

Minutes of Authority meeting

9 May 2018

Strategic delivery:

Safe, ethical
effective
treatment

Consistent
outcomes and
support

Improving standards
through intelligence

Details:

Meeting	Authority
Agenda item	2
Paper number	HFEA (27/06/18) 882
Meeting date	27 June 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)	Publication on the HFEA website
Organisational risk	<input checked="" type="checkbox"/> Low <input type="checkbox"/> Medium <input type="checkbox"/> High
Annexes	-

Minutes of the Authority meeting on 09 May 2018 held at Church House, 27 Great Smith Street, London SW1P 3NZ

Members present	Sally Cheshire Kate Brian Anne Lampe Anthony Rutherford Anita Bharucha	Margaret Gilmore Bobbie Farsides Ruth Wilde Andy Greenfield
Apologies	Yacoub Khalaf Bishop Lee Rayfield	
Observers	Steve Pugh (Department of Health and Social Care)	
Staff in attendance	Peter Thompson Nick Jones Richard Sydee Clare Ettinghausen Catherine Drennan Paula Robinson	Helen Crutcher Erin Barton Anna Quinn Catherine Burwood

Members

There were 9 members at the meeting, 6 lay members and 3 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 third 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 Yacoub Khalaf and Bishop Lee Rayfield.
- 1.3.** Declarations of interest were made by:
 - Anthony Rutherford (clinician at a licensed centre)

2. Minutes of Authority meeting held on 14 March 2018

- 2.1.** Members agreed the minutes of the meeting held on 14 March 2018, subject to minor amendments, for signature by the Chair.
- 2.2.** A member asked if the action raised in paragraph 12.5 of these minutes had been actioned. The Chair confirmed that it had.

3. Chair's report

- 3.1.** The Chair began by talking about the HFEA Annual Conference which was held on 15 March 2018. Over 300 attendees from clinics attended and the response so far was overwhelmingly positive. The Chair was pleased to note that the new Parliamentary Under Secretary of State for Mental Health and Inequalities, Jackie Doyle Pryce, spoke at the conference, as well as Louise Brown, the first person born as a result of IVF, and John Webster, the doctor who helped deliver her.
- 3.2.** The Chair was particularly pleased that we were able to focus on our agenda of high quality patient care. It was also clear that clinic staff were pleased to be able to interact with Authority members about this area.
- 3.3.** The Chair thanked all who participated in helping make the conference a success, including the members who chaired workshops.
- 3.4.** The Chair provided members with a summary of events that she had attended since the last Authority meeting in March:
- On 11 April the Chair led a good debate at the Progress Educational Trust conference under the theme 'The Real Cost of IVF'. The event involved academics and medical professionals, as well as patients and other lay people with an interest in the area.
 - On 17 April the Chair, along with the Chief Executive, attended the Donor Conception Network's (DCN) 25th Anniversary celebration, hosted by Baroness Hayter of Kentish Town. The Chair was pleased to be able to congratulate the founders of the DCN, Walter Merricks (a former Authority member) and Olivia Montuschi for how they managed to sustain the organisation over 25 years. The Chair took the opportunity to offer her thanks for all the support and help that the DCN has provided for donors, donor conceived people and their families.
- 3.5.** The Chair stated that taking into account the above, plus events such as the 30th anniversary of the British Infertility Counselling Association, 2018 would be a milestone year for the fertility sector.

4. Chief Executive's report

- 4.1.** The Chief Executive also reported on the HFEA Annual Conference and thanked those who helped make it such a successful day.
- 4.2.** The Chief Executive reported that on 23 March he and the rest of the Senior Management Team had attended the Quarterly Accountability Meeting with the Department for Health and Social Care (DHSC). The annual accountability meeting with the DHSC will be attended by the Chair and Chief Executive at the end of May.
- 4.3.** The Chief Executive reported that on 17 April he attended a Breakfast Roundtable at the House of Lords, organised by Lord David Willetts in his capacity as the Chair of the British Science Association. The discussion was on the role of business in the public debate on new technologies and scientific advancements. Topics such as genome editing featured.
- 4.4.** Also on 17 April the Chief Executive and Director of Strategy and Corporate Affairs attended a meeting with Fiona Fox, CEO of the Science Media Centre.

