

Minutes of the Authority meeting on 24 January 2024

Members present	Julia Chain Tim Child Zeynep Gurtin Jonathan Herring Graham James Alex Kafetz	Alison McTavish Gudrun Moore Geeta Nargund Catharine Seddon Christine Watson
Apologies	Frances Flinter Alison Marsden	Steve Pugh DHSC Amanda Davies DHSC
Advisers	Jason Kasraie, Special Adviser	
Observers	Adrian Thompson, Board Apprentice Farhia Yusuf (Department of Health and Social Care – DHSC) Kath Bainbridge (DHSC)	
Staff in attendance	Peter Thompson Clare Ettinghausen Rachel Cutting Tom Skrinar	Paula Robinson Anna Wilkinson Shabbir Qureshi Alison Margrave

Members

There were 11 members at the meeting – 8 lay and 3 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. The Chair welcomed Jason Kasraie, in his role as Special Adviser to the Authority and Adrian Thompson, who has joined the Authority for a year as a Boardroom Apprentice.
- 1.2. The Chair also welcomed observers online and stated that the meeting was being 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)

2. Minutes of the last meeting and matters arising

- 2.1. A member proposed that the last sentence of minute 5.12 be amended and it was agreed that the Chief Executive would consult with the Chair on the amended wording.
- 2.2. With this amendment members agreed that the minutes of the meeting held on 15 November 2023 were a true record and could be signed by the Chair.

Matters arising

- 2.3.** Members were advised that the matters arising items had either been actioned as detailed in the paper presented to the meeting or that an update would be presented to members under the Directors' report in agenda item 5.

3. Chair and Chief Executive's report

- 3.1.** The Chair gave an overview of her engagement with key stakeholders and her attendance at the decision-making committees of the Authority.
- 3.2.** The Chair informed the Authority about her attendance at the PET Conference in December 2023 and Fertility 2024 which was held in Edinburgh in January. On both occasions she spoke about the law reform proposals, these were well received by participants and there was overall support for change. Members who had attended these events agreed that HFEA's presence was very well received.
- 3.3.** The Chair informed the Authority that together with the Director of Strategy & Corporate Affairs she had attended the Women's Health Summit, where the Parliamentary Under Secretary of State had set out the government's priorities for the Women's Health Strategy in 2024.
- 3.4.** The Chair referred to the proposed minor updates to GD 0007 which were circulated to members for approval via correspondence in early January. Members had agreed to these changes and the updated General Direction 0007 will come into force on 19 February 2024.
- 3.5.** The Chair informed members that she would be undertaking visits to clinics in 2024 and would be meeting the Scottish minister in May 2024.
- 3.6.** The Chief Executive provided an update on the key external activities contained in the paper presented to the Authority.
- 3.7.** The Chief Executive spoke about the DHSC Audit and Risk Committee meeting which he attended with the Audit & Governance Committee Chair and Director of Finance & Resources. This had been a productive meeting and HFEA had been able to frame its key risks to the DHSC Committee.
- 3.8.** The Chief Executive spoke about the all-staff event held in December and the positivity around this event. The results of the annual staff survey had been presented and he provided details of the key findings many of which scored more favourably than the average for the public sector or NHS.

Decision

- 3.9.** Members noted the Chair and Chief Executive's report.

4. Committee Chairs' reports

- 4.1.** The Chair invited Committee Chairs to add any other comments to the presented report.
- 4.2.** In the absence of the Licence Committee Chair (Alison Marsden), the Deputy Chair of the committee (Graham James) gave an overview of recent meetings and said there had been several cases of notable compliance improvements which had been pleasing to note.

- 4.3.** The Statutory Approvals Committee (SAC) Chair (Jonathan Herring) provided further insight to the work of the committee. He explained that when an application for a PGT-M condition is received the Executive will consider whether there are similar conditions which could be licensed at the same time. He stated that a number of applications for conditions which also include deafness had been received and the committee had asked the Executive and peer reviewers to undertake a full review of autosomal recessive deafness conditions.
- 4.4.** The Scientific and Clinical Advances Advisory Committee Chair (Tim Child), informed the Authority that the next meeting will be held in early February. He reported that three members and an external adviser had visited Newcastle Fertility Centre at Life in December to hear first hand about their mitochondrial donation programme.
- 4.5.** The Audit and Governance Committee (AGC) Chair (Catharine Seddon) gave an update on the work of the committee highlighting the discussion on the risk register and strategy, she gave assurance to the Authority that there is appropriate mitigations in place. She informed Authority that the committee had agreed a new timetable for the Choose a Fertility Clinic (CaFC) update, which will allow for three years of verified data to be used and the committee felt that this would be in the best interests of patients. She provided further updates on the mitigations in place to enable the Authority to identify fake OTR websites, the HR bi-annual report including the staff survey and the committee's annual review of effectiveness. After the formal meeting members participated in a training session on good governance, which had been well received.
- 4.6.** The Chair spoke about the importance of the work undertaken by the various committees and expressed her thanks to the Chairs and all members for their commitment to this work.

