

## Minutes of the Authority meeting on 15 November 2023

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| Members present     | Julia Chain<br>Tim Child<br>Frances Flinter<br>Zeynep Gurtin<br>Jonathan Herring<br>Alex Kafetz<br>Jason Kasraie       | Alison McTavish<br>Alison Marsden<br>Gudrun Moore<br>Geeta Nargund<br>Catharine Seddon<br>Christine Watson |
| Apologies           | Graham James   |  |
| Observer            | Steve Pugh (Department of Health and Social Care – DHSC)<br>Farhia Yusuf (Department of Health and Social Care – DHSC) |  |
| Staff in attendance | Peter Thompson<br>Clare Ettinghausen<br>Rachel Cutting<br>Tom Skrinar  | Paula Robinson<br>Dina Halai<br>Anna Wilkinson<br>Shabbir Qureshi<br>Alison Margrave                       |

### Members

There were 13 members at the meeting – 8 lay and 5 professional members.

## 1. Welcome and declarations of interest

- 1.1. The Chair opened the meeting by welcoming Authority members, HFEA staff and DHSC colleagues present.
- 1.2. The Chair also welcomed observers online and stated that the meeting was being audio recorded in line with previous meetings and for reasons of transparency. She stated that the recording would be made available on our website to allow members of the public to hear it.
- 1.3. Declarations of interest were made by:
  - Geeta Nargund (Clinician at a licensed clinic) and
  - Jason Kasraie (PR at a licensed clinic).

## 2. Minutes of the last meeting and matters arising

- 2.1. Members agreed that the minutes of the meetings held on 13 September 2023 were a true record and could be signed by the Chair.

### Matters arising

- 2.2. Members were advised that all the matters arising items had been actioned as detailed in the paper presented to the meeting.

### 3. Chair and Chief Executive's report

- 3.1. The Chair noted that the [HFEA's proposals for law reform](#) had been published on 14<sup>th</sup> November 2023. She expressed her thanks to the HFEA team as well as many others including respondents to the public consultation and members of the Legislative Reform Advisory Group. This marked the end of the first stage of this work and the HFEA will now consider the next steps in further work on the main areas of change.
- 3.2. The Chair gave an overview of her engagement with key stakeholders and her attendance at the decision-making committees of the Authority. The Chair highlighted the meeting with Fertilis, an organisation which brings together most of the large private sector clinic groups in the UK.
- 3.3. The Chair informed the Authority that she will attend the PET Conference and Fertility 2024 and will speak on the proposed law reform proposals.
- 3.4. The Chief Executive informed the Authority that as the Public Bodies Review report has not yet been published, this agenda item will not be considered today but he hoped that it would be published soon.
- 3.5. The Chief Executive provided an update on the key external activities in the paper presented to the Authority. He highlighted his attendance at the human embryos in medical research conference in Berlin and spoke of the high esteem in which the HFEA model is held.
- 3.6. The Chief Executive spoke about the CsaP (Centre for Science and Policy) Workshop he attended on the governance of stem cell-based embryo models in the UK. These models currently fall outside the current regulatory framework and there is a desire to create a voluntary code.
- 3.7. In response to a question, the Chief Executive provided further insight into the REAL (Research and Economic Analysis for the Long term) Challenge annual lecture on 'What will the NHS look like at 100?' It was noted that this lecture was available on YouTube and the Chief Executive undertook to send the details to members.

#### Decision

- 3.8. Members noted the Chair and Chief Executive's report.
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### 4. Committee Chairs' reports

- 4.1. The Chair invited Committee Chairs to add any other comments to the presented report.
- 4.2. The Licence Committee Chair (Alison Marsden), gave an overview of recent meetings and spoke about the impact of the work of the inspectors and how our inspection and licensing system is making a positive difference to the work of the Authority.
- 4.3. The Statutory Approvals Committee (SAC) Chair (Jonathan Herring) provided further insight to the work of the committee. He explained the process that when a PGT-M condition is approved, a definition of the condition must be created that can be understood by a lay member of the public. He spoke about how the committee draws on expert advice and lived experience for preparing this definition.

