Minutes of Authority meeting 12 September 2018

Strategic delivery:	☐ Safe, ethical effective treatment	☐ Consistent outcomes and support	☐ Improving standards through intelligence

Details:	
Meeting	Authority
Agenda item	2
Paper number	HFEA (14/11/18) 893
Meeting date	14 November 2018
Author	Catherine Burwood, Senior 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 12 September 2018 held at 10 Spring Gardens, London, SW1A 2BU

Members present	Sally Cheshire (from item 8) Margaret Gilmore Andy Greenfield Anita Bharucha Anne Lampe Anthony Rutherford	Gudrun Moore Jonathan Herring Kate Brian Rachel Cutting Ruth Wilde Yacoub Khalaf
Apologies	Bobbie Farsides Richard Sydee	
Observers	Samantha Hayhurst (Department of Health and Social Care) Steve Pugh (Department of Health and Social Care)	
Staff in attendance	Peter Thompson Clare Ettinghausen Nick Jones Anna Quinn Catherine Drennan Caylin Joski-Jethi	Helen Crutcher Laura Riley Paula Robinson Sharon Fensome-Rimmer Sumrah Chohan

Members

There were 12 members at the meeting; seven lay and five professional. The Deputy Chair led the meeting until the end of item 7, at which point the Chair arrived and took over.

Agenda

An item on the egg freezing report was not brought to this meeting, as indicated in the minutes of the 27 June 2018 meeting. The report was published on the morning of 12 September 2018 and a copy was sent to the members.

1. Welcome, apologies and declarations of interest

1.1. The Deputy Chair opened the meeting by welcoming Authority members and members of the public to the fifth meeting of 2018. As with previous meetings, it was audio-recorded, and the recording would be 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. Apologies were received from Bobbie Farsides and Richard Sydee, the Director of Finance and Resources.

1.3. Declarations of interest were made by:

- Anthony Rutherford (Clinician at a licensed centre)
- Rachel Cutting (Clinician at a licensed centre)
- Yacoub Khalaf (Clinician at a licensed centre)

2. Minutes of Authority meeting held on 27 June 2018

2.1. Members agreed the minutes of the meeting held on 27 June 2018 for signature by the Chair of the meeting.

3. Chair's report

3.1. The Deputy Chair welcomed three new Authority members: Jonathan Herring, Gudrun Moore and Rachel Cutting. The new members introduced themselves to the rest of the Authority. The Deputy Chair also confirmed that a fourth new member, Emma Cave, would join the Authority at a later date this year.

3.2. On 5 July the Chair opened the Science Museum exhibition marking the 40th anniversary of IVF. The Deputy Chair also attended this event. On the same day the Chair attended the NHS 70th birthday celebrations at Westminster.

3.3. The Deputy Chair also delivered a speech to the Society for Reproduction and Fertility, in relation to the anniversary, on 25 July 2018.

3.4. On 7 August the Chair led an Appointments Committee meeting with Margaret Gilmore and Anita Bharucha.

3.5. On 8 August the Chair appeared on the Victoria Derbyshire programme on BBC 2 to discuss egg freezing. The Chair sat on a panel with other professionals from the sector and a patient. The Deputy Chair advised that the Director of Strategy and Corporate Affairs would provide information about the newly published egg freezing report later in the meeting.

3.6. On 29 August the Chair gave an interview to the Health Service Journal regarding a report on the economic cost of multiple births. The HFEA jointly commissioned the report with the Multiple Births Foundation, the British Fertility Society (BFS) and the Royal College of Obstetricians and Gynaecologists (RCOG).

4. Chief Executive's report

4.1. On 28 June the Chief Executive attended the opening of the new Digital Catapult Centre in Stevenage. The centre provides much needed manufacturing capacity for companies developing therapeutic medicines from stem cells. The new centre is a key element of the government's industrial strategy for bio-sciences.

4.2. Along with Authority member Yacoub Khalaf, the Chief Executive met Siobhain McDonagh MP on 4 July to discuss Ovarian Hyperstimulation Syndrome (OHSS).