- 4.5.** On 23 April the Chief Executive attended the opening of the Cell and Gene Therapy Catapult manufacturing centre in Stevenage. The new centre will support the development of new large-scale manufacturing, helping to bring cell and gene therapies to market.
- 4.6.** The Chief Executive also reported that on 23 April he and the Director of Strategy and Corporate Affairs attended a meeting with policy leads from the Wellcome Trust.
- 4.7.** The Chief Executive participated in the Royal Institution's event to celebrate the 200th anniversary of the publication of Mary Shelley's Frankenstein on 24 April. The Chief Executive spoke on the theme of the ethics of gene editing.
- 4.8.** The Chief Executive reflected that he had been struck by the degree of support for the HFEA and our way of regulating, at all of these events. Many opinion formers see the HFEA model as one which has managed to allow innovation whilst maintaining public trust. A recent House of Lords report on Artificial Intelligence makes the same point. In many contested areas of public policy, the kind of ethical oversight provided by the HFEA is increasingly seen as way to make progress on such issues.
- 4.9.** On 24 April the Chief Executive also attended the UAE-UK business council, along with the Director of Compliance and Information. There is work across government to sell healthcare expertise overseas and the Chief Executive noted how the international standing of the HFEA is very high.
- 4.10.** The Chief Executive indicated that the HFEA have been in discussions with the UAE about a potential training package, where we would train inspectors overseas so that they can establish their own inspection capabilities. The Chief Executive reported that he signed a memorandum of understanding (MoU) with the UAE Department of Health at this event, signalling our intention to try to reach agreement on a package of work. The Chief Executive advised members that the MoU makes no contractual commitments and that, should we reach that stage, we shall only do so after legal advice. The HFEA is also in discussion with the DHSC regarding keeping any revenue earned, as this is vital to any such work being viable. The Chief Executive noted that members would be kept updated with progress.
- 4.11.** The Chief Executive reported on the NHS Confederation Annual Lecture he attended on 1 May. The lecture was given by Dr Jennifer Dixon, CEO of the Health Foundation, on how the NHS has developed since 1948 and what might help guide it over the next 30 years.

Press coverage

Fertility Trends report

- 4.12.** The Chief Executive noted that the trends report was launched on the day of the last meeting, 14 March, with moderate coverage the day after.
- 4.13.** The Chair gave numerous radio interviews to regional BBC bureaux, which meant the report gained some further coverage over the following days.

Unregulated Scottish sperm donor

- 4.14.** The Chief Executive reported that there had been a number of stories in the Scottish press about an online sperm donor. The HFEA gave a comment to the Daily Record setting out the risks of unregulated donation and encouraging people to use a licensed clinic.

Egg freezing petition

- 4.15.** The Chief Executive spoke about an Evening Standard report regarding a petition to change the law around the ten year limit on gamete storage.
- 4.16.** The Chief Executive highlighted that it was important to remember that the ten year limit is a matter for the Government to consider. Egg freezing remained of interest to the media and more stories could be expected.
- 4.17.** The Chief Executive noted that we will be publishing a report on egg freezing later in the year.

Understanding Fertility report in the Times

- 4.18.** The Chief Executive reported that the HFEA gave information and a comment to writers working on a report by Raconteur that was published in The Times at the end of April.
- 4.19.** Authority member Kate Brian also wrote an article on what to consider when having treatment overseas.

Questions

- 4.20.** A member asked about the recent learning visit from delegates from the UAE, and enquired whether the HFEA felt pressure as an arms length body to be self-funding. The Chief Executive reminded members that we were funded by a mixture of fees from the sector we regulate and grant-in-aid from the DHSC. He added that there were no plans to change this. However, work with overseas bodies might provide an opportunity to earn additional revenue for consultancy work. Without keeping any revenue raised, however, there would be no incentive for the HFEA to participate.

