

Minutes of Authority meeting 3 July 2019

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

Details:

Meeting Authority
Agenda item 2
Paper number HFEA (11/09/19) 923
Meeting date 11 September 2019
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Output:

For information or decision? For decision
Recommendation Members are asked to confirm the minutes as a true record of the meeting
Resource implications
Implementation date
Communication(s)
Organisational risk Low Medium High

Annexes

Minutes of the Authority meeting on 03 July 2019 held at Church House, Deans Yard, Westminster, London SW1P 3NZ

Members present	Sally Cheshire Margaret Gilmore Anita Bharucha Anthony Rutherford Emma Cave Rachel Cutting	Bobbie Farsides Jonathan Herring Gudrun Moore Ruth Wilde Yacoub Khalaf Ermal Kirby
Apologies	Anne Lampe Kate Brian	
Observers	Steve Pugh Dafni Moschidou (Department of Health and Social Care - DHSC)	
Staff in attendance	Peter Thompson Clare Ettinghausen Richard Sydee Catherine Drennan	Laura Riley Paula Robinson Debbie Okutubo

Members

There were 12 members at the meeting – eight lay members and four professional members.

1. Welcome, apologies and declarations of interest

- 1.1. The Chair opened the meeting by welcoming Authority members, the public and staff present. She stated that the meeting was audio recorded in line with previous meetings and the recording would be made available on our website to allow members of the public who were not at the meeting to listen to deliberations.
- 1.2. There were two apologies for absence, Anne Lampe and Kate Brian.
- 1.3. Declarations of interest were made by;
 - Rachel Cutting (Person Responsible (PR) at a licensed centre)
 - Yacoub Khalaf (PR at a licensed clinic)
 - Anthony Rutherford (Clinician at a licensed clinic)

2. Minutes of Authority meeting held on 8 May 2019

- 2.1. Members agreed that the minutes of the meeting held on 8 May 2019 be signed by the Chair subject to corrections handed in before the meeting.

3. Chair's report

- 3.1.** On 29 May, the Chair met Michael Johnson-Ellis from twodaddies.co.uk, to discuss how they could work together to help couples from the LGBT community.
- 3.2.** The Chair and Chief Executive (CE) later that day had the Annual Accountability meeting with the Department of Health and Social Care (DHSC). The Chair described it as a positive meeting and explained that the DHSC recognised our achievements and performance for the past year.
- 3.3.** On 12 June, the Director of Strategy and Corporate Affairs, CE and the Chair met Jane Denton to discuss possible next steps on reducing multiple births and a range of other strategic issues.
- 3.4.** Later that day the Chair and CE went to the House of Lords to attend the 20th Anniversary celebrations of the National Institute of Health and Care Excellence (NICE).
- 3.5.** The Chair thanked members and staff involved in the HFEA Conference on 13 June for helping to make it such a success. She noted that the fact that we reached capacity early and had a waiting list showed just how sought-after places were. She further commented that this year we focused on providing learning opportunities, with four workshops running three times in the day. Early indications were that the day was very well received. Feedback was being analysed and the Chair had written to thank all speakers.
- 3.6.** On 28 June the Chair met Jane Stewart, the Chair of the British Fertility Society (BFS), in York.
- 3.7.** Lastly, it was noted that the annual ESHRE conference was held in Vienna and members of the HFEA's Scientific and Clinical Advances Advisory Committee (SCAAC) had hosted the annual horizon scanning meeting with international colleagues.

4. Chief Executive's report

- 4.1.** On 14 May, the CE gave a presentation on regulation and innovation to the Regulators Innovation Network seminar organised by the Department of Business, Energy and Industrial Strategy. The CE commented that the Government's recent publication on regulation and the 'fourth industrial revolution' (artificial intelligence etc.) featured a case study of our work on mitochondrial donation.
- 4.2.** On 21 May the CE had a visit from Osamu Ishihara MD, Professor and Chair from the Department of Obstetrics and Gynaecology at Saitama Medical University, who was reviewing the regulatory scheme in Japan and wanted to see how we did things.
- 4.3.** On 23 May the CE met with Kazuto Kato, Professor and Chair of the Department of Biomedical Ethics and Public Policy School of Medicine, Osaka University.
- 4.4.** Later that day the CE had a meeting with Michael Morrison from the University of Oxford, who is working on a research project looking at the regulation of new technologies in ART, and another meeting proposed with Joyce Harper, one of the SCAAC advisers.
- 4.5.** On 29 May the CE attended the Licenced Centres Panel meeting.

