

Authority paper

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

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

Members

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

Members present

Sally Cheshire (Chair)
Dr Susan Price
Professor David Archard
Dr Andy Greenfield

Anthony Rutherford
Dr Alan Thornhill
Kate Brian

Margaret Gilmore
Yacoub Khalaf
Anita Bharucha

Apologies

Bishop Lee Rayfield
Rebekah Dundas

Observers

Ted Webb (DH)
Steve Pugh (DH)

Staff in attendance

Peter Thompson
Nick Jones
Juliet Tizzard
Sue Gallone

Catherine Drennan
Hannah Verdin
Joanne Anton

Siobhain Kelly
Anjeli Kara
Charlotte Keen

1. Welcome, apologies and declaration of interests

- 1.1. The Chair opened the meeting by welcoming Authority members, in particular Margaret Gilmore, Yacoub Khalaf and Anita Bharucha who were attending their first Authority meeting as members. The Chair also welcomed members of the public, including attendees from Scotland and New Zealand.
- 1.2. As with previous meetings, it was being audio-recorded and the recording would be made available on the HFEA website to enable interested members of the public who were not able to attend the meeting to listen to the HFEA's deliberations. This was part of the HFEA's drive to increase transparency about how the Authority goes about its business.
- 1.1. Apologies were received from Bishop Lee Rayfield and Rebekah Dundas.
- 1.2. Declarations of interest were made by:
 - Anthony Rutherford (Consultant in Reproductive Medicine and Gynaecological Surgery at a licensed centre)
 - Kate Brian (Regional organiser for London and the South East for Infertility Network UK)
 - Yacoub Khalaf (Person Responsible at a licensed centre)
 - Dr Alan Thornhill (for item 10 only)

2. Minutes of Authority meeting held on 11 March 2015

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

3. Chair's report

- 3.1. The Chair informed members that, since the last Authority meeting, she had attended a range of events with organisations in the IVF sector and the wider health and care system, although fewer events than usual due to the period of purdah before the general election.
- 3.2. On 17 March, the HFEA held their second Annual Conference, which was a great success, and the Chair expressed her thanks to everyone who took time to attend the event, with a special thank you to all the speakers and the HFEA staff who helped put the conference together.
- 3.3. The Chair, together with the Chief Executive, the Directors and the Chief Inspector, had indicated an interest in visiting clinics outside of the regular inspection schedule in order to hear what clinics felt about their performance and where they thought improvement was needed. These visits would then enable the HFEA, as the regulator, to consider how to help improve the quality of care. The Chair and the Chief Inspector had already visited St Mary's in Manchester and visits to Leeds and Guy's and St Thomas' were scheduled, with others to follow.
- 3.4. Looking ahead, the Chair advised members that she had been invited to speak at the Northern Fertility Nurses Conference in Leeds on 29 May.
- 3.5. Finally, the Chair advised members that she, together with the Chief Executive, had their annual accountability meeting with the Department of Health on 27 May to review the HFEA's performance over the 2014/15 business year and to identify key priorities for 2015/16.

