Minutes of Authority meeting 18 January 2017

Strategic delivery:	☐ Setting standards	☐ Increasing and informing choice	☐ Demonstrating efficiency economy and value
Details:			
Meeting	Authority		
Agenda item	2		
Paper number	HFEA (15/03/17) 825		
Meeting date	15 March 2017		
Author	Erin Barton, Governance 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 18 January 2017 held at Church House, 27 Great Smith Street, London SW1P 3NZ

Members present	Sally Cheshire (Chair) Dr Andy Greenfield Kate Brian Dr Anne Lampe Anthony Rutherford Bishop Lee Rayfield	Yacoub Khalaf Margaret Gilmore Anita Bharucha Ruth Wilde Bobbie Farsides
Apologies	None	
Observers	Jeremy Mean (Department of Health)	
Staff in attendance	Peter Thompson Nick Jones Juliet Tizzard Paula Robinson	Anjeli Kara Richard Sydee Joanne McAlpine Erin Barton

Members
There were 11 members at the meeting, 7 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 first meeting of 2017. As with previous meetings, it was audio-recorded and the recording was made available on our website to enable interested members of the public who could not attend the meeting to listen to our deliberations.

1.2. Declarations of interest were made by:

- Anthony Rutherford (Person Responsible 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)
- Ruth Wilde (Senior Fertility Counsellor at a licensed centre)

2. Minutes of Authority meeting held on 15 December 2016

2.1. Members agreed the minutes of the meeting held on 15 December, subject to one minor amendment, for signature by the Chair of the meeting.

3. Chair's report

3.1. The Chair provided members with a summary of events that she attended with organisations in the IVF sector and the wider health and care system since the Authority meeting on 16 November 2016.

- On 18 November, the Chair participated in the Philomathia Symposium 2016 in Cambridge, on the theme of 'body politics'. She then attended the Royal College of Obstetricians and Gynaecologists annual dinner.
- On 7 December, she chaired a session on the 14-day rule at the Progress Educational Trust conference.
- On 15 December, she chaired the extraordinary Authority meeting on mitochondrial donation, and on 11 January she chaired the Multiple Births Stakeholder meeting.
- Finally, the Chair informed members that later that day she, together with the Chief Executive, were to meet Clara Swinson, the HFEA's new senior sponsor at the Department of Health.

4. Chief Executive's report

4.1. The Chief Executive advised members that on 24 November he attended the Association of Chief Executives annual conference and on 7 December he attended the Audit and Governance Committee before going to the PET conference in the afternoon.

4.2. On 6 January, the Chief Executive spoke at Fertility 2017 in Edinburgh, the joint conference of the British Fertility Society, Association of Clinical Embryologists and the Society for Reproduction and Fertility. The Chief Executive gave an overview of our strategic priorities for the coming year, focusing on the range of regulatory levers we have including the use of soft powers, like information, to bring about culture change in the sector.

4.3. On 11 January, the Chief Executive attended the Multiple Births Stakeholder meeting and on 12 January he attended the quarterly Healthcare Leaders senior talent board meeting.

Organisational change

4.4. On 29 November, the Chief Executive held a leadership away day for all of the department heads and senior management team (SMT) to reflect on the results of the annual staff survey and to prepare for the annual all staff away day, held on 13 December.

4.5. The Chief Executive reported that the results of the staff survey suggested a significant decline in morale in most areas when compared to the previous year's survey, although 90 per cent of staff have a clear understanding of the organisation's purpose and objectives. The all staff away day provided an opportunity for frank discussion and, whilst it was recognised that there may be little scope for change in some areas, staff agreed to set up six 'task and finish' groups, with the aim to make recommendations for change within the next three months on the following issues:

- Resources and workload
- Leadership and managing change
- Line-management and performance

- Careers and recruitment
- Learning and development
- Engagement and action.

