Authority meeting - agenda

20 January 2016

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

Agenda item		Time
1.	Welcome, apologies and declaration of interests	1:00pm
2.	Minutes 11 November 2016 **HFEA (20/01/2016) 779**	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 (20/01/2016) 780** For information	1:45pm
7.	Information for Quality: update **HFEA (20/01/2016) 781** For information	2:15pm
8.	Applications to use Register data for epidemiology studies **HFEA (20/01/2016) 782** For information	2:35pm
	Break	**2:45pm**
9.	Embryo testing: testing for more than one condition at a time **HFEA (20/01/2016) 783** For decision	2:55pm
10.	Government initiatives around better regulation **HFEA (20/01/2016) 784** For information	3:35pm
11.	Any other business	4:00pm

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 (20/01/2016) 780		
Meeting date	20 January 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 comments are incorporated into this Authority paper. The Department of Health reviews our performance at each DH Update meeting. The Authority receives this summary paper at each meeting, enhanced by additional reporting from Directors. The Authority's views are fed back to the subsequent CMG performance meeting.		
Organisational risk	☐ Low	☒ Medium	☐ High
Annexes	Annex 1: Strategic performance report – October data		

1. Introduction

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

1.2. Most of the data relates to the position at the end of October 2015. The delivery totaliser, however, reflects the position at the end of December.

1.3. The IfQ milestones in the totaliser have been significantly updated to reflect the latest agile planning decisions, made in December at the commencement of the beta phase. This has resulted in additional milestones being added to the calendar of future deliverables (on which the totaliser diagram is based), mainly at the key points of March, July and October 2016.

1.4. An update on the financial position at the end of quarter three (ie, at the end of December 2015) will be given verbally at the meeting.

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

2. Recommendation

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

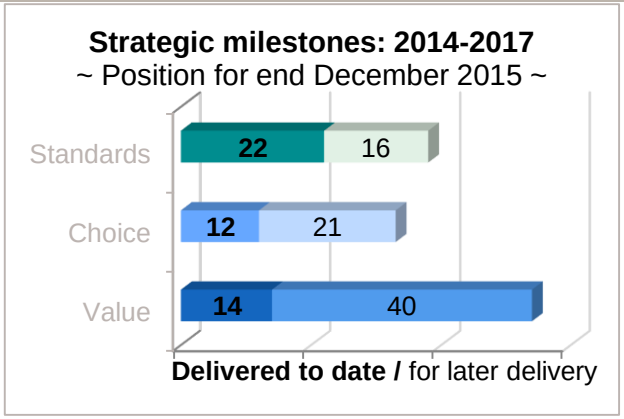
Annex A - HFEA strategic performance scorecard

1. Summary section

Dashboard – October data

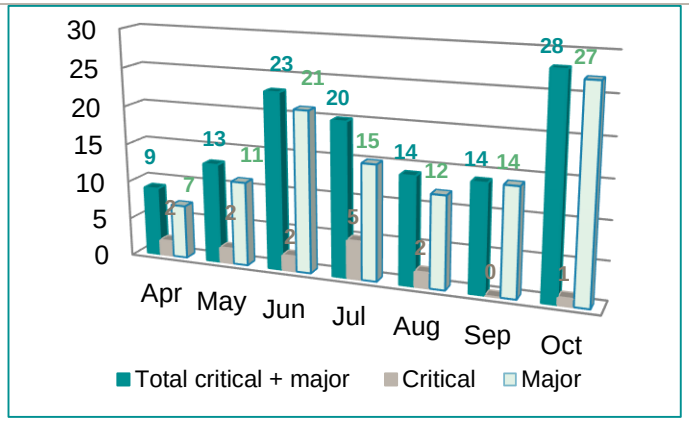
Strategic delivery totaliser

(see overleaf for more detail)



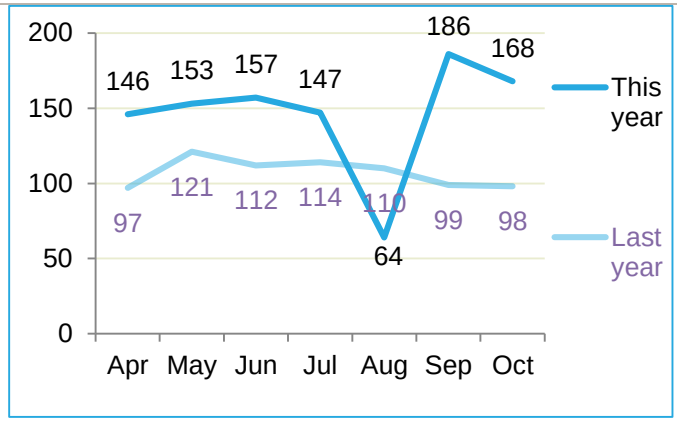
Setting standards:

critical and major recommendations on inspection

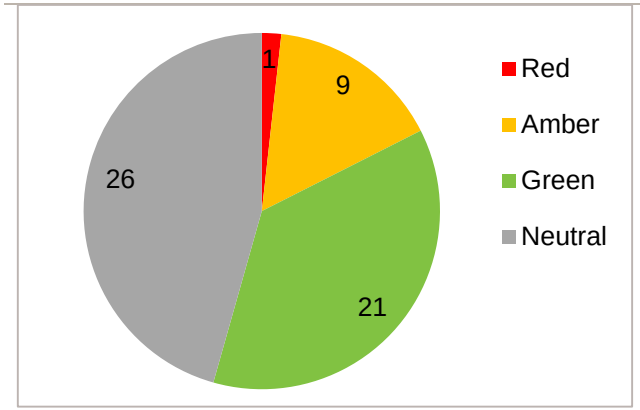


Increasing and informing choice:

public enquiries received (email)



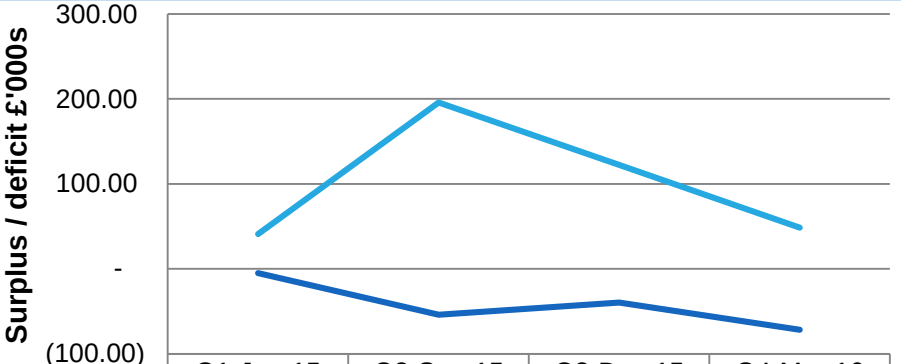
Overall performance - all indicators:



(See RAG status section for detail.)

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

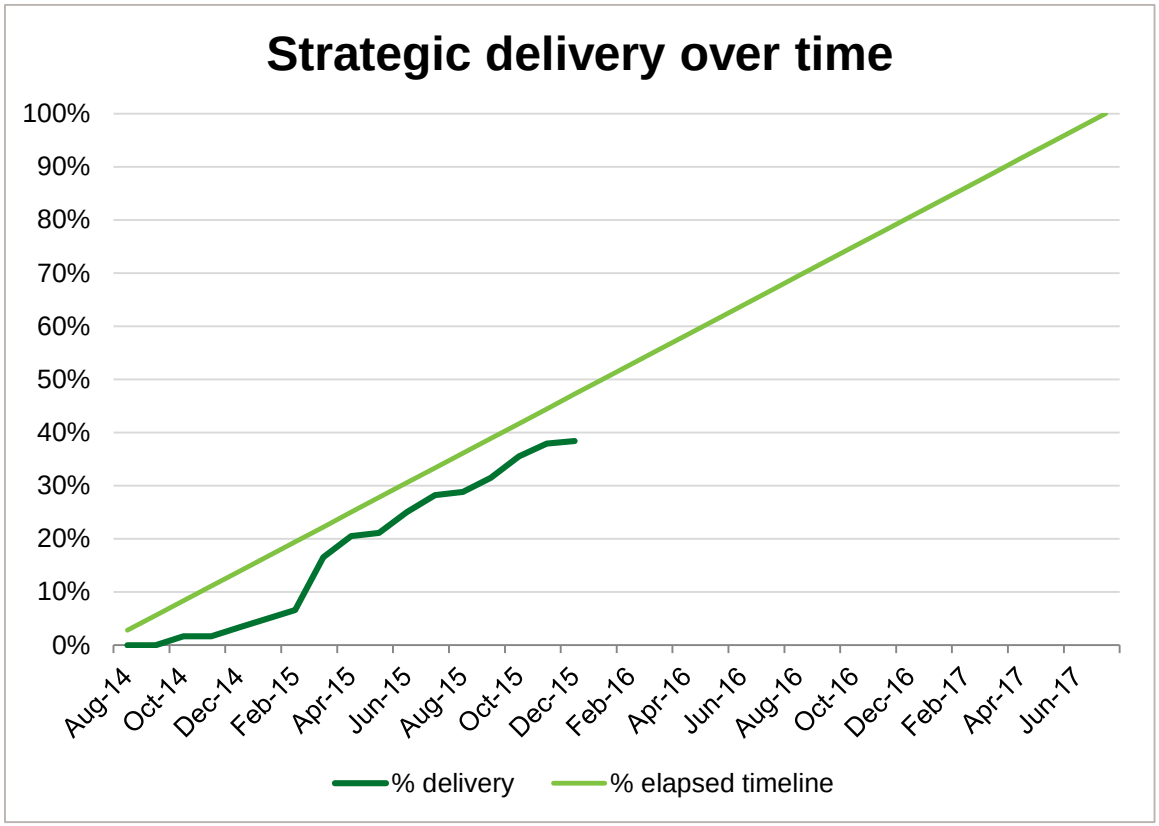
This graph details our overall position as at 30 Sep 2015 (Q2) and our forecast position as at 31 March 2016. The components making up the surplus/deficit are shown by two other graphs (income and expenditure), in the budget status summary in the commentary section below.

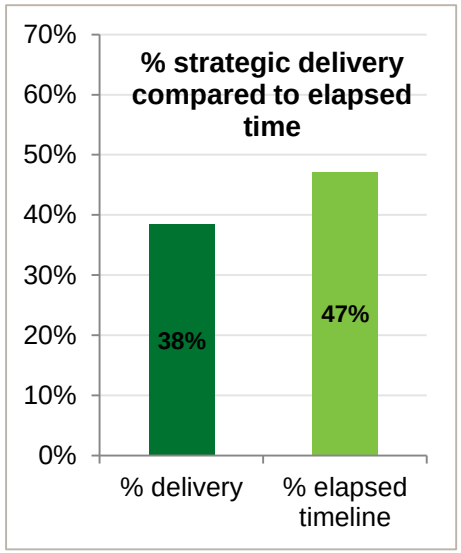


	Q1-Jun-15	Q2-Sep-15	Q3-Dec-15	Q4-Mar-16
Budgeted surplus/deficit	(5.04)	(53.98)	(39.66)	(71.86)
Forecast surplus/deficit	40.79	196.01	122.18	48.36

Dashboard - Commentary

Strategic delivery (to end of December) – summary:





The totaliser data has been significantly updated in December, to add the main features of IfQ delivery during beta phase. The work on beta has already started. There are a large number of key IfQ milestones that will be reached in (particularly) March, July and October of 2016. 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 (albeit at risk at the time of writing, since we still await the formal GDS approval). This re-casting of the totaliser data to include more future deliverables has made us appear 'behind' on the above graph. However now that real product development has commenced (this is what the beta phase consists of), we should expect to see the delivery line start to converge with the elapsed timeline, from this point onwards.

Strategic delivery for September to December

1. 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.

2. 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.

3. 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 the item will not now be heard by the approval board until January 2016. For the time being we are proceeding with the beta phase at risk, since otherwise we would need to stand down our suppliers and the programme would lose impetus. Detailed beta phase planning has been completed, setting out the products and user stories that will be built and tested in each beta 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 October 2015

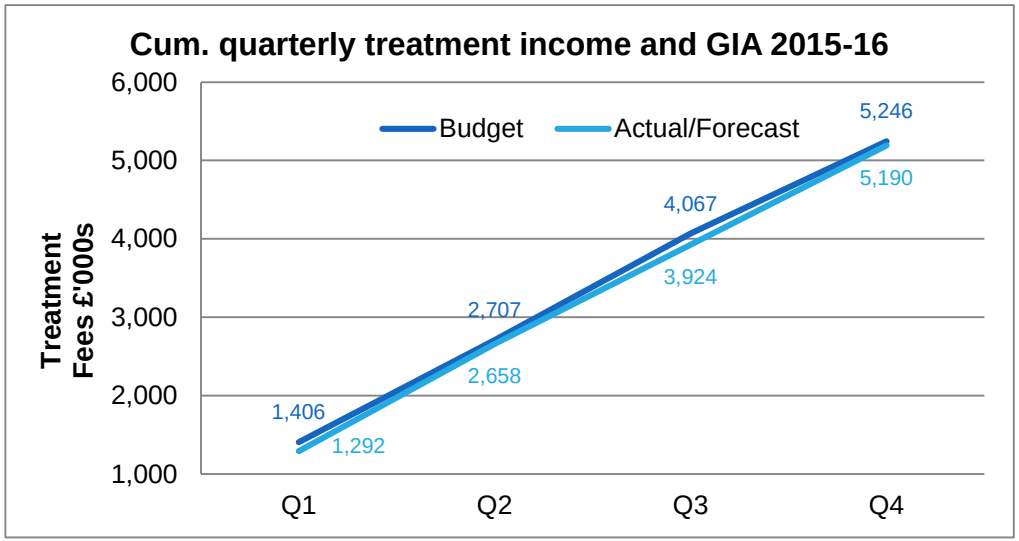
The red key performance indicator (KPI) shown in the 'overall status - performance indicators' pie chart on the dashboard is as follows:

The number of working days from the day of inspection to the day the draft report is sent to the PR has a target of 90% in 20 working days. In October this indicator was performing at 57% in 20 working days, due to illness and special leave in the inspectorate. However no report was sent later than 28 working days, and the overall indicator for the whole end-to-end licensing process was unaffected, and remains within its KPI.

Several projects are currently rated amber for risk, based mainly on resourcing strains while we also deliver the Information for Quality Programme and a range of other work. It is also worth noting that both turnover and sickness absence are on amber. Our turnover is at 18.5% (compared to a target of 5-15%), while our sick leave was at 2.8% in October, which is unusually high for us. It is worth noting, however, that we recently dropped our KPI from 3% to 2.5%, and have also put some effort into reminding managers to record sickness leave promptly so that we can be certain it is fully recorded in time for the figures each month to be reported.