4. Chief Executive's report

- 4.1. The Chief Executive advised members that he had attended the Audit and Governance Committee (AGC) on 18 March and would also be attending AGC in June for the end year accounts and annual governance statement sign-off.
- 4.2. On 20 April, the Chief Executive met the CEO of the Health and Social Care Information Centre (HSCIC) to discuss ways in which the HFEA and the HSCIC could work more closely together.
- 4.3. The Chief Executive advised members that the Welsh Language Commissioner had written to inform him of the intention to carry out a standards investigation. The investigation would determine whether, as an organisation which provides services in Wales, the HFEA should have to comply with the Welsh language commission standards. The investigation would begin on 25 May and last for 12 weeks. If the HFEA was required to do more following that investigation, this would be expected in March 2016. The Chief Executive advised members that he would keep them informed of developments.
- 4.4. Press Coverage: the Chief Executive summarised press coverage since the last Authority meeting, details of which had been circulated to members. He emphasised that purdah not only impacted on the amount of public work which could be carried out, but also on the extent to which the organisation could be as active in commenting on stories during that period. However, there were two stories which had cut through the election coverage and made the headlines.
- 4.5. CRISPR (Clustered Regularly Interspaced Short Palindromic Repeats): there had been considerable coverage of research in China on "genome-editing", where the Crispr technique had been used for the first time on human embryos. In terms of treatment possibilities, this technique was illegal in the UK, although it was legal in research, of which there was none at present.
- 4.6. The HFEA had received a number of press enquiries on this topic, although purdah had prevented the Executive from commenting in detail. Professor Robin Lovell-Badge had, however, spoken on the Today programme on Radio 4 and had provided a balanced account of the possibilities and potential problems with the treatment. He had advised that he could see its value in research but was less convinced as to any advantage it might offer over established procedures such as preimplantation genetic diagnosis (PGD) in treatment. Professor Lovell-Badge had also spoken very highly of the HFEA and the regulatory regime in the UK.
- 4.7. Another issue involving the HFEA during this period was a judicial review in the High Court of a decision taken by the HFEA's Statutory Approvals Committee (SAC) about the export of gametes to the USA. There were strict reporting restrictions around the case. However the judge would reach a verdict shortly.
- 4.8. Finally, the Chief Executive advised members that the HFEA's Director of Strategy and Corporate Affairs, together with an Authority member, had recently participated in a Progress Educational Trust (PET) debate on the HFEA's plans to introduce a patient feedback mechanism on the HFEA website. The British Medical Journal (BMJ) was planning to publish a piece on the debate in mid-May.

5. Strategic performance report

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

- 5.2. For the 2014/15 financial year, the Director of Finance and Resources advised members that there was a deficit of £186k in the management accounts which reflected the reduction in treatment fee income and unplanned expenses in relation to legal advice.
- 5.3. The Director of Finance and Resources advised members that the 2014/15 financial accounts were currently being audited and the following was therefore a pre-audit summary.
- 5.4. Before receiving the £920k grant-in-aid (GIA) from the Department of Health, the deficit in the financial accounts was £1,644k after year-end adjustments. With GIA the shortfall was £724k. However, the planned spend on IfQ from reserves (£565k) had to be taken into account and the true shortfall in the accounts was therefore £159k, as expected. The total reserves were therefore reduced to £2,590k.
- 5.5. In terms of signing off the annual report and accounts, the Director of Finance and Resources advised members that the report had been scaled down to the statutory requirements, primarily consisting of the strategic report, Directors' report, the remuneration report and the annual governance statement. The new report was based on an in-house style review which had helped to streamline the process. There was also far less information about Authority and Committee members within the annual report, although the full information which would continue to be available on the HFEA website.
- 5.6. The Director of Finance and Resources advised members that the annual report and accounts would be presented to the AGC on 10 June. The full document would then be circulated to Authority members for clearance, by exception, by 15 June. The annual report and accounts would then be signed off and laid before Parliament by the National Audit Office by the end of June.
- 5.7. The Director of Finance and Resources advised members that, for the 2015/16 financial year, budgets had been set with the assumption of a similar level of treatment fee income to the 2014/15 financial year. The GIA revenue had been confirmed by the Department of Health, with the same level of administrative GIA as for 2014/15, along with a small amount of programme GIA which would help offset the discount offered for elective single embryo transfer (eSET). The Director of Finance and Resources advised members that she was still awaiting confirmation for a small amount of capital funding for a refresh of the HFEA's IT equipment. The budget was very tight for the coming year, with some uncertainties around legal costs and future accommodation costs. There are spare reserves of just over £1m, allocated primarily to the IfQ programme.
- 5.8. The Director of Finance and Resources provided an overview to members on how the HFEA was delivering in relation to the 'efficiency, economy and value for money' part of the strategy. This part of the strategy consisted of two main streams:
 - The reduced effort and costs for centres being regulated, and
 - Keeping costs to a minimum and increasing value.
- 5.9. The Director of Finance and Resources reminded members that the objective was "ensuring the HFEA remains demonstrably good value for the public, sector and Government by ensuring we are easy to deal with and that we offer a professional and cost-effective service in all that we do."
- 5.10. The component parts of this, listed below, were set out in the strategy:

