Minutes of Authority meeting 6 July 2016

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

Details:	
Meeting	Authority
Agenda item	2
Paper number	HFEA (14/09/2016) 805
Meeting date	14 September 2016
Author	Charlotte Keen, Information Access and Policy Manager
Output:	
For information or decision?	For decision
Recommendation	Members are asked to confirm the minutes as a true and accurate record of the meeting
Resource implications	
Implementation date	
Communication(s)	
Organisational risk	☐ Low ☐ Medium ☐ High
Annexes	

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

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

Members

There were 9 members at the meeting, 5 lay members and 4 professional members

1. Welcome, apologies and declarations of interest

1.1. The Chair opened the meeting by welcoming Authority members and members of the public to the fourth meeting of 2016. As with previous meetings, it was being audio-recorded and the recording would be made available on the HFEA website to enable interested members of the public who were not able to attend the meeting to listen to the HFEA's deliberations.

1.2. Declarations of interest were made by:

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

2. Minutes of Authority meeting held on 11 May 2016

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

3. Chair's report

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

3.2. On 19 May, the Chair, together with the Chief Executive, attended the HFEA Annual Accountability meeting with the Minister for Health, Jane Ellison, and members of the HFEA's sponsor team.

3.3. On 23 May, the Chair chaired an Appointments Committee to extend the membership of one of the Audit and Governance Committee (AGC) members for a further 15 months.

3.4. On 25 May, the Chair, together with the Chief Executive and the Director of Strategy and Corporate Affairs, met Professor Geeta Nargund, the Medical Director from CREATE Health.

3.5. On 7 June, the Chair and the Chief Executive met representatives from Fertility Fairness to discuss NHS commissioning.

3.6. On 14 June, the Chair, together with another Authority member, attended a seminar at the Department of Health on board effectiveness, to which all Department of Health's arm's length bodies (ALBs) were invited, and on 29 June the Chair and the Chief Executive met with Dr Alan Thornhill, a former Authority member.

4. Chief Executive's report

4.1. The Chief Executive advised members that, on 13 May, he met the Chief Executives of the Human Tissue Authority (HTA) and the Health Research Authority (HRA) to discuss how the three ALBs could work more closely together.

4.2. On 16 May, the Chief Executive, together with the Director of Strategy and Corporate Affairs, met officials from the Scottish Executive, to discuss their plans for a national strategy for gamete donation in Scotland.

4.3. On 8 June, the Chief Executive, the Director of Strategy and Corporate Affairs and another Authority member, met with Professor Con Michaels from the National Health and Medical Research Council (NHMRC), which carries out a similar role to the HFEA for the Australian Government, to discuss mutual interests in the licensing of embryo research.

4.4. On 13 June, the Chief Executive attended the Scientific Clinical Advances and Advisory Committee (SCAAC),the AGC committee meeting on 15 June, and the Infertility Network UK reception at the Houses of Parliament on 27 June.

4.5. The Chief Executive informed members that the triennial review, which had looked at the functions of the organisation and whether those functions were carried out in the most efficient way possible, had not yet been signed off. This was not because of any problems, but rather because the sign-off process was complex.

4.6. The Chief Executive reminded members that, at previous Authority meetings, he had explained that Departments were required to publish innovation plans by spring 2016 and that ALBs were now required to follow suit. The HFEA's draft plan had issued on 26 April and the consultation

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

4.7. The Executive believed that the regulatory scheme in place managed to support innovation in a way which also ensured public confidence; indeed it was evident that regulation in bio-sciences had actually fostered innovation rather than hindered it. It was important to note it was the UK, with its robust regulation, that had led to world firsts like mitochondrial donation and the recent decision to allow genome editing in research. The HFEA's innovation plan set out those achievements.

4.8. The Chief Executive advised members that Sue Gallone, the Director of Finance and Resources for both the HFEA and the HTA, had taken the decision to retire in the autumn. Sue would be greatly missed and members would have the opportunity to say thank you to her at the Authority meeting in September. A recruitment advertisement had been issued for a new shared Director and members would be advised on progress.

4.9. Press Coverage: the Chief Executive summarised press coverage since the last Authority meeting, details of which had been circulated to members. It had been a busy few months, with some important emerging issues.

4.10. M case: the Chief Executive advised members the HFEA had received the Court of Appeal judgement regarding the M case, where a mother and father sought to export their deceased daughter's eggs to the US under Special Directions. The judgement of the Appeal Court did not dispense with the need for informed consent, despite the fact that it upheld the appeal and had remitted the case back to the Statutory Approvals Committee (SAC).