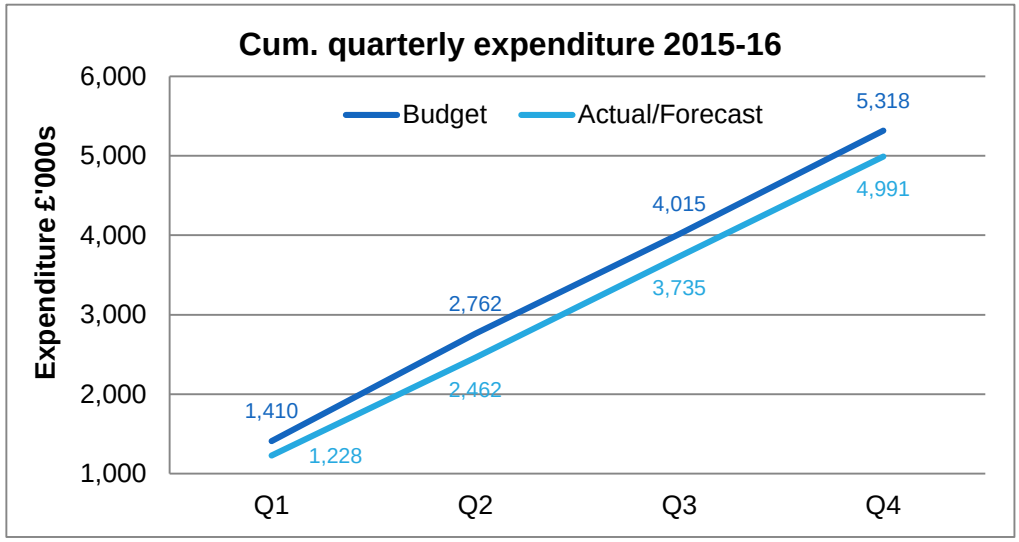
Budget status – October data

The dashboard shows the overall surplus/deficit position. The graphs below show how the surplus or deficit has arisen. These figures are updated quarterly, approximately one month after the end of each quarter. A verbal update on the position at the end of quarter three will be given at the meeting.



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

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



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

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

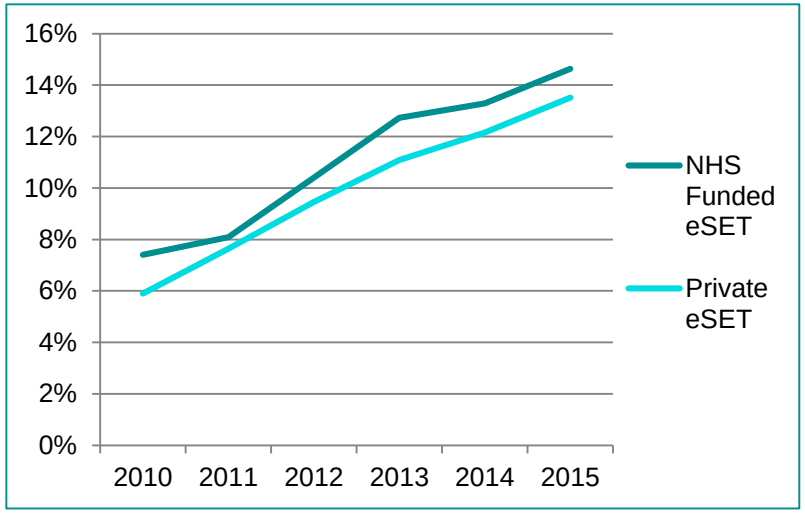
Quality and safety of care

The following figures and graphs are drawn from a data run on 2 December 2015.

ESET split by private/NHS:

Funding	Year					
	2010	2011	2012	2013	2014	2015*
NHS Funded:						
Recorded as eSET	4294	4903	6264	7868	8443	8947
	7%	8%	10%	13%	13%	15%
Not recorded as eSET	19283	19492	17869	17723	17837	15653
	33%	32%	30%	29%	28%	26%
Private:						
Recorded as eSET	4629	5698	6856	7731	8509	3422
	6%	8%	9%	11%	12%	14%
Not recorded as eSET	31019	31545	30400	29387	29560	26922
	53%	52%	50%	48%	46%	45%

Graph: eSet % trends NHS/private:



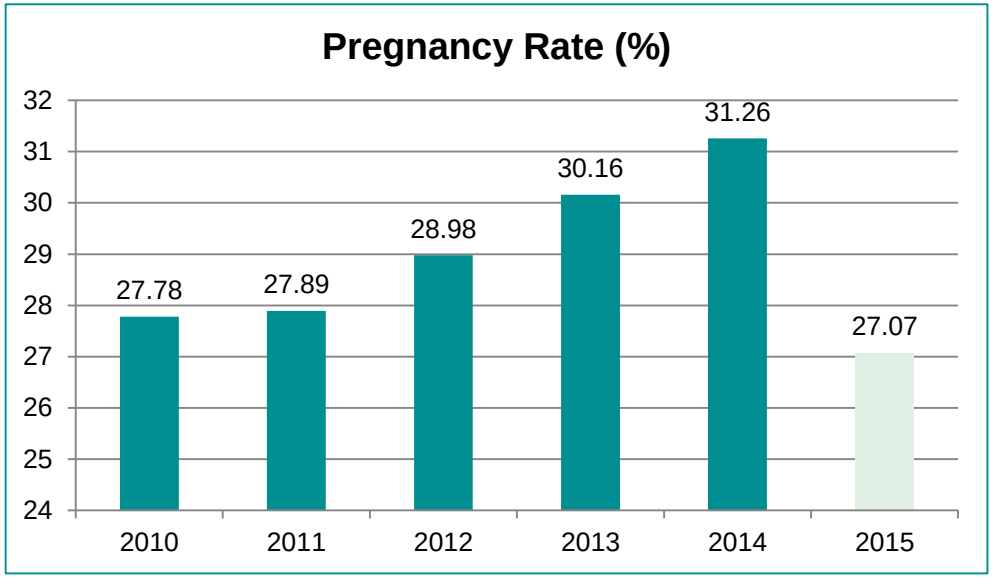
* NB Data for 2015 was still incomplete at the time the report was run.

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

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

Years	All cycles	Pregnancies	Pregnancy rate
2010	58018	16116	27.78
2011	60569	16895	27.89
2012	60231	17453	28.98
2013	61834	18649	30.16
2014	63571	19875	31.26
2015	60031	16253	27.07

Graph showing the pregnancy rate over recent years:



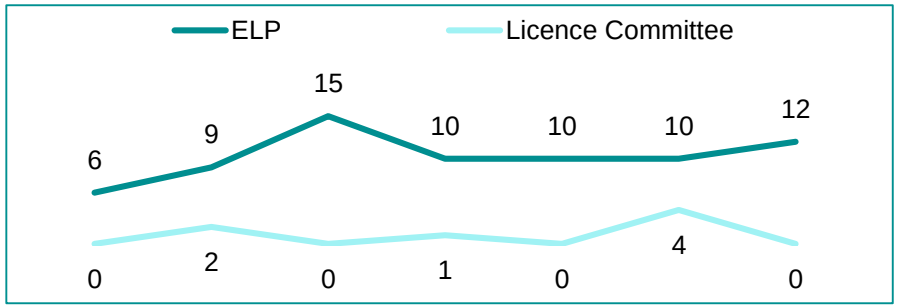
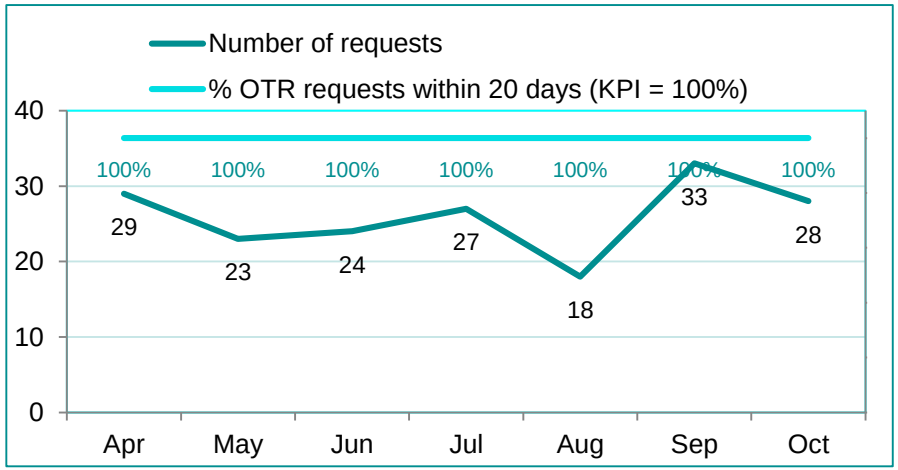
Explanatory text: Looking at all IVF treatment forms, and providing a count of pregnancies - as recorded on the early outcome form.

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:

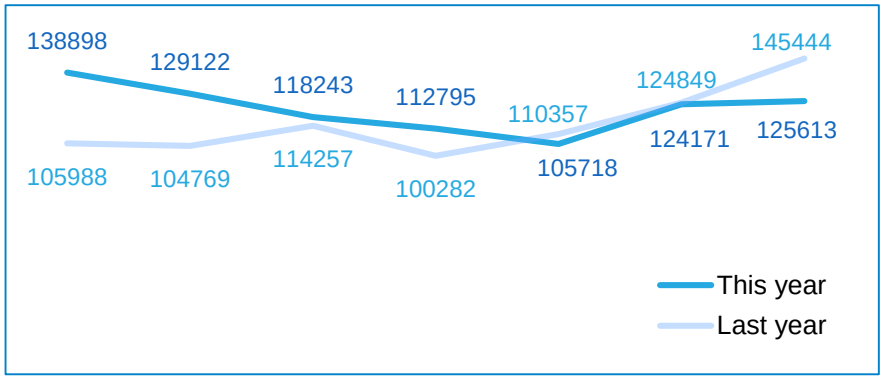
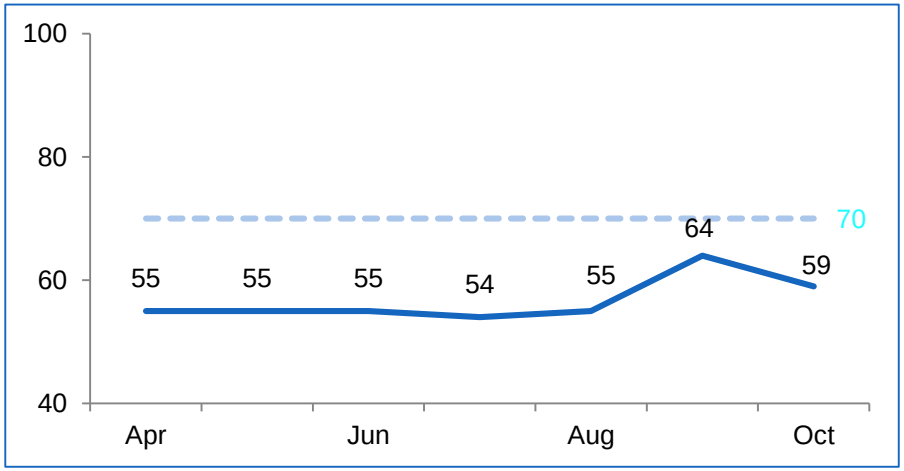
- number of risk tool alerts (and themes)
- common non-compliances (by type)
- incidents report (and themes).

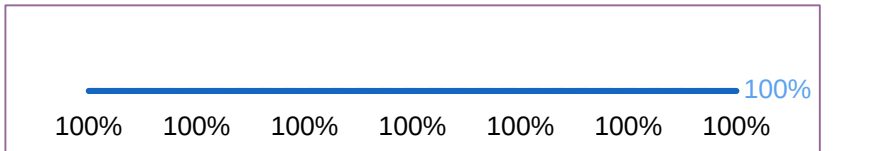
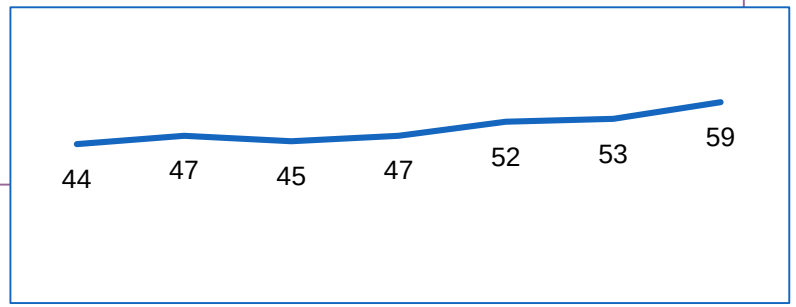
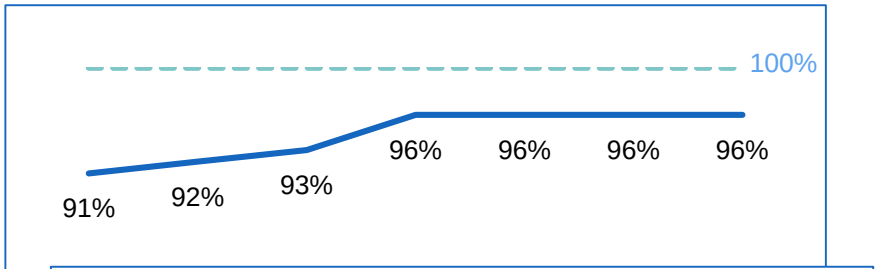
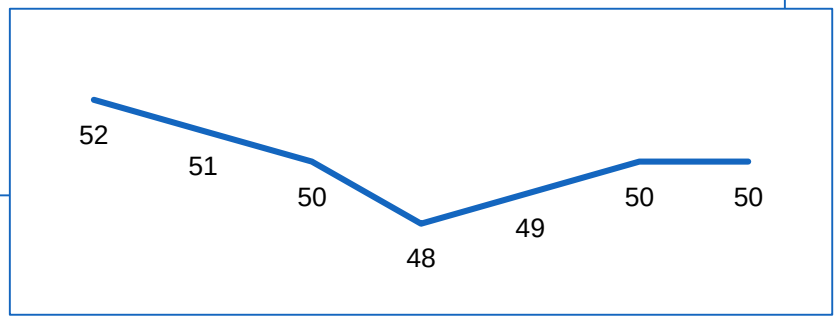
2. Indicator section