- Prioritising efforts and the application of resources in accordance with the strategy
 - Continuing to engage with clinics on fees
 - Ensuring the HFEA's governance tools underpinning decisions were in place
 - Facilitating access to information and fulfilling Government requests
 - Sharing with other organisations
 - Internally provided services running smoothly.
- 5.11. The HFEA was delivering this part of the strategy so far through the following actions:
- Engagement and accountability through the Fees group, with two meetings held so far
 - No increase in fee levels paid by clinics since 2006
 - Cost control (2014/15 performance and 2015/16 budgets)
 - Benefits, and challenges, of shared finance resources
 - Efficiencies through co-location with the CQC
 - Efficient facilities services largely led through the CQC
 - Planning for the future move of offices, making best use of the Crown Estate
 - Professional relationships with the Department of Health and auditors
 - An effective Audit and Governance Committee (AGC).
- 5.12. The Director of Finance and Resources also reminded members of the other aspects of efficiency, economy and value, which were:
- Meeting legal and Parliamentary requirements
 - Delivery of the people strategy
 - Regulatory efficiency
 - Evidence based decision making
 - The IfQ programme.
- 5.13. The Director of Finance and Resources concluded that, at this stage, the HFEA was on course to deliver the strategy, although there were inevitable challenges which had been reflected in the strategic risks. The Director of Finance and Resources emphasised, however, that the HFEA was fully equipped to deliver and meet those challenges.
- 5.14. The Director of Strategy and Corporate Affairs updated members on the feedback from the HFEA Annual Conference on 17 March. The conference had been an opportunity to educate and train sector staff on a number of issues, as well as demonstrate how the HFEA had been delivering its strategy over the past year. Members noted a high proportion of the audience were attending an HFEA conference for the first time and tended to be more junior clinic staff. The conference had also attracted a larger audience than before with well over 200 in attendance.
- 5.15. The Director of Strategy and Corporate Affairs informed members that the HFEA would shortly select suppliers to carry out the design and development work

around the new website and other systems. The Executive was also giving further consideration to how the patient feedback section of the website could be presented in a way that was meaningful and representative but equally engaging and encouraging. The Director of Strategy and Corporate Affairs advised members that she would provide them with an update at their July meeting.

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

6. Committee Chairs' update

- 6.1. The Chair of the Statutory Approvals Committee (SAC) reported that the committee had met on 26 March and 30 April. There had been three PGD applications and three Special Directions in March to consider, all of which were approved. There had been seven PGD applications and one Special Direction at the meeting in April, all of which were approved.
- 6.2. The Chair of the Licence Committee advised members that the committee had met on 12 March, 20 April and 7 May. On 12 March, the committee considered two initial treatment and storage licences, one of which was granted and one adjourned. The committee also considered a renewal for a treatment and storage licence (granted), a change of a Person Responsible (approved), a Grade A incident report and a number of other reports which the committee noted. At the meeting in April, the committee considered an initial research application which was granted and in May, the minutes of which had not yet been published, the committee considered two research licence renewals, an executive update and an update on the Grade A incident initially reported at the March meeting.
- 6.3. In the absence of the Chair of AGC, the Director of Finance and Resources advised members that the committee had met on 18 March and had received reports on:
- Risks and shared finance resources
 - Financial policies (including the updated counter-fraud policy)
 - An IfQ update from the Director of Compliance and Information
 - The strategic risk register from the Head of Business Planning
 - Interim feedback from the National Audit Office
 - A progress report from DH Internal Audit
 - The annual report and accounts.
- 6.4. The Scientific and Clinical Advances Advisory Committee (SCAAC) met outside the normal committee schedule on 1 April to consider new technologies for embryo testing.
- 6.5. A member requested that, for future Authority meetings, updates from the Executive Licensing Panel (ELP) be included in the committee updates item. The Chair explained that ELP was an internal committee at the HFEA which dealt with the less controversial and less novel aspects of licensing that were not required to go to a formal Licence Committee. The Chair of ELP agreed to provide a report on the committee's business as part of the committee update agenda item from the next Authority meeting onwards.