4.6. Each group will be led by a member of the SMT and a Head of department, and will consist of volunteers from across the organisation. There will also be an overarching piece of work on pay and benefits led by the Director of Finance to address the impact of restrictions in public sector pay on staff morale.

4.7. The Chief Executive said that, at the staff away day, he also told staff about the proposed organisational changes that need to be implemented as a result of the new strategy and the completion of the Information for Quality (IfQ) programme. These changes include:

- Forming a new Intelligence team with a Head to be located in the Strategy and Corporate Affairs Directorate
- Bringing together the existing Governance and Licensing team with the Business Planning team under a single Head
- Recasting the Information and IT functions under a new Chief Information Officer role in the Compliance and Information Directorate

4.8. A formal, one-month consultation with all staff will shortly begin and will include 1:1 discussions with the staff directly affected by the changes. The new structure will be finalised in February or early March 2017. SMT planned to redeploy staff where possible but accepted that there could be a small number of staff without the necessary skills for a position within the new organisational structure. The Chief Executive assured members that the change would be handled properly and sensitively, and that any final proposals would be put before the Remuneration Committee.

4.9. Some members were keen to receive further information and agreed that the information disseminated to staff will be available for those who were interested.

Press coverage

4.10. The Chief Executive informed members that there was a lot of high-profile coverage of both our work and fertility issues in general.

4.11. The Authority's decision in December to permit the use of mitochondrial donation techniques in treatment was very well covered in the press at home and abroad. The Chair gave interviews to a number of different national and international broadcasters, which appeared on various news channels. There were hundreds of articles written in the following days. The coverage was almost universally favourable, both in terms of the decision and recognition for the work done by the panel and our staff over the numerous reviews.

4.12. There were reports of a baby born in Ukraine following the use of mitochondrial donation. The Chief Executive reminded members that the use of these techniques to treat infertility is not permitted in the UK; it can only be used to avoid serious mitochondrial diseases.

4.13. Treatment add ons: In late November, BBC Panorama broadcast a half hour show on the use of treatment add ons, the supplementary treatments given to patients to increase their chances of success. The programme was based on research by the Oxford Centre for Evidence-Based Medicine which concluded that many treatment add ons were either unproven or counterproductive. We gave a statement to Panorama and some interviews around the issue after

the show was broadcast including the Victoria Derbyshire show the following day. There was a mixed response to both the programme and the published research from the sector but both highlighted some essential truths: that many clinics are offering add ons, that the price of each add on varies significantly, that patients are confused and that the evidence base for most add ons is weak. This message was reiterated by the Chief Executive at the Fertility 2017 conference in January. These were all issues that we have been considering for a while, and which will be covered in more detail later in the meeting.

4.14. The Chief Executive informed members that during the previous week, the BMJ Online published a study by Manchester University which suggested that clinics were 'cherry picking' the outcomes data published on their websites. We prepared a statement which was given to a few media outlets. The Chief Executive assured members that the inspection team check clinic websites on a regular basis, and that the duty for clinics to act responsibly in presenting data within certain parameters is part of the Code of Practice. However, the Chief Executive acknowledged the need to revisit current guidance on clinic websites in light of the proposed changes to Choose a Fertility Clinic.

5. Committee Chairs' updates

5.1. The Chair of the Statutory Approvals Committee (SAC) reported that the committee met on 24 November and 15 December. It considered five preimplantation genetic diagnosis (PGD) applications in November, all of which were approved, and two requests for Special Directions, one of which was approved and one adjourned for further information. At the December meeting, five PGD applications were considered, all of which were approved.

5.2. The Chair of the Licence Committee advised members that the committee had met on 12 January to consider one research licence renewal application and one executive update. The minutes have not yet been published.