- 4.6.** On 30 May Professor Nick Macklon and Dr Kamal Ahuja from London Woman's Clinic had a meeting with the CE to discuss the rules relating to the import and export of donated material in the UK.
- 4.7.** On 4 June the CE had a meeting with Denise Kaye and Julie Ounaha from the Department for International Trade, to discuss how best they could support us in providing advice to overseas' governments in relation to health and social care.
- 4.8.** On 7 June the CE attended an Association of Chief Executives (ACE) seminar on Brexit, devolution and the impact on public services and another ACE event on 27 June on the role of public bodies in the government's industrial strategy.
- 4.9.** On 13 June the CE attended our Annual Conference. He expressed his thanks to staff and members for their contribution to making the day such a success. Looking ahead the plan was to step back and review our stakeholder engagement activities in the round, to see what role future conferences could play.
- 4.10.** On the same day, the CE had a meeting with Louise Johnson, CEO of VARTA, the regulatory body for ART in Victoria, Australia. He noted that challenges faced by VARTA and the HFEA were very similar and included developments in DNA testing and treatment add-ons.
- 4.11.** On 19 June, the CE and Policy Manager gave evidence to the House of Commons' Women and Equalities Select Committee as part of their inquiry into the provision of health and social care to LGBT communities.
- 4.12.** On 20 June, the Director of Finance and Resources, Director of Strategy and Corporate Affairs and the CE met with the Competition and Markets Authority.
- 4.13.** On 25 June, the CE attended a DHSC delivery partners meeting on EU Exit. He described it as the first of many in an increase in planning activity around preparations for a potential 'no deal' EU exit on 31 October.

5. Committee Chairs' reports

Licence Committee

- 5.1.** The deputy Chair of the Licence Committee reported that the committee met on 2 May 2019 and considered seven items: one initial research; one renewal research; three renewals for treatment and storage, which were all granted, and two executive updates which were noted.

Statutory Approvals Committee

- 5.2.** The Chair of the Statutory Approvals Committee (SAC) reported that the committee met on 30 May 2019 and considered three pre-implantation genetic diagnosis (PGD) items. Two PGD applications were approved and the minutes signed. One PGD application was adjourned pending further information.
- 5.3.** On 27 June 2019 two PGD applications and two Special Direction were considered. The Chair of SAC advised that the minutes from the June meeting were still in draft.

Executive Licensing Panel

- 5.4.** The Chair of the Executive Licensing Panel (ELP) advised members that the panel had met five times since the last Authority meeting, on 1 May, 7 May, 21 May, 4 June and 25 June. The panel

considered 15 items in total: two licence renewal applications; seven interim inspection reports; five licence variation applications; and one application for Special Directions.

- 5.5.** The Chair of ELP also reported that 13 Licensing Officer considerations were approved: nine for EU certificates, three for changes of Licence Holder and one for a change of centre name.

Audit and Governance Committee (AGC)

- 5.6.** The Chair of the Audit and Governance Committee (AGC) reported that the committee met on 18 June and aside from the usual standing items and updates from the internal and external auditors, the committee also received reports on:

- responding to organisational capability, staff opinion and turnover and ongoing work around corporate values
- an update on the office move, which is on the agenda for this Authority meeting
- an update from the digital programme on progress relating to system development, data migration and the implementation of the new register
- updates on resilience, business continuity management and cyber security
- The Cabinet Office revised Functional Standards for Counter Fraud, which provided the committee with a benchmark against which they would assess our counter fraud activities and approach
- the strategic risk register
- existing contracts
- the draft annual report and accounts.

Scientific and Clinical Advances Advisory Committee

- 5.7.** The Chair of the SCAAC welcomed five new members at the June meeting, including Erial Kirby and four new external advisers. SCAAC is now made up of five Authority Members and 11 external advisers.
- 5.8.** Topics discussed at the meeting were Artificial Intelligence (AI), the new 2020 – 2023 HFEA Strategy, Fertility trends, Embryo culture media. Topics for the annual HFEA horizon scanning meeting that took place during the ESHRE conference were also discussed and would be integrated as appropriate into their workplan.

Decision

- 5.9.** Members noted the Committee chairs' reports.

6. Licensing and approvals activity report

- 6.1.** A new report, to garner Authority members' views on its usefulness, was presented by the Head of Planning and Governance.
- 6.2.** The Head of Planning and Governance suggested that the intention of the report was to enhance the current way of reporting, making the information easier to digest and more informative for members, by providing it in paper form and giving some longer-term trends alongside the recent picture, for context and interest.