7. Information for quality: update and data dictionary

- 7.1. The Director of Compliance and Information explained that the IfQ programme was a comprehensive review of the information that the HFEA held, the systems that governed the submission of data, the uses to which it was put and the way in which the information was published.
- 7.2. The Director of Compliance and Information explained that IfQ was a critical component of the HFEA's strategy and encompassed:
- The redesign of the HFEA's website and Choose a Fertility Clinic (CaFC)
 - The redesign of the 'Clinic Portal' and combining it with data submission functionality that was currently provided in the HFEA's separate Electronic Data Interchange (EDI) system
 - A revised dataset and data dictionary approved by the Standardisation Committee for Care Information (SCCI)
 - A revised Register to include the migration of historical data contained within the existing Register
 - The redesign of the HFEA's internal IT systems.
- 7.3. The Director of Compliance and Information reminded members that, in order to proceed with the programme, approval had been required by both the Department of Health and the Government Digital Service. As reported at the last Authority meeting, there had been a delay in the approval process, and this inevitably had resulted in some financial and implementation consequences in terms of expenditure in the next financial year and the time-line of the programme. However the business case, which had originally been submitted on 18 December 2014, was approved on 28 April 2015 for both the infrastructure and the public facing digital aspects of the programme. However, the digital approval was conditional in nature in the sense that proceeding to implementation would require the HFEA to seek further approval. At the point of the first stage – 'alpha' production – an assessment would be made by the Department of Health who in turn would have to satisfy the Government Digital Service standards.
- 7.4. The Director of Compliance and Information advised members that this process could potentially introduce substantial financial risk if there were any further delays. However, steps had been taken with the Department of Health and the Government Digital Service to clarify and confirm respective roles and accountability in order to minimise negative impacts.
- 7.5. The Director of Compliance and Information advised members that the Executive had spent considerable time thinking about risks, risk assurance and managing any identified risks, including the following activities:
- Continued DH Internal Audit engagement
 - The IfQ programme risks had been integrated into the organisational risk framework and were monitored carefully
 - A Government Gateway Review – part of the Office for Government Commerce approach relating to major projects – was commissioned in 2014:
 - The findings were reported to the HFEA on 1 April and were broadly positive
 - The programme was awarded an amber rating

- Key issues identified included the impact of the programme on the organisation as it moved from technological change to organisational change.
- 7.6. The Director of Compliance and Information advised members that, although there was a strong internal technical team working on the programme, it had always been recognised that external supplier involvement was vital to the programme's success. A procurement exercise had therefore been carried out and overseen by the Crown Commercial Service. The closing date for tenders was 6 May 2015 with an encouraging volume of interest from external suppliers.
- 7.7. Work on the data dictionary was also progressing with meetings held with professional groups and discussions with researchers. There had been positive preparation for migrating data to a new register system, a key risk being diligently managed within the programme, and until all milestones had been met no migration would take place.
- 7.8. Following a discussion, Authority members noted:
- The approval received for the IT elements of the IfQ Programme by the Department of Health and the conditional approval received from the Government Digital Service in April 2015
 - The procurement process had commenced with a tender return date of 6 May 2015
 - The broadly positive report of the Government Gateway review
 - Progress as regards the collection of data relating to specific research-related aspects of assisted reproduction treatment and progress relating to the migration of historic data to the new Register.