4.3. On 5 July the Chief Executive attended the NHS 70th birthday celebrations with the Chair.

4.4. On 10 July the Chief Executive participated in the Health and Care Leaders Scheme quarterly senior talent board. This is a board made up of leaders from the Department of Health and Social Care (DHSC) and its arm's length bodies (ALBs) to identify and manage talented individuals.

4.5. On 21 August Laura Riley, Head of Regulatory Policy, Anna Quinn, Scientific Policy Manager, and the Chief Executive met staff from the Royal Society of Biology to discuss areas of mutual interest such as genome editing.

Press Coverage

40th anniversary of IVF

4.6. As well as opening the Science Museum exhibition as mentioned earlier, the Chair also gave various interviews at the event.

4.7. Authority member Yacoub Khalaf also gave a number of interviews at another Science Museum event, including to Sky News, Channel 5 News and Al Jazeera.

4.8. The Chief Executive noted that our social media output around these events proved very popular making us part of the wider conversation about fertility and the 40th anniversary.

Egg freezing/National Patient Survey

4.9. The Chief Executive advised that these were areas which had also gained press interest recently.

OHSS/welfare of the woman and storage limit campaigns

4.10. Two campaigns about OHSS/women's welfare and the ten-year gamete storage limit have begun recently.

4.11. Siobhain McDonagh MP is leading a campaign seeking to have the law changed to strengthen protections for women's safety, especially in relation to OHSS. We responded to a number of press enquiries regarding OHSS, setting out the facts underlying this issue, and reassuring people that severe OHSS is thankfully very rare. Yacoub Khalaf represented the HFEA on BBC London in August reiterating this.

4.12. The other campaign is seeking to have the ten-year gamete storage limit increased so that gametes can be stored for longer. The issue of ten-year storage is for Parliament as it requires a change in the law.

5. Committee Chairs' reports

Licence Committee

5.1. The Chair of the Licence Committee advised members that the Committee met on 12 July and 6 September. Six items were considered at each meeting.

5.2. In July the committee considered one initial storage application; two research renewals; one treatment (including embryo testing) and storage renewal; one investigation report; and one additional inspection report. Three applications were approved and one adjourned. The committee noted the interim inspection report/investigation.

5.3. In September the committee considered two research renewal applications; one treatment and storage renewal; one treatment and storage renewal including a Grade A incident; and two executive updates. The minutes were yet to be finalised so the Chair of the Licence Committee was unable to provide details about the decisions made.

Statutory Approvals Committee

5.4. The Chair of the Statutory Approvals Committee (SAC) advised members that the Committee met on 28 June, 26 July, 13 August and 30 August.

5.5. In June the committee considered six pre-implantation genetic diagnosis (PGD) applications and one application for special directions. The PGD applications were approved and the special directions application was adjourned.

5.6. In July the committee considered three mitochondrial donation applications; five PGD applications; and one application for special directions. All applications were approved.

5.7. The Chair of SAC explained that the 13 August meeting was an extraordinary meeting arranged at short notice due to a delayed application caused by an issue with the HFEA's portal and the patient potentially losing funding for her treatment. The application was approved.

5.8. At the second meeting in August the committee considered two mitochondrial donation applications; five PGD applications; and one application for special directions. The minutes for these items were yet to be signed so the outcomes could not be given.

5.9. The Chair of SAC noted that most recent PGD applications have featured multiple conditions to be considered.

Executive Licensing Panel

5.10. The Chair of the Executive Licensing Panel advised members that the Panel had met six times since the last Authority meeting, on 6 July, 20 July, 1 August, 16 August, 29 August and 11 September. 24 items were considered in total: one initial licence application; ten renewal applications; ten interim inspection reports; one variation of licence application; one executive update; and one human leukocyte antigen (HLA) testing application. 22 applications were approved. The panel deferred decisions in relation to one renewal application and one interim inspection report.

5.11. The Licensing Officer considered 12 applications, which were all approved: eight EU import certificate applications; three change of licence holder applications; and one voluntary revocation.

Appointments Committee

5.12. The Deputy Chair advised members that the Committee had met on 7 August. The committee considered the renewal of three members of the independent Appeals Committee whose first terms were ending shortly. All three reappointments were approved.