5. Committee Chairs' reports

Statutory Approvals Committee

- 5.1.** The Chair of the Statutory Approvals Committee (SAC) advised members that the Committee met on 22 March and 26 April. All applications considered in March were approved: five pre-implantation genetic diagnosis (PGD) applications and five special direction applications (relating to two clinics). The minutes of the April Committee had not yet been signed so decisions could not be reported. Five PGD applications and two special direction applications were considered.

Executive Licensing Panel

- 5.2.** The Chair of the Executive Licensing Panel advised members that the Panel had met four times since the last Authority meeting, on 16 March, 28 March, 10 April and 25 April. 15 items were considered: four renewal applications, eight interim inspection reports and three variation of licence applications. All were approved, except one renewal application which was deferred.
- 5.3.** The Licensing Officer considered three applications, which were all approved: one change of licence holder, one change of centre name and one voluntary revocation of a licence.

Licence Committee

- 5.4.** The Chair of the Licence Committee advised members that the Committee met on 3 May to consider an executive update regarding one clinic. The minutes for this had not yet been signed. The Chair of the Committee also confirmed that the minutes from the 8 March meeting were now signed. Two applications, relating to a treatment renewal and a research renewal, were approved, and one item, regarding an interim inspection report, was adjourned.

PGD explanatory note - minor revisions

- 5.5.** The Head of Planning and Governance presented a paper setting out minor revisions to the pre-implantation genetic diagnosis (PGD) explanatory note used by SAC to assist in its consideration of applications for the approval of new conditions. The proposed changes were for clarity only and did not involve changes to the Authority's existing policy on PGD.
- 5.6.** The text currently referred to Licence Committee, since the original document predated the formation of SAC. Therefore, this reference should be updated.
- 5.7.** The Head of Planning and Governance explained that minor changes were proposed to paragraphs 2.1 and 2.3 to clarify the considerations of patient experience in reaching a decision.
- 5.8.** One member highlighted that, although happy with the proposed changes, she would be wary about sending a message to clinics that it may be advantageous to ask their patients to submit information in support of an application, since SAC makes its decision based on the condition. The Head of Planning and Governance acknowledged this point but clarified that the HFEA sought patient feedback on PGD conditions that are due to be considered, only through a website link and the inclusion of information provided by the Genetics Alliance.
- 5.9.** The Chair of SAC confirmed that it had been agreed that the new document was clear and had been approved by SAC.

Decision

- 5.10.** Members agreed to the proposed changes to the PGD explanatory note, for use at all subsequent SAC meetings.

6. Performance report

- 6.1.** The Director of Strategy and Corporate Affairs spoke about improving Statutory Approvals Committee (SAC) administrative processes; egg freezing and multiple birth reports due to be produced and plans for a PR event in the autumn on clinic leadership.
- 6.2.** The Director of Compliance and Information reported that three performance indicators were classified as red (outstanding errors; percentage of Freedom of Information, Environmental Information Regulations and Data Protection Act requests responded to within statutory deadlines; and the average number of working days from day of inspection

to draft reports being sent to PRs). There was one indicator classified as amber: 'unplanned' leavers.

- 6.3.** Regarding SAC, overall, performance around pre-implantation genetic diagnosis (PGD) processing had improved, with all PGD indicators receiving a green rating in March.
- 6.4.** The Director of Compliance and Information provided members with an update on the data submission project, reporting on progress towards the go-live date of 1 October 2018.
- 6.5.** Members raised the topic of capital cover in relation to this project. The Director of Compliance and Information advised that the target launch date was originally April 2018, and therefore expenditure for the project this year was unbudgeted. The Director of Finance and Resources advised members that the HFEA had applied for additional capital cover to fund the remainder of the project. This request was with the DHSC for approval. It was expected that the HFEA would receive the increased capital cover, but if it was not received we would not spend the money: thus, there was no financial risk.
- 6.6.** The Director of Finance and Resources reported on the end of financial year position. The HFEA held a surplus of £456k, £290k higher than budgeted. We usually planned to underspend by £50k. A number of underspends (in particular within our legal budget) had contributed to this.
- 6.7.** Regarding income, the last two months of the year saw lower IVF activity than for the same period in 2016/17. This had offset the increased activity during the middle of the year. The Director of Finance and Resources noted that current figures may be underreported due to a lag in reporting. There had been a minor decrease in DI cycles compared to 2016/17.
- 6.8.** The Director of Finance and Resources spoke about the HFEA's readiness for the General Data Protection Regulation. We were broadly compliant, with all data held by the HFEA now audited. The HR system would be upgraded, as well as our document management system, to ensure personal data held about staff complied.
- 6.9.** Members questioned progress with NHS benchmark pricing. The CEO outlined the background to this issue and advised that an agreement on the way forward was close.

