Committee

2.11. In addition to members of Audit and Governance Committee, the following persons shall usually attend its meetings:

~~a)~~q) the Chief Executive (or his delegated representative)

~~b)~~r) the Director of Finance and Resources

~~c)~~s) the Head of ~~Governance and Licensing~~Corporate Governance

~~d)~~t) the Committee Secretary

~~e)~~u) a representative from the Department of Health

~~f)~~v) a representative from the Authority's internal auditors, and

~~g)~~w) a representative from the Authority's external auditors.

2.12. The Committee Chair may invite such other persons (including employees) as he/she considers appropriate, to attend the meetings of the committee and/or to provide advice to inform the deliberations of the committee.

2.13. The Committee Chair may determine when and whether it is necessary or desirable for any non-members of the Audit and Governance Committee to withdraw from the meeting to enable the committee to deliberate in private.

3. The Statutory Approvals Committee

Purpose of the committee

3.1. The purpose of the Statutory Approvals Committee is to keep under review and to authorise the use of embryo testing; to authorise the use of mitochondrial donation treatment; to issue Special Directions for the import/export of gametes; and to authorise the use of novel processes in licensed activities.

Delegated powers and functions of the Statutory Approvals Committee

3.2. The Authority delegates to the Statutory Approvals Committee the following powers:

~~a)~~x) the authorisation of the use of embryo testing for conditions not previously authorised by the Authority (under Schedule 2, paragraph 1ZA(1)(a), (b) and (c) of the Act)

~~b)~~y) the authorisation of the use of embryo testing to establish whether the tissue of any resulting child would be compatible with that of a sibling that suffers from a serious medical condition (under Schedule 2, paragraph 1ZA(1)(d)

z) the authorisation of the use of embryo testing to establish whether an embryo is one of those whose creation was brought about by using the gametes of a particular person (under Schedule 2, paragraph 1ZA(1)(e)

~~c)~~aa) the authorisation of the use of maternal spindle transfer (MST) and/or pronuclear transfer (PNT) for a named patient (under The Human Fertilisation and Embryology (Mitochondrial Donation) Regulations 2015)

~~d)~~bb) the issuing of Special Directions for the import/export of gametes or embryos (under section 24 of the Act), and

~~e)~~cc) the authorisation of the use of novel processes in licensed activities.

3.3. The functions of the Statutory Approvals Committee shall include:

~~a)~~dd) keeping under review the genetic conditions authorised by the Authority for embryo testing.

Membership of the Statutory Approvals Committee

3.4. The Statutory Approvals Committee shall consist of no more than six members, which shall include:

~~a)~~ee) a Committee Chair (who shall be a lay Authority member)

~~b)~~ff) a Deputy Committee Chair (who shall be a lay Authority member);

~~c)~~gg) up to four other Authority members.

3.5. The Chair of the HFEA shall appoint the members of the Statutory Approvals Committee.

3.6. Members of the Statutory Approvals Committee shall usually be appointed for a term of three years.

Meetings of the Statutory Approvals Committee

3.7. The quorum for a meeting of the Statutory Approvals Committee shall be three including the Committee Chair or Deputy Committee Chair and two other members.

3.8. The Statutory Approvals Committee shall usually meet 12 times per year. At the discretion of the Chair, the committee may meet additionally at short notice (and, if necessary, by telephone- or video-conference) if the Chair considers there is an item (or items) which cannot be delayed until the next meeting.

3.9. No member of the Statutory Approvals Committee present at a meeting shall abstain from voting.

3.10. Decisions of the Statutory Approvals Committee to authorise embryo testing or novel processes, or to issue Special Directions, require a simple majority (and in the event of a tie, the Committee Chair shall have a casting vote).

Attendance at meetings of the Statutory Approvals Committee

3.11. In addition to members of the Statutory Approvals Committee, the following persons shall usually attend its meetings:

~~a)~~hh) a legal adviser

~~b)~~ii) a specialist adviser

~~c)~~jj) the Head of Corporate Governance ~~and Licensing~~

~~d)~~kk) the Committee Secretary.

3.12. The Committee Chair may invite such other persons (including employees) as he/she considers appropriate, to attend the meetings of the Statutory Approvals Committee and/or to provide advice to inform the deliberations of the Statutory Approvals Committee.

3.13. The Committee Chair may determine when and whether it is necessary or desirable for any non-members of the committee to withdraw from the meeting to enable the committee to deliberate in private.

4. The Remuneration Committee

Purpose of the committee

4.1. To consider matters relating to remuneration and human resources.

Delegated powers and functions of the Remuneration Committee

4.2. The Authority delegates to the Remuneration Committee the power to approve annual employee pay levels.

4.3. The functions of the Remuneration Committee shall be to:

~~a)~~ll) develop the Authority's pay policy and strategy

~~b)~~mm) monitor overall levels of remuneration

~~c)~~nn) review, moderate and approve the remuneration of the Chief Executive and Directors, and

~~d)~~oo) consider human resource issues referred to it by the Chief Executive or Chair of the Authority.

Membership of the Remuneration Committee

4.4. The Remuneration Committee shall consist of three members, which shall include:

~~a)~~pp) a Committee Chair (who shall be the Chair of the Authority)

~~b)~~qq) a Deputy Committee Chair (who shall be the Deputy Chair of the Authority), and

~~c)~~rr) the Chair of the Audit and Governance Committee.

Meetings of the Remuneration Committee

4.5. The quorum for a meeting of the Remuneration Committee shall be two.

4.6. The Remuneration Committee shall usually meet at least once a year.

Attendance at meetings of the Remuneration Committee

4.7. The Committee Chair may invite such other persons (including employees) as he/she considers appropriate, to attend the meetings of the Remuneration Committee and/or to provide expert advice to inform the deliberations of the committee.

4.8. The Committee Chair may determine when and whether it is necessary or desirable for any non-members of the Remuneration Committee to withdraw from the meeting to enable the committee to deliberate in private.

5. The Appointments Committee

Purpose of the committee

5.1. To oversee the appointments of external members contributing to the work of the committees and working groups.

Functions of the Appointments Committee

5.2. The Authority delegates to the Appointments Committee, the following functions:

~~a)~~ss) Advising the Chair of the HFEA on the appointment of all non-Authority members to the committees and working groups

~~b)~~tt) Monitoring the balance of expertise, experience and backgrounds of committee members in accordance with the purpose and requirements of each committee or working group, and

~~c)~~uu) Oversight of the Authority's mechanisms for identifying and appointing non-Authority members to the committees and working groups.

Membership of the Appointments Committee

5.3. The Appointments Committee shall consist of three members, which shall include:

~~a)~~vv) a Committee Chair (who shall be the Chair of the Authority)

~~b)~~ww) a Deputy Committee Chair (who shall be the Deputy Chair of the Authority), and

~~c)~~xx) the Chair of the Audit and Governance Committee.

Meetings of the Appointments Committee

5.4. The quorum for a meeting of the Appointments Committee shall be two.

5.5. The Appointments Committee shall usually meet at least once a year.

Attendance at meetings of the Appointments Committee

5.6. The Committee Chair may invite such other persons (including employees) as the he/she considers appropriate, to attend the meetings of the Appointments Committee and/or to provide expert advice to inform the deliberations of the Committee.

5.7. The Committee Chair may determine when and whether it is necessary or desirable for any non-members of the Appointments Committee to withdraw from the meeting to enable the committee to deliberate in private.

6. The Scientific and Clinical Advances Advisory Committee

Purpose of the committee

6.1. The purpose of the Scientific and Clinical Advances Advisory Committee is to advise the Authority on scientific and clinical developments (including research) in assisted conception, embryo research and related areas.

Functions of the Scientific and Clinical Advances Advisory Committee

6.2. The functions of the Scientific and Clinical Advances Advisory Committee shall be to:

~~a)~~yy) make recommendations to the Authority on the safety and efficacy of ~~policy implications arising out of~~ scientific and clinical developments (including research) in assisted conception, embryo research and related areas

zz) make recommendations to the Authority on patient information relating to those scientific and clinical developments

~~b)~~aaa) advise the Authority on significant implications for licensing and regulation arising out of such developments, and

~~c)~~bbb) where required, work with the Authority members to consider the social, ethical and legal implications arising out of such developments.

Membership of the Scientific and Clinical Advances Advisory Committee

6.3. The Scientific and Clinical Advances Advisory Committee shall consist of five Authority members, which shall include:

~~a)~~ccc) a Committee Chair (who shall be an Authority member)

~~b)~~ddd) a Deputy Committee Chair (who shall be an Authority member), and

~~c)~~eee) three other Authority members.

6.4. In addition, up to eight other persons, who shall not be Authority members, shall be appointed as expert advisers to the committee. Such persons shall not be entitled to vote.

6.5. At least one of the Authority members of the Scientific and Clinical Advances Advisory Committee shall have clinical or scientific expertise.

6.6. The Chair of the HFEA shall appoint the members of the Scientific and Clinical Advances Advisory Committee.

6.7. Members of the Scientific and Clinical Advances Advisory Committee shall usually be appointed for a term of three years. Expert advisers may be appointed for a period of one, two or three years.

Meetings of the Scientific and Clinical Advances Advisory Committee

6.8. The quorum for a meeting of the Scientific and Clinical Advances Advisory Committee shall be three including the Committee Chair or Deputy Committee Chair of the committee.

6.9. The Scientific and Clinical Advances Advisory Committee shall usually meet three times each year.

Attendance at meetings of the Scientific and Clinical Advances Advisory Committee

6.10. The Committee Chair may invite such other persons (including employees) as he/she considers appropriate, to attend the meetings of the Scientific and Clinical Advances Advisory Committee and/or to provide expert advice to inform the deliberations of the committee.

6.11. The Committee Chair may determine when and whether it is necessary or desirable for any non-members of the Scientific and Clinical Advances Advisory Committee to withdraw from the meeting to enable the committee to deliberate in private.

7. Oversight Committee

Purpose of the Oversight Committee

7.1. The purpose of the Oversight Committee is to fulfil the functions set out in the Human Fertilisation and Embryology (Disclosure of Information for Research Purposes) Regulations 2010 ('the 2010 Regulations').

Functions of the Oversight Committee

7.2. The functions of the Oversight Committee shall be to:

~~a)~~fff) monitor the grant of authorisations to access Authority Register data made under the Human Fertilisation and Embryology (Disclosure of Information for Research Purposes) Regulations 2010

~~b)~~ggg) monitor the processing of patient-, partner- and child-identifying Register data by research establishments

~~c)~~hhh) consider annual reports submitted by research establishments

~~d)~~iii) consider such other matters relating to the 2010 Regulations as the Committee determines

~~e)~~jjj) oversee the functions of the Register Research Panel and the Register Research Review Panel

~~f)~~kkk) make recommendations to the Register Research Panel and the Register Research Review Panel about improvements to processes and the operation of the Panels

~~g)~~lll) approve any memorandum of understanding (MoU) or any contractual arrangements between the Authority and other public bodies with an interest in the safeguarding of personal information in the United Kingdom where these relate to the disclosure of Authority Register data for research purposes, and

~~h)~~mmm) approve variations of and amendments to such MoUs, contracts and agreements.

Membership of the Oversight Committee

7.3. The Authority is the Oversight Committee and, when performing the statutory functions of the Oversight Committee as set out in regulation 21 of the Human Fertilisation and Embryology (disclosure of information for research purposes) regulations 2010, the relevant sections of the Standing Orders will apply.

Meetings of the Oversight Committee

7.4. The quorum for a meeting of the Oversight Committee shall be four.

7.5. The Oversight Committee shall consider an overview report submitted by the Register Research Panel at least once a year.

Attendance at meetings of the Oversight Committee

7.6. The Chair of the HFEA may invite such other persons (including non-Authority members and representatives from the Department of Health) as he/she considers appropriate, to attend the

meetings of the Oversight Committee and/or to provide expert advice to inform the deliberations of the committee.

7.7. The Chair of the HFEA may determine when and whether it is necessary or desirable for any non-members of the Oversight Committee to withdraw from the meeting to enable the committee to deliberate in private.

8. Executive Panels concerned with Disclosure of Information for Research Purposes

Register Research Panel

Purpose of the Register Research Panel

8.1. The purpose of the Register Research Panel is to consider applications made under the Human Fertilisation and Embryology (Disclosure of Information for Research Purposes) Regulations 2010 ('the 2010 Regulations').

Delegated powers and functions of the Register Research Panel

8.2. The Authority delegates to the Register Research Panel, the power to:

~~a)~~nnn) authorise access to Register data for the purposes of medical or non-medical research, and

~~b)~~ooo) deny, suspend, revoke, vary or impose conditions upon authorisation to access Register data.

8.3. The functions of the Register Research Panel shall be to:

~~a)~~ppp) comply with the requirements of the 2010 Regulations

~~b)~~qqq) review annual reports submitted by research establishments

~~c)~~rrr) publish lay summaries of research projects involving the use of Authority Register data

~~d)~~sss) submit a report to the Authority's Oversight Committee about the work of the Register Research Panel not less than once a year

~~e)~~ttt) refer appeals against the decisions of the Register Research Panel to the Register Research Review Panel, and

~~f)~~uuu) liaise and collaborate with any appropriate bodies in the UK with an interest in the safeguarding of personal data and the oversight of research studies involving the linkage of complex datasets.

Membership of the Register Research Panel

8.4. The Register Research Panel shall consist of:

~~(1)~~vvv) the Director of Compliance and Information, who will act as the Chair of the Register Research Panel

~~g)~~www) the Authority's Caldicott Guardian, and

~~h)~~xxx) the Head of Information Technology.

Meetings of the Register Research Panel

8.5. The quorum for a meeting of the Register Research Panel shall be three.

8.6. Meetings of the Register Research Panel will be scheduled as required and in accordance with any memorandum of understanding between the Authority and bodies responsible for national information governance.

8.7. Meetings of the Register Research Panel will be private.

Attendance at meetings of the Register Research Panel

8.8. In addition to the Chair and members of the Register Research Panel, such other employees as the Chair considers necessary may attend the meetings of the Register Research Panel.

8.9. The Chair of the Register Research Panel may invite such other persons (including non-Authority members and representatives from the Department of Health) as the Chair considers appropriate, to attend the meetings of that panel and/or to provide expert advice to inform the deliberations of the panel.

Register Research Review Panel

Purpose of the Register Research Review Panel

8.10. To consider appeals against the decisions of the Register Research Panel in accordance with Regulation 12 of the 2010 Regulations.

Delegated powers and function of the Register Research Review Panel

8.11. The Authority delegates to the Register Research Review Panel, the power to:

~~(1)~~yyy) uphold or overturn the decisions of the Register Research Panel

~~i)~~zzz) authorise access to Register data for the purposes of medical or non-medical research, and

~~j)~~aaaa) deny, suspend, revoke, vary or impose conditions upon authorisation to access Register data.

Membership of the Register Research Review Panel

8.12. The Register Research Review Panel shall consist of:

~~(1)~~bbbb) the Chief Executive, who will act as the Chair of the Register Research Review Panel, and

~~k)~~cccc) the Senior Information Risk Owner (SIRO) of the Authority.

Meetings of the Register Research Review Panel

8.13. Meetings of the Register Research Review Panel shall be scheduled as required following receipt of an appeal against the decisions of the Register Research Panel.

Attendance at meetings of the Register Research Review Panel

8.14. In addition to the Chair and members of the Register Research Review Panel, such other employees as the Chair considers necessary may attend the meetings of the Register Research Review Panel.

8.15. The Chair of the Register Research Review Panel may invite such other persons (including non-Authority members and representatives from the Department of Health) as the Chair considers appropriate, to attend the meetings of that panel and/or to provide expert advice to inform the deliberations of the panel.

Standing Orders: Annex B
Instrument of delegation in respect of Authority licensing functions

1. Licensing functions delegated to a Licensing Officer

Consideration of the following variations of licences on application (under Section 18A(2) of the Act): • change of licence holder, and • change of a centre's name or address.
Consideration of applications for voluntary revocation of licences under Section 18(1) of the Act

2. Licensing functions delegated to the Executive Licensing Panel

All powers delegated to a Licensing Officer in table 1, above, plus:
Consideration of applications for initial licences for treatment, storage and provision of non-medical fertility services, and exercise of the Authority's power to grant such licences under Section 16 of the Act
Consideration of applications for the renewal of licences for treatment, storage and provision of non-medical fertility services, and exercise of the Authority's power to grant such licences under Section 16 of the Act
Consideration of renewal applications for research licences, which the Licence Committee has not reserved to itself for consideration or which do not raise complex or controversial issues, and exercise of the Authority's power to grant such licences under Section 16 of the Act
Consideration of interim inspections reports (treatment and/or storage, and research)
The following variation of licences either on application or otherwise:- • change of Person Responsible (under Section 18A(1) of the Act) • changes to licensed activities (under Section 18A(2) of the Act), and • change of a centre's premises (under Section 18A(2) of the Act).
Authorisation to undertake HLA tissue typing for genetic conditions previously authorised by the Authority
Consideration of reports of random unannounced inspections
Consideration of reports of targeted inspections
Consideration of executive proposals to place non-standard conditions on licences and exercise of the Authority's power to issue notices under Section 19 of the Act
Exercise of the Authority's power to issue directions under sections 24(5A) to (5E) and 24(13) of the Act

3. Licensing functions delegated to Licence Committee in relation to research licences

All powers related to research licences delegated to a Licensing Officer in table 1 and Executive Licensing Panel in table 2, above, plus:
Consideration of applications for initial research licences and exercise of the Authority's power to grant such licences under Section 16 of the Act
Consideration of renewal applications for research licences and exercise of the Authority's power to grant such licences under Section 16 of the Act
Consideration of Grade A incidents and, where appropriate, Grade B incidents
Consideration of executive proposals to revoke/suspend licences and exercise of the Authority's powers to revoke/suspend licences in accordance with sections 18(1) and (2) and 19(c) of the Act
Consideration of representations under Section 19(4) of the Act
Exercise of the Authority's powers to vary a licence in accordance with Section 18A of the Act
Exercise of the Authority's power to issue notices under Section 19 of the Act

4. Licensing decisions delegated to Licence Committee relating to treatment and/or storage licences

All powers delegated to a Licensing Officer in table 1 and Executive Licensing Panel in table 2, above, plus:
Consideration of applications for initial licences for treatment, storage and provision of non-medical fertility services, and exercise of the Authority's power to grant such licences under Section 16 of the Act
Consideration of Grade A incidents and, where appropriate, Grade B incidents
Consideration of executive proposals to revoke/suspend licences and exercise of the Authority's powers to revoke/suspend licences in accordance with Sections 18(1) and (2) and 19(c) of the Act
Consideration of representations under Section 19(4) of the Act
Exercise of the Authority's powers to vary a licence in accordance with Section 18A of the Act

Standing Orders: Annex C

Protocol for the conduct of meetings of the Authority's Executive Licensing Panel

This Protocol is made by the Authority in accordance with its powers under paragraph 9 of Schedule 1 to the Human Fertilisation and Embryology Act 1990 (as amended) ('**the Act'**) to regulate its own proceedings; its duty as a public body to comply with the Human Rights Act 1998; its common law duties and powers to ensure fairness in its procedures; and its duties under paragraph 8.4 of the statutory code of practice for regulators to enforce in a transparent manner, and to be transparent in the way in which it applies and determines penalties.