4.11. Samantha Jeffries case: the Chief Executive advised members that there had been some media coverage of a case which was not yet in court, involving Samantha Jeffries who was seeking permission to continue to store embryos made with her and her dead husband's gametes. As this case was on-going, the Chief Executive advised members that it would be inappropriate to go into detail, but the HFEA hoped that a satisfactory conclusion could be reached without a full hearing. The Chief Executive emphasised that the HFEA had made it clear to clinics for some time that they must not align the storage period to which a patient consents with the period for which they had paid for storage.

4.12. Treatment add-ons: the Chief Executive advised members that there had been some reporting in the press on the issue of fertility treatment 'add-ons'. The Chair had given a quote to the Independent saying that the HFEA was concerned about the issue. The Chief Executive advised members that the HFEA would be working on this over the coming months and the new website would be an opportunity to provide clear advice to patients.

4.13. Surrogacy: the Chief Executive informed members that, in June, the President of the Family Court made a declaration of incompatibility under the Human Rights Act 1998 in relation to the Human Fertilisation and Embryology (HFE) Act 1990 (as amended) regarding the prohibition on single fathers applying for a parental order. The Department of Health had not contested the case, having already conceded that the relevant statutory provisions were incompatible. There had been a reasonable amount of press attention, although the HFEA were not directly involved given its limited role in the context of surrogacy.

5. Committee chairs' updates

5.1. In the absence of the Chair of SAC, a member reported that the committee had met on 26 May and 24 June. There had been four preimplantation genetic diagnosis (PGD) applications in May, three of which were approved and one adjourned, pending receipt of further legal advice. At the June meeting, the minutes of which had not yet been published, seven PGD applications and one Special Directions application had been considered.

5.2. The Chair of SCAAC reported that the committee had met on 13 June and had considered the following items:

- A novel process application for embryo selection
- CE marking guidance
- HFEA website content review – treatment 'add-ons'
- Alternative methods to derive embryonic and embryonic-like stem cells.

5.3. The Chair of SCAAC also welcomed Tony Rutherford who had joined the committee as a new member.

5.4. The Deputy Chair of AGC advised members that the committee had met on 15 June, and had received reports on:

- People Strategy and HR Risks (staff survey results), from the Chief Executive
- IfQ risk management, from the Director of Compliance and Information
- The recent work of the Internal and External Audit teams
- Implementation of audit recommendations, from the Finance and Accounting Manager
- Information assurance and security, from the Director of Finance and Resources and the Head of IT
- Strategic risks, from the Project Risk and Performance Manager
- The Annual Report and Accounts, including the Annual Governance Statement, from the Head of Finance
- The AGC forward plan.

5.5. The Deputy Chair of AGC drew members' attention to the AGC annual report, which was produced following the 2015 review of committee effectiveness. The report summarised the committee's work during 2015/16 and the key point to note was that AGC was satisfied with the arrangements the HFEA had in place for risk management and assurance.

5.6. The Deputy Chair of the Licence Committee reported that the committee had met on 20 June and had considered one licence renewal application which was granted.

5.7. The Director of Strategy and Corporate Affairs advised members that the Executive Licensing Panel (ELP) had met four times since the last Authority meeting on 20 May, 6 and 17 June and 1 July. The panel had considered 24 items in total, one of which had been referred to the Licence Committee and the rest of which were approved. There were ten renewal licence applications; six interim inspection reports; two voluntary revocations and six licence variations.

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

6. Strategic performance report

6.1. The Director of Strategy and Corporate Affairs summarised her directorate's delivery against the HFEA strategy, including the day-to-day and business as usual activity as well as the high level work being done to achieve the strategy.

6.2. During the last 12 months, the directorate had handled over 300 media enquiries, issued 18 proactive statements and had nearly 300 references to the HFEA in media outlets across 14 countries. 50 PGD applications had been processed, 88 licences had been issued, 68 Parliamentary Questions answered and 99 Freedom of Information requests handled, all within the appropriate deadlines.

6.3. In terms of communications, the HFEA annual conference attracted 220 delegates, 70 Clinic Focus articles had been issued, 77,000 new words for the website drafted, and the HFEA now attracted almost 3000 Twitter followers, an 800 increase over the last 12 months. 20 stakeholder meetings had been held, representatives of the HFEA had spent over 15 hours at fertility shows and over 2000 public enquiries had been handled.