Decision

- 6.10.** Following discussion, members noted the latest performance report.

7. Strategic risk register

- 7.1.** The Risk and Business Planning Manager advised members that, in March, CMG decided to cease holding a separate quarterly risk meeting and agreed to refer detailed reviews of the strategic risk register to the Senior Management Team (SMT). This was to allow Directors to formally consider the risk register at more frequent, monthly intervals and for Heads to focus on operational handling of risks and identifying emerging risk sources. The Risk and Business Planning Manager explained that Heads were still involved in the strategic risk register, giving updates on actions, and that Directors engaged with their management teams, on both operational and strategic risk, regularly.

- 7.2.** The Risk and Business Planning Manager provided an update on the latest reviews of the risk register. SMT reviewed all risks, controls and scores at its meeting on 16 April. The organisational change risk was removed; as the organisational change programme was now complete, save for a single ongoing recruitment campaign, this was no longer a strategic risk in its own right. Any remaining risk sources related to organisational change were included under the remaining risks. None of these six risks were above tolerance.
- 7.3.** The finance risk was considered by the Director of Finance and Resources following the SMT meeting, in light of the most recent developments relating to DHSC budget approvals.
- 7.4.** Members noted that although the financial risk remained within tolerance, some aspects, such as capital cover, created knock on business risks relating to the completion of IT development work. These business risks required mitigations and this needed to be fully reflected in the risk register.
- 7.5.** Members also noted that the C1 risk, relating to knowledge and capability, also applied to Authority members and Committees, something which may become relevant with new members being recruited shortly.
- 7.6.** Members also raised the issue of cyber security. They were assured that the HFEA should be in a good position because of our renewed systems and because regular testing had been undertaken by independent security consultants throughout the development process.

Decision

- 7.7.** Following discussion, members noted the latest edition of the strategic risk register.

8. Treatment add ons

- 8.1.** The Scientific Policy Manager presented the work being done around treatment add ons, providing an update on actions taken so far and summarising proposed new work to ensure that patients are offered treatments which are evidence based, whilst encouraging responsible innovation within the sector.
- 8.2.** The Scientific Policy Manager recently attended a meeting at the Nuffield Council on Bioethics who were scoping a piece on work on novel treatments and innovation. The meeting involved parties interested in fertility, surgery, cancer drugs, as well as colleagues from the Medicines and Healthcare Products Regulatory Agency, the General Medical Council, the Advertising Standards Agency and many others, present. This was a group the HFEA was seeking to stay involved with.
- 8.3.** Members were presented with information about the nine most commonly offered treatment add ons that the HFEA was focusing on.
- 8.4.** The HFEA had gathered information confirming that add ons are offered in around 70% of clinics, often at additional cost. Most add ons did not have a strong evidence base to show effectiveness and many clinics were not making it clear to patients that this evidence was weak. Patients were confused about the merits of add ons and were not sure who to trust for information.

- 8.5.** The Scientific Policy Manager provided details on progress in the area of information provided to patients, including the website traffic light rating system developed in consultation with the Scientific and Clinical Advances Advisory Committee (SCAAC), which will give a visual indication of the evidence base for each add on.
- 8.6.** The HFEA was consulting on version 9 of the Code of Practice, which will include a revised guidance note 4: 'Information to be provided prior to consent'. The main additions related to how clinics communicate the effectiveness of treatments and using unproven/emerging technologies.
- 8.7.** Following the formation of a stakeholder working group, the HFEA would next develop a consensus statement on how to introduce new technologies into clinical practice.
- 8.8.** Finally, the Scientific Policy Manager spoke about how add ons could be improved by publicising the consensus statement and encouraging clinics to follow its guidance. We will also explore how we can encourage and perhaps facilitate research which would add to the evidence base for add ons.
- 8.9.** Members were encouraged by this piece of work, positively noting features such as the traffic light system and the consensus statement.
- 8.10.** Members asked questions about methodology, particularly around what treatments were to be considered add ons. The Scientific Policy Manager explained the approach taken to date and acknowledged that we were still developing and improving the methodology.