This protocol aims to ensure fairness and consistency in the proceedings before the Authority's Executive Licence Panel ('the panel') and should be followed save where fairness requires otherwise.

The panel shall retain the power and duty to take such action, (provided always that any action is consistent with the requirements of the Act) as they consider appropriate and necessary to ensure fairness in a particular matter.

This protocol was approved by the Authority on 9 September 2009.

~~2.~~1. Composition and function of the panel

1.1. The Authority shall maintain an Executive Licensing Panel.

1.2. The function of the panel is to:

(a) perform the Authority's licensing functions under the Act in accordance with the delegated powers specified in the Authority's Standing Orders, and

(b) promote compliance with the requirements of the Act and the Code of Practice issued by the Authority.

1.3. In making its decisions, the panel shall have regard to relevant policies and guidance approved by the Authority.

1.4. The panel shall consider matters on the papers at a meeting in accordance with the provisions of this Protocol.

1.5. The panel shall consist of a Chair and Deputy Chair (or Deputy Chairs) and a pool of employees, appointed by the Chief Executive from amongst the employees of the Authority. In the absence of the Chair of the Panel, a Deputy Chair or other person nominated by the Chair of the Panel may act as Chair of the Panel.

1.6. The panel shall sit with three members at each meeting.

1.7. No member of the panel present at a meeting shall abstain from voting.

1.8. Decisions of a panel shall be taken by simple majority and the Chair of the Panel shall not have a casting vote.

1.9. Members of the panel shall attend regular training and update sessions on human rights and regulatory law, and matters relating to the provision of fertility treatment.

2. Advisers to committees

2.1. Where the Chair of the Panel considers it appropriate, the panel may seek written advice from a legal, clinical or specialist adviser before making its decision.

2.2. The Chair of the Panel shall ensure that the applicant, the proposed or actual Person Responsible, licence holder or person whose licence is under consideration is afforded a reasonable opportunity to comment on any written advice received by the panel before the panel makes its decision.

2.3. Where the Chair of the Panel considers it appropriate, the panel may sit with a legal adviser in attendance. Any advice provided in the course of a meeting shall be recorded in the minutes.

2.4. Where the panel does not accept the advice tendered by an adviser, the Chair of the Panel should ensure that:

(a) a written record is kept of the advice tendered, and the reasons why the panel refused to accept that advice, and

(b) the written record is sent to the person concerned, together with the decision of the panel, and the reasons for its decision.

3. Secretary to the Panel

3.1. A secretary shall be present at every meeting of the panel.

3.2. The function of the secretary shall be to make all administrative arrangements necessary for the proceedings of the panel to be effective, and to keep a record of:

(c) the panel's decision and of the reasons for such decision

~~(c)~~(d) any advice tendered by a legal, clinical or specialist adviser, and

~~(d)~~(e) any declarations of interest (or potential conflicts of interest) made by a member of the panel during the proceedings.

3.3. The secretary shall not participate in the decision making of the panel (and is not entitled to vote).

4. Determination of agenda items

4.1. In determining the agenda for the panel, the relevant officers shall have regard to the instrument of delegation set out in Annex B to the Authority's Standing Orders.

4.2. Where the relevant officers are unsure whether a matter should be placed on the agenda of the panel or on the agenda of the Licence Committee, the presumption should be that the matter should be placed on the agenda of the panel. Where necessary, the Chair of the Panel should be consulted.

5. Conduct of meeting

5.1. The panel shall consider matters on the papers.

5.2. Subject to paragraph 5.3, only the Chair and members of the panel, the Secretary, and the Head of Corporate Governance ~~and Licensing~~ may be present at a meeting of the panel.

5.3. Employees of the Authority who have been appointed to the panel, or an external lawyer or auditor charged by the Authority with audit and evaluation of the effectiveness of the panel may attend a meeting of the panel as observers, or as part of their induction training. However, such observers shall not take any part in the discussion or deliberation of the panel, and are not entitled to vote.

6. Documents before the panel

6.1. At each meeting, the panel shall have access to:

(a) this protocol

(b) relevant edition(s) of the HFEA Code of Practice

(c) the Human Fertilisation and Embryology Act 1990 (as amended)

(d) the Human Fertilisation and Embryology (research purposes) Regulations 2001 (where relevant)

(e) General Directions 0008 (where relevant), and any other relevant directions issued by the Authority

(f) any relevant decision trees and explanatory notes approved by the Authority

(g) 'Guidance for Authority and committee members on handling conflicts of interest'

(h) ~~the indicative applications guidance on the time period for which licences should be granted~~'Guidance on licensing' (where relevant)

~~(i) the indicative sanctions guidance (where relevant)~~

~~(j)~~(i) the licence application (where relevant) and any relevant documentation in support of the application from the applicant and/or proposed person responsible for the centre to be licensed

~~(k)~~(j) the recommendation of the Authority's inspector dealing with the matter and any relevant supporting documentation (usually including three years' worth of a centre's licensing history, as appropriate, and in the case of applications for a research licence, any relevant academic literature and advice from the Authority's Scientific and Clinical Advances Advisory Committee)

~~(l)~~(k) the compliance and enforcement policy.

6.2. The panel shall not usually receive the recommendation of the Authority's Inspector dealing with the matter or any relevant supporting documentation from that inspector, unless the applicant or person concerned (as appropriate) has been provided with a reasonable opportunity to comment on this material beforehand.

7. Panel papers

7.1. The Secretary shall usually send the papers for a meeting of the panel to the Chair and members of the panel scheduled to attend the meeting, seven days in advance of the meeting.

7.2. Upon receipt of the papers, members of the panel must identify any potential conflicts of interest as soon as possible.

7.3. Where an actual or potential conflict is identified, members must inform the Chair of the Panel and the secretary as soon as possible, and the procedure set out in the 'Guidance for Authority and committee members on handling conflicts of interest' shall be followed in deciding whether or not a conflict exists.

7.4. No member of the panel shall consider a matter if that member has an actual or potential conflict of interest in relation to that matter.

7.5. Members of the panel shall read the papers thoroughly in advance of the meeting and shall refrain from discussing matters to be considered by the panel with anyone except the other members of the panel, at the panel meeting.

7.6. Members of the panel shall only discuss panel business and the papers to be considered by the panel when the panel is in session.

8. Procedure to be followed at the meeting

8.1. Before any papers are considered by the panel, the Chair of the panel should:

(a) check that the panel is quorate, and

(b) ask for declarations of interest from each member.

8.2. Any interests declared should be noted and recorded by the secretary.

8.3. Where a potential or actual conflict is identified, the panel should follow the procedure set out in the 'Guidance for Authority and committee members on handling conflicts of interest'.

8.4. Each item on the agenda should be considered separately.

8.5. Where the panel is considering an application to grant or renew a licence, the Chair should direct the members of the panel to consider the requirements of Section 16 of the Act.

8.6. In makings its decision, the panel may be aided by the relevant decision tree. Each stage of the decision tree should be considered separately, and in order.

8.7. Before the panel makes its decision, the Chair may adjourn to:

(a) seek the advice of a legal, clinical or specialist adviser, and

(b) require further information from the applicant or person responsible for the centre to be licensed (as appropriate), or from the Authority's inspector dealing with the matter.

8.8. In accordance with section 16(4) of the Act, where the panel considers that the information provided with an application is insufficient to enable it to determine that application, it need not consider the application until the applicant has provided it with such further information as the panel may require.

9. Decision to be taken by the panel

Applications to grant a licence (for the purposes of the panel, this covers renewal applications only)

9.1. On each application before it, the panel must decide:

(a) whether the requirements of section 16 of the Act have been satisfied, and if so, whether to make a proposed decision to grant (renew) the licence

(b) if the proposed decision is for the licence is to be granted (renewed), whether it is on the same or different terms, including whether any additional conditions should be attached to the licence in addition to the standard licence conditions, and

(c) if the proposed decision is for the licence is to be granted (renewed), for what period that new licence is to be granted.

9.2. In determining the period of any licence to be granted (renewed), the panel should consider the indicative applications guidance.

Particular requirements for applications authorising embryo testing

9.3. Before the panel can grant an application authorising the testing of embryos, it must consider the requirements of paragraph 1ZA of Schedule 2 to the Act.

9.4. Where the application seeks authorisation for the testing of an embryo in circumstances in which there is a particular risk that an embryo may have a gene, chromosome or mitochondrion abnormality, the panel must consider the requirement of paragraph 1ZA(2) of Schedule 2 to the Act. In particular, the panel must be satisfied that there is a significant risk that a person with the abnormality will have or develop a serious physical or mental disability, a serious illness or any other serious medical condition.

10. Procedure for adding non-standard conditions and for refusal, variation or revocation of licence

10.1. If the panel is minded to refuse an application to grant, revoke or vary a licence, or minded to grant a licence subject to non-standard conditions, it must follow the procedure in section 19(1) of the Act.

10.2. If the panel is minded to revoke a licence on application, it must follow the procedure in section 19A(2) of the Act.

10.3. If the panel is minded to vary or revoke a licence otherwise than on application, it must follow the procedure in section 19(2) of the Act.

10.4. If the panel is minded to vary a licence otherwise than in accordance with the application, it must follow the procedure in section 19(3) of the Act.

10.5. In all cases where the panel has refused, varied or revoked a licence otherwise than on application, it must issue a notice under section 19A (4) and (5) of the Act.

10.6. After issuing any notice under section 19A (4) and (5) of the Act, the panel must refer the matter to the Licence Committee for consideration and have no further dealings with the matter.

11. Reasons for the panel's decision

11.1. The panel shall give reasons for each decision that it makes. These reasons must be recorded in the minutes.

11.2. The reasons shall set out:

(a) any relevant findings of fact made by the panel

(b) any matters taken into account by the panel (including any advice received from a legal, clinical, scientific or specialist adviser), and

(c) why the panel reached its decision.

11.3. Additionally, in the case of applications to authorise embryo testing for gene, chromosome or mitochondrion abnormalities, the reasons must set why the panel is satisfied that there is a significant risk that a person with the abnormality will have or develop a serious physical or mental disability, a serious illness or any other serious medical condition, and why the disability/illness/condition is considered to be serious.

11.4. The reasons should tell the person concerned in broad terms why the decision was reached, and may in some circumstances require an explanation of why a particular argument was rejected.

11.5. Where additional conditions have been proposed the reasons should indicate why the panel considers this course of action to be a proportionate response to any concerns identified from the papers before it.

11.6. The reasons should refer to the indicative applications guidance and indicative sanctions guidance where relevant.

12. Postponements and adjournments of meetings

12.1. The Chair may, of his or her own motion, or upon the application of a party to the proceedings, postpone any meeting of which notice has been given before such meeting begins.

12.2. The Chair may, of his or her own motion, adjourn the proceedings at any stage.

12.3. In considering whether or not to grant a request for postponement, or to adjourn, the Chair of the Panel should, amongst other matters, have regard to-

(a) the public interest in the expeditious disposal of the proceedings

(b) fairness to the parties, and

(c) the conduct of the person seeking the postponement or adjournment.

12.4. Where the proceedings have been postponed or adjourned, the secretary should, as soon as practicable, notify the parties of the date and time of the postponed or resumed meeting.

13. Burden and standard of proof

13.1. The Authority's inspector dealing with the matter should bear the burden of establishing that a licence should be revoked, varied (otherwise than on an application) or that a licence should be suspended.

13.2. The person to whom the notice under section 19(1) is given should bear the burden of establishing that a licence should not be refused or additional conditions should not be imposed.

13.3. Where facts are in dispute, the panel should consider whether they have been established in accordance with the civil standard of proof.

13.4. Where the panel considers that a finding on disputed facts can only be made after oral evidence is heard, it shall refuse the application and issue a notice of proposal under Section 19; invite the person to whom the notice is addressed to make oral representations to the Licence Committee and refer the matter for a hearing to be held in accordance with the Human Fertilisation and Embryology Act (procedure for revocation, variation or refusal of a licence) regulations 2009 (as amended).

14. Evidence at meetings

14.1. The panel may receive any written or real evidence whether or not such evidence would be admissible in a civil court of law in England and Wales, provided that it is satisfied that such evidence is relevant to the issues on which it has to make a decision, and that it is fair to admit such evidence.

14.2. The panel shall have regard to the Code of Practice in the circumstances set out in section 25(6) of the Act.

15. Directions

15.1. The Authority has delegated to the panel the power to issue directions under sections 24(5A) to (5E) and 24(13) of the Act.

15.2. When:

(a) postponing or adjourning the consideration of a matter

(b) making a proposed decision to refuse, vary, suspend or revoke a licence, or

(c) considering evidence of an adverse incident or non-compliance with the Act, Code of Practice, licence conditions or directions issued by the Authority,

the panel should consider whether or not to issue directions under section 24 of the Act.

16. Evaluation and report to the Authority

16.1. The Chair of the Panel shall hold regular periodic meetings for the purpose of reviewing decisions made by the panel to ensure consistency in the panel's decision making processes.

16.2. The Chair of the Panel shall present a report to the Chair of the Licence Committee at six monthly intervals detailing the activities of the panel and identifying trends and feedback for the sector.

16.3. The Chair of the Executive Licensing Panel shall prepare an annual written report to the Authority detailing the activities of the panel (see also the equivalent paragraph for Licence Committee).

Standing Orders: Annex D
Protocol for the conduct of meetings of the Licence Committee

This Protocol is made by the Authority in accordance with its powers under paragraph 9 of Schedule 1 to the Human Fertilisation and Embryology Act 1990 (as amended) ('**the Act'**)to regulate its own proceedings; its duty as a public body to comply with the Human Rights Act 1998 ; its common law duties and powers to ensure fairness in its procedures; and its duties under paragraph 8.4 of the statutory code of practice for regulators to enforce in a transparent manner, and to be transparent in the way in which it applies and determines penalties.

This protocol aims to ensure fairness and consistency in the proceedings before the Authority's Licence Committee and should be followed save where fairness requires otherwise.

The Licence Committee shall retain the power and duty to take such action, (provided always that any action is consistent with the requirements of the Act) as they consider appropriate and necessary to ensure fairness in a particular matter.

This protocol was approved by the Authority on 9 September 2009 and adopted by the Chairs of the Authority's Licence and Research Licence Committees on the same date.

1. Composition and function of the Committee

1.1. The Authority shall maintain a Licence Committee.

1.2. The function of the Licence Committee is to:

(a) perform the Authority's licensing functions under the Act in accordance with the delegated powers specified in the Authority's Standing Orders, and

(b) promote compliance with the requirements of the Act and the Code of Practice issued by the Authority.

1.3. In making its decisions, the Licence Committee shall have regard to policies approved by the Authority, and where relevant, to the indicative applications guidance and indicative sanctions guidance.

1.4. Save where a Licence Committee is considering representations in accordance with Section 19 of the Act, it shall consider matters on the papers at a meeting in accordance with the provisions of this protocol.

1.5. Where a Licence Committee is considering representations made under section 19(4) of the Act, it shall follow the procedure set out in the Human Fertilisation and Embryology (Procedure for Revocation, Variation or Refusal of Licences) Regulations 2009 (as amended).

1.6. The Licence Committee shall consist of no more than six members including a Chair and Deputy Chair, appointed by the Chair of the Authority. In the absence of the Committee Chair, the Deputy Chair or other person nominated by the Chair of the HFEA may act as Committee Chair.

1.7. The quorum for a meeting of the Licence Committee shall be three.

1.8. No member of a Licence Committee present at a meeting shall abstain from voting.

1.9. Decisions of a Licence Committee shall be taken by simple majority (and the Chair of a Licence Committee shall not have a casting vote).

1.10. Where there is a tied vote:

(a) in the case of an application for a licence, that application shall not be granted

(b) in the case of a proposal to impose non-standard conditions on a licence, or to vary, suspend or revoke a licence, that proposal shall not succeed, and

(c) in any other case, the motion under consideration by the Licence Committee shall not be passed.

1.11. Members of the Licence Committee shall attend regular training and update sessions on human rights and regulatory law, and matters relating to the provision of fertility treatment.

2. Advisers to the Committee

2.1. A legal adviser shall be present at every meeting of the Licence Committee.

2.2. Where the Chair of the Licence Committee considers it appropriate, a clinical, scientific or specialist adviser may be present at a meeting or hearing of that Committee.

2.3. The function of an adviser to a Committee shall be to:

(a) advise that committee on any areas within the adviser's expertise, and

(b) intervene to advise that committee on an issue where it appears that without an intervention there is the possibility of an error being made.