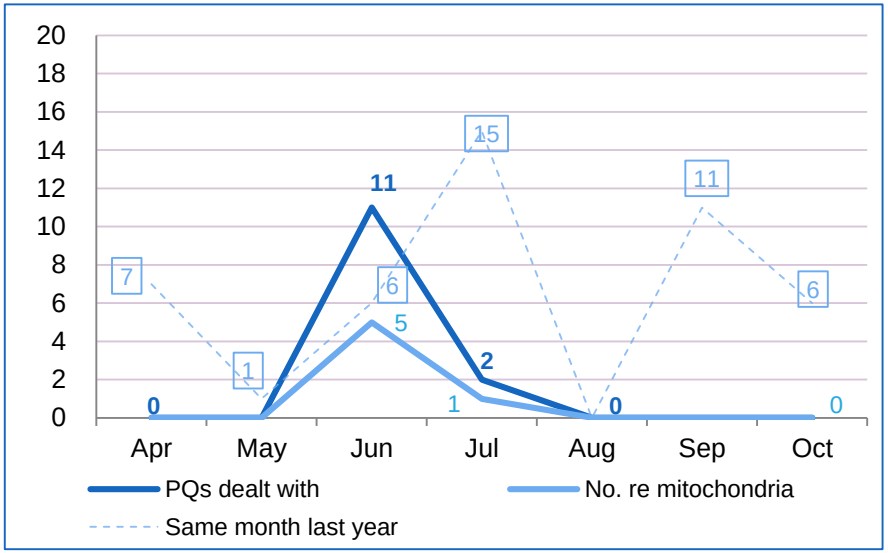
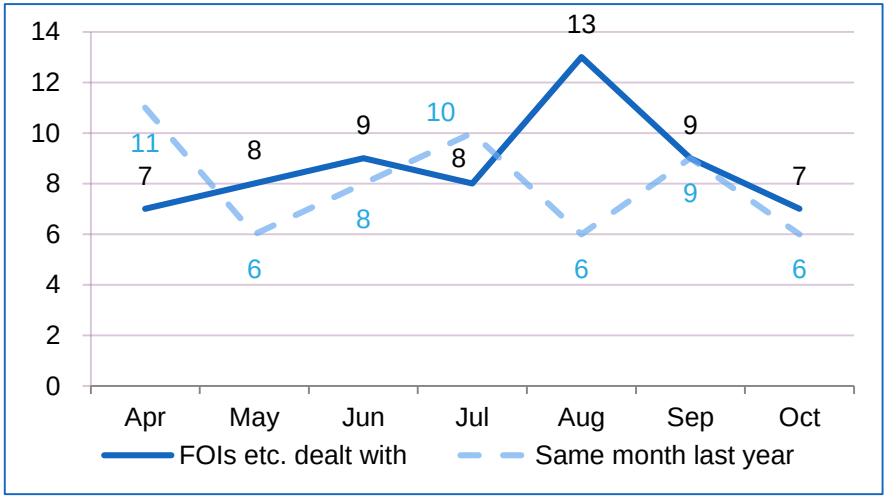
Key performance and volume indicators – October data:

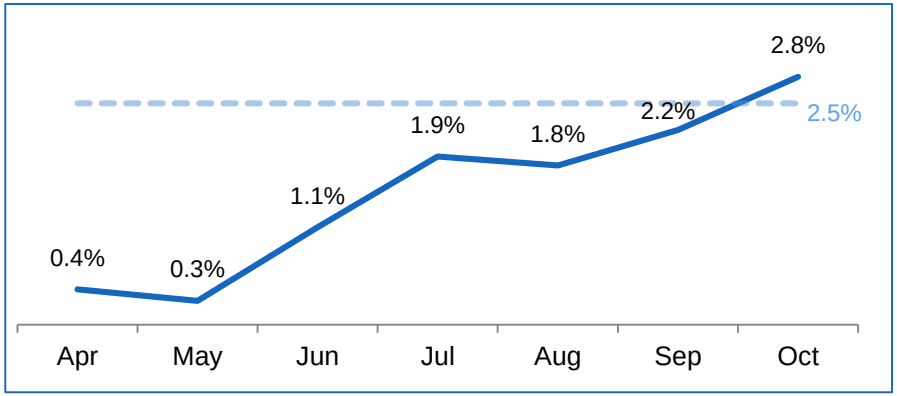
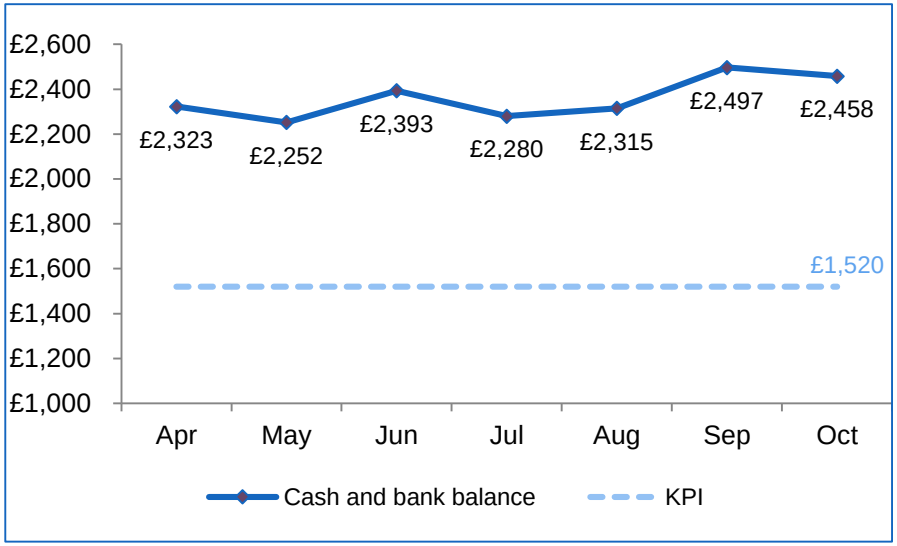
Indicator	Performance	RAG	Recent trend[1]	Aim[2]	Notes
Setting standards: improving the quality and safety of care through our regulatory activities.					
Licensing decisions made: - **By ELP** - **By Licence Committee**	12 0	⇩		No KPI – tracked for workload monitoring purposes	Volume indicator (no KPI 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% (28)	★		Maintain at 100% ↑	KPI: 100% of complete OTR requests to be responded to within 20 working days (excluding counselling time) The dip in August reflected 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 compared to previous year (trend arrow indicates movement since previous month)	125,613 145,444	⇧		No KPI – tracked for general monitoring purposes.	Volume indicator showing general website traffic compared to the same period in previous year. Measured on the basis of 'unique visitors'.
Efficiency, economy and value: ensuring the HFEA remains demonstrably good value for the public, the sector and Government.					
Average number of working days taken for the whole licensing process, from the day of inspection to the decision being communicated to the centre.	59 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.	59	★			
Annualised (rolling year) percentage of PGD applications processed within three months (66 working days)	96%	⇔		Reach and maintain 100%	KPI: As above. (Annualised score). Performance has reached target, but the annualised figure is still being adversely affected by complex multi-type applications received during the rolling year, which take longer to process.
Average number of working days taken.	50	★			

Indicator	Performance	RAG	Recent trend[1]	Aim[2]	Notes
Number of requests for contributions to Parliamentary questions	Total = 0	⇔		No KPI – tracked for general monitoring purposes.	Volume indicator.
Number of Freedom of Information (FOI), Environmental Information Regulations (EIR) requests and Data Protection Act (DPA) requests	7	⇩		No KPI – tracked for general monitoring purposes.	Volume indicator.

Indicator	Performance	RAG	Recent trend[1]	Aim[2]	Notes
Staff sickness absence rate (%) per month.	2.8%	⇧		 Achieve 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	£2,458k	⇩		 Reduce	KPI: To move closer to minimum £1,520k cash reserves (figure agreed with DH).

Management accounts:

October accounts:

Income & Expenditure Account	Oct-2015					
Accounting Period						
Cost Centre Name						
Department Name						
	Year to Date			**Full Year**		
	Actual YTD £	**Budget YTD £**	**Variance YTD £**	**Forecast £**	**Budget £**	**Variance £**
Income						
Grant-in-aid	560	560	-	1,120	1,120	-
Licence Fees	2,465	2,487	-22	4,097	4,120	-23
Other Income	53	4	50	56	6	50
Total Income	**3,078**	**3,050**	**28**	**5,273**	**5,246**	**27**
Revenue costs - Charged to Expenditure						
Salaries	2,125	2,216	-91	3,712	3,807	-95
Other Staff costs	134	145	-11	251	258	-7
Authority/Committee costs	90	103	-13	162	166	-4
Other Compliance costs	37	23	14	58	39	19
Other Strategy costs	51	105	-54	178	175	3
Facilities costs incl non-cash	198	209	-11	341	355	-14
IT costs costs	52	62	-10	106	106	-
Legal costs	138	277	-139	257	340	-83
Professional Fees	49	39	11	78	68	10
Total Revenue costs	2,873	3,178	-305	5,142	5,314	-172
Total Surplus/(Deficit) before Capital & Project costs	**205**	**-128**	**333**	**130**	**-69**	**199**
Capital & Project - Reserves funded						
IFQ	358	526	-167	935	1,135	-200
Donor Support	8	9	-1	20	20	-
Other Capital costs	-	-	-	100	100	-
TOTAL NET ACTIVITY	**366**	**535**	**-168**	**1,055**	**1,255**	**-200**

Commentary:

Summarised management accounts October 2015 – commentary

Income

Treatment fee income improved slightly up to the end of October with the shortfall now approximately 1% less than expected. We continue to keep a close eye on this. The forecast income reflects the earlier shortfall on treatment fees and the unbudgeted legal award made.

Expenditure

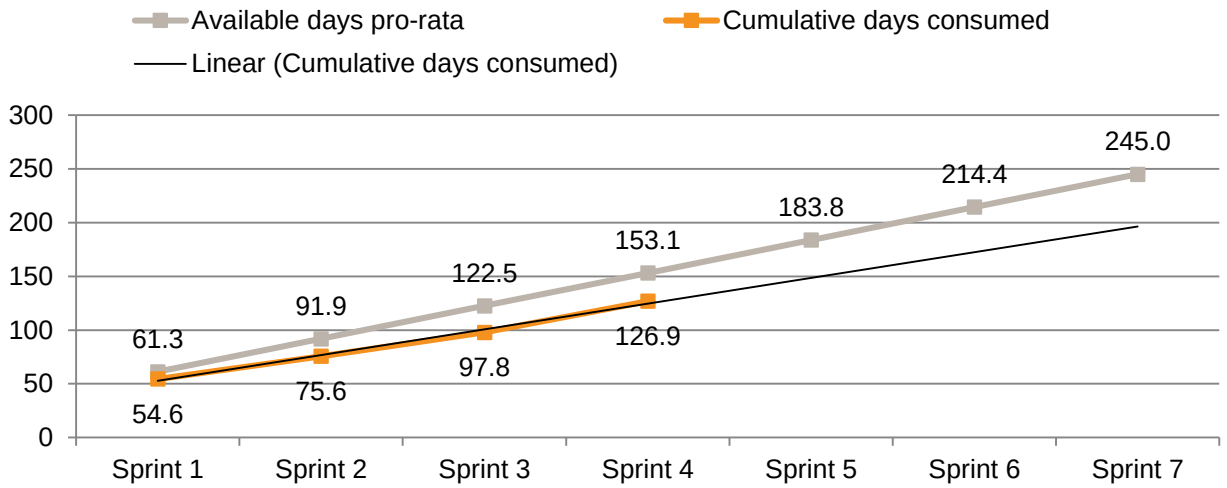
Year to date expenditure is almost 10% below budget at the end of October. Legal costs continue to be less than expected at this point in the year and the salary budget is underspent, due to vacancies.

A detailed review of the likely spending for the remainder of the year was conducted after the end of quarter two and the forecast reflects the current expectation. A further review will be conducted in January (post Q3). Before spend on IfQ, we are forecasting overall expenditure to be 3% lower than what we have budgeted.

IfQ and Other Project costs

The pace of spend increased slightly in October (cumulative spend now at £358k compared to budget of £526k) with the year to date underspend reducing to 32%. Likely expenditure for the rest of the year has been reviewed and re-profiled. We expect that £200k (18%) of the total £1,135k will now be spent in 2016/17. We have informed the DH of this development.

IfQ indicators: October update

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?	**October:** The annual health check is scheduled to be commenced in December.
Monthly	Timescales: burndown chart showing remaining estimate of work.	Is there scope creep/over-run?	**October:** Throughout October the team has continued to refine the way that sprint progress is monitored and recorded using TFS online throughout Alpha. The team is on-track to provide meaningful data from Beta phase.
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.	**October:** Resource usage figures have been provided to the end of Alpha, with those figures considered by the IfQ Programme Board. Measures are being put in place to ensure monthly reporting figures are produced by Reading Room in a timely manner and validated at the Project Board level. 

IfQ indicators: October update

Frequency / trigger point	Metric	Purpose	Latest status:
Monthly	Cost: earned value (% complete * estimated spend at completion)	Is the spend in line with milestone delivery?	There are four things we can attribute value to: websites and CaFC; Clinic Portal; the Register and internal systems; defined dataset, discovery, stakeholder engagement etc. Currently, 25% of the value of the 1.8M programme cost at completion has been attributed to each project. **October:** Earned value continued to increase well through October in line with the development of design prototypes for Website/CaFC and Clinic Portal. In addition, foundational work in the internal systems and data migration processes was completed, with continued progress at a whole-of programme level expected throughout November.