5.3. The Director of Strategy and Corporate Affairs advised members that the Executive Licensing Panel (ELP) met four times since the Authority meeting on 16 November; on 18 November, 2 and 20 December, and 13 January. At the first three meetings, the panel considered one treatment and storage renewal application which was approved; one interim inspection report, where the licence was continued; three initial licence applications, all of which were granted; and eight licence variations, all of which were approved. At the meeting on 13 January, the minutes of which have not yet been published, the panel considered one treatment and storage renewal application, two interim inspections and four licence variations.

5.4. The Chair of Audit and Governance Committee (AGC) advised members that the committee met on 7 December, and considered the following items:

- Updates from the Internal and External Audit teams
- Register and Compliance Risks, and an update on the IfQ programme and managing risks, from the Director of Compliance and Information
- Strategic risks, from the Head of Business Planning
- The implementation of audit recommendations
- Disclosure and barring service (DBS checks), from the Chief Executive

- Cyber security: information security and testing, from the Head of IT - a topic the committee felt it was important to revisit more regularly particularly as the IfQ programme nears completion
- Contracts and procurement, and the whistle blowing policy, from the Head of Finance
- An annual review of AGC's effectiveness, which was overall very positive; the committee were keen to take on board feedback and planned to distinguish clearly between items that were for information and items for decision.

5.5. Our internal auditors, PwC, interviewed members of the Authority on behalf of the Department of Health's internal audit group who are encouraging Arm's Length Bodies in the health sector to undergo a review of their board effectiveness. The Chair informed members that an early report presented to AGC was overwhelmingly positive and that the final report will highlight any recommendations.

6. Strategic performance report

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

6.2. The Director of Strategy and Corporate Affairs summarised the activities within her Directorate, including recent work following on from the Multiple Births Stakeholder meeting. The Policy team is in the process of analysing five years of patient feedback relating to the provision of information and decision-making in clinics surrounding elective single embryo transfer (eSET). Early analysis shows that patients want more information from both their clinics and external sources, and this was fed into work on the relevant sections of the new website. It was evident that in some clinics patients were given inconsistent advice from different members of clinic staff and that often information was provided too late in the treatment pathway. It was noted that there was a common misconception amongst those women opting for a double embryo transfer against the advice of their clinic, that this would increase their chances of success, when recent publications have shown that this is not necessarily true. These misconceptions will be addressed through the One at a Time campaign.

6.3. Further collaborative work is being done to collect data on the number of multiple births coming from licensed treatment in the UK, unregulated treatments or from treatment overseas. She advised members that, whilst performance in the sector is very good as a whole and has come a long way in five years, there are still a handful of clinics not achieving the target of less than 10% of all births being multiple births. The inspection team will work closely with those clinics to try to improve their services.

6.4. Some members were particularly interested in the growing difference in the proportion of eSET between NHS funded cycles and privately funded cycles. It was decided that further analysis of eSET as a proportion of those eligible, rather than as a proportion of all cycles, could provide a better understanding of other factors such as potential differences in the culture of NHS and private clinics, or the attitudes of their respective patients.

6.5. The Director of Strategy and Corporate Affairs reminded members that the annual conference will take place on 16 March, and that their participation on the day will be much appreciated.

Registration for the conference will be launched on 1 February in Clinic Focus. The Chair and Chief Executive have already agreed some of the themes for the day but the main focus will be the new Strategy for 2017-2020.

6.6. The Director of Finance summarised the position towards the end of the financial year. At the end of December, there was a surplus of £590k. Actual income was consistently around 15% more than budgeted throughout the year, and this was not expected to change. At the end of December, we were under-spending against budget by around £40k. The Director of Finance advised members that, although it is difficult to accurately forecast income generated from treatment, this will be carefully monitored.

6.7. The Director of Compliance and Information informed members that whilst the organisation performed well against most indicators, there were three which fell below target. The number of working days between an inspection and the draft report being sent to the Person Responsible (PR), and as a consequence the total number of days taken for the whole licensing process, were marginally outside of the KPI. This was due to the complexity of the report and an increased number of inspections during this period. There was also a higher rate of staff sickness absence, which was thought to be seasonal and heavily affected by the small size of the organisation.