8. Equality Act update

- 8.1. The Authority and Committee Business Manager provided members with a brief overview of the Equality Act 2010. The Act came into force in 2010 and the purpose was to consolidate and extend previous anti-discrimination legislation. The Act established nine 'protected characteristics' and prohibited certain kinds of conduct in respect of people having these characteristics.
- 8.2. The HFEA was not a named 'public authority' for the purposes of the Act and was not therefore subject to the specific duties (publishing equality information and setting equality objectives). The Equality and Human Rights Commission guidance states that implementation of the Equality Act should be appropriate to the size of the organisation and its functions.
- 8.3. The Act, however, does set out a general public sector equality duty (PSED) and the HFEA was subject to this general duty. The general duty came into force in April 2011 and required public bodies to have due regard to the need to:
- Eliminate discrimination, harassment and victimisation
 - Advance equality of opportunity between people from different groups
 - Foster good relations between people from different groups.
- 8.4. The Authority and Committee Business Manager advised members that, following the change of government in 2010, the coalition had launched the 'Red Tape Challenge', the aim of which was to reduce regulations on organisations and companies and equalities was a theme of this piece of work.

- 8.5. As a result of this, a PSED review was carried out to establish if it was operating as intended. The review was announced in May 2012 and promised to assess the effectiveness of the PSED specific duties and be extended to include the general duties. The report of the steering group was published in September 2013. The report made it clear that the Equality and Human Rights Commission (EHRC) needed to provide better guidance for public bodies on how to comply with the Equality Act. The report, whilst acknowledging the importance of the Act and the good work shown by organisations in adhering to the duty, stated that public bodies needed to take a proportionate approach to compliance and not seek to 'gold plate'. The report also specified that regulators had an important role to play in implementation and the principles of the PSED should be embedded in core functions. It was agreed that there should be a full evaluation of the PSED in 2016 when the general duty had been in force for five years.
- 8.6. In line with the recommendations from the PSED review, pressure on resources and in adherence with the strategic aim of the HFEA, the 2015 update had been approached as a 'health check' on where the Authority was now in terms of its requirements under the Act. The Authority and Committee Business Manager advised members that the HFEA currently maintained a good level of compliance and in some areas had made improvements. The table at Annex A of the paper showed the standing at the last review, which had been carried out in 2010, a review of progress in 2015 and an updated risk rating. In addition to the specific actions identified, members were advised that the IfQ programme would provide further benefits with accessibility being at the heart of the website development.
- 8.7. The Authority and Committee Business Manager recommended to members that a full review was carried out following the outcome of the government review in 2016. However, since the HFEA's Equality Champion had stepped down, having come to the end of her term, the Authority should now appoint a new board level Equality Champion.

Decision

- 8.8. Following a discussion, Authority members:
- Noted the progress set out in Annex A of the paper and supported the actions set out in Annex B
 - Agreed to a full review and report back to the Authority in 2017 following the outcome of the government review in 2016
 - Agreed to the appointment of a new Board Level Equality Champion.
- 8.9. The Chair confirmed that Kate Brian had agreed to take on the role of the HFEA's Equality Champion.

9. Draft licensing process and guidance for regulating mitochondrial donation

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

would reflect, and take into account, the extensive work carried out over the past four years, including:

- A public dialogue exercise which explored the ethical aspects and practical implications of allowing such techniques within regulation
 - Three reviews on the safety and efficacy of methods to avoid mitochondrial disease.
- 9.2. The Policy Manager advised members it was important to note that, although the treatments themselves were novel, there were already existing regulatory frameworks within which the HFEA could operate.
- 9.3. **Safety and efficacy:** the Policy Manager reminded members that the scientific expert panel concluded there had been no evidence to date to suggest that the new mitochondrial donation techniques were unsafe. The expert panel did, however, recommend that further safety and efficacy tests should take place before treatment was offered and it was expected that such research would support the conclusions the panel had reached so far.
- 9.4. Three of these further tests were deemed by the panel to be essential before MST or PNT were used in treatment. Before the first clinical application of MST or PNT was considered, it was therefore appropriate, and expected by Parliament and stakeholders, that a further assessment would be made on the outcomes of the three tests. On present plans, once the Authority had been made aware that these tests had been completed, it would convene an expert panel to make that assessment and the panel's report would then be presented to the Authority.
- 9.5. **Licensing and authorisation:** the Policy Manager advised members that, in terms of licensing and authorisation, the Regulations envisaged a two stage process.
- 9.6. Stage one would cover the licensing of the clinic to undertake mitochondrial donation and would include the following steps:
- The clinic applying to vary its existing treatment licence
 - The Inspectorate assessing the competence of the clinic and the suitability of its premises
 - The Licence Committee considering the application and (if successful) varying the clinic's licence to perform PNT and/or MST.
- 9.7. Stage two would involve the authorisation to undertake the treatment on a case-by-case basis. This would include the following steps:
- The clinic would submit a patient application form
 - The Statutory Approvals Committee (SAC) would assess the application on the basis of:
 - The particular risk of that patient passing on mitochondrial disease
 - The significance of the risk to a patient's child, and
 - The seriousness of the resulting disease.
- 9.8. The Policy Manager advised members that the paper set out a list of key questions that the HFEA proposed asking in the case-by-case application form. The questions were based on what was required by the Regulations, the current understanding of the biology involved, and careful scrutiny of the expert panel's scientific reviews. The Executive had also worked with members who had