Earned value

Project	May-15	Jun-15	Jul-15	Aug-15	Sep-15	Oct-15
Websites and CaFC	10%	12%	15%	15%	17%	20%
Clinic Portal	10%	12%	15%	15%	17%	20%
Register and internal systems	5%	7%	8%	10%	12%	15%
Discovery	100%	90%	95%	100%	100%	100%
IfQ Total earned value	31%	30%	33%	35%	37%	39%
% of spend to date	**38%**	**39%**	**43%**	**44%**	**45%**	**48%**

IfQ indicators: October update

<table>
<tr><th>Frequency / trigger point</th><th>Metric</th><th>Purpose</th><th>Latest status:</th></tr>
<tr><td>Monthly</td><td>Quality: category A requirements dropped or postponed during this period</td><td>Are key requirements being lost from the programme which could trigger a change in the business case?</td><td>October: No key requirements lost.</td></tr>
<tr><td>Monthly</td><td>Stakeholder engagement: combined stakeholder engagement score</td><td>Are we keeping stakeholders with us? Is it getting better or worse?</td><td>October: We have continued to hold the fortnightly show and tell sessions to keep staff up to date. Internal and external stakeholders took part in the user testing for the website. CaFc and portal.
<table>
<tr><th></th><th colspan="2">June 16 - July 15</th><th colspan="2">July 16 - Aug 15</th><th colspan="2">Aug 16 - Sept 15</th><th colspan="2">Sept 16 - Oct 15</th></tr>
<tr><th></th><th>Page views</th><th>Unique</th><th>Page views</th><th>Unique</th><th>Page views</th><th>Unique</th><th>Page views</th><th>Unique</th></tr>
<tr><td>IfQ Homepage</td><td>0</td><td>0</td><td>60</td><td>27</td><td>45</td><td>20</td><td>30</td><td>14</td></tr>
<tr><td>Juliet’s Blog</td><td>30</td><td>23</td><td>9</td><td>9</td><td>11</td><td>10</td><td>3</td><td>3</td></tr>
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<tr><td>IfQ Blog 4</td><td>0</td><td>0</td><td>0</td><td>0</td><td>10</td><td>7</td><td>8</td><td>5</td></tr>
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<tr><td>IfQ Blog 6</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>4</td><td>3</td></tr>
<tr><td>IfQ Glossary</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>10</td><td>6</td></tr>
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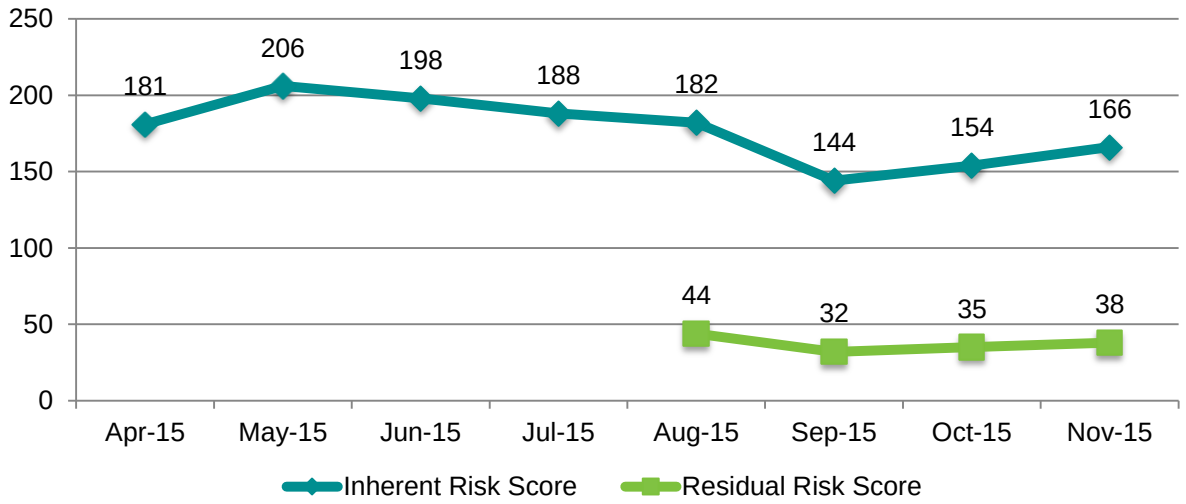
IfQ indicators: October update

Frequency / trigger point	Metric	Purpose	Latest status:
Monthly	Risks: sum of risk scores (L x I)	Is overall risk getting worse or better (could identify death by a thousand cuts)?	**October:** Key areas of risk for the Programme remain stable from September. These remain centered on data migration work, in particular regarding decisions about timing for cleansing and migrating 'must' and 'should' data, and striking an appropriate balance with achieving sufficient quality. These risks are being proactively managed, with IfQ Programme Board reviewing the details of the work in August, and deciding appropriate resourcing and timing parameters for the work in September. A second key area of risk for the IfQ programme has been determining the delivery and resourcing plan to support the required internal systems work. A key milestone for addressing this area of risk was achieved in September, through finalising the IfQ programme plan. The overall risk score for the IfQ Programme has increased again, relating primarily to the risk of delayed beta commencement having impacts on key milestones and programme budget. This risk is being managed by IfQ Programme Board, who have agreed to progress to Beta phase at risk in anticipation of expected GDS approval following the already achieved DH approval process. 

IfQ indicators: October update

Frequency / trigger point	Metric	Purpose	Latest status:
Quarterly	Benefits: value (£) of tangible benefits planned to the delivered by the programme	Is the value of the benefits increasing or decreasing? Could trigger a review of the business case.	**October:** Reporting is expected to be able to commence from the beta stage onwards.

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 (20/01/2016) 781		
Meeting date	20 January 2016		
Author	Nick Jones, Director of Compliance and Information		
Output:			
For information or decision?	For information		
Recommendation	The Authority is asked to: • Note the progress made on the Programme.		
Resource implications	Nil		
Implementation date	During 2015–16 and 2016–17 business years		
Communication(s)	Regular throughout 2015–16		
Organisational risk	☐ Low	☐ Medium	☒ High
Annexes	N/A		

1. Background

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

- The redesign of our website and Choose a Fertility Clinic (CaFC) function
- The redesign of the 'Clinic Portal' (used for interacting with clinics) and combining it with data submission functionality that is currently provided in our separate EDI (Electronic Data Interchange) system (used by clinics to submit treatment data to the HFEA)
- A revised dataset and data dictionary which will be submitted for 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 and data dictionary
- Revisions to programme timeline
- Arrangements for programme management

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

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

2.2. The first 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) was scheduled for a panel meeting on 11 January 2016.

2.3. Rather than delay progress, and incur 'downtime costs' and informed by the result of the first stage assessment, the Corporate Management Group agreed with the proposal from the IfQ Programme Board to proceed 'at risk.' An oral update on progress here will be provided at the meeting.

3. The HFEA annual conference

3.1. Building on the proof-of-concept work presented at the last meeting, the teams have already made good progress at the end of last year and the beginning of this year in building a working website and clinic portal (the products).

3.2. A centre-piece of the HFEA conference will be showcasing the progress made and generating a sense of anticipation for the roll-out of the 'beta' version of the products as well as introducing the proposed new data dictionary together with the plans we are making for the data submission part of the clinic portal, following in release 2 (currently scheduled for October 2016).

4. Data migration and data dictionary

4.1. 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.

4.2. Substantial cleansing activity is being undertaken by the Information and IT teams such that the burden placed on clinics to undertake this work has been minimalised.

4.3. That said, 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 take place over the next 3-4 months. We have been communicating with clinics preparing them for this step 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.

4.4. Progress has been slower than hoped with exposing the data dictionary (the items of information that we require to be submitted by clinics about treatments) to stakeholders and for accreditation by the Health and Social Care Information Centre. This is becoming a risk to delivery – albeit it becomes critical towards the middle of the year. Members will be asked to sign off the data dictionary at its March meeting.

5. Revisions to programme timeline

5.1. A detailed (and revised) IfQ Programme Plan was finalised and signed off by the IfQ Programme Board in December 2015, in line with the overall £1.134m agreed by Authority.

5.2. The timeline has been amended – and as such the public beta for the website and clinic portal has been pushed back approximately 3 months and 2 months

respectively – with both now expected to be launched (for beta testing) in July 2016.

5.3. This is principally a consequence of first stage approval delay; some loss of momentum in the period prior to the commencement of beta and more realistic expectations about what could be achieved during the holiday period. In discussion with stakeholders we are confident that an approach of 'getting it right' is preferable to one of 'getting it out.'

Milestone	Current Milestone	Proposed Revised Milestone
Website & CaFC		
Release 1		
Website R1 Public Beta	01-Mar-16	**01-Jun-16**
Website R1 Live	19-Apr-16	**27-Jul-16**
Clinic Portal		
CP Release 1		
Early adopters (CP Private beta)	19-Apr-16	19-Apr-16
CP R1 Live	23-May-16	**27-Jul-16**
Register Data Migration		
Cleanse "Can't migrate unless fixed" data	14-Jan-16	**31-Jan-16**
Clinic cleansing of data	13-Apr-16	13-Apr-16
Cleanse Historical Register data	17-May-16	17-May-16
Data cleansing completed	31-May-16	31-May-16
DM LOAD 5 (Go Live)	20-Sep-16	20-Sep-16
Clinic Portal Release 2	**28/10/2016**	**28/10/2016**

6. Programme management

6.1. IfQ programme oversight has now been absorbed by the 'in-house' Programme Management Office (PMO) function, further to the departure of the dedicated Programme Manager with contractor status. Good arrangements were put in place for handover. Whilst in its early days, this arrangement is working well. The Programme has well established project boards with detailed oversight of each individual project, and the PMO will deal principally with programme governance, contractual matters, budget controls, external approvals mechanisms and the continued running of the IfQ Programme Board.

7. Recommendation

7.1. The Authority is asked to

- Note the progress made on the IfQ Programme.

Annual update of the HFEA Register Research Panel

Strategic delivery:	☐ Setting standards	X Increasing and informing choice	☐ Demonstrating efficiency economy and value
Details:			
Meeting	Authority		
Agenda item	8		
Paper number	HFEA (20/01/2016) 782		
Meeting date	20 January 2016		
Author	Suzanne Hodgson, Researcher in Statistics and Epidemiology		
Output:			
For information or decision?	For information		
Recommendation	The Authority is asked note the activity of the Register Research Panel.		
Resource implications	None		
Implementation date	Immediately		
Communication(s)	Internal communication to members of the Register Research Panel and staff involved in its administration.		
Organisational risk	X Low	☐ Medium	☐ High
Annexes	None		

1. Authority oversight

1.1. The HFEA Register Research Panel (RRP) was set up in 2010 after the law changed to allow the disclosure to external researchers of patients' identifying information. The Authority remains the statutory Oversight Committee and therefore has a duty to exercise oversight of the work of the RRP. This paper fulfils this statutory requirement and has one main purpose: to report on the work of the panel since January 2015.

2. Register Research Panel activity since January 2015

2.1. Since the last report in January 2015, the Panel has received and approved one new application (see 3.5). The Panel has sat on two occasions, to consider a new application. The Executive has continued to meet and correspond with prospective researchers.

2.2. One member of the Panel, the Head of Governance and Licensing, has left the HFEA. His role on the Panel, and as Caldicott Guardian, will be replaced by the new Head of Corporate Governance when in post.

3. Update on studies approved in previous years

Cancer risk and mortality in women after IVF, UCL (approved 2010)

3.1. The principal investigator, Professor Alastair Sutcliffe, presented some of the results of this study at the American Society for Reproductive Medicine in October 2015. The abstract can be found on page e37 of the conference abstract book here: www.asrmannualmeeting.org/tyfoon/dnld/pe6afeb6186f44fe80f/abstracts.pdf

The study reported that there was a small increase in the rate of ovarian cancer in women who had received IVF. This was thought to be linked to the causes of infertility women were seeking treatment for, rather than exposure to the drugs, but the researchers did leave open the possibility that IVF affected the risk. The remainder of the analysis (covering breast and uterine cancer) should be published soon.

Mortality and general health in children born after IVF, UCL (approved 2012)

3.2. After some delays last year, and some changes in research team staff, we are currently preparing the data to be transferred to the HSCIC for linkage later this month.

Development and validation of statistical models to predict pregnancy outcomes following in-vitro fertilisation (IVF) treatment, University of Aberdeen (approved 2013)

3.3. The researchers have completed their analysis and have two papers planned for publication this year.

EpiHealth Outcomes Project: The effect of maternal age, embryo cryopreservation and culture on perinatal outcomes and child health, University of Manchester (approved 2013)

3.4. The researchers are still working on their analysis of the data we provided and plan to start writing up in the next few months.

Investigating the impact of culture media on IVF treatment and child health outcomes: A national culture media questionnaire and HFEA Register data linkage study, University of Manchester (approved 2015)

3.5. This study aims to identify the impact of different culture media on subsequent live birth rates and birth weights by linking together register data with a questionnaire completed by clinics detailing their media regimes. The researcher will be attending the HFEA offices to complete the linkage and analyses at the end of the month.

4. Other papers using HFEA data published this year

Live birth rate associated with repeat in vitro fertilisation treatment cycles[i]

4.1. This study aimed to determine the live birth rate both per egg stimulation and with repeated cycles. It was published in the Journal of the American Medical Association in December 2015. The researchers found that among women in the United Kingdom undergoing IVF, the cumulative live-birth rate after six cycles was 65.3%, with variations by age and treatment type. Their findings suggest there is evidence to support the efficacy of extending the number of IVF cycles beyond three or four. The paper is available freely online here: http://jama.jamanetwork.com/article.aspx?articleid=2478204 and received significant press coverage, being reported in The Times, Daily Mail, Daily Express and on BBC radio.

Treatment cycles factors affecting embryo viability and uterine receptivity[ii]

4.2. This statistical modelling study was published in the Reproductive BioMedicine Online in November 2015 and attempted to distinguish between factors acting on the embryo directly and those acting through the uterine environment. This found that (as would be expected) maternal age has a major effect, mainly on the embryo, but also on the uterine factors to a lesser extent. This work suggests that embryo culture has both direct effects of the in-vitro environment during the first few days of the embryo's life; but also the delay in transfer following extended culture or cryopreservation may well lead to an altered

uterine environment for the embryo post-transfer. The paper is available online to subscribers only: **http://www.rbmojournal.com/article/S1472-6483(15)00546-5/abstract**

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[i] Smith A, Tilling K, Nelson S, Lawlor D. Live birth rate associated with repeat in vitro fertilization cycles. Journal of American Medical Association. 2015;314(24):2654-2662.

[ii] Roberts S, Hann M, Brison D. Factors affecting embryo viability and uterine receptivity: Insights from an analysis of the UK registry data. Reproductive Biomedicine Online. 2015;0,0

Embryo testing: Testing for more than one condition at a time

Strategic delivery	X Setting standards	X Increasing and informing choice	☐ Demonstrating efficiency economy and value
Details			
Meeting	Authority		
Agenda item	9		
Paper number	HFEA (20/01/2016) 783		
Meeting date	20 January 2016		
Author	Anjeli Kara, Regulatory Policy Manager		
Output			
For information or decision?	For decision		
Recommendation	To decide on one of the policy options set out in this paper, while considering balancing patient choice with the handling and interpretation of genetic information		
Resource implications	HFEA policy staff resources		
Implementation date	01 April 2016 (Update to Code of Practice)		
Communication(s)	Both internal and external communications on possible changes to guidance on embryo testing in the Code of Practice		
Organisational risk	☐ Low	X Medium	☐ High
Annexes	Annex A: Proposed amendments to guidance note 9: PGS Annex B: Proposed amendments to guidance note 10: Embryo testing		

1. Background

1.1. Over the years, embryo testing technologies have developed to enable practitioners to carry out the same tests with more speed and accuracy. The latest technologies, however, can also test for more than one genetic condition or abnormality at a time. This development, brought with technologies called karyomapping and next generation sequencing (NGS), has implications for how we regulate embryo testing and how clinics handle the additional genetic information generated.