2.4. With the consent of the Chair of the Licence Committee, an adviser who is present at a meeting of that committee may be present during the private deliberations of the committee, but the adviser shall not participate in the decision making of that committee (and is not entitled to vote).

2.5. The Chair of the Licence Committee shall ensure that a written record is kept of any advice tendered to the committee by an adviser.

2.6. The Chair of the Licence Committee shall also ensure that a written record is kept of any interventions made by an adviser during the private deliberations of that committee.

2.7. The Chair of the Licence Committee shall ensure that a copy of any advice tendered by an adviser to that committee is sent to the parties to the proceedings.

2.8. Where any advice tendered by an adviser to the Licence Committee is not accepted by that committee:

(a) the Committee Chair shall ensure that a written record is kept of the advice tendered, and the reasons why the committee refused to accept that advice; and

(b) a copy of the record of the advice tendered and the reasons why the committee refused to accept that advice should be sent to the parties to the proceedings.

3. Executive support to the committee

3.1. A secretary shall be present at every meeting of the committee.

3.2. The function of the secretary shall be to make all administrative arrangements necessary for the proceedings of the Licence Committee to be effective, and to keep a record of:

(a) the committee's decision and the reasons for such decision

(b) any advice tendered by a legal, clinical, scientific or specialist adviser (and any interventions made by them when they are present during the private deliberations of the committee), and

(c) any declarations of interest (or potential conflicts of interest) made by a member of the committee during the proceedings.

3.3. The Secretary shall not participate in the decision making of the committee (and is not entitled to vote).

3.4. The Head of Corporate Governance ~~and Licensing~~ shall usually be present at every meeting of the committee. At the conclusion of every meeting of the Licence Committee, the Head of Corporate Governance ~~and Licensing~~ shall collate feedback from the Chair and members of the committee on matters that the Chair considers should be brought to the attention of the Authority's Director of Compliance and Information.

4. Determination of agenda items

4.1. In determining the agenda for a committee, the relevant officers shall have regard to the instrument of delegation set out in Annex B to the Authority's Standing Orders.

4.2. Where the relevant officers are unsure whether a matter should be placed on the agenda of a committee or on the agenda of the Executive Licensing Panel, the presumption should be that the matter should be placed on the agenda of the panel. Where necessary, the Committee Chair should be consulted.

5. Conduct of meeting

5.1. The Licence Committee shall consider matters on the papers.

5.2. Subject to paragraph 5.3 only the Chair and members of the committee, the Head of Corporate Governance ~~and Licensing~~ and the secretary, and advisers to that committee may be present at the meeting of the committee.

5.3. Members of the Licence Committee, or employees who have been appointed to the Executive Licensing Panel, may attend a meeting of the committee as observers, or as part of their induction training. However, such observers shall not take any part in the discussion or deliberation of the committee, and are not entitled to vote.

6. Documents before the committee

6.1. At each meeting, the Licence Committee shall have access to:

(a) this protocol

(b) relevant edition(s) of the HFEA Code of Practice

(c) the Human Fertilisation and Embryology Act 1990 (as amended)

(d) the Human Fertilisation and Embryology (Research Purposes) Regulations 2001 (where relevant)

(e) Direction 0008 (where relevant), and any other relevant Directions issued by the Authority

(f) any relevant decision trees and explanatory notes approved by the Authority

(g) Guidance for Authority and committee members on handling conflicts of interest

(h) ~~the indicative applications guidance on the time period for which licences should be granted~~'Guidance on licensing' (where relevant)

~~(i) the indicative sanctions guidance~~

~~(j)~~(i) the licence application (where relevant) and any relevant documentation in support of the application from the applicant and/or proposed person responsible for the centre to be licensed

~~(k)~~(j) the recommendation of the Authority's inspector dealing with the matter and any relevant supporting documentation (usually including three years' worth of a centre's licensing history as appropriate, and in the case of applications for a research licence, any relevant academic literature and advice from the Authority's Scientific and Clinical Advances Advisory Committee)

~~(l)~~(k) the compliance and enforcement policy.

6.2. The Licence Committee shall not usually receive the recommendation of the Authority's inspector dealing with the matter or any relevant supporting documentation from that Inspector, unless the applicant or person concerned (as appropriate) has been provided with a reasonable opportunity to comment on this material beforehand.

7. Committee papers

7.1. The secretary shall usually send the papers for a meeting of the Licence Committee to the Chair and members of that committee seven days in advance of the meeting.

7.2. Upon receipt of the papers, members of the committee must identify any potential conflicts of interest as soon as possible.

7.3. Where an actual or potential conflict is identified, members must inform the Committee Chair and the secretary as soon as possible, and the procedure set out in the 'Guidance for Authority and committee members on handling conflicts of interest' shall be followed in deciding whether or not a conflict exists.

7.4. No member of the Licence Committee shall consider a matter if that member has an actual or potential conflict of interest in relation to that matter.

7.5. Members of the committee shall read the papers thoroughly in advance of the meeting and shall refrain from discussing matters to be considered by the committee with anyone except the other members of the committee, at the committee meeting.

7.6. Members of the committee shall only discuss committee business and the papers to be considered by the committee when the committee is in session.

8. Procedure to be followed at the meeting

8.1. Before any papers are considered by the Licence Committee, the Committee Chair should:

(a) check that the committee is quorate, and

(b) ask for declarations of interest from each member.

8.2. Any interests declared should be noted and recorded by the secretary.

8.3. Where a potential or actual conflict is identified, the Committee Chair should follow the procedure set out in the 'Guidance for Authority and committee members on handling conflicts of interest'.

8.4. Each item on the agenda should be considered separately.

8.5. Where the committee is considering an application to grant or renew a licence, the Chair should direct the members of the committee to consider the requirements of section 16 of the Act.

8.6. In makings its decision, the committee may be aided by the relevant decision tree. Each stage of the decision tree should be considered separately, and in order.

8.7. Before the committee makes its decision, the Chair may adjourn to:

(c) seek the advice of a legal, clinical or specialist adviser, and

~~(c)~~(d) require further information from the applicant or person responsible for the centre to be licensed (as appropriate), or from the Authority's Inspector dealing with the matter.

8.8. In accordance with section 16(4) of the Act, where the committee considers that the information provided with an application is insufficient to enable it to determine that application, it need not consider the application until the applicant has provided it with such further information as the committee may require.

9. Decision to be taken by the committee

Applications to grant a licence (including renewals)

9.1. On each application before it, the committee must decide:

(a) whether the requirements of section 16 of the Act have been satisfied, and if so, whether to make a proposed decision to grant (renew) the licence

(b) if the proposed decision is for the licence to be granted (renewed), whether it is on the the same or different terms, including whether any additional conditions should be attached to the licence in addition to the standard licence conditions, and

(c) if the proposed decision is for the licence to be granted (renewed), for what period that that new licence is to be granted.

9.2. In determining the period of any licence to be granted (renewed), the committee should consider the indicative applications guidance.

Particular requirements for applications authorising embryo testing

9.3. Before the Licence Committee can grant (or renew) an application authorising the testing of embryos, it must consider the requirements of paragraph 1ZA of schedule 2 to the Act.

9.4. Where the application seeks authorisation for the testing of an embryo in circumstances in which there is a particular risk that an embryo may have a gene, chromosome or mitochondrion abnormality, the Licence Committee must consider the requirement of paragraph 1ZA(2) of schedule 2 to the Act. In particular, the Licence Committee must be satisfied that there is a significant risk that a person with the abnormality will have or develop a serious physical or mental disability, a serious illness or any other serious medical condition.

Particular requirements for applications for research licences

9.5. Before the committee can grant (renew) an application for a research licence, it must consider the requirements of paragraphs 3(5) and 3A (1) of schedule 2 to the Act.

9.6. In particular, the committee must be satisfied that any proposed use of embryos or human admixed embryos is (and in the case of applications for renewal) or remains necessary for the purposes of the research.

9.7. In addition, the committee must consider whether the activities to be authorised by the licence are or remain necessary or desirable:

~~(a)~~(d) for the listed purposes set out in paragraph 3A (2) or in regulations;

~~(b)~~(a) for the purpose of providing knowledge that may be capable of being applied for the purpose of;

~~(c)~~(b) increasing knowledge about serious disease or other serious medical conditions; or

~~(d)~~(c) developing treatments for serious disease or other serious medical conditions.

10. Procedure for adding non-standard conditions and for refusal, variation or revocation of licence

10.1. If the committee is minded to refuse an application to grant, revoke or vary a licence, or minded to grant a licence subject to non-standard conditions, it must follow the procedure in section 19(1) of the Act.

10.2. If the committee is minded to vary or revoke a licence, it must follow the procedure in section 19(2) of the Act.

10.3. If the committee is minded to vary a licence otherwise than in accordance with the application, it must follow the procedure in section 19(3) of the Act.

10.4. In all cases, the committee must issue a notice. In addition to issuing the notice, the committee must give the person to whom the notice is addressed, an opportunity to make representations before making its decision. Representations may be oral and written.

10.5. Representations shall not be considered by the committee that issues the notice. Where a notice has been issued by the Licence Committee, any representations shall be considered by a Licence Committee normally comprised of members who are not Authority members. Where a notice has been issued by the Executive Licensing Panel, representations may be considered by the Licence Committee.

10.6. Where the person to whom the notice has been given indicates that he wishes to make representations, the committee hearing those representations shall consider the matter in accordance with the provisions of the Human Fertilisation and Embryology Authority (procedure for revocation, variation or refusal of a licence) regulations 2009 (as amended).

10.7. Where after the expiry of the period of 28 days from the date on which the notice was served, the person to whom the notice was given has not responded, or has confirmed that he does not wish to make representations, the committee shall resume its consideration of the matter and shall proceed to make its decision.

11. Reasons for the committee's decision

11.1. The committee shall give reasons for each decision that it makes. These reasons must be recorded in the minutes.

11.2. The reasons shall set out:

(d) any relevant findings of fact made by the committee;

(e) any matters taken into account by the committee (including any advice received from a from a legal, clinical, scientific or specialist adviser); and

(f) why the committee reached its decision.

11.3. Additionally, in the case of applications to authorise embryo testing for gene, chromosome or mitochondrion abnormalities, the reasons must set why the committee is satisfied that there is a significant risk that a person with the abnormality will have or develop a serious physical or mental disability, a serious illness or any other serious medical condition, and why the disability/illness/condition is considered to be serious.

11.4. Additionally, in the case of applications to grant (renew) licences for research, the reasons must set out why the committee is satisfied that any proposed use of embryos or human admixed embryos is or remains necessary for the purposes of the research, and why the committee considers that the activities to be authorised by the licence are or remain necessary or desirable:

~~(a)~~(g) for the listed purposes set out in paragraph 3A (2) or in regulations; or

~~(b)~~(h) for the purpose of providing knowledge that may be capable of being applied for the purpose of:

i. increasing knowledge about serious disease or other serious medical conditions, or

ii. developing treatments for serious disease or other serious medical conditions.

11.5. The reasons should tell the person concerned in broad terms why the decision was reached, and may in some circumstances require an explanation of why a particular argument was rejected.

11.6. Where additional conditions have been proposed the reasons should indicate why the committee considers this course of action to be a proportionate response to any concerns identified from the papers before it.

11.7. The reasons should refer to the indicative applications guidance and indicative sanctions guidance where relevant.

12. Postponements and adjournments of meetings

12.1. The Chair may, of his or her own motion, or upon the application of a party to the proceedings, postpone any meeting of which notice has been given before such meeting begins.

12.2. The Chair may, of his or her own motion, adjourn the proceedings at any stage.

12.3. In considering whether or not to grant a request for postponement, or to adjourn, the Committee Chair should, amongst other matters, have regard to:

~~1.1.1.k.1.~~(a) the public interest in the expeditious disposal of the proceedings

~~1.1.1.k.2.~~(b) fairness to the parties, and

~~1.1.1.k.3.~~(c) the conduct of the person seeking the postponement or adjournment.

12.4. Where the proceedings have been postponed or adjourned, the secretary should, as soon as practicable, notify the parties of the date and time of the postponed or resumed meeting.

13. Burden and standard of proof

13.1. The Authority's inspector dealing with the matter should bear the burden of establishing that a licence should be revoked, varied (otherwise than on application) or that a licence should be suspended.

13.2. The person to whom the notice under section 19(1) is given should bear the burden of establishing that a licence should not be refused or additional conditions should not be imposed.

13.3. Where facts are in dispute, the Licence Committee should consider whether they have been established in accordance with the civil standard of proof.

13.4. Where the committee considers that a finding on disputed facts can only be made after oral evidence is heard, it shall refuse the application and issue a notice of proposal under Section 19; invite the person to whom the notice is addressed to make oral representations and hold a hearing in accordance with the Human Fertilisation and Embryology Act (procedure for revocation, variation or refusal of a licence) regulations 2009 (as amended).

14. Evidence at meetings

14.1. The committee may receive any written or real evidence whether or not such evidence would be admissible in a civil court of law in England and Wales, provided that it is satisfied that such

evidence is relevant to the issues on which it has to make a decision, and that it is fair to admit such evidence.

14.2. The committee shall have regard to the Code of Practice issued by the Authority in the circumstances set out in section 25(6) of the Act.

15. Directions

15.1. The Authority has delegated to the Licence Committee the power to issue directions under sections 24(5A) to (5E) and 24(13) of the Act.

15.2. When:

~~1.1.1.k.1.~~(d) postponing or adjourning the consideration of a matter

~~1.1.1.k.2.~~(e) making a proposed decision to refuse, vary, suspend or revoke a licence, or

~~1.1.1.k.3.~~(f) considering evidence of an adverse incident or non-compliance with the Act, Code of Practice, licence conditions or directions issued by the Authority,

the Chair should consider whether or not to issue directions under section 24 of the Act.

16. Evaluation and report to the Authority

16.1. The Chair and Deputy Chair of the Licence Committee shall hold regular periodic meetings for the purpose of reviewing decisions taken by the Committee to ensure consistency in the decision-making processes of the Committee, and to hear updates from the Chair of the Executive Licensing panel on the activities of the panel. The Chair may also reflect on any general licensing trends or issues arising from such review and propose such action to the Executive or Authority as they consider appropriate.

16.2. The Chair of the Licence Committee shall prepare an annual written report to the Authority detailing the activities of his/her Committee (see also the equivalent paragraph for the Executive Licensing Panel).

Standing Orders: Annex E

Code of Conduct for Authority members and the seven principles underpinning public life

1. Code of Conduct for Authority members

All Authority members **undertake** to:-

- have regard to the functions and duties of the Authority set out in sections 8 and 8ZA of the Human Fertilisation and Embryology Act 1990 (as amended) ("the Act") and which are annexed to this code, when undertaking the business of the Authority or a committee
- comply with the Standing Orders and relevant protocols and policies approved by the Authority when undertaking the business of the Authority or a committee
- follow and support by example the principles published by the committee on standards in public life (the Nolan principles) which are annexed to this code
- follow and support by example best practice on equality and diversity issues and promote compliance by others
- in the conduct of Authority business, treat people equally and fairly and not discriminate unlawfully against anyone on the basis of any protected characteristics including their race or racial group, sex (including gender reassignment), sexual orientation, religion or belief marriage or civil partnership, pregnancy and maternity, age or disability
- in carrying out their public functions, have due regard to the need to eliminate any conduct prohibited under equality legislation including the Equality Act 2010, and to promote equality of opportunity and foster good relations between people with protected characteristics and others
- comply with the statement of general principles published by the Authority in accordance with Section 8(ca) (ii) of the Human Fertilisation and Embryology Act 1990 (as amended) which are annexed to this code
- ensure that actions taken in a personal capacity do not bring the Authority into disrepute
- in their interactions with each other and with employees, model the 'ways of working' agreed by the Authority
  - taking responsibility
  - challenging well
  - taking interest in others' ideas
  - demonstrating enthusiasm.
- be alert to the possibility of any conflicts of interest, and to declare any potential conflicts as soon as practicable
- in the event of a potential conflict of interest, consult and follow the Authority's 'Guidance for Authority and committee members on handling conflicts of interest'
- ensure that entries relating to them in the register of interests maintained by the Authority are accurate, complete and up-to-date
- declare any hospitality received which may be relevant to their work as an Authority member in the register of interests maintained by the Authority for that purpose

- only discuss Authority and committee papers at formal meetings of the Authority or committee to which the papers relate
- keep the deliberations of the Authority or committee meetings which are not open to the public confidential, and not to disclose such deliberations to any external party (save in accordance with the Authority's publication policy or where required to by a court, or by law)
- ensure that any telephone or videoconferencing facilities used to attend Authority or committee meetings are appropriate and ensure confidentiality
- use any information acquired solely by virtue of their membership of the Authority or a committee only for the purpose of Authority or committee proceedings, and not to use such information for personal gain
- comply with the provisions of section 33A of the Human Fertilisation and Embryology Act 1990 (as amended) and to uphold strictly the confidentiality of any patient identifying information that may be revealed to them as members of the Authority or of a committee
- make no public comment on behalf of the Authority without first obtaining approval from the Chair of the Authority
- when providing media interviews or commenting in public, make it clear that they are speaking in a private capacity or as an Authority member
- make every effort to attend all meetings, hearings and training sessions at which their presence is required
- once diaries have been checked and meetings scheduled, only cancel their attendance under exceptional and wholly unavoidable circumstances
- take all reasonable steps to give advance warning of absence to the Chair of the HFEA or committee of which they are a member in the event that they are unable to attend a scheduled meeting or hearing
- prepare for any meeting or hearing by reading any papers sent to them beforehand, and
- undertake periodic training provided or organised by the Authority.

2. The seven principles underpinning public life

The principles of public life apply to anyone who works as a public office-holder. This includes all those who are elected or appointed to public office, nationally and locally, and all people appointed to work in the civil service, local government, the police, courts and probation services, NDPBs, and in the health, education, social and care services. All public office-holders are both servants of the public and stewards of public resources. The principles also have application to all those in other sectors delivering public services.

Selflessness

Holders of public office should act solely in terms of the public interest.