6.4. In terms of the strategy (setting standards), the Director of Strategy and Corporate Affairs advised members that a call for evidence had recently been issued for the expert scientific panel on mitochondrial donation, chaired by Dr Andy Greenfield. The call for evidence was published on 21 June and was triggered by two pieces of research published, one by the Newcastle research laboratory taking a step forward in the assessment of the new mitochondrial donation techniques. The scientific expert panel was subsequently re-convened, with two new members, to consider these new areas of research. The call for evidence, which would close on 12 July, gave people the opportunity to submit other pieces of research and the panel would meet on 18 and 19 July.

6.5. The Director of Strategy and Corporate Affairs advised members that a significant amount of new information had been drafted for the new HFEA website, including on donation and treatment abroad, which would help prospective patients make an informed choice. Future pieces of work included a new project shortly due to commence on embryo research, a review of the Code of Practice, and a consideration of the extent to which the new Clinic Portal could be used to develop learning tools for clinics.

6.6. The Director of Strategy and Corporate Affairs informed members that, on 5 July, the HFEA had published the link, to clinics only, to the beta version of the new website and CaFC. As mentioned earlier in the meeting, SCAAC had considered information about treatment 'add-ons', which would be available on the website once it had been reviewed, and significant progress had also been made on NHS service provision.

6.7. For the autumn, the Director of Strategy and Corporate Affairs advised members that there would be an information campaign to promote the new information on treatment 'add-ons'. The new

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

6.8. The Director of Strategy and Corporate Affairs advised members that the 2015/16 expenditure for her directorate was within budget, with a 45% saving on annual conference costs.

6.9. The Director of Finance and Resources gave an overview of financial performance and advised members that the 2015/16 accounts were finally laid before Parliament on 4 July and were now available on the HFEA website. In relation to the management accounts and the position in 2016/17, the Director of Finance and Resources advised members that there was one correction in the strategic performance report on page five, where the surplus on income was reported as at the end of April. The figure of £436k quoted was, in fact, the year-end position, and the position as at the end of April was actually a surplus of £57k. The Director of Finance and Resources informed members that the trend of surplus on income had continued, although it was very difficult to forecast whether that would continue for the rest of the financial year, particularly with additional legal costs likely.

6.10. The Director of Finance and Resources advised members that debtor control, a partially automated system, was running smoothly and, as a result, the HFEA did not currently have any debts.

6.11. The Director of Compliance and Information summarised activities within his Directorate. Many staff within the Directorate were heavily involved with work on the IfQ programme. In relation to the inspection and compliance activities, members were advised that the 2015/16 inspection year had been a particularly busy one, with a 40% increase year on year. However, members noted that the average number of working days taken for the whole licensing process, from the day of inspection to the decision being communicated to the clinic, was at its lowest which was testament to the hard work of the team.

6.12. Following a discussion, members noted the latest strategic performance report.

7. Strategic risk register

7.1. The Project Risk and Performance Manager provided members with an overview of the risks, showing the relative risk tolerance positions and residual risk scores. Five of the twelve risks remained high and were deemed above tolerance:

7.2. Legal challenge: a relatively high risk tolerance of 12 was set for this particular risk due to the inevitability of some degree of resource diversion owing to the nature of the HFEA's work. The residual risk was currently at tolerance.

7.3. IfQ – improved information access: the residual risk of 12 was higher than tolerance (set at a medium level of 8) due to approval process delays at the first stage of the programme, and the risk to the quality of the final product that could be delivered if there were any further approval delays encountered.

7.4. IfQ – delivery of promised efficiencies: the residual risk of 12 was higher than tolerance (set at a medium level of 9) with further Government Digital Service (GDS) approval delays potentially adversely affecting the quality and extent of the final product.

7.5. Data – incorrect data being released: although good controls were in place for dealing with PQs and other externally generated requests, volumes could not be controlled, nor the complexity of requests. Recent volumes and complexity had been high. The residual risk of 9 was therefore higher than the tolerance threshold of 8.

7.6. Capability – knowledge and capability: the residual risk of 9 was above the current tolerance level of 6. Staff turnover could lead to fluctuations in overall capability, although the period of highest turnover appeared to be ending, with two posts at Head level having been filled, although there would be a period of bedding in.

7.7. Members noted the latest version of the strategic risk register.

8. Information for Quality: update

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

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

8.2. The Director of Compliance and Information explained that this presentation was to update members on:

- The work in progress in readiness for public beta, and the approval process to proceed to a fully live service
- Data migration and cleansing
- Programme timelines and budget implications.