- 4.4.** The Scientific and Clinical Advances Advisory Committee Chair (Tim Child), gave an update on the work of the committee. He spoke about the presentation given to the committee on health outcomes in children born from ART. The committee had also removed artificial egg activation treatment from the list of treatment add-ons in line with professional guidelines on best practice which had been issued recently.
- 4.5.** The Audit and Governance Committee (AGC) Chair (Catharine Seddon) gave an update on the work of the committee, highlighting the discussion on closing recommendations from internal audit. The committee held a deep dive discussion on legal risks and the Chief Executive was thanked for preparing the discussion paper, Progress against Governmental Functional Standards continues to be monitored. Members were invited to attend the forthcoming training session on good governance. The AGC Chair reported that she will attend the Department of Health and Social Care (DHSC) Audit and Risk Committee meeting in early December with the Chief Executive and Director of Finance and Resources.
- 4.6.** The Chair spoke about the importance of the work undertaken by the various committees and expressed her thanks to all members for their commitment to this.

#### Decision

- 4.7.** Members noted the Committee Chairs' reports.

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## **5. Performance report**

- 5.1.** The Chief Executive introduced the performance report and stated that of the 17 KPIs, four are red, three amber, seven green and three neutral. As a small organisation any long-term sick leave will have a negative impact on this KPI and as reported earlier these are distinct cases not related to stress or workload.
- 5.2.** The Chief Executive reported that the HFEA is nearly operating at full headcount, carrying one staff vacancy. The Chief Executive expressed his thanks to the staff, but especially the HR team, for filling vacancies quickly.
- 5.3.** PRISM activity levels continue to be stable with an average error rate of just 3.4%. He reported that several clinics have an error rate above 4% so a targeted approach to address this will be taken.
- 5.4.** The Chief Executive spoke about the benefits of the new database structure and how it will be easier for the HFEA to manipulate and manage its data.
- 5.5.** A member congratulated the HFEA team in driving down the PRISM error rate and expressed thanks to all involved in this work.

#### Compliance and Information

- 5.6.** A member asked whether there was increased pressure on the OTR team due to the success of the #WholsMyDonor campaign and asked whether there are any concerns regarding available resources to respond to enquiries and clear the backlog. The member questioned whether future reporting could include details on time elapsed from application to issuing information.

- 5.7.** The Director of Compliance and Information responded that the OTR team has not been able to solely focus on processing applications as they have had to prioritise the development and testing of the system and training. The focus for the team had been to ensure that the tools were in place to be able to manage and report on the data. This development work has now been completed so the team will be able to focus on applications to start to reduce the backlog. It was noted that the time taken to deal with enquiries will depend in part on the response of others as clinics have 28 days to respond to requests from the HFEA and donors have 20 days to respond to being notified that a request for their identifiable information has been made.
- 5.8.** The Director of Compliance and Information stated that inspector workload remains high, and this is impacted by long-term sick leave and turnover of staff. Training of the new inspectors is going well, and they are now attending inspections.
- 5.9.** It was reported that an independent IT data back-up audit had been conducted and the results will be reported through the Audit and Governance Committee. Security penetration testing has been carried out and additional measures will be put in place to mitigate any vulnerabilities. The business continuity plan has been redrafted and this now includes critical incident management; the revised plan is currently at review stage.
- 5.10.** The Director of Compliance and Information reported that the team are looking at the DSPT submission for the next year, noting the increased demands of this submission.
- 5.11.** The business case for the Epicentre (inspection and licensing tool) replacement is being drafted and a meeting is planned for later this month with the DHSC procurement team.

### Strategy and Corporate Affairs

- 5.12.** The Director of Strategy and Corporate Affairs informed members that over the weekend NHS England had published information stating that they were stopping funding PGT-M. It is the HFEA's understanding that this was an error and we have received clarification that the commissioning arrangements are unchanged. NHSE have apologised for the concern and confusion that this has caused. It was noted that between 600-700 patients a year benefit from this successful, cost-effective treatment which provides families with the opportunity of having a child free from significant hereditary disease.
- 5.13.** Reference was made to the recent Government announcement on changes to the law regarding 'shared motherhood' and same-sex couples with non-transmissible HIV. An update and a timetable for this change will be shared with clinics when we have more information on it.
- 5.14.** The Authority were informed that there had been over 260 pieces of media coverage on our law reform proposals with most focus on proposed changes to provide information about donors to parents, on request, after the birth of a child. The ethnic diversity in fertility treatment report will be published later this year and will include a call to action.
- 5.15.** The data dashboards will go live later this year on the HFEA website, and this will make using and understanding the HFEA's data easier.
- 5.16.** The Code of Practice update had been published and laid in Parliament at the end of October. Thanks were expressed to colleagues in DHSC for their assistance with this.