Integrity

Holders of public office must avoid placing themselves under any obligation to people or organisations that might try inappropriately to influence them in their work. They should not act or take decisions in order to gain financial or other material benefits for themselves, their family, or their friends. They must declare and resolve any interests and relationships.

Objectivity

Holders of public office must act and take decisions impartially, fairly and on merit, using the best evidence and without discrimination or bias.

Accountability

Holders of public office are accountable to the public for their decisions and actions and must submit themselves to the scrutiny necessary to ensure this.

Openness

Holders of public office should act and take decisions in an open and transparent manner. Information should not be withheld from the public unless there are clear and lawful reasons for so doing.

Honesty

Holders of public office should be truthful.

Leadership

Holders of public office should exhibit these principles in their own behaviour. They should actively promote and robustly support the principles and be willing to challenge poor behaviour wherever it occurs.

Strategic risk register

Strategic delivery:	☒ Setting standards	☒ Increasing and informing choice	☒ Demonstrating efficiency economy and value
Details:			
Meeting	Authority		
Agenda item	10		
Paper number	HFEA (09/03/2016) 790		
Meeting date	9 March 2016		
Author	Paula Robinson, Head of Business Planning		
Output:			
For information or decision?	For information		
Recommendation	The Authority is asked to note and comment on the latest edition of the strategic risk register.		
Resource implications	In budget		
Implementation date	Ongoing		
Communication(s)	The risk register is reviewed quarterly by the Corporate Management Group (CMG), and presented at every Audit and Governance Committee (AGC) meeting. AGC last reviewed the risk register at its meeting on 9 December, and will review it again at its next meeting on 16 March.		
Organisational risk	☐ Low	☒ Medium	☐ High
Annexes	Annex 1: Strategic risk register		

1. Latest reviews

1.1. CMG reviewed the risk register at its meeting on 14 February. Six of the thirteen risks are above tolerance. CMG reviewed all risks, controls and scores. CMG's specific comments are contained in the risk register at Annex A.

1.2. The risk register was last discussed at AGC on 9 December, and the Committee will receive the risk register again at its meeting on 16 March. Any comments from the Authority will be fed back to the Committee then. No changes were proposed in December.

2. Risk assurance mapping

2.1. The new activity of risk assurance mapping has recently started up in the HFEA, as part of the internal audit programme. The Department of Health internal audit team ran a half day workshop with managers on 10 February, focusing on our highest risk operational area, people management and resourcing (capacity, capability, resource prioritisation, etc.).

2.2. The workshop approach was well received by staff, and we now have a report for consideration internally, making a number of suggestions for possible additional risk mitigations in this area.

3. Recommendation

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

Annex A - HFEA strategic risk register 2015/16

Risk summary: high to low residual risks

Risk area	Risk title	Strategic linkage[1]	Residual risk	Current status	Trend*
Office move	OM1: Office move	Efficiency, economy and value	**16 – High**	Above tolerance	⊙⇔⇔
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	⇔⇔⇔⇔
Information for Quality	IfQ3: Delivery of promised efficiencies	Efficiency, economy and value	**12 – High**	Above tolerance	⇔⇔⇔⇧
Data	D2: Incorrect data released	Efficiency, economy and value	**12 – High**	Above tolerance	⇔⇩⇔⇧
Data	D1: Data loss or breach	Efficiency, economy and value	**10 – Medium**	At tolerance	⇔⇔⇔⇔
Financial viability	FV1: Income and expenditure	Efficiency, economy and value	**9 – Medium**	At tolerance	⇔⇔⇔⇩
Donor conception	DC2: Support for OTR applicants	Setting standards: donor conception	**9 – Medium**	At tolerance	⇔⇔⇔⇔
Capability	C1: Knowledge and capability	Efficiency, economy and value	**9 – Medium**	Above tolerance	⇔⇔⇔⇔
Regulatory model	RM1: Quality and safety of care	Setting standards: quality and safety	**8 – Medium**	At tolerance	⇔⇧⇔⇔
Regulatory model	RM2: Loss of regulatory authority	Setting standards: quality and safety	**8 – Medium**	At tolerance	⇔⇔⇔⇔
Information for Quality	IfQ2: Register data	Increasing and informing choice: Register data	**8 – Medium**	At tolerance	⇔⇔⇔⇔
Donor conception	DC1: OTR inaccuracy	Setting standards: donor conception	**4 – Low**	At tolerance	⇔⇔⇔⇔

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

Recent review points are: AGC 7 October ⇨ CMG 18 November ⇨ AGC 9 December ⇨ CMG 4 February.

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

CMG overview – summary from February risk meeting

CMG reviewed the risk register and discussed each risk in detail at its meeting on 4 February.

CMG confirmed that the departure of three Heads (two for new jobs, one on maternity leave) was being managed by Directors covering the roles in the interim while recruitment was completed. Recruitment to the Head of Policy post had successfully taken place internally, so there was no gap between post holders. Recruitment for the other two posts, Head of Corporate Governance and Chief Inspector, was also successful, but there has been an unavoidable gap of several months before the successful candidates could take up their posts, leading to some additional pressures across affected teams.

CMG reviewed the three strategic risks relating to IfQ, in particular to see if their relative scores seemed correct. The discussion identified that IfQ3 (the risk of not achieving planned efficiency savings) was partly subject to the same GDS gateway review requirements as IfQ1 (engagement channels), and that the risk levels of the two risks should therefore be the same. Therefore, CMG raised the risk level of IfQ3 to 12.

CMG updated the legal challenge risk (LC1) to reflect the latest position on active legal cases, but made no change to the score for this risk.

CMG raised the risk level for D2 (release of incorrect data) to 12, to reflect a resurgence in the volume of PQs received after a quieter period. This was potentially compounded by the recent loss of some corporate knowledge, owing to turnover.

CMG also discussed risks relating to the office move, and agreed that further assurance was needed to ensure that all managers had a good grasp of the tasks and timelines. Cultural risks were also recognised, given that the HFEA would be moving into the same space as another organisation. It was agreed that further corporate discussion was needed after the meeting, to ensure that surrounding themes, some of which may be outside the scope of the move project, were picked up effectively (ie, the right channel could be the ways of working group, SMT or CMG, rather than the move project).

CMG also considered operational risks (under a separate report), and noted the need to add floor security to our operational risks. The building was now largely empty, and on a number of recent occasions, workmen had been found in the HFEA's offices before and after normal working hours. It was not always the case that there was a good explanation for this, although the majority of the occurrences had proved to be legitimate. The landlord had already been reminded of their obligation to inform us every time workmen needed to visit the floor. HFEA staff had challenged the individuals each time this had happened, which may itself reduce the incidence. The possibility is also being explored of isolating the floor from external visitors via the door security system.

Criteria for inclusion of risks:

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

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

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

Risk scoring system
See last page.

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

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

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

Causes / sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Inspection/reporting failure.	Inspections are scheduled for the whole year, using licence information held on Epicentre, and items are also scheduled to committees well in advance.	In place – Nick Jones	At tolerance. The Head of Governance and Licensing and the Chief Inspector have both left the HFEA (in late November and mid January, respectively). Recruitment has taken place, but neither of the new members of staff have started yet. Meanwhile ownership of controls has moved upwards to the relevant Director. The need to manage this gap, together with the action plan being implemented in connection with legal parenthood consent issues, has raised the residual risk likelihood from 1 (very unlikely) to 2 (unlikely) – from November through to June 2016.
	Audit of Epicentre conducted to reveal data errors. Queries now routed through Licensing, who hold a definitive list of all licensing details.	Completed October 2015 – Juliet Tizzard	
	Inspector training, competency-based recruitment, induction process, SOPs, QMS, and quality assurance all robust.	In place – Nick Jones	
Monitoring failure.	Outstanding recommendations from inspection reports are tracked and followed up by the team.	In place – Nick Jones	
Unresponsiveness to or mishandling of non-compliances or grade A incidents.	Update of compliance and enforcement policy.	Significant progress – revision discussed at September 2015 Authority – revised policy Spring 2016 - Nick Jones	
	Staffing model provides resilience in the inspection team for such events – dealing with high-impact cases, additional incident inspections, etc..	In place – Nick Jones	
Insufficient inspectors or licensing staff	Inspection team up to complement. The new Chief Inspector is expected to join the HFEA in early May 2016.	In progress – Nick Jones	

	Licensing team up to complement following earlier recruitment. The new Head of Corporate Governance is expected to join the HFEA in March 2016.	In progress – Juliet Tizzard
Recruitment difficulties and/or high turnover/churn in various areas; resource gaps and resource diversion into recruitment and induction, with impacts felt across all teams.	So far recruitment rounds have yielded sufficient candidates, although this has required going beyond the initial ALB pool to external recruitment in some cases.	Managed as needed – Nick Jones
	Additional temporary resources available during periods of vacancy and transition.	In place – Rachel Hopkins
	Group induction sessions put in place where possible.	In place – Nick Jones
Resource strain itself can lead to increased turnover, exacerbating the resource strain.	Operational performance, risk and resourcing oversight through CMG, with deprioritisation or rescheduling of work an option.	In place – Paula Robinson
Unexpected fluctuations in workload (arising from eg, very high level of PGD applications received, including complex applications involving multiple types of a condition; high levels of non-compliances either generally or in relation to a particular issue).	Staffing model amended in May 2015, to release an extra inspector post out of the previous establishment. This increased general resilience, enabling more flex when there is an especially high inspection/report writing/application processing workload.	In place – Nick Jones
	Greater sector insight into our PGD application handling processes and decision-making steps achieved in the past few years; coupled with our increased processing times from efficiency improvements made in 2013 (acknowledged by the sector).	In place – Nick Jones
Some unanticipated event occurs that has a big diversionary impact on key resources, eg, legal parenthood consent issues, or several major Grade A incidents occur at once.	Resilient staffing model in place.	In place – Nick Jones
	Update of compliance and enforcement policy (and application of existing policy, meanwhile).	Significant progress – revision discussed at September 2015 Authority – revised policy Spring 2016 – Nick Jones

	A detailed action plan in response to the legal parenthood judgement is in place. There has been correspondence with clinics, who have completed full audits. PRs are responsible for the robustness of the audit. The HFEA has required that clinics support affected patients – using Barts as a good example. In working with clinics, the HFEA has experienced good cooperation. All clinics engaged and have provided assurances about current practice. Through a detailed review of every clinic's responses, a summary list of all concerns is being produced. Management review meetings are taking place for all clinics at which there are handling concerns or anomalies. Plan of action in place to address all of the concerns identified, with direct follow up with centres who did not respond at all. Where there are engagement concerns, we will do short-notice inspections, focused on parenthood consent. Range of lessons learned identified.	In progress – Nick Jones	On legal parenthood, a strong set of actions is in place and continues to be implemented. As at 20 January 2016, 28 of our 92 clinics had one or more anomaly. < 5 clinics are now subject to ongoing inquiry. Seven cases have been determined in court to date. Nine cases are currently under consideration. There is no certainty about future cases.

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 – Juliet Tizzard	At tolerance. Although two additional risk sources exist at present (website outages until the new beta website is live and the plan of work to address legal parenthood consent issues), these are being well managed and/or tolerated, and the overall risk score has not increased.
	Learning from past representations and Appeal Committee hearings incorporated into processes.	In place – Juliet Tizzard	
	Appeals Committee membership maintained. Ongoing process in place for regular appointments whenever vacancies occur or terms of office end.	In place – Juliet Tizzard	
	Staffing structure for sufficient committee support.	In place – Juliet Tizzard	
	Decision trees; legal advisers familiar.	In place – Juliet Tizzard	
	Proactive management of quoracy for meetings.	In place – Juliet Tizzard	
	New (ie, first application) T&S licences delegated to ELP. Delegations to be revisited during 2016 review of Standing Orders. Licensing Officer role to take certain decisions from ELP – implementation due end of 2015.	To be put in place – Juliet Tizzard Licensing Officer role – postponed pending recruitment of Head of Corporate Governance Delegations in SOs – April 2016 (tbc)	

Failing to demonstrate competence as a regulator	Update of compliance and enforcement policy (and application of existing policy, meanwhile).	Significant progress – revision discussed at September 2015 Authority – revised policy Spring 2016 - Nick Jones
	Inspector training, competency-based recruitment, induction process, SOPs, quality management system (QMS) and quality assurance all robust.	In place – Nick Jones
Effect of publicised grade A incidents.	Staffing model provide resilience in inspection team for such events – dealing with high-impact cases, additional incident inspections, etc.	In place – Nick Jones
	SOPs and protocols with Communications team.	In place – Nick Jones
	Fairness and transparency in licensing committee information.	In place – Nick Jones
	Dedicated section on website, so that the public can openly see our activities in the broader context.	In place – Nick Jones
Administrative or information security failure, eg, document management, risk and incident management, data security.	Staff have annual information security training (and on induction).	In place – Dave Moysen
	TRIM training and guidance/induction in records management in place. Head level 6 month contract recruited to manage the office move and review records management.	In place – SMT
	The IfQ website management project has reviewed the retention schedule.	Completed – August 2015 – Juliet Tizzard
	Guidance/induction in handling FOI requests, available to all staff.	In place – Juliet Tizzard
	Further work planned on records management in parallel with IT strategy.	Linked to IT strategy work – in progress – Jamie Munro/David Moysen
Until the IfQ website project has been completed, there is a continued risk of HFEA website outages, as well as difficulties in uploading updates to web pages.	Alternative mechanisms are in place for clinics to get information about materials such as the Code of Practice (eg, direct communications with inspectors, Clinic Focus).	In place – Nick Jones

	The IfQ work on the new website will completely mitigate this risk (the new content management system will remove the current instability we are experiencing from using Red-Dot). This risk is informing our decisions about which content to move first to the beta version of the new site.	In progress – beta phase February 2016 – Juliet Tizzard
Negative media or criticism from the sector in connection with legally disputed issues or major adverse events at clinics.	HFEA approach is only to go into cases on the basis of clarifying legal principles or upholding the standards of care by challenging poor practice. This is more likely to be perceived as proportionate, rational and necessary (and impersonal), and is in keeping with our strategic vision.	In place - Peter Thompson
HFEA process failings that create or contribute to legal challenges, or which weaken cases that are otherwise sound, or which generate additional regulatory sanctions activity (eg, legal parenthood consent).	Licensing SOPs, committee decision trees in place. Mitochondria donation application tools completed.	In place – Juliet Tizzard
	Update of compliance and enforcement policy (and application of existing policy meanwhile).	Significant progress – revision discussed at September 2015 Authority – revised policy Spring 2016 - Nick Jones
	Seeking the most robust possible assurance from the sector with respect to legal parenthood consent issues, and detailed plan in operation to address identified cases and anomalies.	In progress – Nick Jones
	QMS and quality assurance in place in inspection team.	In place – Nick Jones

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

Causes / sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Inability to extract reliable data from the Register.	Detailed planning and programme management in place to ensure this will be possible after migration. Migration strategy developed, and significant work being done to identify and cleanse all of the data that will require correction before migration can be done. Decisions are being made about the degree of reliability required in each data field. For those fields where 100% reliability is needed, inaccurate or missing data will be addressed as part of project delivery.	All aspects – detailed project planning in place – Nick Jones	Above tolerance. Managing these risks has formed an intrinsic and essential part of the detailed project planning and tendering, throughout. Following a lengthy delay, we received formal approval for both the data and digital elements of IfQ in late April 2015. The digital side of the programme received only partial approval; full delivery still requires additional gateway approvals at this stage (ie, prior to beta).
Unable to work out how best to improve CaFC, and/or failure to find out what data/information patients really need.	Stakeholder engagement and extensive user research completed as intrinsic part of programme approach. This is being elaborated further during subsequent sprints.	In place and ongoing – Juliet Tizzard	
Stakeholders not on board with the changes.	In-depth stakeholder engagement done, 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, either because the work needed is larger than anticipated, or as a result of the protracted approval periods associated with required DH/GDS gateway reviews.	Costs were taken into account as an important factor in consideration of contract tenders and negotiations. Attempts have been made to discuss the GDS review process and long timelines with those responsible at DH, although so far our approaches have unfortunately not met with success.	In place – Nick Jones Being pursued – Nick Jones	The Department of Health gateway review took place in November and awarded a high score to the HFEA, but we still did not receive a formal decision on this by the Government Digital Service board until mid-January (a month later than expected). This meant that the beta (build) stage initially had to proceed at risk (now resolved). However, obtaining this approval also meant committing to a number of requirements and conditions which need to be added to the delivery; and a further two approval gateways are still to come. If there are further blockages at those stages (public beta and go-live), this will have more of an impact, since this will mean pausing the work (ie, it will not be possible to proceed at risk at those stages). Therefore, there remains an ongoing risk of negative impact from the lengthy GDS gateway review processes. Owing to the previous delays, it has been necessary to extend
Redeveloped website does not meet the needs and expectations of our various user types.	Programme approach and some dedicated resources in place to manage the complexities of specifying web needs, clarifying design requirements and costs, managing changeable Government delegation and permissions structures, etc. User research done, to properly understand needs and reasons. Tendering and selection process included clear articulation of needs and expectations.	In progress – delivery by end June 2016 – Juliet Tizzard	
Government and DH permissions structures are complex, lengthy, multi-stranded, and sometimes change mid-process.	Initial external business cases agreed and user research completed. Final business case for whole IfQ programme was submitted and eventually accepted. Both GDS approvals sought so far have been granted, albeit with some delays. Additional sprints of work have been incorporated in beta, in an attempt to allow sufficient time (and resources) for the remaining GDS gateway review processes and subsequent formal approval mechanisms. The beta timeline has been extended by 3 months to compensate for previous and anticipated future delays.	In place – Juliet Tizzard In place – Nick Jones (decision received April 2015) In place – Nick Jones	