- 6.3.** Members were invited to comment. Members noted that it was useful to see trends and know that it could help towards better planning. It also reflected the volume and complexity of work carried out by inspectors and the licensing team, as well as the committees themselves.
- 6.4.** Members suggested that should this format of reporting licensing information be taken forward, that it would still need to maintain transparency by including previous committee decisions.
- 6.5.** Members agreed that this report needed to measure and discuss issues that were different from the State of the Sector report on compliance provided to Authority on an annual basis.

Decision

- 6.6.** Authority members agreed to receive further reports to note, and that the Head of Planning and Governance should review the measures and data included over time.

7. Audit and Governance Committee annual report

- 7.1.** The Chair of the Audit and Governance Committee (AGC) presented the annual report summarising the AGC's activity during the year and gave the Committee's opinion on HFEA's risk management and internal control arrangements.
- 7.2.** She commented that the Committee remained satisfied with the arrangements for risk management and the assurance processes and that the report formed part of the assurance process which supported the Accounting Officer's Annual Governance Statement.
- 7.3.** The AGC Chair also stated that the issue of proportionality played a key role. The size of the organisation determined what recommendations could be taken on and to what extent. It was noted that during the review of committee effectiveness this was also highlighted.
- 7.4.** There was some discussion about the role of the AGC. In response to a question, the Director of Finance and Resources commented that the Authority delegated responsibility to the AGC in relation to the annual report and accounts and the AGC then hold the Executive to account. The CE in his capacity as the Accounting Officer signs off the accounts if there are no material changes following the AGC meeting.
- 7.5.** The Chair of the Authority commented that we needed to feel assured because as an organisation we take audit and governance very seriously and this puts the Authority and the organisation in a good position for such a small organisation. She further thanked the four AGC members for their robust scrutiny.

Decision

- 7.6.** Authority members noted that the HFEA's governance systems was well established and there was a commitment to making continuous improvements to them.
- 7.7.** They also noted that the AGC was satisfied with the arrangements for risk management and the assurance processes.
- 7.8.** Lastly that the CE in his capacity as the Accounting Officer would sign off the annual accounts.

8. Performance report

- 8.1. A report summarising performance data up to the end of May 2019 was presented to the Authority.
- 8.2. The Director of Strategy and Corporate Affairs commented that a range of initiatives and events had either taken place or were scheduled to take place during and after the summer, including the Law Commission's consultation on surrogacy, following up on changes to the Code of Practice from last year and looking forward to the leadership event for PRs in the autumn. Members were thanked for their support on particular areas of work such as patient support and clinic leadership.
- 8.3. The Director of Strategy and Corporate Affairs would be attending the next meeting of the Women's Health Taskforce with Kate Brian.
- 8.4. The Authority's ambition to enhance the use of our data was starting to be realised with a record amount of interest in using our data. Further information would be brought to Authority later in the year in a report on the Register Research Panel.
- 8.5. Members suggested that the Executive could make better use of Clinic Focus to disseminate information and that it would also assist in the coverage of debates and enable better collaboration.
- 8.6. The Director of Finance and Resources provided an overview of treatment income issues and stated that at the end of the first quarter, we would take a critical look at financial requirements across all directorates and review our income expectations.
- 8.7. The CE (in the absence of a Director of Compliance and Information) commented that the director appointment process was ongoing and interviews were set to be held later in the month. The CE thanked the inspection team for covering the management gap.
- 8.8. Lastly, the CE commented that the team were preparing for the new State of the Sector report in the Autumn and that there was progress on international work including in the United Arab Emirates (UAE) and possibly Costa Rica.

Decision

- 8.9. Members noted the latest performance report.

9. Code of Practice

- 9.1. The proposed changes to the Code of Practice were presented to the Authority.
- 9.2. The Human Fertilisation and Embryology Act 1990 (as amended) (the Act) covered the use and storage of sperm, eggs and embryos for human application, as well as all research involving the use of human and admixed embryos.
- 9.3. It was noted that one of the purposes of the Code of Practice was to support licensed clinics to comply with the Act and relevant legislation by regularly reviewing, updating and publishing the Code, as it provided guidance on licensed activities for professionals that performed them.