1.2. The Scientific and Clinical Advances Advisory Committee (SCAAC) has been watching the development of these technologies over the past few years, and referred the issues to the Ethics and Standards Committee (ESC) for consideration of the legal and ethical implications in 2014. We discussed the issues with stakeholders at an embryo testing workshop in December 2014, and through correspondence with a number of professional bodies and a genetic charity. The stakeholder views gathered support the use of these technologies in practice and the concept of testing for more than one disease at a time. These findings were presented to the Authority in May 2015.

1.3. The Authority expressed misgivings about the type of patients currently being offered preimplantation genetic screening (PGS)[1] 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. This paper addresses the Authority's comments before asking for a decision on whether it is appropriate to test for more than one condition or abnormality at a time. The Authority's choice will come down to where it wishes to strike the balance between maximising patient choice and being concerned about the implications of handling and interpreting additional genetic information.

1.4. The options for regulating embryo testing technologies and handling the complex information generated as a result are set out in this paper. Before considering them, we provide background on the latest technologies; outline SCAAC's most recent discussions on PGS (including revised guidance for consideration); and consider how complex test results could be managed and interpreted in clinical practice.

2. What are the latest embryo testing technologies?

2.1. There are two main types of embryo testing: preimplantation genetic diagnosis (PGD)[2] and PGS[1]. Technologies used in PGD identify embryos that are at risk of being affected by an inherited genetic or chromosomal condition by looking for irregularities

[1] Preimplantation genetic screening (PGS) identifies embryos carrying an abnormal number of any of the 23 pairs of chromosomes. Embryos that are shown to carry a common chromosomal abnormality are not transferred.

[2] Preimplantation genetic diagnosis (PGD) identifies embryos carrying a specific genetic mutation or chromosomal translocation that is known to exist in the patient couple's family history. Embryos that are affected by the condition being tested for are not transferred and therefore do not result in a child being born. Embryos that are carriers and non-carriers for the condition can be transferred.

in DNA (ie, mutations) or by looking at chromosomal translocations[3]. PGS screens embryos for common chromosomal abnormalities (eg, an increase or decrease in the number of chromosomes) that can cause miscarriage or IVF failure. There are therefore two ways embryos can be tested: by chromosome analysis[4] (PGS and PGD for chromosomal translocations) and detecting mutations in DNA (PGD for genetic conditions).

Next generation sequencing

2.2. Next generation sequencing (NGS) – the latest technology in chromosome analysis – involves fragmenting the DNA in a cell from an embryo and checking parts of chromosomes (rather than analysing chromosomes as a whole which all previous technologies allowed). This offers increased accuracy, higher resolution, and lower diagnostic costs. For these reasons NGS is becoming the 'go-to' technology for detecting chromosomal abnormalities, and allows PGS and PGD for chromosomal translocations to be carried out at the same time. NGS is also widely used across the NHS in genetic testing laboratories.

Karyomapping

2.3. Like other technologies for detecting genetic conditions, karyomapping works by tracing the gene for a serious condition in affected prospective parents or family members, and comparing it to the genetic material of their embryo(s) to see if it carries the same mutation – this is known as haplotyping. Due to the higher resolution it provides and the shorter time it takes to generate results, karyomapping is becoming the 'gold standard' in targeted haplotyping and for detecting genetic mutations, and can also carry out PGD for multiple genetic conditions at once (as long as a reference sample is available for all conditions being tested for).

2.4. While karyomapping is primarily used for detecting genetic conditions, it can also be used for complete chromosome analysis. Therefore, when used alongside a reference sample, karyomapping enables PGD and PGS to be carried out at the same time (ie, more than one genetic condition or chromosomal abnormality can be tested for at a time).

2.5. It is not possible – as technology currently stands – to test an embryo for an assortment of conditions from an embryo biopsy sample alone, as a reference sample from a relative with a condition would not exist. It is worth noting, however, that advances in genetic testing could make it possible for embryo testing to be carried out without the need for a reference sample, and for whole genome sequencing technologies to become widely available in the future.

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[3] Chromosomal translocations occur when DNA from one chromosome is swapped with DNA on another chromosome. If there is no gain or loss of DNA, it is called a balanced translocation.

[4] Chromosome analysis involves looking at the number of chromosomes present in a cell and/or identifying whether parts between chromosomes, which are not from the same person, have been rearranged.

Incidental findings

2.6. Incidental findings are genetic findings that are unintentionally discovered when testing an embryo with the latest technologies. These findings are unrelated to the medical condition for which testing has been sought and cannot always be interpreted. This means an incidental finding that cannot currently be interpreted may, or may not, have a clinical effect on a child born.

2.7. The latest embryo testing technologies can highlight incidental findings. Incidental findings from NGS may include gains or losses of parts of chromosomes, and mosaicism[5] in embryos. Incidental findings from karyomapping can include genome-wide chromosome malsegregation (which can indicate abnormal fertilisation and other early abnormal events in the embryo) and gains or losses of parts of chromosomes. This means that when PGD is carried out to test for specific conditions, incidental findings about chromosomal abnormalities may be revealed. Conversely, when PGS is carried out to test for chromosomal abnormalities, the test may also reveal information about certain conditions linked to chromosomal abnormalities or information about other chromosomal problems.

3. Embryo testing technologies and the law

3.1. PGS and PGD is regulated by the Human Fertilisation and Embryology Act 1990 (as amended) (the Act) in different ways.

Preimplantation genetic screening

3.2. A patient may have their embryos screened for a range of chromosomal abnormalities which might be causing repeated IVF failure or miscarriages, if the following criterion in the Act is met:

> Schedule 2, 1ZA(1)(a): 'establishing whether the embryo has a gene, chromosome or mitochondrion abnormality that may affect its capacity to result in a live birth.'

3.3. There is no specific authorisation process in place for the use of PGS in individual cases; centres which are licensed for embryo testing validate the use of PGS for each category of patients to which it is offered.

Preimplantation genetic diagnosis

3.4. PGD can be carried out by a centre with an embryo testing licence, providing patients meet the criterion laid out in the Act:

> Schedule 2, 1ZA(1)(b): 'in a case where there is a particular risk that the embryo may have any gene, chromosome or mitochondrion abnormality,

[5] Mosaicism is the phenomenon where cells from the same person/embryo have two or more populations of cells with different genetic makeup.

establishing whether it has that abnormality or any other gene, chromosome or mitochondrion abnormality.'

3.5. In practice, this means that PGD for inherited genetic and chromosomal conditions can be carried out where there is an existing known risk of a genetic disease in a family (ie, meets the 'particular risk' requirement). Once this risk has been established, PGD can be offered to patients with a family history of a serious inherited condition, providing the HFEA has agreed that the disease in question is sufficiently serious (ie, known as 'significant risk') and is included on the list of authorised PGD conditions.

3.6. Although the use of PGS and PGD in clinical practice are well established, use of the latest embryo testing technologies gives rise to two new scenarios:

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

Carrying out PGS and PGD at the same time

3.7. We sought legal advice about whether PGS and PGD can be carried out at the same time. The advice concluded that embryo testing for PGS and PGD should be considered separately and the requirements for each must be satisfied before testing is carried out. The Act requires that embryo testing cannot be carried out unless 'one or more' of the purposes set out are met. This means that if a patient satisfies the requirements for PGS, it does not act as a gateway to carrying out PGD. Likewise, if a patient satisfies the requirements for PGD, this does not mean that the patient is automatically eligible for PGS. However, if a patient satisfies the requirements for both PGD and PGS, both forms of embryo testing can be carried out at the same time.

Carrying out PGD for more than one genetic condition

3.8. We already know that it is possible for a couple who are unlucky enough to have a family history of two diseases to test their embryos for both conditions – provided both diseases are on the Authority's list of authorised PGD conditions. This is because they fulfil the particular risk requirement for both conditions. However, whether it would be possible to test for more than one disease when the couple has a particular risk of just one condition required clarification.

3.9. The legal advice indicates that it would be possible for an embryo that has satisfied the particular and significant risk requirements for PGD for one genetic condition, to also be tested for additional conditions at the same time, provided they satisfy the significant risk test. There is no need for the additional genetic conditions to meet the particular risk requirement too.

4. SCAAC's recommendations on PGS

4.1. In line with the Authority's recommendation 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 (and patient information on the HFEA website should reflect this).
- Guidance around information provision 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.
- Patients should be given information explaining the misdiagnosis rate associated with PGS for aneuploidy.

4.2. In light of the Committee's comments, proposed amendments to the PGS guidance note are set out at Annex A of this paper. Amendments to the patient information are currently underway and will go live with the launch of the new website.

5. Handling, interpreting and sharing the complex data generated through the latest embryo testing technologies

5.1. Beyond the legal considerations, we need to think about how centres and their patients should deal with the information generated from the latest embryo testing technologies. How should information be shared between professionals, patients and their wider families, and what should be done with information that cannot currently be interpreted? Further, what kinds of consent do patients need to give and what kind of counselling support should they be able to access?

5.2. Following the Authority's discussion on this topic in May 2015, we have considered how other organisations that have needed to address similar questions have approached this area (eg, Genomics England). We have also considered best practice guidelines issued jointly by the Royal College of Physicians, the Royal College of Pathologists and the British Society for Human Genetics, and by the Association of Clinical Genetic Science. These guidelines address consent and confidentiality in clinical genetic practice[6], and targeted NGS[7], respectively. Both guidelines have been taken into account in the recommendations below, and should be referenced when providing guidance to the sector.

5.3. Before considering how all of the relevant information gathered would come together in a typical patient experience of undergoing PGS and PGD using the latest technologies,

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[6] Royal College of Physicians, the Royal College of Pathologists and the British Society for Human Genetics. Consent and confidentiality in clinical generic practice: Guidance on genetic testing and sharing genetic information (A report of the Joint Committee on Medical Genetics): www.bsgm.org.uk/media/678746/consent_and_confidentiality_2011.pdf

[7] Association for Clinical Genetic Science. Practice guidelines for targeted next generation sequencing analysis and interpretation: www.acgs.uk.com/media/774807/bpg_for_targeted_next_generation_sequencing_may_2014_final.pdf

the following sections summarise the sector and stakeholder opinions gathered to date, and highlight the key points of the best practice professional guidelines.

Rights to information generated by embryo testing technologies

5.4. The storing of genetic information raises confidentiality issues for patient(s) undergoing treatment and any potential consent taken during the consultation process. This is a complex area, and obtaining and retaining genetic information about any individual engages Article 8 of the European Convention of Human Rights. Article 8(1) states that everyone has the right to respect their own private and family life, although this privacy needs to be balanced against the rights and freedom of others. The right not to know is recognised in Article 10.2 of the Convention on Human Rights and Biomedicine, which notes that everyone is entitled to know any information collected about their health; however, the wish to not be informed should also be observed.

5.5. In the context of genetic testing, there can be wider familial implications as a patient may not wish to receive certain information about their genetic status, such as information which indicates that they may suffer from a disorder for which there is no cure. The Authority already recognises this and provides guidance in the Code of Practice for managing PGD for non-disclosure[8].

5.6. Stakeholders largely agreed that many patients would want access to any information generated through embryo testing, however ambiguous the findings may be. They felt that patients should see an expert in interpreting genetic data and discuss their options in the light of the information generated. This thought is echoed in professional guidance on sharing genetic information[6].

'Blocking out'

5.7. Some stakeholders thought that genetic information which cannot help select an optimal embryo for transfer should not be tested for. For this to happen in clinical practice, areas of array-based technologies would be 'blocked out' to avoid testing for conditions that are not on the Authority's list of authorised PGD conditions. However, blocking out would only be possible with array-based technologies, would not be adaptable to all the latest embryo testing technologies (eg, karyomapping), and could exclude future technologies.

5.8. If blocking out is carried out in practice, in accordance with external legal advice, the Authority would need to be satisfied that it is to prevent the embryo from being tested for abnormalities, rather than preventing the dissemination of information about such a test.

Interpreting information generated by embryo testing technologies

5.12. As noted above, the latest technologies in embryo testing can generate incidental findings. It is current practice for diagnostic laboratories to flag these findings to centres and state, where necessary, whether they are able to determine the effect an

[8] PGD for non-disclosure is where patients at risk of a late onset disease wish to use PGD to avoid the condition without discovering whether or not they themselves will develop the disease later in life

anomaly may have on a child born. Therefore, the decision currently lies with the clinician on which embryo to transfer in accordance with HFEA guidance.

5.13. For this particular reason, stakeholders have flagged the importance of obtaining patient consent and offering access to both genetic and infertility counsellors. This would enable patients to make informed choices about their treatment and the handling of genetic information that may be gathered, and would provide them with emotional support both before and after testing has occurred. Reports generated by diagnostic laboratories that highlight incidental findings to centres (as outlined above), was considered fit for purpose by stakeholders.

Counselling and recording consent for embryo testing technologies

5.14. Due to the complexity of embryo testing and the factors involved, it is widely considered by stakeholders, the sector and professional guidelines that patients – including affected family members that provide reference samples – should be given access to both genetic and infertility counsellors[9], before and after testing. This is so patients fully understand how the technologies work, the information technologies might reveal – both positive and negative – the information they want to receive, and are given sufficient time and emotional support to consider the implications.

5.15. It was widely felt that consent should be recorded and tailored to the type of embryo testing taking place, and note patient wishes around the disclosure of information. This is reflected in professional guidance on sharing genetic informaiton[6] and practised by the 100,000 genomes project which uses the latest genetic testing technologies.

Future genetic testing technologies

5.16. It is important to acknowledge that genetic testing is a rapidly evolving field. Non-invasive prenatal testing is a sophisticated blood test that examines the DNA of a fetus in the maternal bloodstream, to determine whether it is at risk of a common chromosomal abnormality. Although this technique does not fall under the remit of the Authority, it is important to note this advance in technology, what it allows, and that it is becoming more available in clinical practice.

5.17. Regarding embryo testing in particular, both the sector and stakeholders flagged that the Authority should consider the likelihood that advances in genetic testing will eventually make it possible for embryo testing to be carried out without the need for a reference sample from an affected relative. Further, if whole genome sequencing becomes more widely available – rather than a specialist test for paying members of the public as is currently the case – this could result in an increased number of PGD cycles (eg, a member of the public could find that they/a relative has a condition after having their genome sequenced and could seek PGD treatment as a result).

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[9] Genetic counsellors have factual information on the risks, incidences and implications of genetic disorders. Infertility counsellors provide patients with emotional support and time to consider implications.

Patient pathways

5.18. Taking the abovementioned information into consideration, Figure 1 shows an overview of how this information would come together for a patient experience undergoing PGD and PGS.

It is worth noting that unlike PGD, there is currently no specific authorisation process in place or particular patient group requirements for the use of PGS in individual cases – this will remain unchanged. However, given the scenarios that the latest embryo testing technologies allow, it is anticipated that there will be additional information, counselling and consent requirements for clinics to meet when treating patients undergoing PGS (eg, access to a genetic counsellor, obtaining consent for non-disclosure of incidental findings, where necessary).