Resource conflicts between delivery of website and business as usual (BAU).	Backfilling where possible/affordable to free up the necessary staff time, eg, Websites and Publishing Project Manager post backfilled to free up core staff for IfQ work.	In place – Juliet Tizzard	the timeline for the beta phase from March to June 2016.
Delivery quality is very supplier dependent. Contractor management could become very resource-intensive for staff, or the work delivered by one or more suppliers could be poor quality and/or overrun, causing knock-on problems.	Programme management resources and quality assurance mechanisms in place for IfQ to manage (among other things) contractor delivery. Agile project approach includes a 'one team' ethos and required close joint working and communication among all involved contractors during the Sprint Zero start-up phase and beyond. 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 were scrutinised carefully as part of project. Appropriate new CMS now chosen, and all involved teams happy with the selection.	In progress – implemented in beta phase, June 2016 – 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 embedded into new ways of working.	In place – Nick Jones	

Potential risks associated with the HFEA's office move in April 2016, in that this will coincide with the delivery period for some IfQ milestones.	Early awareness of the potential for disruption means that this can be managed through careful planning. A 'null sprint' has been scheduled across the time of the move, both to allow for some disruption while staff move and unpack, but also to allow for any unanticipated business continuity issue that could arise.	Considered and in place – Nick Jones/Sue Gallone/Jamie Munro	

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. Extensive 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.
The firm (Avoca) which was scheduled to provide assurance on data migration has gone out of business.	The HFEA is considering other sources of assurance, and will agree a new plan shortly.	To be resolved by end March – Nick Jones	
Historic data cleansing is needed prior to migration.	A detailed migration strategy is in place, and data cleansing is in progress.	In place – Nick Jones/Dave Moysen	
Increased reporting needs mean we later discover a barrier to achieving this, or that an unanticipated level of accuracy is required, with data or fields which we do not currently focus on or deem critical for accuracy.	IfQ planning work 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	

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 – Nick Jones	
Potential risks associated with the HFEA's likely office move in April 2016, in that this will coincide with the delivery period for some IfQ milestones.	Early awareness of the potential for disruption means that this can be managed through careful planning. A 'null sprint' has been scheduled across the time of the move, both to allow for some disruption while staff move and unpack, but also to allow for any unanticipated business continuity issue that could arise.	Considered and in place – Nick Jones/Sue Gallone/Jamie Munro	

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

Causes / sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Poor user acceptance of changes, or expectations not managed.	Stakeholder involvement strategy in place and user testing being incorporated into implementation phase of projects.	In place – Nick Jones/Juliet Tizzard	Above tolerance. This risk is also affected by GDS approvals and the associated delays (see IfQ1).
Clinics not consulted/involved enough.	Working with stakeholders has been central to the development of IfQ, and will continue to be. Advisory Group and expert groups have ended, but a stakeholder group for the implementation phase is in place. Workshops are planned with the sector regarding how information will be collected through the clinic portal.	In place – Nick Jones/Juliet Tizzard	
Scoping and specification are insufficient for realistic resourcing and on-time delivery of changes.	Scoping and specification were elaborated with stakeholder input, so as to inform the tender. Resourcing and timely delivery were a critical part of the decision in awarding the contract.	In place and contracts awarded (July 2015) – Nick Jones	
Efficiencies cannot, in the end, be delivered.	Detailed scoping phase included stakeholder input to identify clinic users' needs accurately. Specific focus in IfQ projects on efficiencies in data collected, submission and verification, etc.	In place – Nick Jones	
Cost of improvements becomes too prohibitive.	Contracts only awarded to bidders who made an affordable proposal.	In place (July 2015) – Nick Jones	

Required GDS gateway approvals are delayed or approval is not given.	Both GDS approvals sought so far have been granted, albeit with some delays. Our detailed planning includes addressing the requirements laid down by GDS as conditions of alpha phase approval. Additional sprints of work have been incorporated in beta, in an attempt to allow sufficient time (and resources) for the remaining GDS gateway review processes and subsequent formal approval mechanisms. The beta timeline has been extended by 3 months to compensate for previous and anticipated future delays.	In place – Nick Jones	
Benefits not maximised and internalised into ways of working.	During IfQ delivery, product owners are in place, as is a communications plan. The aim is to ensure that changes are developed involving the right staff expertise (as well as contractors) and to ensure that the changes are culturally embraced and embedded into new ways of working.	In place (June 2015) – Nick Jones	
Potential risks associated with the HFEA's likely office move in April 2016, in that this will coincide with the delivery period for some IfQ milestones.	Early awareness of the potential for disruption means that this can be managed through careful planning. A 'null sprint' has been scheduled across the time of the move, both to allow for some disruption while staff move and unpack, but also to allow for any unanticipated business continuity issue that could arise.	Considered and in place – Nick Jones/Sue Gallone/Jamie Munro	

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

Causes / sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Complex and controversial area.	Panel of legal advisors from various firms at our disposal for advice, as well as in-house Head of Legal.	In place – Peter Thompson	Above tolerance. **Current cases:** One case decided in the HFEA's favour at summary judgment, but has now been appealed (8 February 2016 – outcome not yet known). The 'M' case regarding the export of gametes for treatment abroad has been granted permission to proceed to trial (in April 2016). The judgment in 2015 on consents for parenthood has had administrative and policy consequences for the HFEA. Further court cases are coming to light now, and more are also likely, although the HFEA is unlikely to participate in legal proceedings directly.
	Evidence-based policy decision-making and horizon scanning for new techniques.	In place – Hannah Verdin	
	Robust and transparent processes in place for seeking expert opinion – eg, external expert advisers, transparent process for gathering evidence, meetings minuted, papers available online.	In place – Hannah Verdin/Juliet Tizzard	
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. (eg, one current case challenging the long-held policy position on storage regulations may need to be decided by a court).	Panel in place, as above, to get the best possible advice. Case by case decisions regarding what to argue in court cases, so as to clarify the position.	In place – Peter Thompson	
Decisions and actions of the HFEA and its committees may be contested.	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 – Juliet Tizzard	

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

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

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

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

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

Causes / sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Poor record keeping	Refresher training and reminders about good records management practice. Head level 6 month contract recruited to manage the office move and review records management.	In place – SMT Head post in place - SMT	Above tolerance. Although we have some good controls in place for dealing with PQs and other externally generated requests, it should be noted that we cannot control incoming volumes, which in January 2015 (for example) were among the highest we have ever experienced. Volumes decreased in the second half of 2015, but have now increased again.
	TRIM review and retention policy implementation work – subsumed by IT strategy.	To sync in with IT strategy – Dave Moysen/Juliet Tizzard	
	Audit of Epicentre to reveal any data errors. All queries being routed through Licensing, who have a definitive list of all licensing details.	Completed October 2015 – Juliet Tizzard	
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. FOI requests are refused when there are grounds for this.	In place – Juliet Tizzard / Nick Jones	

	PQ SOP revised and log created, to be maintained by new Committee and Information Officer/Scientific Policy Manager.	In place - Juliet Tizzard	
Answers in Hansard may not always reflect advice from HFEA.	The PQ team attempts to catch any changes to drafted wording that may unwittingly have changed the meaning. HFEA's suggested answer and DH's final submission both to be captured in new PQ log.	In place – Juliet Tizzard / Peter Thompson	
Insufficient understanding of underlying system abilities and limitations, and/or of the topic or question, leading to data being misinterpreted or wrong data being elicited.	As above – expert staff with the appropriate knowledge and understanding in place.	In place – Juliet Tizzard / Nick Jones	
Servicing data requests for researchers - poor quality of consents obtained by clinics for disclosure of data to researchers.	There is a recognised risk of centres reporting research consents inaccurately. Work to address consent reporting issues is being planned.	Actions to be confirmed – under discussion in February 2016 – Nick Jones	

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

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

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

Causes / sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Lack of counselling availability for applicants.	Counselling service pilot established with external contractor in place.	In place (June 2015) – Nick Jones	At tolerance. The pilot counselling service has been in place since 1 June 2015, and we will make further assessments based on early uptake and the delivery experience. Reporting to the Authority will occur annually during the pilot period.
Insufficient Register team resource to deal properly with OTR enquiries and associated conversations.	Additional member of staff dedicated to handling such enquiries. However, there is currently also one member of staff on long term sick leave, and this together with work pressures from IfQ delivery means there is still some pressure on team capacity (being discussed by managers).	In place, with current team capacity issue under discussion – Nick Jones	
Risk of inadequate handling of a request.	Trained staff, SOPs and quality assurance in place.	In place – Nick Jones	
	SOPs reviewed by Register staff, CMG and PAC-UK, as part of the pilot set-up. Contract in place with PAC-UK for pilot delivery.	Done (May 2015) – ongoing management of the Pilot by Rosetta Wotton.	

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

Causes / sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Fee regime makes us dependent on sector activity levels.	Activity levels are tracked and change is discussed at CMG, who would consider what work to deprioritise and reduce expenditure.	Monthly (on-going) – Sue Gallone	At tolerance. Previous 2014/15 overspend was able to be met from reserves. 2015/16 on course for small under-spend but risk of legal costs remains. In November 2015, the Authority approved a proposal to increase per-cycle fees by £5 (to £80) and to end the small 'eSET discount' for elective single embryo transfer, which has been in place for a few years to assist with the introduction of the Authority's multiple births policy (now firmly established and in place). This should help secure sufficient funds going forward. Treasury approval for the fee change has been received (February 2016).
	Fees Group created enabling dialogue with sector about fee levels. Fee increase agreed (November 2015), Treasury approval received (February 2016), and eSET discount to end.	In place. Fees Group meetings in April and October, ongoing – Sue Gallone	
GIA funding could be reduced due to changes in Government/policy	A good relationship with DH Sponsors, who are well informed about our work and our funding model.	Quarterly meetings (on-going) – Sue Gallone	
	Annual budget agreed with DH Finance team alongside draft business plan submission.	December annually – Sue Gallone	
	Detailed budgets for 2016/17 are being prepared for Directorate Review DH has previously agreed our resource envelope.	In place – Sue Gallone	
Budget setting process is poor due to lack of information from directorates	Quarterly meetings with directorates flags any 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.	Periodic review of actual and budgeted spend by IfQ project board and monthly budget meetings with finance.	Ongoing – Wilhelmina Crown	
	Cash flow forecast updated.	Monthly (on-going) – Morounke Akingbola	

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

Causes / sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
High turnover, sick leave etc. leading to temporary knowledge loss and capability gaps.	People strategy will partially mitigate. Mixed approach of retention, staff development, and effective management of vacancies and recruitment processes.	Done – May 2015 – Rachel Hopkins	Above tolerance. This risk and the set of controls remains focused on capability, rather than capacity. There are obviously some linkages, since managing turnover and churn also means managing fluctuations in capability and ensuring knowledge and skills are successfully nurtured and/or handed over. Since the HFEA is a small organisation, with little intrinsic resilience, it seems prudent to have a low tolerance level for this risk. At present we are carrying two Head vacancies pending new starters.
	Staff have access to civil service learning (CSL); organisational standard is five working days per year of learning and development for each member of staff.	In place – Rachel Hopkins	
	Organisational knowledge captured via records management (TRIM), case manager software, project records, handovers and induction notes, and manager engagement.	In place – Rachel Hopkins	
The new UK government may implement further cuts across all ALBs, resulting in further staffing reductions. This would lead to the HFEA having to reduce its workload in some way.	The HFEA was proactive in reducing its headcount and other costs to minimal levels over a number of years. We have also been reviewed extensively (including the McCracken review). Turnover is variable, and so this risk will be retained on the risk register, and will continue to receive ongoing management attention.	In place – Peter Thompson	

Poor morale leading to decreased effectiveness and performance failures.	Engagement with the issue by managers. Ensuring managers have team meetings and one-to-one meetings to obtain feedback and identify actions to be taken.	In place – Peter Thompson
	Staff survey and implementation of outcomes, following up at December 2015 all staff conference.	Survey and staff conference done – Rachel Hopkins Follow-up communications in place (Staff Bulletin etc.) – Peter Thompson
Differential impacts of IfQ-related change and other pressures for particular teams could lead to specific areas of knowledge loss and low performance.	Staff kept informed of likely developments and next steps, and when applicable of personal role impacts and choices.	In place – Nick Jones
	Policies and processes to treat staff fairly and consistently, particularly if people are 'at risk'.	In place – Peter Thompson
Additional avenues of work open up, or reactive diversions arise, and need to be accommodated alongside the major IfQ programme.	Careful planning and prioritisation of both business plan work and business flow through our Committees. Regular oversight by CMG – standing item on planning and resources.	In place – Paula Robinson
	Early emphasis given to team-level service delivery planning, with active involvement of team members. CMG will continue to review planning and delivery.	In place – Paula Robinson
	Planning for 2016/17 prioritises IfQ delivery, and therefore strategy delivery, within our limited resources.	In place as part of business planning (2015 onwards) – Paula Robinson
	IfQ has some of its own dedicated resources.	In place – Nick Jones
	There is a degree of flexibility within our resources, and increasing resilience is a key consideration whenever a post becomes vacant. Staff are encouraged to identify personal development opportunities with their manager, through the PDP process, making good use of CSL.	In place – Peter Thompson

Regarding the recent work on licensing mitochondrial replacement techniques, there is a possible future risk that we will need to increase both capability and capacity in this area, depending on uptake (this is not yet certain).	Future needs (capability and capacity) relating to mitochondrial replacement techniques and licensing applications are starting to be considered now, but will not be known for sure until later. No controls can yet be put in place, but the potential issue is on our radar.	Issue for consideration when applications commence – Juliet Tizzard	

Risk area	Description and impact	Strategic objective linkage	Risk scores			Recent trend	Risk owner
Office move OM 1: Office move	There is a risk that the office move could compromise our capability and capacity to deliver our strategy.	Efficiency, economy and value: ensuring the HFEA remains demonstrably good value for the public, the sector and Government.	Inherent risk level:			New ⊙⇔⇔	Sue Gallone
			Likelihood	Impact	Inherent risk		
			5	4	20 Very high		
			Residual risk level:				
			Likelihood	Impact	Residual risk		
			4	**4**	**16 High**		
			Tolerance threshold:		6 Medium		

Causes / sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Contractual risks.	Contract signed.	In place (December 2015) - Sue Gallone	Above tolerance.
Preparation and space planning risks, including establishing clarity about the facilities available in the building (eg, lockers).	Project manager in place. Staff engagement group established. Detailed information available about the new office space. Visits started, building relationship with NICE facilities team.	From now until the move – Jamie Munro	
Storage availability will be limited. The HFEA has some unavoidable paper records in Register team, Legal, Finance.	Planning work being done to identify unavoidable paper records, and to determine whether any of these can be scanned to reduce storage needs. Contractor to be hired to take on all the scanning.	Plan agreed in February 2016 – to be implemented in February/March – Jamie Munro	
Potential for culture clash with other organisations that share the same space but have a different culture and their own staff rules.	Project team giving consideration to NICE's staff rules and whether the HFEA wishes to adopt them. Communication with staff about any non-negotiable considerations that may impact on culture. There may need to be some senior level negotiation with NICE about messaging and the HFEA retaining its own culture and rules. We will allow some time after the move for people to adapt to the changed environment, and will then consider whether any changes or further negotiations with NICE (or the British Council) are needed.	Consideration of actions before the move – Jamie Munro Consideration of actions after the move - SMT	

The office will be shared with another organisation, and there will be generally less space, and limited meeting room availability.	The meeting room risk partly applies to smaller meetings such as one to ones. Larger meeting room availability in the building is limited and will be a challenge. Some meeting rooms are being secured in advance from April/May onwards (on a like-for-like basis). Further thought will need to be given to how to secure the rest of the needed meeting space. Staff engagement group to consider cultural and ways of working impact of having less 'free space' in which to have impromptu or small meetings. Trips to the new office will be planned so that staff can see the space. Our IT kit will be replaced with laptops/tablets before the move, so that smaller desks will not be an issue. There will be preparation planned in before the move, to deal with the reality of reduced storage (eg, 'Tidy Fridays' etc. - but staff capacity for this will be very limited owing to IfQ and other high workloads).	From now until the move and slightly beyond – Jamie Munro	
The actual move – practical risks.	We will be moving minimal kit and no desks, reducing both risk and cost. Detailed planning and communications will take place with all involved, including contractors, NICE and HFEA staff. Following procurement framework to select contractors, and selecting carefully.	From now until the move – Jamie Munro	
Cabling risks – ensuring communications lines are available to HFEA in new office. .	Establish needs and place orders as necessary.	From now until the move – David Moysen	

IT risks (information security, business continuity, introduction of new equipment and Office 365 upgrade in advance of move).	Office 365 upgrade project in place to include issuing of new laptops. Register safeguards will be put in place; security of new Comms Room will be considered with NICE. Business continuity plan already in place, and arrangements will continue for now – to be reviewed after move. Planned timing of surrounding tasks (eg, IfQ milestone delivery) will need to allow for some down-time. Back-ups will continue and will be stored off site as now.	From now until the move and slightly beyond – David Moysen	
People risks: resources to participate in planning, packing etc., turnover and/or extra management work resulting from change of location, engagement on ways of working, willingness to adapt etc.	Staff engagement, communications and HR contractual considerations built into project plan. Staff engagement group being established and first meeting being planned. Staff being issued with new, smarter IT kit, including tablets/laptops replacing PCs, a better access method for secure HFEA login, and Office 365 available.	In place and ongoing – Jo Triggs	
Diversion from business. Coincides with the delivery period for some IfQ milestones, which are key to delivering our strategy to publicly announced timescales. Some other work will also coincide because of year-end considerations.	Early awareness of the potential for disruption means that this can be managed through careful planning and prioritisation.	Detailed planning and awareness raising from November 2015 onwards – Paula Robinson (and all managers)	

Cost increase compared to current rent (potentially including additional costs for both internal and external meeting rooms).	Unavoidable, but in keeping with DH requirements which will reduce costs overall for the health ALBs as a whole group. Costs factored into to funding required from 2016/17. Business case includes ensuring the HFEA is in line with Government Estates Strategy.	In place – Sue Gallone	
Project failure - The move could fail to take place if unforeseen issues arise, or the timetable could be jeopardised by factors outside the HFEA's control.	Contract secured and planning is in place. Should the new building become unavailable for some reason, at any point, (eg, fire, flood), business continuity arrangements would apply while a new plan was put in place. (There is no option to stay on in Finsbury Tower beyond April.)	Detailed risk-based planning in place – Jamie Munro	

Scoring system

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 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

Risk Score = Impact x Likelihood

Likelihood

Business plan 2016/17

Strategic delivery:	☒ Setting standards	☒ Increasing and informing choice	☒ Demonstrating efficiency economy and value
Details:			
Meeting	Authority		
Agenda item	11		
Paper number	HFEA (09/03/2016) 791		
Meeting date	9 March 2016		
Author	Paula Robinson, Head of Business Planning		
Output:			
For information or decision?	For decision		
Recommendation	The Authority is asked to approve the Business Plan for 2016/17, subject to the addition of year end information, Department of Health (DH) confirmation of the budget, and final DH approval.		
Resource implications	In budget. Rated medium for risk, given limited resources and a challenging set of activities to deliver.		
Implementation date	Throughout 2016/17 business year.		
Communication(s)	Publication on HFEA website and Intranet.		
Organisational risk	☐ Low	☒ Medium	☐ High
Annexes	Annex 1: Business plan for 2016/17		

1. Background

1.1. The Authority agreed a draft of the new business plan for 2016/17 at its November meeting. The content has now been developed further, and the business plan is at an advanced stage.