8.3. Approvals and beta progress: the Director of Compliance and Information reminded members of the several stages that government IT programmes must progress through:

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

8.4. The IfQ programme was required to pass assessments against the 18 GDS standards by the Department of Health. The Director of Compliance and Information advised members that, on 11

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

8.5. The Director of Compliance and Information informed members that the beta version of the new HFEA website had been released to clinics only on 5 July, with the beta version release of the new Clinic Portal imminent. This additional, interim, phase would enable clinic audiences to access the website over a two-week period to view the new content. Following this period, it was expected that the new HFEA website and Clinic Portal would be made available to all in 'public beta' in mid-July for a period of approximately eight to ten weeks. Following public beta, a further full gateway assessment by the Department of Health against the GDS standards would be required. This was scheduled for September 2016.

8.6. Data migration and data cleansing: members were reminded that there was a certain amount of data cleansing that clinics were required to carry out before the data could be migrated to the new Register. The Director of Compliance and Information advised that the Register Information team was currently working with clinics on 'severity one errors'. In total, around 3,500 errors were being reviewed, prior to the data migration to the revised Register. To date, 1,240 errors had been fixed. A well-managed and successful data migration process was central to realising many of the anticipated benefits of the IfQ Programme, and to managing risk, and the AGC, at its meeting in June, had explored the risks in some depth. In recognition of the importance of the data migration process, external suppliers had been engaged to develop a strategy for completing the data migration process appropriately. Members were advised that a procurement exercise was underway to identify a suitable third party, in order to provide assurance that the steps required in the data migration strategy were being completed correctly.

8.7. The Director of Compliance and Information advised that, throughout the entire data migration process, and when the new Register structure was operational, the existing Register database would be retained as a reference. This would ensure that there was no risk that the data migration activity would compromise the actual data held in the current Register structure.

8.8. Timelines and budget implications: the Director of Compliance and Information reminded members that a revised programme plan had been finalised and signed off by the IfQ Programme Board in January 2016, in line with the overall £1.134m agreed by the Authority. On 24 May, the Senior Management Team (SMT) decided to allocate an additional £90k to the overall Programme budget to ensure that critical staff were retained on the team.

8.9. The Director of Strategy and Corporate Affairs provided members with a demonstration of the new HFEA website and CaFC, and the Director of Compliance and Information with a demonstration of the Clinic Portal.

8.10. Following a discussion, Authority members noted:

- The work in progress in readiness for public beta, and the approval process to proceed to a fully live service
- Progress since the last Authority meeting
- Data migration and cleansing
- Programme timelines and budget implications.

9. Inspection ratings

9.1. The Head of Corporate Governance presented this item and advised members that part of the redesigned Choose a Fertility Clinic (CaFC) service would include a new inspection rating, based on the length of the clinic's licence. This simple, evidence-based measure would feature alongside the patient rating and the birth rates, to help patients get an overall picture of the quality of the clinic.

9.2. Each clinic's entry on the new CaFC would include:

- A description of the clinic taken from the inspection report
- An inspection rating out of five stars based on the length of the licence
- A general description of how a rating was generated and a clinic specific explanation if no rating was shown
- The date of the most recent inspection and the date the licence was due to expire
- A link to the full report and licensing minutes.

9.3. The Head of Corporate Governance explained that most clinics held a four-year licence and would therefore have a five star rating. All clinics with four or three ratings were on shorter licences because of concerns about their compliance. A one rating would apply to a clinic which had such a poor record of compliance or engagement from the Person Responsible (PR) that the licensing committee felt unable to grant any licence until such a time that certain non-compliances had been addressed. The Head of Corporate Governance emphasised that this rating was usually short-lived, assuming that the PR was able to demonstrate compliance and be given a proper licence relatively quickly.

9.4. Some clinics would have no rating appear (a 'null rating'). Clinics with a 'null' rating would be those on a two-year initial licence. This was standard practice since a new clinic would not yet be able to demonstrate a history of compliance. Some clinics on Special Directions might also temporarily appear as having a null rating if, for example, an HFEA administrative error had caused their licence to appear to expire before a new one was issued.

9.5. However, the Head of Corporate Governance explained that situations could arise when it was not clear where the fault lay, perhaps because there was a number of contributory factors. In such cases, the Executive recommended case-by-case consideration by the licensing committee as to whether a one rating or a null rating should be shown. As long as the reason for the decision was included in the minutes, no further guidance would be required from the committee.