Decision

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

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. Regarding the HR KPIs, he reiterated that 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 unrelated to stress or workload. In response to a question, he stated that if the long-term sickness rate was removed the actual sickness rate would be 0.48%.
- 5.2.** PRISM activity levels continue to be stable with an average error rate of just 3.4%. The 32 clinics with an error rate above 4% will continue to receive a targeted approach to address this.
- 5.3.** The Chief Executive informed members that eight clinics have volunteered to be pilots for the 10 family limit alerts, and it is anticipated that this pilot will start in February. In response to a question, he confirmed that the limit is applicable only to use in the UK, regardless of the source of donation. He reiterated that HFEA does not have jurisdiction outside the UK.
- 5.4.** In December 2023 the Audit & Governance Committee agreed a new timetable for the Choose a Fertility Clinic (CaFC) update. Verification with clinics will commence in January 2024 and run until Summer 2024 with the process of sign-off and publication starting in Autumn 2024.

Compliance and Information

- 5.5.** The Director of Compliance and Information informed members that as a small team, the compliance team was being impacted by long-term absence. Whilst this puts additional pressure on the inspection team it has not resulted in a clinic not being able to have a licence renewed.
- 5.6.** The Fuller Independent Inquiry phase one report raised some wider concerns about regulation and the compliance team had reviewed each recommendation to see if there is any learning which could be relevant to the HFEA. For example, a point raised was that the HTA appears to view inspections in isolation. On review the HFEA, when preparing for an inspection, considers non compliances from previous inspections as well as other issues such as incidents, complaints and whistleblowing. As these are all taken into account it was considered the HFEA do not view inspections on isolation.
- 5.7.** A member commented that the recommendations contained within the Fuller Independent Inquiry phase one report were also being considered by regulators outside the health sector, especially regarding getting assurance rather than being reassured. The Director of Compliance and Information agreed and commented on the process which the HFEA uses to assure itself, by collecting desk-based evidence before an inspection.
- 5.8.** The Director of Compliance and Information stated that there had been staff turnover again in the OTR Team, but these vacancies had been successfully recruited to. The case management system is working well and should be beneficial in helping to manage and categorise the waiting list.
- 5.9.** Members were informed that the baseline assessment for the Data Security and Protection Toolkit has started and will be completed by end of February and that the audit on business continuity will commence this quarter. The business case for the Epicentre replacement has been presented to the Department and meetings have been held with the DHSC procurement team.

Strategy and Corporate Affairs

- 5.10.** The Director of Strategy and Corporate Affairs spoke about the high workload being successfully managed by the Licensing Team.
- 5.11.** The report on Ethnic Diversity in fertility treatment was published in December, and she highlighted key disparities identified in the report. To further this work the HFEA, British Fertility Society, Fertility Network UK and the Royal College of Obstetricians and Gynaecologists agreed a call to action to reduce disparities in access to and outcomes for Black, Asian and ethnic minority patients. Members were informed that the Royal College of General Practitioners had now joined this call for action.
- 5.12.** A member congratulated the HFEA team for this excellent report and the media attention it has received.
- 5.13.** The Director of Strategy and Corporate Affairs informed members that a soft launch of the dashboard had taken place, and that these are ground breaking and probably the first of their kind in the world. She encouraged members to use and promote the dashboard.
- 5.14.** Members were informed that the HFEA's first Instagram Live was held on 16 January and this had received positive feedback, thanks were given to the staff involved in organising it. Updates

were provided on other media engagements especially around the topics of egg freezing, funding and donation.

5.15. Members were informed that it is now possible to exclude internal traffic from the HFEA's website sessions data, so as to provide a 'top 3' most viewed web pages.