5.13. The committee also appointed three new members to the Licence Committee that considers representations, leading up to three current members' final terms ending shortly.

6. Performance report

6.1. The Chief Executive introduced this item and covered several areas, including the upcoming PR leadership events in November; Brexit and the prospect 'no-deal' would

have on guidance and standards in the sector; staffing and the higher than expected levels of 'unplanned' leavers; and a planned office move, which will likely see the HFEA moving to a new base in Stratford in 2020. The Chief Executive advised that progress updates on the office move would be given at future Audit and Governance Committee (AGC) and Authority meetings.

6.2. The Chief Executive also provided the members with information about the finance performance data, including confirmation that the DHSC had given permission for the HFEA to increase our capital budget.

6.3. The Chief Executive explained that the data given in the finance commentary section of the performance scorecard presented in the papers was incorrect. The commentary indicated that we were below our budget position, when in fact we were forecasting a year end surplus.

6.4. In relation to information given about increasing income from IVF and DI cycles, the members enquired about differences between the levels of treatments at private and NHS clinics, and whether there are differences across the UK nations. The Chief Executive advised that information such as this could be found in the Fertility Trends report.

6.5. The Director of Compliance and Information provided information about: delays in PGD application processing; how the counselling provider used by the HFEA to support opening the register (OTR) work had withdrawn their services; and the new EU directive and the higher than expected number of applications received for clinics to become Importing Tissue Establishments (ITEs).

6.6. The Director of Compliance and Information also provided an update on the data submission programme, advising members that work was in the final stages.

6.7. The Director of Compliance and Information reported that overall performance was good with three indicators classified as red and three amber.

6.8. Three indicators relating to SAC were classified as red. We have seen the knock-on effects of the technical issues with our information systems in April and May, reported to Authority previously and now resolved, which caused a backlog of applications. This will impact Key Performance Indicators (KPIs) for the next month or so.

6.9. Additionally, as the PGD conditions being applied for become more complex and obscure, the consideration of them also becomes more complex and time consuming. The position in relation to SAC indicators has been also exacerbated by the need to implement mitochondrial donation application processing effectively.

6.10. The amber indicators related to: 'unplanned' leavers; outstanding errors; and average number of working days from day of inspection to the day the draft report is sent to the PR.

6.11. The Director of Strategy and Corporate Affairs provided the members with information about: the 40th anniversary of IVF celebrations and events, including a debate in the House of Lords; the publication of new report about the cost of multiple births with the Multiple Births Foundation, Fertility Network UK (FNUK) and the RCOG; the launch of the egg freezing report today; the new version of the Code of Practice, which was with

the Secretary of State for Health and Social Care for approval; work on the consensus statement on treatment add-ons; and planned events for PRs taking place in November.

Decision

6.12. The members noted the performance report.

6.13. The members noted that proposals on the operation of the Donor Conceived Register would be brought to the November 2018 meeting of the Authority.

6.14. The members congratulated the small team involved in the data submissions programme. The members also agreed that it was important to ensure that the sector has time and support to respond to these changes when they go live.

7. Business plan 2019/20

7.1. The Head of Planning and Governance and the Risk and Business Planning Manager presented an outline of the proposed business plan for 2019/20, the full draft of which would be presented to the Authority in November before being given to the DHSC for sign off by March.

7.2. The Head of Planning and Governance explained that the HFEA was in the last year of our current strategy, and the business plan will indicate what actions we would take in the coming year to ensure delivery of the strategy.

7.3. The Risk and Business Planning Manager advised the members of work completed to meet the strategy to date, and went through the outline of the proposed 2019/20 business plan:

Safe, ethical, effective, treatment

7.4. Work would be completed in relation to leadership; embedding patient feedback into our processes; recognising excellent patient care; and benchmarking the performance of clinics.

Consistent outcomes and support

7.5. Work would be completed in relation to ensuring compliance with the new Code of Practice requirements regarding patient support; embryo research; defining factors that lead to successful outcomes; benchmarking treatment prices; and counselling support services for those applying for Register information.