5.19. Taking on board this patient experience pathway, Annex D details how the Code of Practice guidance note on embryo testing could be amended.

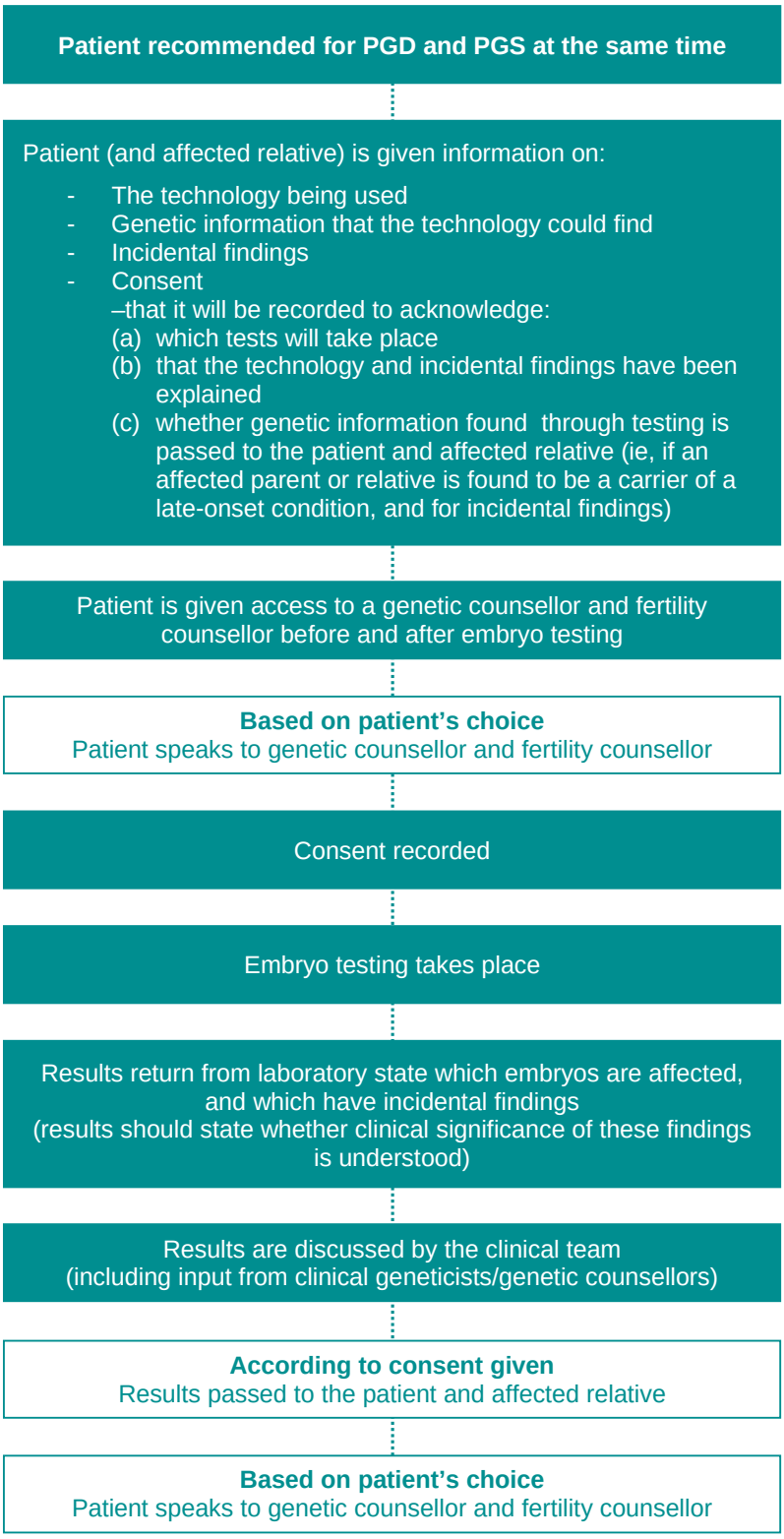

Figure 1: Summary pathway of patient undergoing PGS and PGD at the same time

6. Policy options

6.1. How should the HFEA regulate embryo testing in light of the latest technologies? The legal advice is clear that:

- PGS and PGD can both be carried out for the same patient, provided that they meet the criteria for both types of embryo test.

  This means it is possible to test for a chromosomal abnormality and a genetic condition at the same time – indeed this is happening in some clinics.

- PGD can be used to test for more than one genetic condition at a time, providing the 'particular risk' requirement is met for at least one condition and the 'significant risk' requirement is met for all conditions.

  This means that two or more genetic conditions could be tested for on the same embryo at the same time. This is happening in clinical practice where a patient meets the 'particular risk' requirement for both conditions (ie, when a patient has more than one inherited disease in their family).

6.2. An important starting point would be the provision of information and genetic counselling to the patient(s) prior to embryo testing as part of the consent process. This would provide the opportunity for the wishes of patients to be obtained and recorded, and a basis for a clinic to act if an abnormality concerned (or perhaps an incidental finding) is identified.

6.3. Stakeholders have suggested that regardless of the type of embryo testing that is carried out, patients must:

- give appropriate consent
- be given sufficient information about the procedure (including the technology used); and
- be given access to a genetic counsellor and/or a clinical geneticist.

Consent and information provision should be specific to the type of testing carried out and there should be a relevant expert available to help patients understand the information generated by the test.

Testing for more than one genetic condition and/or chromosomal abnormality at a time

6.4. As outlined above, the legal advice is clear that the Act allows for PGS and PGD to be carried out at the same time, and PGD to be used to test for more than one condition at a time. However, it is appropriate to allow this? The Authority is asked to decide one of the following possible policy options.

- Option 1: To prohibit testing for more than one genetic condition or chromosomal abnormality at a time
- Option 2: To allow testing of more than one genetic condition or chromosomal abnormality at a time, making sure that patients consent to receive (or not receive) the information generated

Option 1	Option 2
Prevents patients undergoing PGD and PGS at the same time; and prevents PGD for more than one disease at a time where the patient only meets the 'particular risk' requirement for one condition. This option would only involve using some of the latest technologies (as blocking is not possible for all).	PGS and PGD can be carried out for the same patient, provided that they meet the criteria for both types of embryo test; and PGD can be used to test for more than one genetic condition at a time, providing the 'particular risk' requirement is met for at least one condition. SCAAC's recommendations on PGS are included in the next Code of Practice update.
Benefits	
Ensures only genetic conditions for which patients' meet the particular risk requirement are tested for.	Patients can make an informed decision about whether they would like to receive any additional genetic information about their embryos, which may increase their chance of a live birth and/or healthy child.
Patients are not faced with receiving incidental findings/genetic information about their embryos, for which the clinical significance is unknown.	Patients are able to give consent confirming their wishes, and are offered both genetic and infertility counselling to help make informed decisions.
	Allows embryo testing using the latest technologies and sets a provision for future advances in the area (eg, consent and genetic counselling).
	Reflects the expert opinions gathered from the sector, stakeholder organisations, professional guidelines and genetic charities.
Risks	
Patients are not informed decision about any chromosomal abnormalities or incidental findings that could affect a child born.	Depending on the number of conditions and abnormalities tested for, this may lead to a reduction in the number of unaffected embryos to transfer.
Blocking is only available on certain embryo testing technologies and not all.	Testing may reveal conditions that have implications on the wider family (eg, late onset conditions).
Does not allow embryo testing using all of the latest technologies and it could prevent the use of future technological advances.	Testing may give rise to incidental findings and genetics expertise may not be available to interpret complex test results.
	Not recommending PGS for a particular patient group may lead to an increase in PGS cycles for patients that may not see a benefit.
	May increase the cost of a treatment cycle.

Table 1: Benefits and risks associated with both policy options.

6.5. Note: In May 2015, three policy options were presented to the Authority, however, one option – to allow testing of more than one genetic condition, but withhold from patients the information that is generated – was considered an inappropriate approach.

Recommendation to the Authority

6.6. The Authority is asked to consider both options and decide on the appropriate approach. The Authority's choice will come down to a decision about where it wishes to strike the balance between maximising patient choice and being concerned about the implications of handling and interpreting additional genetic information.

6.7. Depending on the approach taken, the Authority is asked to approve the proposed amended guidance to the sector on 'PGS' (for Option 1 and 2) and 'embryo testing' (for Option 2, only) as set out at Annex A and B of this paper, respectively. These changes will be incorporated in the April 2016 update of the Code of Practice.

Annex A: Proposed amendments to guidance note 9: Preimplantation genetic screening (PGS)

Mandatory requirements
Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

Schedule 2

Licences for treatment

1 (1) A licence under this paragraph may authorise any of the following in the course of providing treatment services–

...

(b) procuring, keeping, testing, processing or distributing embryos…

Embryo testing

1ZA (1) A licence under paragraph 1 cannot authorise the testing of an embryo, except for one or more of the following purposes–

(a) establishing whether the embryo has a gene, chromosome or mitochondrion abnormality that may affect its capacity to result in a live birth,

(b) in a case where there is a particular risk that the embryo may have any gene, chromosome or mitochondrion abnormality, establishing whether it has that abnormality or any other gene, chromosome or mitochondrion abnormality,

Licence conditions

T88 With respect to any embryo testing programme involving biopsy the centre must ensure that:

a. no embryo is transferred to a woman where that embryo or any material removed from it or from the gametes that produced it, has been subject to a test that supplies genetic information about the embryo, unless the test has been expressly authorised by the Authority, and

b. any information derived from tests on an embryo, or any material removed from it or from the gametes that produced it, is not used to select embryos of a particular sex for social reasons.

T89 With respect to any embryo testing programme the centre must ensure that embryo testing is only being carried out for those genetic conditions that are expressly authorised by the Authority.

HFEA Guidance
Staff to be involved in PGS

9.1 The centre should ensure that a multidisciplinary team is involved in providing the embryo testing service. The team should include reproductive specialists, embryologists, clinical geneticists, genetic counsellors, cytogeneticists and molecular geneticists. It should maintain close contact with the primary care physician.

9.2 Treatment should include patient support following embryo testing.

The use of PGS

Interpretation of mandatory requirements 9A

An embryo may be tested to establish whether it has a particular chromosomal abnormality only if:
a) that abnormality may affect its capacity to result in a live birth, or
b) there is a particular risk that it has that abnormality, and where the Authority is satisfied that there is a significant risk that a person with that abnormality will have or develop a serious medical condition.

An embryo may be tested for PGS and PGD where the requirements for each have been satisfied before testing is carried out. Fulfilling the requirements for PGS does not act as a gateway to carrying out PGD, and vice versa.

9.3 The centre should ensure that before people seeking treatment give consent to PGS for aneuploidy, they are given information explaining:

(a) the procedure and risks associated with the procedure
~~(b) the unproven nature of the procedure, in particular that:~~
~~(i) more robust clinical and laboratory trials are needed to assess whether or not PGS can significantly increase live birth rates~~
~~(ii) the method of fluorescent in situ hybridisation (FISH) on embryos, using a limited number of chromosomes, is not effective at increasing live birth rates~~
(b) that more robust clinical and laboratory trials are needed to assess whether or not PGS can significantly increase live birth rates
~~(c) that embryos biopsied may not be available for cryopreservation and for use in subsequent treatment cycles~~
(c) the failure and misdiagnosis rates associated with PGS for aneuploidy, including the fact that false results can be positive or negative
~~(d) that the more chromosome tests are carried out, the higher the possibility of the test not working and the lower the chance of finding suitable embryos for transfer~~
(d) the concept of mosaicism, and the effect that this could have on the accuracy of results
(e) that PGS techniques are capable of detecting segmental aneuploidies which may generate results where the clinical significance is not known
(f) that there is no guarantee against a miscarriage occurring, despite PGS for aneuploidy being performed, and
(g) the financial and emotional costs where treatment fails and there is no live birth following PGS for aneuploidy.

9.4 Before providing PGS, the centre should ensure that those seeking treatment have had sufficient opportunity to fully consider the possible outcomes and their implications.

9.5 Embryos from which biopsies have been taken, or resulting from gametes from which biopsies have been taken, should not be transferred with any other (non-biopsied) embryos in the same treatment cycle.

~~**9.3** Centres should ensure that they keep up to date with relevant literature and professional guidance in order to validate the use of PGS for each category of patient to which they offer it. Validation should also be based on data from previously published studies and retrospective evaluation of the clinic's own data.~~

9.6 Where patients seek PGS, but do not wish to be informed of any additional genetic information that may be found via sophisticated genetic testing methodologies (eg, segmental aneuploidies), where possible, guidelines around PGD for non-disclosure (paragraphs 10.10-10.12) should be adhered to.

See also:
Guidance note 10 – Embryo testing and sex selection

PGS and counselling

9.7 Where PGS is carried out using technologies that give rise to additional genetic information, the centre should ensure that people seeking treatment have access to clinical geneticists, genetic counsellors and, where appropriate, infertility counsellors before and after treatment has occurred.

9.8 The centre should work closely with the local genetics team of those seeking treatment.

Prohibitions on embryo selection

Interpretation of mandatory requirements 9B
The law requires that the centre should not select embryos of a particular sex for social reasons.

NOTE: Guidance note 10 (Embryo testing and sex selection) contains all the guidance and mandatory requirements relevant to embryo testing in general. Centres offering PGS should familiarise themselves with this guidance note as well.

Other legislation, professional guidelines and information

Royal College of Physicians, the Royal College of Pathologists and the British Society for Human Genetics – Consent and confidentiality in clinical generic practice: Guidance on genetic testing and sharing genetic information (A report of the Joint Committee on Medical Genetics)

Association for Clinical Genetic Science – Practice guidelines for targeted next generation sequencing analysis and interpretation

Annex B: Proposed amendments to guidance note 10: Embryo testing and sex selection

Mandatory requirements

Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

Schedule 2 – Activities that may be licensed under the 1990 Act

Licences for treatment

Embryo testing

1ZA (1) A licence … cannot authorise the testing of an embryo, except for one or more of the following purposes–

(a) establishing whether the embryo has a gene, chromosome or mitochondrial abnormality that may affect its capacity to result in a live birth,

(b) in a case where there is a particular risk that the embryo may have any gene, chromosome or mitochondrion abnormality, establishing whether it has that abnormality or any other gene, chromosome or mitochondrion abnormality,

(c) in a case where there is a particular risk that any resulting child will have or develop–

(i) a gender-related serious physical or mental disability,

(ii) a gender-related serious illness, or

(iii) any other gender-related serious medical condition,
establishing the sex of the embryo,
...

(e) in a case where uncertainty has arisen as to whether the embryo is one of those whose creation was brought about by using the gametes of particular persons, establishing whether it is.