genetics expertise and would be seeking further views from relevant stakeholders.

- 9.9. **Regulatory framework:** the Policy Manager advised members that the Executive had reviewed the Code of Practice, the various reports on public attitude, safety and efficacy and regulatory considerations in order to identify areas where guidance or requirements pertaining to mitochondrial donation would need to be added or amended. The main policy issues would include :
- Clinic staff expertise, skills and experience to ensure that the staff involved had sufficient competence in the embryological techniques
 - Ensuring the appropriate equipment and environment were in place
 - Mitochondrial donor screening and selecting mitochondrial donors
 - Donor compensation and the ten family limit
 - Follow-up study requirements
 - Consent and information provision.
- 9.10. **Register information:** the Policy Manager advised members that the paper set out the information the HFEA was required to collect for mitochondrial donation treatments. Clinics wishing to carry out mitochondrial donation would need to submit information to the HFEA about:
- The mitochondrial donor
 - The patient being treated
 - The sperm provider(s), and
 - Treatment details, including:
 - The date
 - How many embryos were created
 - Which techniques were used
 - The fate of any embryos created
 - The outcome where embryos were transferred.
- 9.11. The Policy Manager advised members that, throughout June 2015, the Executive would seek focused stakeholder feedback on key areas to ensure that the HFEA had gathered the relevant expertise. The proposed questions set out in the paper concentrated mainly on the technical and operational issues.
- 9.12. The Policy Manager provided members with a summary of next steps. As mentioned, in June 2015 the Executive would be seeking stakeholder views. A further update would be presented to the Authority at its meeting in July 2015 with an Authority decision in September 2015 for the Regulations to be ready to come into force on 29 October 2015.
- 9.13. **Discussion points:** it was important to emphasise the provisional nature of the discussion, that it did not represent a settled policy decision and was very much a work in progress.
- 9.14. **Safety and efficacy:** members agreed with the approach set out in the paper and noted that it was not yet clear when the results of the further tests would be available. The Chief Executive pointed out that the HFEA had delegated the assessment of safety and efficacy to an expert panel, given the highly technical nature of the work. If the panel was of the view that, once the tests had taken place, that both MST and PNT techniques were safe and effective, that would be

the most practical way of proceeding and the HFEA would be guided by the panel's expertise.