6.8. Following the discussion, members noted the latest strategic performance report.

7. Strategy 2017-20

7.1. The Head of Business Planning introduced the Strategy for 2017-2020 which, once approved by the Authority, will be finalised ready for the annual conference in March and subsequently published on the website in April 2017. The new strategy retains the existing vision of high quality care for everyone affected by fertility treatment but focuses on the following areas in order to meet patients' needs at various stages before, during and after treatment:

- safe, ethical, effective treatment
- consistent support and outcomes
- improving standards through intelligence.

7.2. The Head of Business Planning set out the new strategic objectives in further detail:

1. Ensure that consistent high quality, safe, treatment is provided by all clinics.
2. Publish clear information for patients about the efficacy and safety of treatments and treatment add-ons, while supporting innovation.
3. Support and promote high quality embryo and data research.
4. Use our data to improve access to donation and treatment.
5. Increase consistency in treatment standards, outcomes, value for money and support for donors and patients.
6. Use our data and feedback from patients to provide a sharper focus in our regulatory work and improve the information we produce.

7.3. Members were advised that the new organisational structure and people strategy will ensure the skills and capacity required to deliver these strategic aims, and that a communications strategy will also be prepared to promote and influence particular issues.

7.4. The Head of Business Planning summarised stakeholder feedback on an earlier draft of the strategy from the Professional Stakeholders Group, the Association of Fertility Patient Organisations and the Licensed Centres Panel, as well as a short survey of 28 patients, all of which was very positive and offered great insight.

7.5. Members commended the new strategy and the aim to use regulatory powers, influence and collaborative working in combination to implement change.

7.6. Members discussed the wording of the aim to promote research and encourage patients to consent to their data being used in research or to donate embryos for research purposes. The Chief Executive explained that patient information and the rate of consent, varies greatly between clinics. This strategic objective is to publish more consistent and digestible patient information across all clinics, and to raise awareness of the benefits of research with the aim to increase both the rate and quality of consents. The anticipated increase in the availability of embryos and data will facilitate high quality research with the potential to improve care and outcomes for patients.

7.7. The Director of Strategy and Corporate Affairs added that more work could be done to promote participation in clinical trials that we do not license and to encourage clinics to embrace a culture of enquiry and treatment led by research. Some members suggested that the data we hold should be more easily accessible to researchers too.

7.8. Some members suggested that the inspection team focus more closely on clinics' abilities to regularly monitor performance and outcomes, and to use training where appropriate to ensure their clinic is meeting the required standards.

7.9. Some members were pleased that the new strategy aims to provide better patient information but wanted to explore ways in which we could use our 'soft powers' to monitor and influence the accuracy of patient information on clinics' websites.

7.10. Many members supported the strategic aim to improve access to donor gametes but felt strongly that access to egg donation – as much as sperm donation - within the UK should also be a priority over the next three years.

7.11. Some members were concerned about the emotional harm associated with fertility treatment and felt that our obligation to regulate safe treatment should also encompass patients' emotional wellbeing.

Decision: Members supported the Strategy for 2017-2020. The Director of Corporate Strategy and Affairs and the Head of Business Planning will continue to work with a sub group of members and the Chair to finalise the wording.

8. Treatment add ons

8.1. The Director of Strategy and Corporate Affairs introduced a paper on treatment 'add ons'. She informed members that, following a review of scientific literature, clinic websites and patient feedback, it was clear that:

- add ons are offered in around 70% of clinics, often at additional cost
- most add ons do not have a strong evidence base to show effectiveness
- many clinics are not making it clear to patients that the evidence of effectiveness is weak

- patients are confused about the merits of add ons and are not sure who to trust for information.