Decision

- 8.11.** The members supported the work completed so far.
- 8.12.** Members agreed with the overall approach but also noted that the HFEA needed to define what was considered normal treatment, in developing this work.

9. Code of practice

- 9.1.** The Policy Manager outlined the proposed Code of Practice update. A new edition of the Code of Practice was in preparation, containing some wide-ranging revisions. Members were provided with a summary of recent engagement with stakeholders and the revisions to the Code currently out for public consultation.
- 9.2.** A working group comprising of a range of clinic and laboratory staff met in December and January. Additionally, in February stakeholder workshops were held in London, Edinburgh, Manchester and Bristol.
- 9.3.** The Policy Manager explained that the public consultation regarding the proposed changes was currently open for six weeks, from 23 April to 1 June 2018 and provided details about how this had been communicated to potential respondents.
- 9.4.** After analysing consultation responses and making any necessary revisions, the final draft Code of Practice would be presented to Authority in June for approval. Subject to sign off by the Secretary of State the new version of the Code would be in effect from 1 October 2018.
- 9.5.** The Chair encouraged members to provide feedback during the consultation.

Decision

9.6. Members noted the updated Code of Practice and proposed next steps.

10. Patient survey

- 10.1.** The Director of Strategy and Corporate Affairs set out the proposed National Patient Survey, following the Authority's approval of the new Intelligence Strategy in January 2018.
- 10.2.** The Director of Strategy and Corporate Affairs highlighted a need for patient feedback that is not linked to a specific clinic building more widely on developments like the NHS Patient Experience Framework which, since 2012, had led to increasing focus on patients' experience of care.
- 10.3.** The Director of Strategy and Corporate Affairs noted that by asking patients in a rigorous, systematic fashion about their experiences of care and treatment, the quality of fertility services could be accurately measured and improvements made. This information did not exist at present and a benchmark measurement would be helpful.
- 10.4.** The Director of Strategy and Corporate Affairs outlined the challenges that could be faced with this piece of work and methods that would be implemented to reduce the risk of these occurring.
- 10.5.** The Director of Strategy and Corporate Affairs relayed to members the areas that the survey would focus on, such as continuity of care and emotional support.
- 10.6.** The results of the survey would be used in four ways: to better understand the patient journey and to identify areas for the HFEA to concentrate on; to sense check existing information (for example, on Choose a Fertility Clinic); to identify problem areas; and to compare results over time. In turn, the survey results would lead to improvements to clinical effectiveness and patient safety as well as helping patients make informed choices and reducing costs. We would analyse and share the information, perhaps working with others in the future.
- 10.7.** The Director of Strategy and Corporate Affairs noted that the HFEA was in the process of receiving tender submissions from research organisations who may be able to conduct the survey.
- 10.8.** Members discussed the proposed survey and were encouraged that the HFEA planned to undertake this work. However, members noted that:
- The Executive should ensure that there was an effective governance process in place to provide assurances on the survey work, to ensure it offers value for money and has a robust and effective methodology to support it.
 - Consideration should be given to survey design, including who was best placed to carry out the survey and what involvement there could be from patients in survey design.
 - The survey should build upon existing work on patient engagement to ensure there was real benefit and that the outcomes could support the organisation's objective to improve standards for patients.

Decision

- 10.9.** Following discussion, members noted the development of the National Patient Survey and agreed that the implementation details and next steps should be discussed with the Chair after the Authority meeting.
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11. Any other business

- 11.1.** No other business was raised.
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12. Chair's signature

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

Signature

Chair

Date