Improving standards through intelligence

7.6. Work would be completed in relation to the national patient survey findings; analysing Register data on success rates; and patient engagement.

Decision

7.7. The members discussed the outline business plan, and in particular treatment add-ons and the HFEA's use of social media to engage with patients and the sector.

7.8. One member asked what had been done to increase consent for research and the Chief Executive advised that the Executive would look into evaluating measures taken to date.

7.9. Following the discussion, members approved the outline business plan for 2019/20.

8. State of the fertility sector

8.1. The Director of Compliance and Information introduced this presentation which provided data about the current state of the fertility sector. He explained that this information would enable the Executive to decide which areas to focus on during inspections and enable us to collaborate with clinics to improve performance.

8.2. The Head of Intelligence provided the members with details about the size and shape of the sector. There had been a 61% growth in activity since 2007/08. The members heard that 84055 treatments and cycles were undertaken in 2017/18, in 130 licenced fertility clinics. The value of the market was estimated as £320m in 2016.

8.3. The members were also presented with information about regional variations in the number and type of clinics licenced, with London having the most, and greatest range of, clinics.

8.4. The members heard how more private clinics are now operating in groups, such as CARE and the Fertility Partnership. These groups control 39% of the market.

8.5. The Chief Inspector reported that there were 101 inspections in 2017/18. When critical or major non-compliances were found, 45% of clinics had improved by the next inspection. Considering all non-compliances, 61% of clinics were identified as being improved by the next inspection; this indicated that the inspection regime was effective.

8.6. The Chief Inspector explained that it is difficult to compare non-compliances at a sector level and presented the reasons for this.

8.7. The members heard that the main three areas of non-compliance at renewal inspections in 2015/16 related to Quality Management Systems (QMS); equipment and materials; and data submission. The main three areas of non-compliance at interim inspections related to QMS; equipment and materials; and procuring, processing and transporting of gametes and embryos. Members heard that whilst the reasons for non-compliance were reasonably stable, overall numbers of non-compliances were increasing.

8.8. Areas that were not meeting the standards expected and that needed development were identified from renewal and interim inspections combined: consent; equipment and materials, including medical devices; and QMS. The members heard that several areas had also improved: witnessing; Third Party Agreements (TPAs); multiple births; and medicines management.

8.9. The members heard that the incident rate in clinics had remained broadly stable, with reported incidents representing less than 1% of all cycles. There had been a decrease in communication and laboratory equipment incidents, but an increase in clinical incidents.

8.10. Complaints had increased with most being about clinical and communication issues. General complaints had increased for the third consecutive year.

8.11. The Head of Intelligence went on to present the members with information about Choose a Fertility Clinic (CaFC) ratings. 1500 patients had given feedback about their clinic, but the Head of Intelligence advised that we would hope for more. The feedback received was predominantly positive.

Decision

8.12. The members discussed the findings and agreed that, although the sector is generally performing well it was important to learn from this information and focus our regulatory work over the coming year.

9. Donor anonymity and direct-to-consumer genetic testing

9.1. The Chief Executive introduced this item explaining that direct-to-consumer genetic testing will have wide ranging impacts, including direct impacts to the HFEA's services.

9.2. The Donor Information Manager explained that the HFE Act 1990 assumes gamete and embryo donor anonymity as a default position. Donor-conceived people and donors have a statutory right of access to certain information held on the Register. However, people discovering donation information without the Act's provisions do not have these rights.

9.3. The Head of Regulatory Policy provided the members with background information about direct-to-consumer genetic testing and advised that there were millions of users of websites providing these services worldwide.

9.4. The Head of Regulatory Policy also provided details about how such websites operate, with genetically 'matched' users often being identified to each other by name. Contact can be made without any mediation or support.

9.5. The members heard how, from the information users received, it was reasonably simple to infer relatedness and go on to find other relatives through social media.

9.6. The Donor Information Manager explained that the possibility of relatedness inference affected all sperm, egg and embryo donors; all donor conceived people of any age; the genetic relatives of donor-conceived people or donors; and recipient parents and families. Other groups affected include people coming into donation; people coming into fertility treatment using donation; and groups on social media who offer advice and share information on using DNA matching to find out a donor's identity.