(2) A licence… cannot authorise the testing of embryos for the purpose mentioned in sub-paragraph (1)(b) unless the Authority is satisfied–

(a) in relation to the abnormality of which there is a particular risk, and

(b) in relation to any other abnormality for which testing is to be authorised under sub-paragraph (1)(b), 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.

(3) For the purposes of sub-paragraph (1)(c), a physical or mental disability, illness or other medical condition is gender-related if the Authority is satisfied that–

(a) it affects only one sex, or

(b) it affects one sex significantly more than the other.

Licence conditions

T86 Embryos that are known to have a gene, chromosome or mitochondrion abnormality involving a significant risk that a person with the abnormality will have or develop:

a. a serious physical or mental disability

b. a serious illness, or

c. any other serious medical condition, must not be preferred to those that are not known to have such an abnormality.

T87 Embryos that are known to be of a particular sex and are known to carry a particular risk, compared with embryos of that sex in general, that any resulting child will have or develop:

a. a gender-related serious physical or mental disability

b. a gender-related serious illness, or

c. any other gender-related serious medical condition, must not be preferred to those that are not known to carry such a risk.

T88 With respect to any embryo testing programme involving biopsy the centre must ensure that:

a. no embryo is transferred to a woman where that embryo or any material removed from it or from the gametes that produced it, has been subject to a test that supplies genetic information about the embryo, unless the test has been expressly authorised by the Authority, and

b. any information derived from tests on an embryo, or any material removed from it or from the gametes that produced it, is not used to select embryos of a particular sex for social reasons.

T89 With respect to any embryo testing programme the centre must ensure that embryo testing is only being carried out for those genetic conditions that are expressly authorised by the Authority.

T91 Centres may use non-invasive procedures, for example metabolomics, to test and select for the viability of embryos. However, centres must not use these procedures to test for specific gene, chromosome or mitochondrion abnormality without prior authorisation from the Authority.

Directions

0008 – Information to be submitted to the HFEA as part of the licensing process

0012 – Retention of records

HFEA Guidance

Staff to be involved in embryo testing

10.1 A senior clinical geneticist should be involved in deciding whether a particular patient should receive treatment involving embryo testing.

10.2 The centre should ensure that a multidisciplinary team is involved in providing the embryo testing service. The team should include reproductive specialists, embryologists, clinical geneticists, genetic counsellors, cytogeneticists and molecular geneticists. It should maintain close contact with the primary care physician or the referring clinician.

10.3 Treatment should include patient support following embryo testing.

Embryo transfer using biopsied embryos

10.4 Embryos from which biopsies have been taken, or resulting from gametes from which biopsies have been taken, should not be transferred with any other (non-biopsied) embryos in the same treatment cycle.

Preimplantation genetic diagnosis for heritable conditions

Interpretation of mandatory requirements 10A

Preimplantation genetic diagnosis (PGD) can be carried out for a heritable condition only in two circumstances:

• where there is a particular risk that the embryo to be tested may have a genetic, mitochondrial or chromosomal abnormality, and the Authority is satisfied that a person with the abnormality will have or develop a serious disability, illness or medical condition, or

• where there is a particular risk that any resulting child will have or develop a gender related serious disability, illness or medical condition. A condition is gender related if the Authority is satisfied that it affects only one sex, or affects one sex significantly more than the other. In the first situation, PGD may be carried out to establish whether the embryo has the suspected abnormality; in the second, PGD may be carried out to establish the sex of the embryo.

An embryo may be tested for PGS and PGD where the requirements for each have been satisfied before testing is carried out. Fulfilling the requirements for PGS does not act as a gateway to carrying out PGD, and vice versa.

10.5 When deciding if it is appropriate to provide PGD in particular cases, the centre should consider the circumstances of those seeking treatment rather than the particular heritable condition.

10.6 The use of PGD should be considered only where there is a significant risk of a serious genetic condition being present in the embryo. When deciding if it is appropriate to provide PGD in particular cases, the seriousness of the condition

in that case should be discussed between the people seeking treatment and the clinical team. The perception of the level of risk for those seeking treatment will also be an important factor for the centre to consider.

10.7 In instances where a patient is undergoing PGD for a heritable condition, a centre may offer PGD for additional condition(s) that do not meet the particular risk requirements but have been deemed, by the Authority, to be of significant risk. Consent should be taken and recorded in patient notes.

10.8 In instances where a patient is undergoing PGD for a heritable condition, a centre may offer preimplantation genetic screening (PGS) at the same time in accordance with guidance note 9. Consent should be taken and recorded in patient notes.

10.9 The centre should consider the following factors when deciding if PGD is appropriate in particular cases:

(a) the views of the people seeking treatment in relation to the condition to be avoided, including their previous reproductive experience
(b) the likely degree of suffering associated with the condition
(c) the availability of effective therapy, now and in the future
(d) the speed of degeneration in progressive disorders
(e) the extent of any intellectual impairment
(f) the social support available, and
(g) the family circumstances of the people seeking treatment.

10.10 Concerns have been raised about the ethical implications of directly testing embryos for a genetic condition without disclosing the test results to the patients (PGD with non-disclosure).

Where patients seek PGD, but do not wish to discover their own genetic status, centres should, where possible, only offer PGD with exclusion testing.

Where patients seek PGD, but do not wish to be informed of any additional genetic information that might occur via sophisticated genetic testing methodologies (eg, segmental aneuploidies), where possible, PGD with exclusion testing should be offered and recorded.

10.11 In exceptional circumstances the centre may offer PGD, but withhold the patient's test results (PGD with non-disclosure). However, this should only be offered under the following conditions:

(a) that patients are given the opportunity to receive genetic counselling on the implications prior to giving consent,
(b) that protocols are established to limit, as far as possible, the risk of unwanted disclosure to the patients. Centres should consider using a different embryology laboratory from their own, in order to minimise the number of centre staff who know the patient's genetic status, and
(c) that no dummy embryo transfers are to be performed.

10.12 The centre should document its reasons for offering PGD with non-disclosure to a patient. This record should include:

(a) written informed consent from the patient to perform PGD with non-disclosure,
(b) a statement from the people seeking treatment confirming that they have been given the opportunity to receive genetic counselling and that they have, prior to giving consent, received information:
  (i) on the risks of inadvertent disclosure,
  (ii) that where all embryos are suitable for transfer this is not evidence of the patient's genetic status,
  (iii) that where no embryos are suitable for transfer this is not evidence of the patient's genetic status,
  (iv) that therefore dummy embryo transfers are not necessary or permissible, and
  (v) that treatment may go ahead which is not medically necessary in cases where the patient (or partner) does not have the genetic condition. This includes information about the potential costs and risks of any medically unnecessary treatments.

Preimplantation genetic diagnosis to establish the identity of gamete providers

Interpretation of mandatory requirements 10B

An embryo may be tested to establish whether it was brought about using the gametes of particular people, where this is uncertain.

Genetic consultation and counselling

10.13 The centre should ensure that people seeking treatment have access to clinical geneticists, genetic counsellors and, where appropriate, infertility counsellors before and after treatment has occurred.

10.14 The centre should work closely with the local genetics team of those seeking treatment.

Information for those seeking preimplantation genetic diagnosis

10.15 The centre should ensure that people seeking PGD are given the appropriate information about the treatment. This should include:

(a) the process, procedures and possible risks involved in IVF and biopsy procedures when providing a sophisticated genetic test.
(b) the experience of the centre in carrying out the procedure.
(c) that sophisticated genetic tests can reveal additional genetic informaiton about an embryo(s) and that the clinical effect of these findings on a child born may not be known.

10.16 The centre should also provide information to those seeking treatment to help them make decisions about their treatment, including:

(a) genetic and clinical information about the condition being tested for
(b) the likely impact of the condition on those affected and their families
(c) information about treatment and social support available, and
(d) information from a relevant patient support group or the testimony of people living with the condition, if those seeking treatment have no direct experience of it themselves.

10.17 If the person seeking treatment has already been given information about the particular genetic disorder, for example from a regional genetics centre, the centre need not provide this information again. However, the centre should ensure that the information has been provided to a satisfactory standard of breadth and clarity.

10.18 Before providing PGD, the centre should ensure that those seeking treatment have had sufficient opportunity to fully consider the possible outcomes of genetic testing and their implications.

Prohibitions in connection with embryo selection

Mandatory requirements

Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

Section 13

(8) Subsections (9) and (10) apply in determining any of the following –

(a) the persons who are to provide gametes for use in pursuance of the licence in a case where consent is required under paragraph 5 of Schedule 3 for the use in question;

(b) the woman from whom an embryo is to be taken for use in pursuance of the licence, in a case where her consent is required under paragraph 7 of Schedule 3 for the use of the embryo;

(c) which of two or more embryos to place in a woman.

(9) Persons or embryos that are known to have a gene, chromosome or mitochondrion abnormality involving a significant risk that a person with the abnormality will have or develop–

(a) a serious physical or mental disability,

(b) a serious illness, or

(c) any other serious medical condition, must not be preferred to those that are not known to have such an abnormality.

(10) Embryos that are known to be of a particular sex and to carry a particular risk, compared with embryos of that sex in general, that any resulting child will have or develop–

(a) a gender-related serious physical or mental disability,

(b) a gender-related serious illness, or

(c) any other gender-related serious medical condition,

must not be preferred to those that are not known to carry such a risk.

(11) For the purposes of subsection (10), a physical or mental disability, illness or other medical condition is gender-related if–

(a) it affects only one sex, or

(b) it affects one sex significantly more than the other.

Schedule 2 – Activities that may be licensed under the 1990 Act

Sex selection

1ZB (1) A licence under paragraph 1 cannot authorise any practice designed to secure that any resulting child will be of one sex rather than the other.

(2) Sub-paragraph (1) does not prevent the authorisation of any testing of embryos that is capable of being authorised under paragraph 1ZA.

(3) Sub-paragraph (1) does not prevent the authorisation of any other practices designed to secure that any resulting child will be of one sex rather than the other in a case where there is a particular risk that a woman will give birth to a child who will have or develop–

(a) a gender-related serious physical or mental disability,

(b) a gender-related serious illness, or

(c) any other gender-related serious medical condition.

(4) For the purposes of sub-paragraph (3), a physical or mental disability, illness or other medical condition is gender-related if the Authority is satisfied that–

(a) it affects only one sex, or

(b) it affects one sex significantly more than the other.

Licence conditions

T86 Embryos that are known to have a gene, chromosome or mitochondrion abnormality involving a significant risk that a person with the abnormality will have or develop:

a. a serious physical or mental disability

b. a serious illness, or

c. any other serious medical condition,

must not be preferred to those that are not known to have such an abnormality.

T87 Embryos that are known to be of a particular sex and are known to carry a particular risk, compared with embryos of that sex in general, that any resulting child will have or develop:

a. a gender-related serious physical or mental disability

b. a gender-related serious illness, or

c. any other gender-related serious medical condition,

must not be preferred to those that are not known to carry such a risk.

T88 With respect to any embryo testing programme involving biopsy the centre must ensure that:

…
b. any information derived from tests on an embryo, or any material removed from it or from the gametes that produced it, is not used to select embryos of a particular sex for social reasons.

Interpretation of mandatory requirements 10C

The law prohibits the selection of an embryo for treatment if it is known to:
a) have a gene, chromosome or mitochondrial abnormality involving a significant risk that the person with the abnormality will develop a serious physical or mental disability, a serious illness, or a serious medical condition, or
b) be of a sex that carries a particular risk that any resulting child will have or develop a gender-related serious physical or mental disability, serious illness, or serious medical condition.

This applies only where there is at least one other embryo suitable for transfer that is not known to have the characteristics. Where there is no other embryo suitable for transfer, an embryo with these characteristics may be transferred.

10.19 The use of an embryo known to have an abnormality as described above should be subject to consideration of the welfare of any resulting child and should normally have approval from a clinical ethics committee.

10.20 If a centre decides that it is appropriate to provide treatment services to a woman using an embryo known to have an abnormality as described above, it should document the reason for the use of that embryo.

NOTE: An example of an embryo not suitable for transfer in this context is one that has no realistic prospect of resulting in a live birth.

See also:
Guidance note 8 – Welfare of the child

Sex selection for social reasons

Interpretation of mandatory requirements 10D

The law requires that the centre should not, for social reasons:
a) select embryos of a particular sex
b) separate sperm samples, or use sperm samples that have been separated, for the purpose of sex selection, or
c) participate in any other practices designed to ensure that a resulting child will be of a particular sex.

Sex selection: sperm sorting for medical reasons

10.21 If sperm is sorted for medical reasons to create (or maximise the chance of creating) embryos of a particular sex for medical reasons, patients should be given information about the process, procedures, possible risks and the experience of the clinic in doing the procedure.

10.22 Due to concerns about the reliability of the technique, sperm that has been sorted for sex selection using gradient methods should not be used for medical reasons.

Preimplantation genetic diagnosis for histocompatibility (tissue typing)

Mandatory requirements
Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

Schedule 2 – Activities that may be licensed under the 1990 Act

Licences for treatment

Embryo testing

1ZA (1) A licence … cannot authorise the testing of an embryo, except for one or more of the following purposes–

…

(d) in a case where a person ("the sibling") who is the child of the persons whose gametes are used to bring about the creation of the embryo (or of either of those persons) suffers from a serious medical condition which could be treated by umbilical cord blood stem cells, bone marrow or other tissue of any resulting child, establishing whether the tissue of any resulting child would be compatible with that of the sibling

…

1ZA (4) In sub-paragraph (1)(d) the reference to "other tissue" of the resulting child does not include a reference to any whole organ of the child.

Interpretation of mandatory requirements 10E

The law requires that the intended recipient of any donated tissue from a child born following tissue typing must:
a) be a sibling of any child born as a result of treatment, and
b) suffer from a serious medical condition that could be treated by umbilical cord blood stem cells, bone marrow or other tissue (excluding whole organs) of any resulting child.

The law also permits tissue typing if the embryo will not, in addition to the histocompatibility test, be tested for a particular genetic or mitochondrial abnormality.

10.23 Where preimplantation tissue typing is to be used with PGD for a heritable condition, the centre should follow the requirements and guidance applicable to a PGD service.

10.24 When deciding whether to use preimplantation tissue typing, the centre should consider the circumstances of each case individually, rather than the fact that the procedure is sought to provide tissue to treat a particular condition.

10.25 When deciding on the appropriateness of preimplantation tissue typing in a particular situation, the centre should consider the condition of the affected child, including:

(a) the degree of suffering associated with their condition
(b) the speed of degeneration in progressive disorders
(c) the extent of any intellectual impairment
(d) their prognosis, considering all treatment options available
(e) the availability of alternative sources of tissue for treating them, now and in the future, and
(f) the availability of effective therapy for them, now and in the future.