1.2. Following submission of our earlier draft in December 2016, our DH sponsors had only minor comments, and indicated that they were broadly content. We submitted a revised draft for their end of January deadline. Budget confirmation has been received.

1.3. The only change since that submission at the end of January is the addition of some activities to address new Government-wide better regulation initiatives, now that we have more information.

2. Remaining content

2.1. Some sections cannot be added until after the end of the business year on 31 March. This includes:

- the 'facts and figures' table relating to the previous business year
- confirmed budget for 2015/16
- standard HR benchmarking information
- the performance indicator section.

3. Review of activities

3.1. The Corporate Management Group (CMG) has reviewed the activities in the business plan so as to ensure that we can be confident of delivery within resources.

3.2. Service delivery plans are being refined, so that teams can manage their delivery of the business plan effectively across the year. At the March CMG meeting, we plan to share our service delivery plans and identify interdependent work, so make sure that the staff resources will be available to deliver the work when it is planned to take place (if not, the sequencing will be adjusted).

4. Recommendation

4.1. The Authority is asked to approve the business plan for 2016/17 for publication in April, subject to the later addition of the material mentioned in paragraph 2.1, confirmation of the budget, and formal permission to publish subsequently being received from DH in the usual way.

Human Fertilisation & Embryology Authority

Annex A

Business Plan

2016/17

www.hfea.gov.uk

Our role and strategic aims

Who we are

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

Our vision for 2014–2017 is:

High quality care for everyone affected by assisted reproduction.

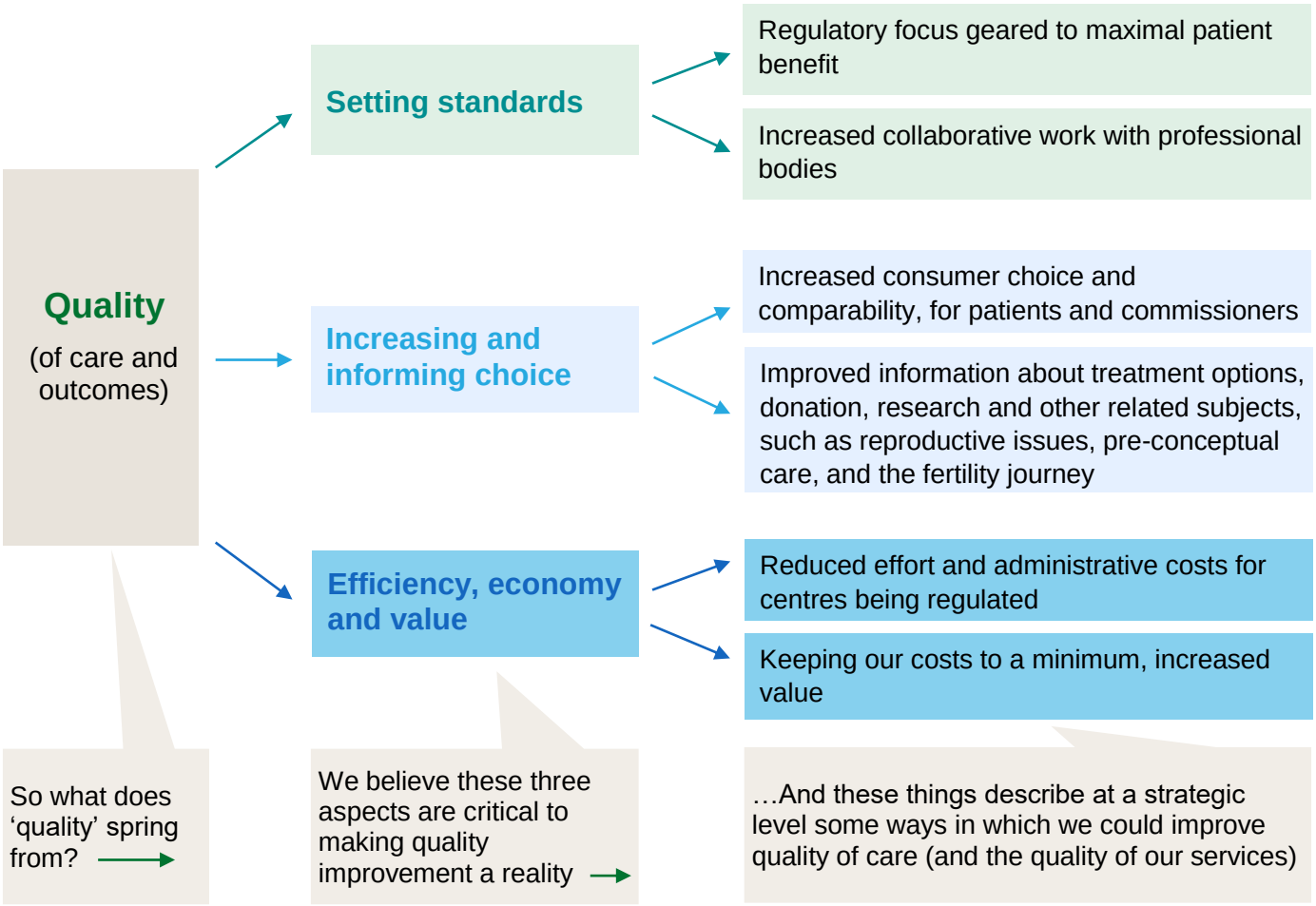
High quality care means…	• safe, ethical and effective care and treatment.
Everyone affected means…	• patients and parents • all those conceived through assisted reproduction • donor-conceived people • egg and sperm donors • clinic staff.
Assisted reproduction means…	• standard fertility treatments •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

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

What can we do to achieve high quality care?

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

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



For the first time, there is now an agreed shared delivery plan for all arms length bodies and the Department of Health. This delivery plan gives high level clarity on objectives across the whole health system. Since we are a specialist body, not all of the Department's priorities are relevant to our work, but our activities fit well within them – most notably in relation to the objective of creating the the safest, highest quality healthcare services possible.

HFEA strategy 2014-2017

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

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

Strategic Objectives

Setting standards

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

Increasing and informing choice

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

Strategic Objectives

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

Efficiency, economy and value

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

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

How we work

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

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

Our legislation and functions

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

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

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

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

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

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

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

- Reviewing information about:
    - human embryos and developments in research involving human embryos
    - the provision of treatment services and activities governed by the 1990 act (as amended).
- Advising the Secretary of State for Health on developments in the above fields, upon request.

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

What we did in 2015/16

Setting standards

Improving the quality and safety of care through our regulatory activities

Delivering the full compliance cycle to maintain standards for patients:

As usual, we undertook our full range of inspection, audit and licensing activities. This ensured clinics were appropriately inspected and monitored against published performance indicators, and issued with licences for up to four years. We also continued our programme of unannounced inspections. Our compliance activities provide assurance on standards and safety for the public and our other stakeholders. We always aim to have a positive overall impact on the quality of care, on outcomes, safety and support, and on the information clinics provide to the HFEA and publish for patients (eg, on their websites).

We also intended to review our inspection regime during the year, but, in the event, the HFEA's triennial review was commissioned by the Department of Health during the business year, so we decided not to run another review at the same time. When our triennial review report is released, we will consider what actions we need to take, based on the report's recommendations, and consider whether another review would be good value or not.

Identifying and implementing ways of improving the quality and safety of care:

We increased our focus on quality and safety of care in our inspection activities – in particular through checking through inspection that properly informed consent, good infection control, medicines management and the use of approved medical equipment were all in place. Our aim is to improve compliance across the sector, improving quality and safety and increasing clinics' understanding of, and adherence to, the correct procedures and the reason these are important - particularly with regard to consent. If clinics are able to take consents correctly, then if an issue subsequently arises (such as the death of someone with gametes in storage), the correct consents are more likely to be in place and are legally clear and robust. This will provide greater certainty for patients at a time of stress, and reduced vulnerability for clinics in terms of expensive adverse legal and reputational risks.

We also continued to evaluate areas of regulatory concern and identify performance levers. Alongside this we increased our focus on learning from incidents, adverse events and complaints from patients, in dialogue with the sector. This included focused work with individual clinics who reported such events, to assist them in improving. We published our annual report on clinical incidents in 2014.

Legal parenthood

From 6 April 2009, women (and the partners of women treated with donor sperm, where the couple is neither married nor in a civil partnership), must give their consent in order for the partner to become the legal parent of any child born. Legal parenthood confers a lifelong connection between a parent and a child, and affects nationality, inheritance, financial responsibility and contact.

In 2015, following a number of consent failures in clinics, Sir James Munby, President of the Family Division of the High Court ruled on a cohort of legal parenthood cases that were brought before him for legal resolution.

In light of his judgment, the HFEA immediately put an additional range of actions in place. The HFEA had previously informed clinics about the legal parenthood consent requirements in various ways. The timeline of the HFEA's actions with respect to legal parenthood (before and after the cases emerged) is set out in full below.

- In 2009 (when the rules were introduced) – a Chair's letter was sent to all clinics, along with guidance; new consent forms were issued; and a series of workshops was held.
- Parenthood was then a specific theme of inspections from January 2010 to 2012.
- June 2013: Two separate cases of failure to take the correct consents in clinics emerged.
- August 2013: The HFEA sent out a Clinic Focus article emphasising the importance of robust consent procedures.
- September to December 2013: An audit was trialled to ensure professional engagement.

- February 2014: A Chief Executive's letter was sent to all clinics, requiring them to conduct a full audit; and announcing that all subsequent inspections would check up on the completeness of this audit process (a clinic responsibility).
- September 2014: A further Chief Executive's letter was sent, reporting on results. Findings indicated widespread poor practice. Several clinics at that stage were supporting patients to obtain the needed legal declaration.
- February 2015 to September 2015: Family Division consideration of eight cases took place.
- The HFEA confirmed to the sector that a legal 'declaration' was necessary in such cases, and that patients must be supported by clinics.
- We began a proactive follow-up process on the progress of all cases.
- The Person Responsible in each clinic was asked to confirm that they were satisfied that their parenthood consent audit had been robust.
- A further Clinic Focus article was published, signed by the Chair and Chief Executive, to ensure clinics were clear as to their responsibilities in seeking consent for parenthood correctly.
- Parenthood has been introduced once again as an inspection 'theme' in 2015/16 and beyond – so as to ensure understanding of this issue is embedded in all clinics. Each inspection report will set out how the clinic has performed in this area.
- A number of anomalies have occurred in a minority of clinics, and within those, the majority have one or two cases.
- As at January 2016, all clinics have engaged with us and have provided assurances about their current practices.
- Seven cases have been determined in court so far, with a further nine cases currently under consideration. Not all patients affected will choose to seek legal resolution.
- Since errors could always be made in clinics, there are limits to what can be found on inspection. However we will continue to send stronger signals about clinics' assurance of the quality of their own systems, and require more robust audits of clinics, so that we have better evidence of the quality of each clinic's compliance.
- In 2016, we will continue to follow up on individual cases and to focus on working closely with those clinics who have uncovered errors. Where appropriate, we will take further enforcement action.
- Legal parenthood consent has been added to our strategic risk register with the aim of closely monitoring and reducing the risk of any recurrence for patients, the concomitant risks for any clinics who make such consent-taking errors, and the HFEA itself.

There are a range of lessons learned from this episode, for both the HFEA and the clinics. These include:

- The need for thoughtful, careful and consultative implementation of new requirements. Change is tricky, and these errors have been made despite careful implementation in 2009.
- The importance of maintaining bespoke consent forms that protect patients' interests.
- That parenthood needs to remain an inspection 'theme' so as to embed understanding in clinics, with samples of records checked.
- That we must ensure that the chances of errors are reduced to a minimum, while recognising that some errors will always be made – there are limits on inspection and regulatory oversight.
- That clinics' assurance of the quality of their systems is important. We now require a robust audit – which we can check.
- That most clinics in most treatments get it right, and that the majority of patients are not facing any doubts about the parenthood status of their child.
- That the errors made in relation to these consents have been many and various, including missing names and signatures, dates inadvertently transposed, missing forms, or the use of self-invented 'in-house' forms produced by clinics, instead of using the HFEA's required form.

- That clinics that take consent well understand that this is not simply an administrative process. These forms confer legal status on family relationships and should therefore be completed with the greatest of care.

Our approach to this issue has been based on transparency and openness, with regular reporting to the Authority and to the Audit and Governance Committee. In working with clinics, we have sought assurances from all clinics, emphasising the PR's responsibility to ensure the robustness of their audits, and that all patients affected must be supported. We have received good cooperation from clinics.

Making the patient experience integral to the way in which we assess clinics' performance:

We increased the amount of patient feedback we obtain before and during inspections, and continued our work through the Information for Quality (IfQ) programme to increase this still further through our new website, in 2016. Patient experiences are now set out more explicitly in the inspection reports that are submitted to licensing committees, so that such experience informs licensing decisions.

Seeking patients' views, and understanding their perspective, as part of the way we work:

Our user research to underpin the IfQ programme enabled us to identify the quality factors that are the most relevant for patients. These findings are being implemented through the IfQ programme (eg, through the revised presentation of Choose a Fertility Clinic, or CaFC). We will subsequently evaluate the impact of this work and see if the approach needs to be refined.

Identifying the best ways to optimise success rates and developing a common improvement agenda:

We have continued to use every opportunity within our role as regulator to maximise the chances of success for patients. We address with clinics any performance alerts in relation to their success rates. We also review emerging procedures and publish any evidence available, working with regulatory partners to ensure there are no inappropriate barriers to the introduction of innovative (safe) new techniques. We have been working towards an improved presentation of our data about success rates on CaFC, through the IfQ programme. We hope this work will collectively lead to improved success rates, over time, and that this will be achieved without disincentivising clinics from treating patients who have an intrinsically lower chance of success because of age or other factors. We are aiming to ensure that patients can more easily optimise their own chances of success through their choice of clinic, and that they arrive in clinics feeling informed about new and emerging techniques and the treatment choices they may be offered. We also want to equip patients with a better and more realistic idea of their own chances of success.

In late 2015, we also updated the multiple births information for patients and professionals, to help minimise and reduce the occurrence of multiple births. This information also helps patients to make informed choices about their treatment options and the associated risks and benefits.

Publishing more HFEA data to drive improvements in clinic performance:

As a result of the IfQ programme, we will shortly be publishing a wider range of performance data on our website. Work on the programme has taken place throughout 2015/16, with a successful alpha stage between July and November 2015, and the beta stage (where products start to be built) commencing in December 2015 following required Government Digital Service approvals.

Publishing more data is an intrinsic aim of the IfQ programme, so as to increase transparency and inform and empower patients. This work will also increase visibility for clinics of sector-wide data, so that they can assess their own performance against it. Our aim is to encourage best value and the best possible treatment outcomes for patients.

Acknowledging that treatment is often unsuccessful:

We have started to explore with our professional stakeholders (including the British Fertility Society (BFS), the Association of Clinical Embryologists (ACE), infertility Network UK (INUK), and the Professional Bodies Group) how we, and clinics, could better address this issue. Better support for patients is needed when treatment has been unsuccessful. Prospective patients should also

enter treatment with a realistic understanding that they may not have a baby, even if they undertake many cycles.

More information and signposting for patients is being produced for our new website. We will do further work with professional stakeholders in the next business year to make clinics more aware of their responsibilities to patients beyond the immediate treatment setting.

Reviewing and advising on issues relating to mitochondrial donation:

This year we implemented a range of agreed statutory changes (further to Parliamentary decisions) to enable clinics to make applications to carry out mitochondrial donation in treatment, for the avoidance of serious mitochondrial disease.

The statutory changes introduced by Parliament were implemented clearly and robustly, with clear information for patients and clinics.

We now await the results of some externally-run safety and efficacy tests, before the first applications can be submitted to us. There will be a further scientific review once the tests have been completed and published.

Maintaining our role as the UK's competent authority for ART in the European Union:

We attend twice yearly competent authority events, and implement associated EU decisions as relevant. By participating, the HFEA gains up-to-date intelligence about European matters, and shapes European decisions so that they better reflect UK practices and perspectives. This year we have begun work on three projects to implement recent EU decisions on the import/export of gametes and on EU coding requirements. This work will continue until April 2017 (the implementation date for the EU Directives).