9.7. The members heard that there is a lack of understanding around the complexities of direct-to-consumer genetic testing, including the potential for unexpected genetic information on relatedness or health issues, and that the HFEA had found that many websites do not offer specific emotional support, information relating to donor conception issues, or signpost users to other support services.

9.8. The Head of Regulatory Policy explained that while we have no regulatory powers in relation to this area, there were several possible responses to direct-to-consumer genetic testing. These included raising patient and donor awareness through the HFEA website, HFEA consent forms and at clinics, and setting out new expectations in the Code of Practice. We could also seek dialogue with UK based genetic matching services in regard to their information giving and signposting to support.

9.9. The Authority was asked to note:

- the rapidly growing number of people using DNA testing and matching websites.

- the implications of discovering a donor or donor conceived person's identity through such websites, including unexpectedly.
- the changing context of HFEA's managed (Donor Conceived Register) DCR and (Opening the Register) OTR services including the offer of emotional support.
- that information is freely available on how to use DNA matching websites to seek donors' or donor-conceived peoples' identifiable information.
- that there is little support available around responding to 'matching' information, or contacting others in relation to matches.
- the summary of possible responses outlined above.

Decision

9.10. The members noted the points above and were encouraged that this topic was being explored in a timely way.

9.11. In discussion the members expressed differing opinions about the level of responsibility the HFEA should or could have towards people who are not covered by the provisions of the Act.

9.12. It was agreed that this could be a potential topic for the next Annual Conference.

9.13. The Chief Executive advised the members that the Executive would continue to explore the responses available for the HFEA and report back to the Authority.

10. Standard licence condition T53 - screening

10.1. The Scientific Policy Manager and Head of Planning and Governance presented a paper about amendments made to standard licence condition T53.

10.2. The Scientific Policy Manager set out the purpose of condition T53 and its requirements, including that 'donor sperm must be quarantined for a minimum of 180 days, after which repeat testing is required. If the blood donation sample is additionally tested by the nucleic acid amplification technique (NAT) for HIV, HBV and HCV, quarantining of the gametes and re-testing of a repeat blood sample is not required. Quarantine and re-testing is also not required if the processing includes an inactivation step that has been validated for the viruses concerned'.

10.3. The members heard that there were discrepancies between our guidance regarding best practice in relation to quarantining and guidance provided by professional bodies.

10.4. The Scientific Policy Manager also explained that there was a potential for varying practice within the sector, along with a risk that centres do not necessarily complete serological testing alongside NAT testing, or do not quarantine samples after any NAT testing has been done.

10.5. The members heard that the HFEA had engaged with the relevant professional bodies, including the Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO), the Association of Clinical Embryologists (ACE), the BFS, and the Association of Biomedical Andrologists (ABA), to agree recommendations relating to NAT testing and quarantine requirements.

10.6. Additionally, SaBTO had agreed to consider the evidence in this area and publish an addendum to their donor selection criteria report 2017, a document which was included in the paper.

10.7. The members heard that the Executive had drafted an improved, up to date and clear articulation of standard licence condition T53.

10.8. The Head of Planning and Governance outlined proposals to update the centrally held list of standard licence conditions on 1 October 2018, to coincide with the implementation of the new Code of Practice. The revised wording would be included on all new or renewed licences issued to clinics after this date. The Executive would manage any risk of misinterpretation of T53 through guidance and the inspection regime.

10.9. The members also heard about plans to highlight the issue through Clinic Focus.

10.10. The Authority was asked to:

- Note and approve the proposed revision of standard licence condition T53.
- Note the intended implementation and communication plan.

Decision

10.11. The members noted and approved the proposed revision of standard licence condition T53. They also noted the intended implementation and communication plan.

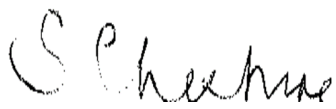
11. Any other business

11.1. There was no any other business discussed.

12. Chair's signature

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

Signature



Chair: Sally Cheshire