- 5.17.** Information was provided about the publication of the treatment add-ons information and the media coverage achieved. In response to a question the Director of Strategy and Corporate Affairs stated that no negative feedback had been received from professionals in the sector.
- 5.18.** Information was provided on the recent patient organisation stakeholder group meeting and the planned professional stakeholder group meeting. Main topics of discussion were the #WholsMyDonor campaign, treatment add-ons and the ethnic diversity in fertility treatment report.

#### Finance

- 5.19.** The Director of Finance and Resources stated that as previously reported the HFEA is currently operating with a small deficit which can be attributed to increases in IT costs and the non-consolidated bonus for staff which was agreed by the Government but needed to be met out of the HFEA's current budget. Forecasted income has dropped slightly. He stated that the Department is aware of the deficit and has not requested any corrective action.

#### Decision

- 5.20.** Members noted the performance report.

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## 6. 2024/25 Budget Proposals

- 6.1.** The Chair introduced this item reminding members that the HFEA is funded by a mix of fees levied on the sector it regulates and Grant In Aid (GIA) from DHSC. It is the Authority's responsibility to set the budget and consideration needs to be given to the reduction in GIA and increasing inflation costs.
- 6.2.** The Director of Finance and Resources introduced the paper and provided further background about HFEA's operating costs stating that approximately 80% of income is raised via licence fees charged to licensed treatment and research establishments with the remainder being provided through GIA from DHSC.
- 6.3.** The expenditure requirements for 2024/25 were explained in detail, noting that the higher levels of inflation experienced over the last couple of years have led to larger increases in staff pay as well as increases in several core areas, such as IT licences.
- 6.4.** Whilst there are no current plans to increase the workforce headcount, the significant pressure on the OTR team needs to be explored as additional staff may be required to service this. HFEA would expect to fund additional in-year operational pressures through efficiencies and flexible use of available resources.
- 6.5.** The Director of Finance and Resources spoke about the reduction in GIA and the expectation from DHSC that fees should be increased to cover this shortfall. An application will be made to DHSC business planning for additional GIA for a replacement system for Epicentre, as it would be difficult to fund the cost of this system through increased fees alone. The proposed increases to fees were explained in detail.
- 6.6.** The Director of Finance and Resources stated that if the Authority approved the budget proposals he would seek agreement from both DHSC and HM Treasury for the proposed fee increases.

- 6.7.** In response to a question from a member the Chair clarified that the proposed increase in fees and the GIA bid for replacing Epicentre are two distinct issues.
- 6.8.** Members discussed the high importance of replacing Epicentre to ensure that the HFEA can continue to meet its statutory inspection and licensing duties. It was noted that a new system should also improve efficiency.
- 6.9.** In response to a question regarding the proposed differential percentage increases to fees for IVF and DI, the Director of Finance and Resources explained that the income from DI is small and therefore not a significant income stream.
- 6.10.** A member expressed their disappointment in the reduced funding from GIA and questioned whether this is being applied consistently across all ALBs. The Director of Finance and Resources responded that the Department's current preference is that regulators should be funded through their chargeable fees rather than GIA.
- 6.11.** In response to questions the Chief Executive explained that it is very difficult to undertake an international price comparison and that over time HFEA fees have generally been below inflation.
- 6.12.** A member stated that most IVF clinics add an 'HFEA fee' onto the patient's bill as an itemised item and they questioned whether the centres should be absorbing some costs rather than levying them all on the patient. The Chief Executive reiterated that the HFEA does not charge fees to individual patients but to licensed clinics; and these establishments then decide whether to pass the costs on or not. It was noted that whilst a round of IVF may cost (at the lower end) between £4,000 - £5,000, the proposed HFEA licence fee for safely regulating this field would be just £100.

#### Decision

- 6.13.** Members agreed the proposed HFEA operating budget for 2024/25.
- 6.14.** Members agreed the fee levels of £100 for IVF and £40 for DI as required to fully fund the HFEA in 2024/25, subject to DHSC and HM Treasury approval.
- 6.15.** Members agreed that the HFEA should bid for £620,000 of additional urgent GIA to cover the cost of replacing Epicentre through the DHSC business planning process.