Improving the lifelong experience for donors, donor-conceived people, patients using donor conception, and their wider families

Providing information about donor conception directly to patients and donors:

Throughout the year, we continued to facilitate and support the ongoing work of the Lifecycle Campaign, established to find new ways of improving sperm and egg donation in the UK. We aim to ensure that potential donors, recipients and donor conceived people have better access to clear, authoritative impartial information about a range of issues. The Lifecycle leaflets explain all the issues, and have been made widely available. Our aim is to ensure that those affected by donor conception feel better informed and supported with respect to the legal aspects and obligations of donation. It is important that all involved (including clinics) understand the lifelong commitment associated with donor conception and the associated legal issues that are relevant to them.

Ensuring that clinics prepare patients adequately for donation and fully understand their role and importance as a lifelong information provider; and that egg and sperm donors are well supported and understand the lifelong commitment that follows from donation:

By continuing to promote the Lifecycle information leaflets and the pack about donor information produced in 2014/15 for clinics, we have achieved improved clarity of role and performance for clinics in relation to donation and associated information guardianship. We have also improved the overall experience for donors, donor-conceived people seeking information and patients and their families.

Collecting and publishing information regarding donor egg and sperm availability in the UK and addressing impacts for patients (for example, by providing more information about the implications of treatment abroad):

Following consultation as part of the IfQ programme in 2014/15, we further explored with stakeholders and professional organisations how best to collect and use UK data on the availability of donated eggs and sperm. We will continue to

progress this work as we conclude the redevelopment of our website in 2016/17.

Improving the provision of counselling support for donor-conceived people wishing to access information held on the HFEA Register:

This year we began a three-year pilot providing support services for applicants to the Register. Counselling support is now offered for all Opening the Register (OTR) applicants (those seeking non-identifying information) and for donor-conceived applicants receiving donor identifying information. Mediation services are also in place for when donors and donor-conceived people meet. Basic mediation training and systems are in place for dealing with identity release to donors and donor-conceived people. Our aim is to ensure that OTR applicants feel more supported and are prepared to deal with the information they receive from us.

As before, we also continued to facilitate timely access to information from the Register for those who are entitled to it. Opening the Register requests continued to be met in a sensitive manner and within required time limits (20 working days, excluding time for counselling), throughout the year.

Implementing new EU requirements relating to the import and coding of donor eggs and sperm:

As mentioned above, we began work on three projects to implement new EU requirements on the import of donor gametes and new EU coding requirements for human tissue and cells. This work is due to complete by April 2017, and will give improved clarity for clinics, patients and donors. It will also provide improved internal clarity and updated procedures for our decision-making committees. The HFEA will then be compliant with the new EU directives when they come into force, and will have robust processes in place to ensure the quality, safety and traceability of imported gametes and embryos.

Increasing and informing choice

Using the data in the HFEA Register of Treatments to improve outcomes and research

Publishing and supplying the information we hold, for the benefit of stakeholders:

We continued to regularly update CaFC information, so as to assist patient choice. This involves a six monthly verification and publication schedule, to maintain the provision of up-to-date and accurate information.

Through the IfQ programme, we are working on improving the presentation of clinic comparison information on CaFC. This work has been based on extensive user research, and the beta phase of work (the building phase) commenced in December 2015. The aim is for the published outcome data to be more useful and easier to understand and to set up positive incentives for improvements, as well as increased consumer choice and clinic comparability.

During the year, we also produced a guide for NHS commissioning bodies to help them to commission the best services for patients using available data. The draft guide for commissioners was road tested in 2015/16, first with our multiple births stakeholder group, and then with a sample of commissioners.

We continued to deepen our relationships with relevant other bodies, such as the Government Digital Service (GDS) the Health and Social Care information Centre (HSCIC) and being an active member of the National Information Board (NIB). This helps us to contribute to the objectives of the wider health system, with respect to information management, and to learn from best practice in data management, systems integrity and security.

We continued our information provision for researchers requesting access to Register data, providing the requested information within 90 calendar days of approval. Our aim is to ensure that Register information is used to best effect, promoting understanding and facilitating good research, ultimately for patient benefit.

Maintaining the Register of Treatments and Outcomes and supporting clinics in reporting the data:

Register data and forms continued to be processed and quality assured throughout the year, through liaison with clinics on errors and omissions and through validation and verification of Register entries. This ongoing process ensures that high quality data is available to develop patient information and to support risk-based regulation and evidence-based policy-making.

Publishing reports on the information we hold for the benefit of stakeholders:

We continued to publish statistical and other reports during the year. These included:

- The 'Fertility treatment in 2014' report covering 2013–2014. This report provides patients, clinic staff and others with up-to-date information about a range of topics, and carries 'official statistics' status.
- Statistical report on multiple births. This provides up-to-date information on progress in reducing the incidence of multiple births following ART.
- Report on incidents and alerts. This report contributes to a culture of openness and information sharing where clinic staff are empowered to report mistakes and learn from each other. It also promotes transparency and maximises opportunities for learning from incidents to improve quality of care for patients.

In addition, we continued throughout the year to manage the ongoing work of the register research panel, which considers applications from researchers to use our register data for linkage studies, which result in publications about health outcomes and success rates.

Ensuring patients have access to high quality meaningful information

Improved HFEA information about treatments available, scientific research, embryo and stem cell research and other fertility subjects:

Through the IfQ programme, we commenced the redevelopment of the content of our website to provide an expanded range of educative and scientific information about current treatments and fertility issues. This will lead to increased information for patients and others. The new website will ensure that our information is accessible, engaging and meaningful, so that patients are better informed and better placed to deal with treatment issues and decisions. Our aim is to ensure that patients feel safe and know they can expect certain standards in clinics, and that prospective patients have clearer information and signposting, and are more aware of the potential risks of new and different treatments as well as the possible benefits.

Enhancing the patient voice in all of our work, including information provision:

Following a consultation to inform the IfQ programme in 2014/15, we established patients' views and information needs which are fundamental to the redesign of our website. Over time, we will be able to make better use, via the new website, of feedback mechanisms, video and integration with social media platforms.

The new website will enable increased feedback opportunities for patients, and easier interaction with us.

Working with clinics and scientific experts to publish information about new treatments:

In redesigning the website, we have also begun to establish improved mechanisms for producing and publishing accessible information when new treatment options emerge, working in collaboration with clinics and experts where necessary (including the professional bodies we work with regularly, and whose input is essential to this process). This will enable us to increase public understanding of emerging new science and future treatment possibilities. It will also ensure patients are better informed and better placed to deal with treatment issues and decisions when such treatments begin

to be offered by clinics, and that they are better placed to judge the merits of any media speculation about new treatments.

Our ongoing annual scientific horizon scanning work also feeds into this, ensuring that early consideration is given to emerging scientific issues and developments.

Enhancing Choose a Fertility Clinic (CaFC) by including user experience scores:

We have developed a method for incorporating user experience scores, as part of the IfQ programme work on the redevelopment of the website. This will be introduced along with the newly redesigned Choose a Fertility Clinic (CaFC) functionality. This will enable patients to take into account other patients' experiences to help them decide on a clinic.

Ensuring that clinics prepare and support patients and donors through the information they give them:

We continued throughout the year to encourage clinics to provide accurate and sufficient information in their websites, publications and other materials given to patients. We do this so that patients and donors can have confidence in the information clinics give them and are in a better position to compare and choose between clinics.

Through asking patients directly (eg, on inspection) and conducting desk-based research, we provided factual feedback to clinics and encouraged best practice, making recommendations for improvements whenever problems were found.

Collaborating with professional stakeholders to put patients in touch with better information and the right sort of care when they first realise they may have a fertility issue:

We collaborated with professional stakeholders throughout the year to put patients in touch with the best advice at the earliest possible stage. We ensured that our current website contained good signposting information, and continued to respond to new enquiries from prospective patients seeking initial information. Our aim is to ensure that patients consistently get good early advice and appropriate referral, regardless of the fertility knowledge of their particular GP.

Efficiency, economy and value

Ensuring the HFEA remains demonstrably good value for the public, the sector and Government

Ensuring the HFEA is easy to deal with and offers a professional and cost-effective service in all that it does:

We achieved this through various means in 2015/16. We continued to use our strategy to help us to prioritise our activities and manage our limited resources to best effect. This is an ongoing process, ensuring that resources are deployed in the interests of high quality care for everyone affected by assisted reproduction (our vision for 2014-2017).

We continued our engagement arrangements with clinics on fees charged, established in 2014/15. This gives accountability and transparency in respect of the fees we charge clinics. Towards the end of the year, the Authority agreed the first change in fees for several years, which, following Department of Health and Treasury approval, will come into effect in April 2016, and will enable us to balance our budget.

We continued to maintain efficient and effective decision-making through our committees, ensuring governance tools underpinning licensing and other decisions were in place and effective.

The HFEA continued to receive a large number of requests for access to information, under various regimes, and we ensured legal and Parliamentary requirements were met.

We maintained our existing relationships and service level agreements (SLAs) with other ALBs, in the interests of efficiencies. These include sharing finance resources with the Human Tissue Authority (HTA), and SLAs for certain HR and facilities services.

These arrangements ensure our infrastructure is effective and supports the delivery of our strategic vision. Our central systems, processes and tools continued to be efficiently run, giving good value and service. At the start of the 2016/17 business year, the HFEA will move to new office premises, alongside another arm's length body (ALB). This move enables best use to the made of Crown Estate property, and is in keeping with the wider interests of government property strategy. Plans for

the move began in November 2015 and will continue until the move takes place in April 2016.

Modifying our ways of working to ensure the organisation is responsive, agile, innovative and effective in achieving its strategic and statutory goals:

We continued our focus on building our staff capacity and skills and maintaining a high quality workforce, in keeping with our people strategy, which supports the delivery of the overall HFEA strategy for 2014 to 2017.

We continued to ensure that our internal compliance processes and systems were up to date and effective, so that regulatory efficiency and quality was maintained and improved. We also maintained an overview of emerging scientific, clinical and legal developments, to ensure that evidence-based decision-making continued to be supported.

The HFEA also participates in the 'One Stop Shop' for life sciences, which was launched in 2014. This initiative brings together expertise from the HFEA, the Human Tissue Authority (HTA), the Health Research Authority (HRA) and the Medicines and Healthcare products Regulatory Authority (MHRA) to provide regulatory advice to those working in the life sciences industry. It was an outcome of the Government's Regenerative Medicine Expert Group and is a good example of constructive joint working between regulators, enabling businesses and other organisations in the life sciences industry to quickly and easily navigate the different regulators and allow them to access the right advice more quickly.

Improving the methods used to submit and verify register data:

We began the process of modernising our Register function and processes, through the IfQ programme. The work to date has been extensive, and continues into the next business year. We have developed a new data dictionary, which will be incorporated into the new Register structure and will then need to be maintained. We have begun to redevelop our data submissions processes and the clinic portal (used by clinics to view, and to provide us with, key information and licensing applications).

We have also started our review of the verification processes for clinic outcomes appearing on CaFC.

Our ultimate aim is to reduce transactional costs for clinics and increase user satisfaction, through achieving 'right first time' data quality, and reducing unnecessary effort by clinics in submitting the required data.

Delivering our strategy in 2016/17

Delivering the strategy

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

High quality care for everyone affected by assisted reproduction.

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

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

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

The activities and projects set out over the next few pages describe how we will meet these strategic objectives in 2016/17. During the year, we will also begin to shape our next strategy for the period 2017 to 2020.

Activities for 2016/17

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

Activities	Methods and channels	Benefits and outcomes	Timescale
	Conducting an options appraisal for the future handling of representations and appeals processes.	To ensure that the HFEA's processes balance sound governance with cost effectiveness.	October 2016 onwards (into 2017/18 business year)
	Processing applications for the licensing of preimplantation genetic diagnosis (PGD), human leukocyte antigen (HLA) and mitochondrial donation.	Growing area of work dealt with effectively and efficiently, with applications processed according to performance indicator timelines. Public confidence assured in the regulation of the new treatment of mitochondrial donation. Decisions on whether to authorise such treatments made, and communicated, in a proper and timely manner for the direct benefit of patients waiting for treatment.	Throughout year
Identifying and implementing ways of improving the quality and safety of care.	Continuing our relentless focus on quality and safety of care in inspection activities – in particular through focusing on shortcomings in the taking and recording of consents, medicines management, data submission, multiple birth rates, and information published on clinics' websites.	Improved compliance and a positive impact on the quality of care, outcomes and safety of patients. Clinics have reduced vulnerability to expensive adverse legal and reputational risks, and greater awareness of these risks. Tracking of non-compliances, and the responsiveness of clinics in completing actions arising from inspection recommendations, in order to measure our impact (through our internal strategic performance monitoring mechanisms). Clinics' understanding of, and adherence to, correct consent procedures (including those associated with legal parenthood) and their understanding of the importance of getting this right, is improved. Patients and donors have a better experience of being asked for consent, and feel fully informed. If an issue subsequently arises (such as the death of someone with gametes in storage), the correct	Throughout year

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

Activities	Methods and channels	Benefits and outcomes	Timescale
	Working with commercial groups of clinics so as to improve quality and compliance on a group-wide basis, when relevant.	A clinic group's central Quality Management System (QMS) can be used to best effect across the whole group. A benefit in one clinic is shared to others in the group without needing to wait for the next inspection date - for the ultimate benefit of patients. A more efficient, effective and quality-driven way of working for the clinics involved and the HFEA.	March 2017
	Collaborating with professional stakeholders (including the British Fertility Society, the BFS) to put patients in touch with better information and services when they first realise they may have a fertility issue.	More informative signposting on our website, for those who are seeking preliminary information about fertility issues and options. Empowering patients, so they feel more equipped and are able to ask the right questions, regardless of the level of knowledge of their own particular GP about fertility issues and available treatments.	March 2017
Acknowledging that treatment is often unsuccessful, and exploring with professional stakeholders how the HFEA and clinics could better address this issue.	Improving the chances of success as much as possible, by publishing a wider range of HFEA data on our website, to drive improvements in clinic performance. This information will be more useful and accessible, and will have a 'journey' focus, so as to better meet the needs of patients whose treatment is not successful. Ensuring the information we provide also enables patients to have realistic expectations (both of actual success rates and of what they should expect of clinics in the event that their treatment is unsuccessful). Continuing to publish the annual Fertility Trends report.	Increased transparency to empower and inform patients. Increased visibility for clinics of sector-wide data so that they can assess their own performance against it. Encouragement of best value and treatment outcomes for patients. Better support where treatment is unsuccessful. Prospective patients enter treatment with a realistic understanding that they may not have a baby, even if they undertake many cycles. More information on our website for prospective patients, and specific signposting for patients who have experienced unsuccessful treatment.	March 2017 November 2016

Activities	Methods and channels	Benefits and outcomes	Timescale
	Ensuring our messaging to clinics conveys the importance of handling the issue of unsuccessful treatment with sensitivity, including offering counselling. Continue to apply pressure on success rates and risk tool alerts related to these, through inspection reports and risk tool alerts.	Clinics more aware of their responsibilities to patients beyond the immediate treatment setting.	
Maintaining our role as the UK's competent authority for ART in the European Union.	Participation in competent authority events and implementation of associated EU decisions.	We attend and participate in two meetings per year. Up-to-date intelligence gained about European perspective, helping to inform UK approach to patient safety and care. Free movement of gametes and embryos enabled within the UK and standards upheld in the UK that are consistent with the rest of the EU.	June and December, annually. Throughout year
Reviewing our embryo research policies and regulation.	Reviewing the consent process in collaboration with the Health Research Authority (HRA), the sector and other stakeholders. Reviewing the Code of Practice guidance and relevant licence conditions. Review the end-to-end application and approval process. Research workshop to identify the barriers to research and innovation. Collaborative work with researchers, peer reviewers and Licence Committee to ensure a common understanding. Establishing clarity on what constitutes 'a single programme of research' within the bounds of the Act (which requires a separate	Review completed, in order that: No embryos are allowed to perish where the gamete providers would prefer them to be donated to research. The application and licensing process remains robust but does not impose unnecessary burdens. This outcome would also help to promote new research for the benefit of the sector, and support (or remove barriers to) innovation.	October 2016 – April 2017

Activities	Methods and channels	Benefits and outcomes	Timescale
	licence for every building) to inform a practical review of the licensing model.		
Strategic objective 2: improving the lifelong experience for donors, donor-conceived people, patients using donor conception, and their wider families.			
Providing information about donor conception directly to patients and donors.	Through the Lifecyle campaign (and through the IfQ work on Choose a Fertility Clinic, CaFC), we will continue to provide information about donation and gamete availability.	Lifecycle campaign leaflets continue to be available, giving a range of important information. Potential donors, recipients and donor conceived people have better access to clear, authoritative impartial information about a range of issues. As a result they feel better informed and supported with respect to the legal aspects and obligations of donation. All involved (including clinics) understand the lifelong commitment associated with donor conception and the associated legal issues that are relevant to them. Improvements to CaFC delivered through the IfQ programme. Improved information about gamete availability.	Throughout year July 2016
Ensuring that clinics prepare patients adequately for donation and fully understand their role and importance as a lifelong information provider; and that egg and sperm donors are well supported and understand the lifelong commitment that follows from donation.	Through the Lifecyle campaign (and through the IfQ work on CaFC), we will continue to provide information about donation.	Clarity of role and performance for clinics in relation to donation and associated information guardianship responsibilities. Improved experience for donors, donor-conceived people seeking information and patients and their families.	Throughout year

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

Activities	Methods and channels	Benefits and outcomes	Timescale
		Increasing and informing choice	
Strategic objective 3: using the data in the HFEA Register of Treatments to improve outcomes and research			
Maintaining the Register of Treatments and Outcomes and supporting clinics in reporting the data.	Register data and forms continue to be processed and quality assured, through liaison with clinics on errors and omissions and through validation and verification of Register entries.	High quality data available to develop patient information and respond to information requests. Risk-based regulation and evidence-based policy-making are better supported.	Throughout year
Publishing and supplying the information we hold, for the benefit of stakeholders.	Regularly updating CaFC information to assist patient choice.	Six monthly verification and publication schedule in place, maintaining provision of up-to-date and accurate information.	Throughout year
	Continued publication of inspection reports on CaFC.	Inspection reports continue to be published via CaFC, providing useful insights for patients.	Throughout year
	Following the implementation of a revised CaFC (under development through the IfQ programme), continuing to develop and improve the presentation of clinic comparison information and user experience scores, guided by patient feedback.	Published outcome data is more useful and easier to understand and sets up positive incentives for improvements. Acquisition of ongoing feedback enables us to evaluate the effectiveness and usability of the new presentation, and to plan future improvements.	March 2017
	Continuing to facilitate timely access to information from the Register for those who are entitled to it.	Opening the Register requests continue to be met in a sensitive manner and within required time limits (20 working days, excluding time for counselling).	Throughout year