- 9.4.** The Code also serves as a useful reference for patients, donors, donor-conceived people and researchers.
- 9.5.** Authority decisions on changes to the Code were needed in relation to:
- Updated sperm screening requirements
 - Direct-to-consumer DNA testing and matching services and the potential impact on donor anonymity
 - Definition of 'failed to fertilise eggs'.
- 9.6.** In addition there were other minor changes to provide clarification or incorporate statutory changes.
- 9.7.** Members were invited to comment on and approve the proposed changes.
- 9.8.** There was some discussion on reasonable expenses and good quality counselling for donors.
- 9.9.** The Executive advised that at s.15.4 the current Code already provides that sperm should be supplied for insemination at home (or another unlicensed site) in exceptional circumstances. The proposed addition is about clarifying that if home insemination does take place, clinics should make sure all other requirements have been met in the same way as if insemination had taken place at the treatment centre; including around the provision of information, offer of counselling and obtaining all relevant consents.
- 9.10.** Members had concerns that it could not be guaranteed that home insemination would be genuinely used as there was room for abuse.
- 9.11.** Members suggested that for greater oversight the wording might be changed to require home insemination only 'under clinical supervision'.

Decision

- 9.12.** Members agreed the changes to:
- surrogacy and parental orders for single people.
 - sperm screening requirements
 - direct-to-consumer DNA testing and matching services
 - the definition to the phrase 'failed to fertilise eggs'
- 9.13.** Members asked the Executive to consider the new wording on:
- Compensation for donors and
 - Home insemination
- 9.14.** with a consideration also to be made of the alternative or additional wording proposed by members within the discussion on these topics. Members asked to be updated at a future meeting with further information around the current policy positions on these topics and their origins.
- 9.15.** Lastly, the Executive were asked to ensure that consistency of language on the counselling offer is used throughout the proposed additions to the Code.

10. Estates update - business case

- 10.1.** The Director of Finance and Resources presented this item to the Authority. It was noted that the HFEA's lease on its current office accommodation, 10 Spring Gardens, would expire at the end of November 2020.
- 10.2.** The Department of Health and Social Care (DHSC) initiated a programme in mid-2018 to move the majority of its central London Arms-Length Boards (ALBs) estate to 'zone 2' locations in line with the wider hub strategy for the Government's London estate. The proposal is that the HFEA moves to new offices in Stratford, east London along with several other Health ALBs
- 10.3.** The DHSC will fund the project and programme support and the cost of physical relocation of organisations to the new accommodation.
- 10.4.** Overall cost would be dependent on final space allocation, in particular the approach taken for shared areas, meeting space and the conference facilities which would be finalised over coming weeks and ahead of signing contracts.
- 10.5.** The Director of Finance and Resources stated that an office move focus group was established in March 2019 to directly involve staff across the organisation in the finalisation of designs and new ways of working in the new accommodation.
- 10.6.** In response to a question, it was noted that feedback regarding the proposed new office layout was positive and the new facilities could provide a significant improvement on the existing accommodation.
- 10.7.** Inevitably the new location would present commuting issues for some employees, but as we move forward with the project the initial focus will be on considering how to mitigate the impact of the move for staff. This would include review of existing home and flexible working policies as well as the provision of excess fares where appropriate.
- 10.8.** It had been added to the strategic risk register as a number of areas had been identified in which the office relocation could impact on the delivery of operational and strategic goals. These include, but not limited to:
- Move to Stratford leading to increased staff turnover
 - Staff resource diverted to relocation activity, negatively impacting on operational delivery
 - Post move facilities not meeting all HFEA requirements – including hosting of meetings.
- 10.9.** In response to a question, it was noted that the floor plan will be shared with Authority members in due course. Members further noted that there were benefits of co-location but the move towards home working needed to be properly managed to avoid fragmentation of teams.

Decision

- 10.10.** The Authority approved the intent to proceed with the move to Stratford subject to affordability and formal contractual commitment to the move.
- 10.11.** Members delegated sign off of the office move to the Executive.

11. Strategy consultation update

- 11.1.** The Head of Planning and Governance gave an update on the strategy consultation. It was noted that she had focussed on the stakeholder engagement events to date and had drawn on the key themes from their feedback.
- 11.2.** There had been positive feedback. The full draft strategy and a summary of all consultation feedback will be presented at the November 2019 Authority meeting.
- 11.3.** Members suggested that individual letters could be sent to PRs to encourage them to complete the consultation survey.

Decision

- 11.4.** Members noted the update.

12. Any other business

- 12.1.** There was no other business.

13. Chair's signature

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

Signature



Chair: **Sally Cheshire**

Date: 11 September 2019