#### Action

- 6.16.** The Director of Finance and Resources to seek approval from DHSC and HM Treasury and implement the decisions regarding the 2024/25 budget.

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## **7. Strategic Risk Register**

- 7.1.** The Risk and Business Planning Manager presented this item and informed members that significant updates to the Strategic Risk Register will be undertaken after this Authority Meeting in preparation for the forthcoming December Audit and Governance Committee meeting.
- 7.2.** The Risk and Business Planning Manager explained the proposed changes and updates for the risk categories contained in the Strategic Risk Register, noting that the strategy risk will be updated once the public bodies review report is published, and that the security risk will be updated with the results of the penetration testing.

Decision

- 7.3.** Members noted the report.
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## **8. Opening the Register - update**

- 8.1.** The Director of Compliance and Information presented the update on Opening the Register (OTR).
- 8.2.** The testing of the OTR RITA reports is nearing completion and once these reports are delivered the SOP will be updated to include these new procedures.
- 8.3.** The Director of Strategy and Corporate Affairs spoke of the success of the #WholsMyDonor campaign and thanked stakeholders for supporting this. Consideration will be given to the planned communications workstream so that applications do not become unmanageable, the other risks as contained in the paper remain unchanged.
- 8.4.** A member questioned whether it is possible to know the average rate of expected enquiries per year for this service. Members of the Executive responded that whilst the numbers of potential applications are known for each year, these are cumulative as not everyone will request the information at the age of 18, and may wait for significant events in their life like marriage or the birth of their own children, and it was unknown how many of those know they are donor-conceived. It would not therefore be possible to estimate the expected average number of enquiries until this service had been operating for a number of years.
- 8.5.** A member raised the risk of fraudulent websites being set up which could promise to fast-track applications for a fee, and questioned whether additional information regarding the importance of gov.uk email addresses could be added to the HFEA website. The Director of Compliance and Information responded that this potential risk is recorded on the strategic risk register and is being actively monitored. Information is already included on the HFEA website, but consideration would be given to see whether this could be strengthened.
- 8.6.** In response to a question the Director of Compliance and Information reiterated that the team had been focussing on the development and testing of the required IT tools as ensuring these are correct will assist in managing the data efficiently and quickly.
- 8.7.** The Chair drew the discussion to a close stating that this is an important standing item on the Authority's agenda.

Decision

- 8.8.** Members noted the update on OTR.
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## **9. Public Bodies Review**

- 9.1.** This item has been deferred to a subsequent Authority meeting as the final report has not yet been published.



## 10. Support Services Update

- 10.1.** The Chair introduced this item stating that whilst a general report had been given on OTR, this focuses on the support services work. This item is brought to the Authority for information now and a further report which requires a decision will be brought to the January 2024 meeting.
- 10.2.** The Policy Manager introduced the paper and provided a recap of the current provision of support services which is in place until September 2024.
- 10.3.** The expected increase in applicants from late 2023 with the availability of identifiable information is likely to have a substantial impact on the demand for, and cost of, a support service over time. Applicants must have been given a suitable opportunity to receive proper counselling before the HFEA is required to give them information; but there is no requirement for the HFEA to provide this counselling.
- 10.4.** The team had looked at international comparisons and reviewed funding options. It was noted support services are not widely provided free of charge, although in some countries there is state or charitable funding, but this is limited. Discussions had been held at stakeholder roundtable meetings, including with patient organisations, professionals and academics. The key takeaways from these meetings included the importance of peer support and reliable high quality information.
- 10.5.** A survey was run in August – September 2023 and 270 responses were received, of which 254 were complete responses. A high-level summary of the results was presented to the Authority. It was noted that respondents perceived that HFEA involvement in commissioning services would result in increased confidence and trust in the services provided. However, the most common type of support accessed was through peer support and information and responses to a question regarding funding indicated that there was some willingness to pay (in whole or in part) for specialist counselling.
- 10.6.** The Policy Manager described the next steps in this work, with final options being brought to the January 2024 meeting for a decision.
- 10.7.** A member summarised their views of the themes arising from this work as: 1) the importance of a single source of information for quality, consistency, and sensitivity; 2) access to peer support; 3) sign posting of information; and 4) potential willingness to accept self-funding of this service.
- 10.8.** A member questioned whether it was possible to bid for central funding for this support service work. The Director of Compliance and Information responded that it is not a realistic option to seek additional funding from DHSC for this work, especially as GIA is being reduced.
- 10.9.** In response to a question, the Policy Manager stated that peer support was defined in the questionnaire, and it did not include 'talking to a friend'.
- 10.10.** A member asked whether it is possible for the January paper to include details of the number of applications accessing the current support service and the feedback on the services provided. The policy manager responded that current numbers of those accessing the service were low and there may be some data sharing issues which will prevent the HFEA accessing the feedback.