Activities	Methods and channels	Benefits and outcomes	Timescale
	Information provision for researchers requesting access to Register data.	Information for researchers is provided within 90 calendar days of approval. Register information is used to best effect, to promote understanding and facilitate good research, and ultimately patient benefit.	Throughout year
	Facilitating access to information under various regimes and fulfilling Government requests.	Legal and Parliamentary requirements continue to be met within time limits.	Throughout year
	To continue to publish statistical and other reports.	'Fertility treatment in 2015' report covering 2014–2015. - Provides patients, clinic staff and others with up-to-date, high quality information about a range of topics. - Provides important information to those affected by donor conception, to patients seeking treatment and to us, to help us to enhance the quality of care that patients and donors receive in clinics, through our regulatory work. - Report carries 'official statistics' status.	March 2017

Activities	Methods and channels	Benefits and outcomes	Timescale
		Report on incidents and alerts. - Contributes to a culture of openness and information sharing where clinic staff are empowered to report mistakes and learn from each other. - Promotes transparency and maximises opportunities for learning from incidents to improve quality of care for patients. - Provides the sector with the most up-to-date information.	November 2016
Maintaining our previously established collaborative information management relationships	Maintaining our good working relationships with relevant other bodies, such as the Government Digital Service (GDS) the Health and Social Care information Centre (HSCIC) and being an active member of the National Information Board (NIB).	We contribute to the objectives of the wider health system, with respect to information management. Learning from best practice and sharing expertise, so that we can make use of each other's strengths and knowledge in data management, systems integrity and security.	March 2017
Strategic objective 4: ensuring patients have access to high quality meaningful information			
Improved HFEA website information about treatments available, scientific research, embryo and stem cell research and other fertility subjects.	Continuing the development of new content for our website (redesigned in 2015/16) to provide an expanded range of educative and scientific information about current and future treatment options, the scientific evidence associated with these, and other fertility issues.	Increased information for patients and others, that is accessible, engaging and meaningful. Prospective patients have clearer information and signposting. Patients better informed and better placed to deal with treatment issues and decisions. Patients feel safe, knowing they can expect certain standards in clinics, and are more aware of the potential risks of new/different treatments as well as the possible benefits.	March 2017

Activities	Methods and channels	Benefits and outcomes	Timescale
	Conducting our annual horizon scanning exercise to ensure we identify relevant new scientific developments.	The Scientific and Clinical Advances Advisory Committee meets to discuss issues identified through horizon scanning three times per year. The horizon scanning panel meets once per year. Policy developments and website material are informed by expert input and an understanding of scientific issues and future developments. Future work planning is improved by early identification of upcoming issues.	Throughout the year June/July Throughout the year
Working with clinics and scientific experts to publish information about new treatments.	Establishing mechanisms for producing and publishing informative and accurate material when new treatment options emerge, working in collaboration with clinics and experts.	More information about new treatments on our website. Increased public understanding of emerging new science and future treatment possibilities. Patients better informed and better placed to deal with treatment issues and decisions when emerging new treatments begin to be offered by clinics and better placed to judge the merits of any media speculation about potential new treatments.	Throughout year
Enhancing the patient voice in all of our work, including information provision.	Further developing our communications with, and information provided to, patients so as to help them to make informed choices about fertility matters. Ensuring patient feedback is continuously incorporated into our core business, for example through user experience ratings of clinics.	Patient views and needs are better incorporated into our work and are reflected in the style and content of the information we provide. There are increased feedback opportunities for patients via the website, and easier interaction with us.	March 2017

Activities	Methods and channels	Benefits and outcomes	Timescale
Responding effectively to specific enquiries from individuals.	Continuing to respond to the many individual patient and public enquiries we receive each year.	Individual patients and members of the public are able to ask specific, sometimes complex, questions and receive a tailored and meaningful response. We remain responsive, and continue to be able to handle the range of one-off enquiries raised by individuals, providing a considered and informed response within a reasonable timescale. We are able to identify any trends and common themes in the enquiries we receive, informing the development of additional information which could be placed (for example) on our website.	Throughout year

Demonstrating efficiency, economy and value

Strategic objective 5: ensuring the HFEA remains demonstrably good value for the public, the sector and Government			
Ensuring the HFEA is easy to deal with and offers a professional service.	Completion of the work started in 2015/16 to modernise the HFEA's Register function and processes (EDI, data submission and verification, the Clinic Portal, and the data dictionary).	Reduced transactional costs for clinics and increased satisfaction. 'Right first time' data quality. Reduction in unnecessary effort by clinics submitting the data.	October 2016
	Continuation of the engagement arrangements with clinics on fees charged, established in 2014/15.	Accountability and transparency in respect of the fees we charge clinics. Fees Group continues to be run effectively. Annual review of fees takes place.	Throughout year

Activities	Methods and channels	Benefits and outcomes	Timescale
Ensuring the HFEA is a good value organisation and makes best use of its limited resources.	Using our strategy to prioritise our activities and manage our limited resources to best effect.	Resources are deployed in the interests of high quality care for everyone affected by assisted reproduction. Speedier service to patients when they interact directly with us. Achieving measurable 'added value' and internal efficiency.	Throughout year
	Ensuring internally provided support services run smoothly and are efficient.	Our infrastructure is effective and supports the delivery of the strategic vision. Central systems, processes and tools are efficiently run, giving good value and service.	Throughout year
	Responding to the HFEA's triennial review report, as required.	Ensuring the organisation is soundly run, providing best possible value, and compliant with Government targets.	To be confirmed
	Building and maintaining our staff capacity and skills, in line with our people strategy.	We are able to maintain the staff capacity and capability to deliver our strategy and our core statutory duties. Continuing to develop our staff to ensure they have the skills they need, through Civil Service Learning and other means.	Throughout year

Activities	Methods and channels	Benefits and outcomes	Timescale
Responding as appropriate to emerging new government rules on transparency and better regulation (the Enterprise Bill, the 'growth duty' and the Regulators' Code).	Complying with new better regulation requirements that may emerge from the current consultation exercise by: Consulting on an innovation plan (Spring 2016). Reporting in our Annual Report on the growth duty and compliance with the Regulators' Code . Complying with the Business Impact Target by identifying and reporting any 'in-scope activity' (a new ongoing duty). Note: Regarding the proposal to establish a Small Business Appeals Champion in every body, it was proposed by BIS in their February 2016 consultation that the HFEA should not be in scope for this requirement. Subject to the outcomes of that consultation no activity is expected in this area.	The HFEA responds consistent with its legal status, and proportionately within our small resource envelope, carefully recognising our duties. Innovation plan consultation. Annual Report publication including additional required information. Compliance with the Business Impact Target for any activities that may be in scope.	Throughout year June 2016 July 2016 Throughout the year
Ensuring the HFEA is an effective collaborator and partner in the interests of the efficiency of the wider Department of Health group of ALBs and other health organisations.	Continued participation in the collaborative 'one stop shop' for life sciences to provide regulatory advice to those working in the life sciences industry.	Continued constructive joint working between the HFEA, the Human Tissue Authority (HTA), the Health Research Authority (HRA) and the Medicines and Healthcare products Regulatory Authority (MHRA). Businesses and other organisations in the life sciences industry enabled to quickly and easily navigate the different regulators and allow them to access the right advice more quickly.	Throughout year

Activities	Methods and channels	Benefits and outcomes	Timescale
	Continuing to share services and infrastructure with other organisations as practicable: Maximising benefit of finance resources shared with HTA. Continuing with service level agreements (SLAs) with relevant other organisations for certain HR services and using Civil Service Learning as a key learning and development provider. Continuing to receive support services from the landlord of our office premises, via an SLA.	We continue to operate in as efficient a way as possible, extracting maximum value from shared support arrangements and seeking other opportunities.	Throughout year
	Moving to new office premises, alongside another arm's length body (ALB).	Best overall use made of Crown Estate property. Overall saving on accommodation achieved for the group of health ALBs as a whole, even if the HFEA's individual accommodation costs have to increase in order to enable this. Further shared services and efficiencies possible for and with other similar organisations in the health ALB family.	April 2016 onwards
	Continued collaborative and partnership working with other ALBs and health regulators UK wide, such as the CQC, MHRA, UKAS, HRA, GMC, NIB and the home nations, maintaining the close positive working relationships that have been developed over the past several years (particularly in response to the McCracken report, reviewing the HFEA and the HTA, which was published in 2013).	Ability to capitalise on previously established relationships, eg, to address issues that require joint working in an efficient and coordinated way, or to establish the best approach if any new areas of regulatory overlap should arise (as was done previously with the CQC, removing overlap in relation to the regulation of medicines management and surgical procedures in clinics).	Throughout year

Activities	Methods and channels	Benefits and outcomes	Timescale
		Continued savings and avoidance of unnecessary administrative or regulatory burden, by avoiding duplication of effort or uncoordinated approaches between regulators.	

Measuring our performance

Facts and figures

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

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

Required HR benchmarking information

In common with other ALBs, we are required to maintain a record of the following standard benchmarking data: [DN: Data is added after year end]

Very senior manager (VSM) to staff complement ratio	
Number of staff earning more than £142,500 now and any planned change during the next planning period	0
HR staff to employee ratio	Xx
Training budget as a percentage of pay bill	Xx
Projected reductions in non payroll staff	Xx

Key performance indicators

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

The table below shows our performance in 2015/16 for a small sample of these indicators. We will continue to track the same indicators, and more, throughout 2016/17. [DN: Data is added after year end]

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

Financial picture

Our finances and high level budget

We receive funding from two main sources: the majority from clinics and the balance from our sponsors, the Department of Health, as grant-in-aid.

The vast majority of fee income arises from individual IVF treatments in regulated clinics. In aggregate, together with licence fees, these cover the costs of regulation: evaluating licence applications, making licensing decisions and issuing licences, managing licences, site visit inspections, managing statutory information flows and providing advice and guidance to licensed establishments.

Treatment fee income has varied over time. A steady increase in the number of treatments enabled us, in October 2011, to cut treatment fees by 28% to reflect that our costs were spread over a much higher number of treatments. In 2012, a discount was introduced for elective single embryo transfer. Subsequent treatment cycles using eggs from the first collection where elective single embryo transfer had previously occurred did not attract a treatment fee. Treatment numbers have now levelled off and treatment income has fallen due to the elective single embryo transfer discount.

Our grant-in-aid funding from the Department of Health has reduced by over 50% since 2010.

Since 2010, our expenditure has also decreased by over 40%. We place great importance on ensuring that our finances are managed efficiently, effectively and in a way which minimises risk. Staff numbers have decreased by 15% since 2010 and we have an Authority of 12 members. We have also made significant efficiencies in office costs and by using framework suppliers and collaborating with other ALBs.

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

Income	£000s
Department of Health funding	938
Treatment and licence fees	4472
Other income	6
Total income	5416
Operating costs, of which	
Staff costs	4060
Other operating costs	1320
Total operating costs	
Capital charges	36
Total revenue expenditure	5416

The HFEA is spending the reserves that have accumulated in previous years from treatment fees on the Information for Quality programme and support services to applicants to the Register. In 2016/17, IfQ spend is expected to be £200k and support services will consume around £50,000 over a three year pilot period.

Other required information

Introduction

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

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

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

Organisational structure and establishment

Over the past few years the HFEA has significantly reduced its staffing, in keeping with overall pressures on the public sector and Government expectations. Our staff complement has reduced from 86 in 2010/11 down to 67 in 2015/16. We have put in place shared services arrangements with other bodies, where feasible. For example, we share part of our finance and resources team staffing with the HTA, our facilities management service is provided by the CQC (since we currently occupy the same premises, although our office location will change, and new arrangements will be put in place, in early 2016/17). We also have a shared services agreement with CQC for recruitment, which will continue.

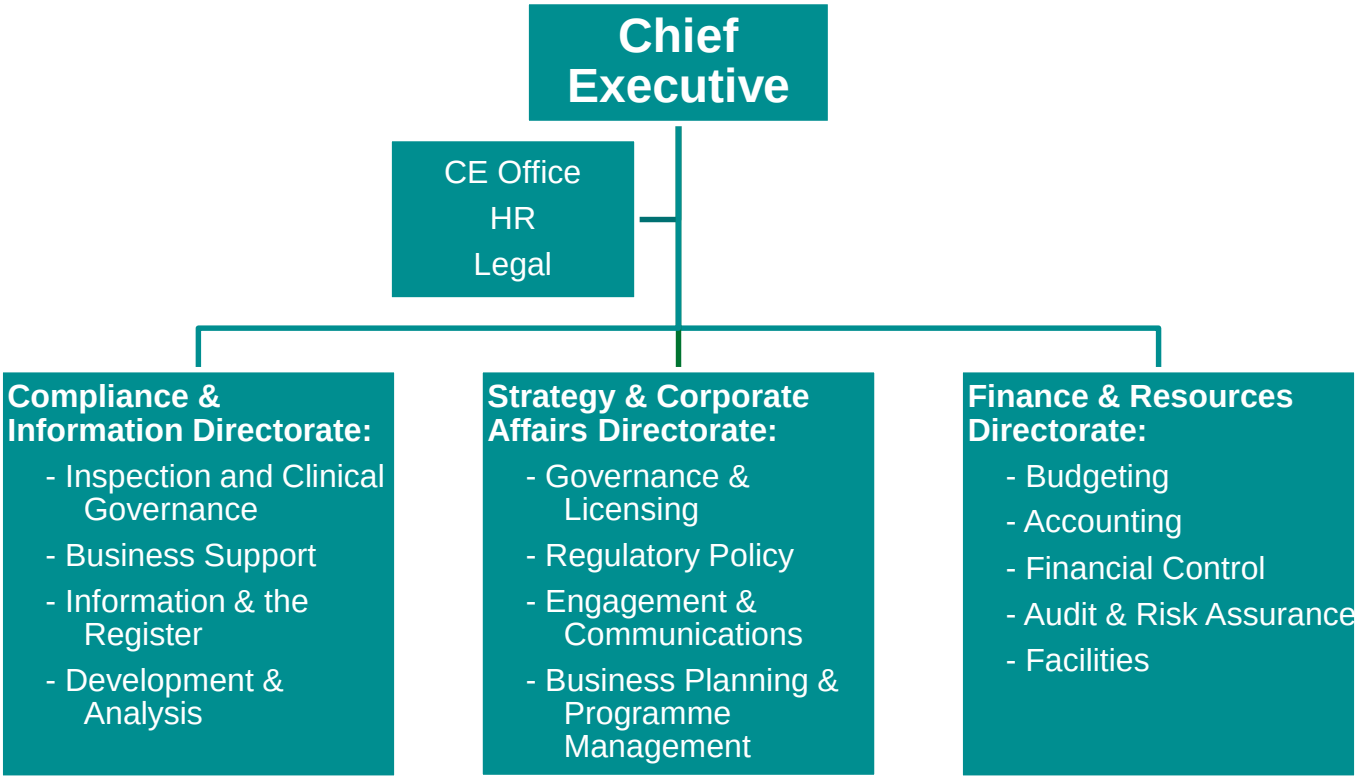
We believe we have reached a point where, having made considerable savings, our size will now need to remain stable for the foreseeable future. Our people strategy, published in 2015, sets out how we will ensure we retain the capability and capacity to deliver our overall strategy for 2014–2017.

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

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

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

The following diagram shows our current organisational structure.



Financial management systems

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

Internal audit

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

Assurance framework

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

Equality Act 2010

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

Whistleblowing policy

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

Transparency requirements

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

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

Information technology (IT) and data security

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

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

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

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

The robust information security arrangements the HFEA has in place, in line with the information governance toolkit, include a security policy for staff, secure and confidential storage of and limited access to Register information and stringent data encryption standards. All staff complete the annual mandatory training on information security and new starters complete this on their first day of employment before starting work.

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

Business continuity

We reviewed our business continuity plan in 2015/16 to ensure it remains fit for purpose. The plan is regularly updated and periodically tested. There is an operational disaster recovery site available if needed.

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

Estates strategy

The HFEA has no estate. Our office strategy remains to be a tenant or co-tenant of a larger Department of Health organisation. In April 2016 we are moving into NICE's office space in Spring Gardens, taking up 269 square metres.

Our tenancy with the CQC will end in May 2016 when the CQC moves completely from the Finsbury Tower.

The HFEA will continue to work with CQC then NICE on health and safety services. We have adopted the CQC's online system for individual workplace assessment and meet with the CQC lead on fire evacuation procedures and fire warden liaison. Similarly, new, arrangements will be put in place as appropriate in our new premises.

Sustainable development

We recycle paper, card, glass, plastic cups, containers and bottles, metal cans and toner cartridges.

After our move, we will have a single multi-function device (for secure printing, scanning and photocopying), pre-set to print on both sides of the paper and in black-and-white. Our IT equipment is re-used and working lives extended where possible and is switched off when not in use. Surplus equipment is either sold or donated. A proportion of our staff are able to work from home, allowing reduced travel impacts, and we expect this proportion to increase slightly following our move to smaller premises.

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

Procurement

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

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

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

We are too small to have a procurement pipeline. The only procurement of significance in 2016/17 will relate to the IfQ programme, which has been subject to specific business cases agreed by the

Department of Health and the Government Digital Service through various highly robust mechanisms. All related procurement in 2015/16 was conducted using CCS frameworks and with close CCS oversight. There will be no procurements over £100,000 in 2016/17.

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

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