9.6. The Head of Corporate Governance explained, in respect of interim inspections, the purpose of which was to check regulatory performance during the period of the licence, there had been a suggestion that the HFEA might review the inspection rating after consideration of the interim inspection report, based on whether the clinic's performance had improved or deteriorated. However, the Executive recommended that latest performance should not affect the inspection rating for the following reasons:

- It would advantage some but disadvantage others
- It would break the link between licence length and rating, resulting in confusion and inconsistency

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

9.7. Members were asked to:

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

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

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

10. Opening the Register report

10.1. The Donor Information Manager presented this item and updated members on activity in the Opening the Register (OTR) service over the last year and, in particular, the pilot support and intermediary service.

10.2. The Donor Information Manager reminded members that the HFEA strategy put patients (including donors and donor-conceived people) and the quality of care they received at the centre of its work.

10.3. The Donor Information Manager informed members that there had been a steady rise year-on-year in the number of OTR applications handled by the HFEA, with over double the amount in 2015 compared to 2010.

10.4. In addition, the Donor Information Manager advised members that 99 donor-conceived individuals had joined the Donor Sibling Link (DSL), the HFEA's voluntary contact register, since its launch in 2010. Under this scheme, registrants agreed to the HFEA sharing their name and contact details with any of their donor-conceived genetic siblings who had also joined. The number registering was still small, with 11 per year in 2011 and 2012, but increasing to 21 per year in 2013 and 2014, and 24 in 2015, but registration was likely to grow significantly in the coming years. In 2015, the HFEA had made the first DSL match and there had been two further matches so far in 2016.

10.5. The HFEA had also received 157 applications from anonymous donors (those who donated after 1991 but before 1 April 2005) to remove their anonymity. Over the last four years, there had been a slight increase in re-registering although numbers were low, with only 14 applying in 2015.

10.6. In 2013, the HFEA received its first application for identifying information from an adult donor-conceived individual with an identifiable donor. In total, seven applications of this nature had been received; two per year in 2013, 2104 and 2105, and one so far in 2016. In each case, the HFEA offered and coordinated support and intermediary assistance to the donor-conceived individuals and donors concerned.

10.7. The Donor Information Manager described the HFEA's pilot support and intermediary service. In July 2014, the Authority approved recommendations to work with stakeholders to scope out models for a three-year pilot and explore, at the same time, what specialist support should be provided for other people affected by donation.

10.8. The HFEA had worked closely with stakeholders to develop a service which provided both of these recommendations. Members had asked that the HFEA retained control over the quality of the service provided by PAC-UK, to whom the contract was awarded, and evaluated that service during the course of the pilot. The evaluation of the first year of the service, set out in more detail in the paper, covered the cost of the service, the level of demand and its value to users and the quality of the service provided by the contractor.

10.9. The cost of the service: the Donor Information Manager advised members that the Authority had set aside a capped budget of £50,000 for the duration of the pilot. Current indications were that this amount would be more than sufficient.

10.10. The level of demand: members were informed that in the first year a total of just seven cases had been referred. Looking ahead, it was difficult to assess the level of demand for the service in the next two years, but given the demand so far it was not expected to be high.

10.11. The quality of service: the Donor Information Manager informed members that all service users were invited to complete a feedback form which was then sent to both PAC-UK and the HFEA. Although the HFEA had not received any feedback forms thus far, informal feedback received had been positive. There had inevitably been a few teething problems, although the quality of the relationship between the HFEA and PAC-UK had improved significantly in recent months.

10.12. As part of the OTR process, applicants were supplied with a link to an online confidential feedback questionnaire. The Donor Information Manager provided members with a summary of those survey responses.

- The majority of respondents discovered they could apply for information from the HFEA register through the HFEA website
- Less than a quarter of respondents said they had spoken to someone at the HFEA before applying, although 100% of those who had rated this experience as helpful or very helpful.
- Expectations among respondents varied in terms of the amount of information they received. 73% considered it adequate, 9% did not have any expectations, 9% expected to receive more information and 9% expected to receive less information.

10.13. The survey also gave respondents the opportunity to add any further comments they had on the information they had received or the process itself, and the majority stated that they had found the process straightforward, efficient and speedy, and were grateful for both the existence of the OTR service and the high level of service received.