- 10.11.** In response to a question regarding costings the Director of Compliance and Information reiterated that the HFEA did not have a statutory requirement to provide this support service.

Decision

- 10.12.** Members noted the report.

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## **11. Add-ons – report back on publication of new ratings systems**

- 11.1.** The Chair introduced this item and stated that the launch of the updated rating system for treatment add-ons marked the successful end of a long period of policy and communications work. The Chair thanked the members of the Scientific and Clinical Advances Advisory Committee and all members of staff who had worked on this.
- 11.2.** The Head of Regulatory Policy (Scientific), introduced the paper and stated that the new categories of add-ons rating system went live last month. On the go live launch date over 1,000 visits were made to the HFEA website and there were over 270 pieces of media coverage.
- 11.3.** The Head of Regulatory Policy referred to the communication activities undertaken and provided further highlights of this.
- 11.4.** The next steps for this work were presented including developing a BAU process for reviewing the evidence base for treatment add-ons and to consider the frequency of review. The HFEA was the first regulatory body in the world to publish information for patients on the efficacy of treatment add-ons, the Cochrane Special Collection and ESHRE have also now published evidence-based reports on add-ons. The HFEA will continue to monitor new sources of reviewed evidence to ensure that HFEA resources continue to respond to UK patients' needs, and explore whether there are any collaborative opportunities in the future.
- 11.5.** The Chair of the Scientific and Clinical Advances Advisory Committee expressed his thanks to all who had worked on this, especially regarding the tight timetable that some of this work was completed in.
- 11.6.** Members expressed their congratulations to the team for delivering this work which had been very well received.
- 11.7.** In response to a question the Head of Regulatory Policy stated that this information had not been sent to commissioning bodies and this would be sent to NHS England to disseminate to the commissioning bodies.
- 11.8.** A member asked if there were any lessons learned from the management of this work which can be carried forward to other projects. The Director of Strategy and Corporate Affairs responded that the new process of reviewing evidence introduced through the add-ons work is already being used for the annual horizon scanning review.
- 11.9.** The Chief Executive commented that this was a time-consuming project and consideration must be given to what kind of policy model suits key pieces of future policy work. The opportunity to collaborate with other organisations will also be considered to see whether efficiency measures can be achieved.

- 11.10.** A member asked whether the HFEA was collecting information on patient treatment additions. The Director of Compliance and Information stated that the HFEA has an agreed data dictionary, and this could not be reviewed until PRISM was fully embedded.

Decision

- 11.11.** The members noted the paper.

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## 12. Any other business

- 12.1.** The Chair thanked members for participating in a workshop immediately before the Authority meeting, where the focus of discussions was the 2025-2028 Strategy.
- 12.2.** The Chair informed members that Jason Kasraie's term will end mid-January 2024, and this will therefore be his last Authority meeting. On behalf of the HFEA the Chair thanked Jason for his contribution and stated that he has agreed to stay as an expert adviser to the Authority on embryology until Ministers appoint a new professional with that skill set. Additionally, he will stay on SCAAC as an external member for a further 12 months.
- 12.3.** The Chair stated that due to the vacancy on the Authority there would need to be a few changes to committee membership.
- 12.4.** Members noted that 2024 would have been the 100<sup>th</sup> birthday of Mary Warnock.
- 12.5.** The Chair reminded members that they can participate in a good governance training session organised by the Audit and Governance Committee being held on 7 December, and that further details are available from the Board Governance Manager.
- 12.6.** There being no further items of any other business the Chair reminded members that the next meeting will be held on 24 January 2024, in person, at the HFEA's offices at 2 Redman Place.

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## Chair's signature

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

Signature



Chair: Julia Chain

Date: 24 January 2024