8.2. Members felt strongly about the issue of treatment add ons and discussed the next possible steps.

8.3. Members discussed the need for agreement on the way novel techniques or add ons are introduced into practice. Members noted the rigorous analysis of the safety and efficacy of mitochondrial donation techniques that was required before moving from research to treatment. It was felt that there should be more research into add ons before they can ethically be introduced and charged for.

8.4. Members acknowledged the limits of publishing patient information as a catalyst for change. However, they were concerned that add ons were so widely available that they were considered the norm and their efficacy remained unquestioned. Members noted the success of the One at a Time campaign, and felt that a similar approach to introduce cultural change across the sector would encourage patients to ask more questions and encourage clinics to innovate responsibly.

Decision: Following discussion, members noted the report and agreed to revisit treatment add ons following further work with stakeholders to develop a consensus around what responsible innovation might look like. The aim was to work with professional societies, patient groups and interested clinics to develop and commit to a consensus. Members also agreed to explore the range of regulatory powers that might be used to regulate treatment add ons, if there is not sufficient progress using softer powers.

9. Code of Practice

9.1. The Regulatory Policy Manager gave an overview of the proposed amendments to the Code of Practice which sought to clarify guidance on the following areas:

- Mitochondrial donation; which had previously been approved in the meeting on 15 December 2016
- Legal parenthood
- Egg sharing arrangements
- Cases where consent to storage is not required
- Storage periods for eggs, sperm and embryos
- Legislation, professional guidelines and information
- Other minor amendments and corrections.

9.2. Members heard that, if approved, the changes will be incorporated in the April 2017 update to the Code of Practice. Members also noted the creation of a separate suite of gender neutral forms and patient information for transgender patients for 1 April 2017, and agreed to the development of guidance on this area for 1 October 2017.

9.3. Members who work in clinics were particularly supportive of the amendments and felt that they would be very beneficial in practice.

9.4. The Regulatory Policy Manager advised members that egg sharing is currently permitted in UK clinics, while egg giving is prohibited. This means that eggs collected in a cycle must be shared between the egg provider and recipient(s) unless there is a clinical and/or medical reason against doing so. The proposed amendments to the Code of Practice sought to clarify the exceptional circumstances where all of a patient's eggs can be given to the recipient - essentially, only where there would otherwise be a risk of harm to the egg provider.

9.5. Members felt that further clarification of the circumstances where there is a risk of harm to the egg provider was necessary in order to prevent clinics from misinterpreting the guidance.

Decision: Following discussion, members agreed to all other proposed amendments, which will be incorporated into the Code of Practice on 3 April 2017.

10. Information for Quality: update

10.1. The Director of Compliance and Information reminded members that the IfQ programme was a comprehensive review of the information that we hold, the systems that govern the submission of data, the uses to which it is put and the ways in which the information is published. It includes:

- The redesign of our 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 will be accredited
- 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.

10.2. The Director of Compliance and Information advised members that in mid December 2016 it was decided that the team should regroup and focus their efforts on the completion of the Clinic Portal which necessarily limited the progress made elsewhere. It was expected that the new Portal will launch the following day, on 19 January 2017.

10.3. Members noted that the launch of the treatment data submission system product for 31 March 2017 is no longer achievable and that we have sought from the Department of Health an extension to the budget of £90,000 in order to allocate additional resources to support the team and maintain pace.

10.4. Following a discussion, Members noted:

- The extension of £90,000 to the Programme budget, subject to Department of Health approval
- Progress since the last Authority meeting, noting the launch of the clinic portal, and plans as regards our website
- The delays to Release 2 – the new data submission system
- Steps in relation to a proposed Information Policy, for incentivising clinics to improve and maintain their performance. The policy and full suite of supporting Directions will be presented to the March 2017 Authority meeting

- Programme expenditure.

11. Any other business

11.1. The Chair of the meeting confirmed that the next meeting will be held on 15 March at Church House, 27 Great Smith Street, London, SW1P 3NZ. 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