10.14. Following a discussion, members noted:

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

11. Multiple births progress

11.1. The Head of Regulatory Policy reminded members that in 2009 the HFEA, together with professional bodies and stakeholder groups, introduced a multiple births policy with the aim to reduce multiple birth rates by promoting elective single embryo transfer (eSET). Central to that policy was the introduction of a series of targets, starting in 2009 with the maximum multiple births rate of 24% for clinics, with the intention to reduce this in steps over a series of years to 10%, which was the current target.

11.2. In 2011, the HFEA published a multiple births data report, based on the 18 months of data available at the time. This showed there had been an initial growth in eSET, a growth in blastocyst transfers and a corresponding decline in multiple pregnancy rates in that short period of time. Since then the Executive had provided annual updates to Authority members, and also provided updates to the Multiple Births Stakeholder Group.

11.3. In 2008, one in four IVF births was a multiple birth, whilst currenlty it was about one in seven. In 2008, the vast majority of patients received a double embryo transfer. However, now, elective single embryo transfer (eSET) was more common. This had drastically reduced multiple births, which continued to decrease although progress had been slower in the last few years.

11.4. The Head of Regulatory Policy advised members that the multiple births policy was very much an outcomes based policy, with the aim to reduce multiple births whilst maintaining pregnancy rates. Overall trends were positive, with pregnancies going up and multiple pregnancies going down, although, as mentioned above, progress had plateaued for the last couple of years. The steady increase in pregnancy rates reflected the increasing use of transferring embryos at blastocyst stage (embryos which had been cultured for a longer period (five to six days) in the laboratory) which generally improved the pregnancy rate. Strikingly, where two blastocysts were put back at one time, the multiple pregnancy rate was high at 35% and 40% at the youngest age group.

11.5. The Head of Regulatory Policy provided an overview of the pregnancy and multiple births rate for those having eSET and those having double embryo transfer. Based on the latest available data (as yet unverified) 37% of double embryo transfers resulted in a pregnancy, but with a multiple pregnancy rate of 30%. However, 43% of pregnancies following eSET resulted in only 2% of multiple births.

11.6. The Head of Regulatory Policy provided a summary of national performance on a clinic by clinic basis, which gave an indication of how well individual clinics were doing in meeting the 10% target rate. This was part of a series of tools used by the HFEA as early warnings for clinics who were unlikely to meet the 10% target or had a sudden spike in multiple births. Inspectors would then

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

11.7. The Head of Regulatory Policy advised members that it was clear clinics were finding it harder to meet the 10% target, with the average being around 14%. It was therefore important to consider how the HFEA could keep up the momentum, a key point raised at the last multiple births stakeholder group meeting. The One at a Time website would soon be embedded into the new HFEA website and the Clinic Portal, which would be an opportunity for the HFEA to continue to promote eSET and the risk of multiple births. After discussions with stakeholders, the headline success rate would be changing to show birth rate as per embryo transferred, as it was felt this was the best indicator of the competence of clinics and sent the right signals to patients about what really mattered when choosing a clinic.

11.8. The Head of Regulatory Policy emphasised that the multiple births rate policy was a good news story for the role of regulation and for public health more generally. Fundamentally, more women were getting pregnant, having healthy pregnancies and babies, and less were going through the increased worry and risk of a multiple birth.

11.9. Following a discussion, members noted the information given in the multiple births report. They supported the proposed steps to reinvigorate the multiple births policy. They also suggested, beyond written information, developing a patient video on this issue.

12. Publication policy

12.1. The Chief Executive advised members that all public bodies were required to operate in an open and transparent way with a key element of this being to publish information in a clear, accessible and easy to find way. The HFEA's publication policy had been in force since 2009, principally covering the publication of Authority and committee papers. This policy had been updated and broadened to include how the HFEA would publish all information on the new website and how information would be disclosed which would not normally be published.

12.2. The Chief Executive informed members that there was an ongoing issue in relation to the amount of supporting information published for licensing decisions. At present, the inspection report and the Licence Committee minutes were routinely published. However, on occasion, with very highly publicised licensing decisions, there had been a call to publish more of the papers presented to the Licence Committee. The Chief Executive advised members that, given the forthcoming project to review the end-to-end process for research licensing, it would be sensible to maintain the status quo regarding the publication of supporting information and lay summaries of research applications. These issues would then be considered as part of that review and by the Authority later in the business year.

12.3. The Chief Executive asked members to email any comments on the revised publication policy and they would be taken into consideration.

13. Any other business

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

14. Chair's signature

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

Signature

Chair

Date