10.26 The centre should also consider the possible consequences for any child who may be born as a result, including:

(a) any possible risks associated with embryo biopsy
(b) the likely long-term emotional and psychological implications
(c) whether they are likely to require intrusive surgery as a result of the treatment of the affected child (and whether this is likely to be repeated), and
(d) any complications or predispositions associated with the tissue type to be selected.

10.27 The centre should also consider the family circumstances of the people seeking treatment, including:

(a) their previous reproductive experience
(b) their views and the affected child's views of the condition
(c) the likelihood of a successful outcome, taking into account:
    (i) their reproductive circumstances (ie, the number of embryos likely to be available for testing in each treatment cycle, the number likely to be suitable for transfer, whether carrier embryos may be transferred, and the likely number of cycles)
    (ii) the likely outcome of treatment for the affected child
(d) the consequences of an unsuccessful outcome
(e) the demands of IVF/preimplantation testing treatment on them while caring for an affected child, and
(f) the extent of social support available.

Information for those seeking preimplantation genetic diagnosis for histocompatibility

10.28 Information given to patients considering preimplantation tissue typing should include:

(a) information about the tissue typing tests to be done

(b) an explanation of the latest evidence about any risk associated with the biopsy procedure for any child who may be born
(c) the overall likelihood of a successful outcome for the affected child, including:
  (i) the likelihood of an embryo with appropriate tissue type being available for transfer following the IVF, biopsy and genetic testing
  (ii) the likelihood of a child being born as a result, taking into account the circumstances of the people seeking treatment and their previous reproductive experience
  (iii) the likelihood of tissue from that child providing a successful treatment
  (iv) the limitations of the treatment for the affected child
(d) the likely impact of the proposed procedure on all family members involved, and
(e) information about other sources of treatment, counselling and social support available.

10.29 If information about the disorder affecting the existing child has already been provided, for example by a regional genetics centre or by the clinical team responsible for that child's care, it will not be necessary to provide this information again. However, the centre should:

(a) ensure that this information is satisfactorily broad and clear, and
(b) obtain a statement to that effect from those providing it.

Follow-up arrangements for preimplantation tissue typing

10.30 Centres offering preimplantation tissue typing should be able to demonstrate that they have arrangements for inviting patients and their families to take part in long-term follow-up studies. These should include long-term medical and psychosocial follow-up studies of children born as a result. Centres should strongly encourage patients and their families to participate in such studies.

See also:
Guidance note 5 – Consent to treatment, storage, donation and disclosure of information
HFEA consent forms

Other legislation, professional guidelines and information

Association of Clinical Embryologists – Accreditation Standards and Guidelines for IVF Laboratories

Royal College of Physicians, the Royal College of Pathologists and the British Society for Human Genetics – Consent and confidentiality in clinical generic practice: Guidance on genetic testing and sharing genetic information (A report of the Joint Committee on Medical Genetics)

Association for Clinical Genetic Science – Practice guidelines for targeted next generation sequencing analysis and interpretation

Government initiatives around better regulation

Strategic delivery:	☐ Setting standards	☐ Increasing and informing choice	☒ Demonstrating efficiency economy and value
Details:			
Meeting	Authority		
Agenda item	10		
Paper number	HFEA (20/01/2016) 784		
Meeting date	20 January 2016		
Author	Nick Jones, Director of Compliance and Information		
Output:			
For information or decision?	For information		
Recommendation	The Authority is asked to: • Note and comment on these emerging proposals from Government. • Note the forthcoming consultation on bodies having a duty under the terms of the Enterprise Bill, and that we do not make a case for exemption. • Endorse our proposed approach to fulfilling these duties (when enacted). • Endorse our proposed approach to continue to resist any duty to appoint a Small Business Appeals Champion.		
Resource implications	Opportunity cost		
Implementation date	During 2016–17 business years		
Communication(s)	Clinic Focus and other communication channels		
Organisational risk	☐ Low	☒ Medium	☐ High
Annexes	N/A		

1. Background

1.1. This paper seeks to outline several related aspects further to the Government's emerging regulatory agenda, for information and comment and for agreeing our response.

1.2. Deregulation is a core part of this Government's commitment 'to boost UK productivity, and back British business' and includes a commitment to 'cut a further £10bn of red tape over this Parliament.'

1.3. There has been a notable stepping up of the scale and pace of these initiatives, with the Department for Business, Innovation and Skills working with Government Departments on their obligations and, in turn, their regulators. The initiatives covered within this paper include:

- The Enterprise Bill incorporating the Business Impact Target and reporting duties relating to 'growth' and the Regulators' Code
- Innovation Plans, further to the Government's productivity ambitions;
- Further to the Small Business, Enterprise and Employment Act 2015, expectations on regulators to introduce a Small Business Appeals Champion.
- Burden Reduction Plan

2. The Enterprise Bill

2.1. This is a wide-ranging 'pro-business' Bill: Alongside those parts relating to regulation are other aspects - including the setting up of a small business commissioner to support small businesses (late payments, resolving disputes and so on); strengthening apprenticeships; prompt payments of insurance claims; reforming business rates; and capping exit payments for public sector workers.

2.2. The regulatory parts already apply to Government Departments, further to the Deregulation Act 2015. The Enterprise Bill seeks to extend those obligations to all regulators across government including the HFEA. We are among 70 or so other regulatory bodies caught by these proposals. The Bill itself does not specify which regulators are being brought into scope; that will be set out in secondary legislation following a six-week public consultation, due to start this month. The Government's preference is for 'comprehensive view of coverage'. It includes 50 or so independent regulators including CQC and HTA.

2.3. There are two main requirements. Firstly a reporting duty; and secondly the business impact target (BIT).

Reporting duty

2.4. We will have to produce annual information on how we meet the requirements of the growth duty (how we have regard to the desirability of promoting

economic growth when exercising our regulatory functions). This duty (on Departments) was introduced in the Deregulation Act 2015. We will also have to report on how we have had regard to the Regulators' Code – the principles of better regulation, which we are bound by and on which we report our performance to Authority from time to time.

2.5. The intention in doing so is to promote greater transparency, allowing Government and business to hold regulators to account on how they have performed in relation to these duties and encourage the sharing of best practice between regulators. Key features are:

- We are permitted do so as part of our general reporting, for example annual report.
- We must obtain the views of businesses on the effect the duties have had – for example in the post-inspection questionnaires.
- If we don't do it properly the Minister may require us to provide more information to him/her.

2.6. It is possible this requirement may apply to our performance in this year 2015/16 and be included in the annual report published in 2016 due to the retrospective nature of the Bill.

2.7. We will be required to: Report our performance annually (within the HFEA annual report) as regards the 'growth duty' and the Regulators' Code.

(ii) The business impact target (BIT)

2.8. This is more challenging and for some regulators more problematic. If included in scope the HFEA must provide a *scored* assessment of the economic impact on *private business* of changes we make on our 'in-scope' regulatory policies and practices during a reporting period. The assessment we make must be verified (at a point to be determined) by an independent body the Regulatory Policy Committee. Further, we must provide a summary of out of scope activity within this period.

2.9. Officials in BIS have reassured regulatory bodies that they are not being set a formal deregulation target or that it will impinge on our respective independence; more so the aim being to 'encourage smarter regulation through greater transparency around *business impacts*.'

2.10. The following are likely to be out of scope:

- Public sector regulation – e.g. NHS clinics. In other words, our duty here applies only as to the effect we have on independently owned clinics;
- The fees and charges we levy;
- Measures that are introduced that have less than 12 months' (i.e. temporary) impact;
- Areas of devolved competence.

2.11. The following will also probably be out of scope:

- Casework such as specific investigation and enforcement activity, or individual decisions on licencing;
- Factual information that does not constitute guidance and individual compliance or best practice advice provided by inspectors or suchlike;
- Activity related to regulatory policy development, such as formal and informal consultations, policy reviews, ad hoc information requests; or
- Changes to the organisation and management of the regulator that are not determined in legislation, even where these result in costs to business.

2.12. Everything else is in scope, and could include:

- Changes in regulator costs resulting from some other (not fees policy) policy change - e.g. changes in number of inspections passed on to the business;
- Compliance activity associated with EU legislation;
- Enforcement policies – how investigations and enforcement will be conducted, such as changes to our Compliance & Enforcement policy;
- Changes in our approach to risk-based regulation;
- Anything that constitutes guidance (information for businesses on how to comply with regulations);
- Changes in policy resulting from consultation;
- Routine information requests, say treatment submissions.

2.13. Ministers have determined that the methodology for calculating impacts will be Equivalent Annual Net Cost to Business. They are not minded to set a de minimis level, but agree it should be proportionate. Ministers have not determined when verification of assessment should happen – just after a proposal has been developed; just after a decision to implement has been made; or after implementation of a decision.

2.14. We will be required to: Carry out assessments of the economic impacts to business of any change to our regulatory policies and practices in line with *Business Impact Target* duties and have these subject to scrutiny by the (independent) Regulatory Policy Committee.

3. Innovation plans

3.1. In July 2015 the Government published its Productivity Plan 'Fixing the foundations: Creating a more prosperous nation', and inter alia, stated

"The government will… require departments to work with regulators to publish Innovation Plans by spring 2016. These will set out how legislation and enforcement frameworks could adapt to emerging technologies and disruptive business models."

3.2. We are advised this is to obtain assurance that UK regulatory framework is working effectively to support innovation and disruptive business models – and

that regulators are using innovation to deliver their own work more effectively, and to reduce burdens on business - in the form of innovation plans. It is stated the preparation of plans will also provide the opportunity for identification and sharing of good practice.

3.3. It is suggested that plans include the following:

- How legislation and enforcement frameworks could adapt to new technologies and disruptive business models to encourage growth;
- An assessment of how new technology is likely to shape the sectors being regulated;
- Actions for how regulators could better utilise new technologies to generate efficiency savings and reduce burdens on business.

3.4. We will be required to: Engage with stakeholders and publish an 'innovation plan' by March 2016.

4. Extending the Regulators' Code to include a requirement on regulators to consider small business appeals' process

4.1. The Small Business, Enterprise and Employment Act 2015requires the appointment of an independent Small Business Appeals Champions for each national non-economic regulator – to scrutinise appeals and complaints processes, make recommendations, and report. Departments and regulators would be expected to consider any recommendations to improve processes made, and either implement them or explain, publicly, why they had decided not to do so.

4.2. We have made representations to the Department of Health and BIS officials jointly, explaining how the regulations for representations and appeals of regulatory decisions made by the Authority are set out in the Human Fertilisation and Embryology Act 1990 (as amended). Officials have agreed to seek Ministers views on exempting the HFEA from this measure. We understand that the Government will bring forward further proposals on implementation shortly.

5. Burden reduction plans

5.1. BIS Ministers have asked the Health and Social Care Information Centre (HSCIC), to work with ALBs (including the HFEA) to develop a plan for 2016/17 on our plans to reduce the regulatory 'burden' on licensed centres.

5.2. HSCIC will have oversight of the plans, the content of which will be regularly reviewed, providing the evidence base contributing towards its measure of burden reduction activity

6. Risks and issues

6.1. We see some risks and issues here at several levels. We and others have raised concerns as to the effect such requirements fetter our independence (and ability to enforce requirements robustly). For example, we may face challenge about the extent and scope of a future change to our policy in a particular when dealing with concerns say in a licensed centre about its compliance with regulatory requirements.

6.2. Linked, is concern that a duty to promote growth (which in itself is unexceptionable) undermines the delicate balance that the HFEA has managed to strike, taking into account the interests of science and innovation and society's concerns about the nature and pace of such developments. This is perhaps best exemplified by the careful and sensitive approach taken to the introduction of mitochondrial transfer.

6.3. As NHS services are exempt from such considerations the requirements engender a sort of two-tier consideration. This is problematic at a practical level that in, say, consulting with stakeholders we take a comprehensive approach rather than a stratified one where the NHS and independent sector is approached differentially.

6.4. Finally, there is the not insignificant challenge to our capacity. Additional requirements placed upon us have a cost – and on the basis that there will be no easing of the restrictions placed upon us regrading headcount and operating budget, then there will be an opportunity cost. It is expected that the reporting duty and BIT requirements will be retrospective - to June 2015. We expect to take two or three proposals a year through the Regulatory Policy Committee (such as changes to the compliance and enforcement policy; operationalising of the new EU directives on coding and import) – all further activity to add to our tricky prioritising considerations.

6.5. We have expressed these concerns at official level with colleagues from the Department of Health and BIS. BIS officials are firmly of the view in their arguments that the requirements are simply an extension of good practice; promote transparency; and that there are safeguards and exclusions are in place. They have also been clear in documentation and in person that Ministers have a strong preference for 'comprehensive' coverage.

Our working position

6.6. Taking that into account and considering the prevailing landscape regarding Government's approach to regulation as a whole, the executive has adopted a working position, as follows.

- We welcome and support the need for any regulator to take into account its impact and the need for collaboration with the sector and for transparency - and \we have worked hard at doing so over many years. For example, all Authority meetings are held in public with an audio recording published subsequent to each meeting; we hold three licensed centre's panel and fees' group meetings per year as well as other stakeholder events; we publish clinic focus directed to licensed centres every month; we undertake regulatory impact assessments for major changes to regulatory requirements; we consult formally and informally; we seek views about the impact of inspection at every inspection; we report to the Authority annually on the impact of compliance activity.
- Regarding the growth duty, and obligation to develop innovation plans, we have been held up (on the latter) by BIS as a centre of excellence regarding our work on mitochondrial donation With some additional consultation, and building on the work undertaken at horizon scanning and our Scientific and Clinical Advances Advisory Committee, we can probably discharge our duty here relatively proportionately. That said, our initial innovation plan may be draft as regards meeting the March 2016 deadline.
- Regarding our reporting duty, as stated above, we report our regulatory impact to Authority annually and within that set out (at relatively high-level) our performance in relation to the Regulators' Code. We will continue to do so and publish a summary of this within our Annual Report.
- Compliance with BIT duties will be more challenging. That said, we believe some of our proposals are simply too small to put through bureaucratic hoops. As such we would self-declare these as 'exempt' – report these as such and run a risk of challenge by BIS Ministers or others. We see this as unlikely.
- The Burden Reduction Plan commitments can be wrapped up in our IfQ proposals and to be set out in our Business Plan.
- We have grave concerns about being caught within the Small Business Appeals' Champion. As such, we welcome the commitment from BIS officials to seek an exemption.

7. Recommendation

7.1. The Authority is asked to

- Note and comment on these emerging proposals from Government.
- Note the forthcoming consultation on bodies having a duty under the terms of the Enterprise Bill, and that we do not make a case for exemption.
- Endorse our proposed approach to fulfilling these duties (when enacted).
- Endorse our proposed approach to continue to resist any duty to appoint a Small Business Appeals Champion.