- 9.15. **Licensing and authorisation:** the Chair of SAC emphasised that it was important to note that PGD was very different to mitochondrial donation in terms of the understanding of 'significant risk' and that mitochondrial donation would be dealt with on a case-by-case basis whereas PGD was a condition-by-condition basis. It would therefore present challenges in terms of authorising and licensing mitochondrial donation. It would be important to consider further what kind of evidence the committee received and how that evidence would be interpreted. The committee would have to adopt a holistic approach. The Chair of SAC suggested that, since it was only a short time until October when the Regulations would come into force, it was very important to prepare both in terms of keeping clinics informed about what they would have to do to present their applications and also ensuring SAC members were equipped to consider applications. It would therefore be helpful to have exercises for committee members to engage in before November in order to allow them to be fully prepared.
- 9.16. Members noted that the Regulations required the Authority to license mitochondrial replacement on a case-by-case basis and agreed in principle the two stage approach of licensing and authorisation.
- 9.17. **Regulatory framework:** a member emphasised that staff competencies and skills should encompass not just the medical competencies but also counselling competencies. In relation to donor information and screening, the Head of Regulatory Policy advised members that the age limit of the mitochondrial donor was an area the Executive wanted to seek expert views on in June.
- 9.18. Members noted that, in relation to follow-up studies, this aspect of the process was not covered in the Regulations, and the Chair advised members that this was something which required careful consideration. The Chief Executive emphasised that, although follow-up studies were a good idea, it would clearly be unethical to require any follow-up.

Decision

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

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

- 10.1. The Regulatory Policy Manager provided members with a background to embryo testing technologies. Preimplantation genetic diagnosis (PGD) and preimplantation genetic screening (PGS) had been available for many years. Technologies used in PGD were used to identify embryos at risk of being affected by an inherited genetic or chromosomal condition. PGS was used to screen embryos for common chromosomal abnormalities that could cause miscarriage or IVF failure.
- 10.2. The Regulatory Policy Manager advised members that, in recent years, significant advances had occurred in embryo testing technologies. The latest developments meant that it was now possible to simultaneously screen embryos

- under PGD and PGS at the same time. New technologies had also presented the ability to generate additional genetic information about conditions/abnormalities not being specifically tested for.
- 10.3. The Regulatory Policy Manager informed members that the Executive had sight of the advances in embryo testing technologies through the HFEA's annual horizon scanning process and they had been discussed by both the Scientific and Clinical Advances Advisory Committee (SCAAC) and the Ethics and Standards Committee (ESC). ESC, at its meeting in June 2014, had recommended that the Executive seek both legal advice and the views of key stakeholders. The Executive had discussed the issues with stakeholders at its annual embryo testing workshop in December 2014 and through correspondence with a number of professional bodies.
 - 10.4. The Regulatory Policy Manager advised members that the latest developments in embryo testing technologies now gave rise to two potential scenarios:
 - That patients may wish to have both PGS and PGD at the same time
 - That patients may wish to use PGD to test for more than one genetic condition at a time.
 - 10.5. The Regulatory Policy Manager advised members that this, in turn, gave rise to the following questions:
 - If a patient satisfied the criteria for PGS, could PGD also be carried out at the same time using the same embryo biopsy sample and vice versa?
 - If a patient satisfied the criteria for PGD for testing one condition, could PGD for another condition also be carried out and would those additional conditions need to meet any other criteria?
 - 10.6. Both legal advice and stakeholder views supported the use of these technologies in practice and the idea of testing for more than one disease at a time. If Authority members were minded to allow testing for more than one disease at a time, they would need to consider how the information generated by the tests would be handled.
 - 10.7. Taking into account the legal advice and views of stakeholders, the Regulatory Policy Manager asked members to consider the three options set out in section five of the paper:
 - Option one: to prohibit the use of PGD to test for more than one genetic condition (the new technologies may be used, but areas of the test must be blocked out)
 - Option two: to allow testing of more than one genetic condition, but withhold from patients the information that was generated
 - Option three: to allow testing of more than one genetic condition, making sure that patients consented to receive (or not receive) the information generated.
 - 10.8. In discussion, some members expressed misgivings about which patients were currently being offered PGS by clinics and how able PGS centres were to interpret complex test results. Members felt that it would be best to review this aspect before considering the policy questions in the paper.
 - 10.9. The Regulatory Policy Manager advised members that SCAAC would consider the use of PGS at its forthcoming meeting in June. A member noted that delaying a decision in relation to the recommendations put to the Authority would not affect

patients and, following a discussion, it was agreed that the Executive should bring this issue back to a later Authority meeting. Members, however, were in agreement that option two was not an appropriate approach.

11. Any Other Business

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

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

Chair



Date

10th July 2015