5.16. Members were informed that work continues on OTR communications, add-ons, Code of Practice, consent forms, law reform and the next fertility trends report.

Finance

5.17. The Director of Finance and Resources referred to the paper and stated that as previously reported the HFEA is currently operating with a deficit of £138k which can be attributed to increases in IT costs, the unplanned non-consolidated bonus for staff which was agreed by the Government but needed to be met out of the HFEA's current budget and a reduction of Grant in Aid (GIA) of £100k. He stated that the Department is aware of the deficit and has not requested any corrective action.

5.18. Members were informed that the proposals for fee increases were with HM Treasury for approval.

5.19. The GIA bid for a replacement for epicentre had been submitted although the Director of Finance and Resources expressed some concern as to when a response might be received. In response to a question, he stated that if the bid was unsuccessful then an additional fee increase could be considered to fund this project, although this is not the HFEA's preferred option. The Chief Executive spoke about the wider pressures on the Department and that he would keep the members informed of any progress.

Decision

5.20. Members noted the performance report.

6. Draft Business Plan 2024-2025

6.1. The Chair introduced this item reminding members that every year the HFEA is required to set a Business Plan for the coming financial year. Resources continue to be tight and therefore the Authority needs to decide what the priorities should be.

6.2. The Risk and Business Planning Manager introduced the paper and explained the planning cycle to produce the Business Plan, including submission to the Department for approval. Once approval is received from the Department the final business plan will be published on the HFEA website.

6.3. In addition to the HFEA's statutory work the Risk and Business Planning Manager spoke about the main priorities for 2024-2025 as detailed in the paper presented to the Authority. In response to a question, he confirmed that they were not listed in order of priority.

6.4. In response to a question the Director of Strategy and Corporate Affairs confirmed that the team will continue to develop further aspects of the law reform proposals, especially focussing on patient safety and protection, and scientific developments. Members were reminded of the good engagement received on the public consultation undertaken by the HFEA, which will be useful for the work going forward.

- 6.5.** A member questioned what the scale of the fee review work would be, noting that the HFEA has fixed expenditure but a variable income stream.
- 6.6.** The Chief Executive responded that the review would look at what model or regime could be used to ensure that the cost of regulation is fairly apportioned without being administratively cumbersome to implement. Consideration of models used by other regulators will be undertaken and then analytical work to ensure that required levels of revenue will be achieved to run the organisation.
- 6.7.** In response to a question the Director of Strategy and Corporate Affairs spoke about prioritising work to actively look at the potential impact of AI on the fertility sector and on new scientific developments such as synthetic gametes and embryo-like models.
- 6.8.** Members were informed about proposed further development of dashboards to enable greater use of HFEA's data and how this could be used in the future to support compliance activities.

Decision

- 6.9.** Members approved the main section of the business plan for 2024-2025, noting that it will be further developed over the next two to three months.

7. Opening the Register - update

- 7.1.** The Director of Compliance and Information presented the update on Opening the Register (OTR) reminding members that there were three main workstreams.
- 7.2.** The new IT system for managing applications went live at the beginning of August and the OTR team has provided positive feedback regarding ease of use and efficiency.
- 7.3.** The testing of the OTR RITA reports is now complete and these have been in use since 22 January. The SOP will now be updated to include these new procedures.
- 7.4.** Continuing, the Director of Compliance and Information stated that a separate report on the future of support services is before the Authority for consideration later in the agenda.
- 7.5.** The Director of Strategy and Corporate Affairs spoke of the success of the #WholsMyDonor campaign and the need to slow down some activity to avoid overloading the team. The second phase of activity has now commenced including activities such as Instagram live Q&A session and new web content.
- 7.6.** Members were informed that several risks had been downgraded due to successful activities such as webinars for clinic staff and engagement in FAQ on the clinic portal.
- 7.7.** Continuing, the Director of Strategy and Corporate Affairs informed the Authority that the three workstreams were ending at the end of the financial year and after this date will be considered as business as usual. The Executive are therefore proposing that the March 2024 OTR report will be the last and after this date any updates will be provided via the Performance Report.

Decision

- 7.8.** Members noted the update on OTR and agreed that after March 2024 future OTR reports will be included in the Performance Report.

8. Future of OTR Support Services

- 8.1. The Chair introduced this agenda item reminding members that they received an information paper in November 2023 and the paper before them now requires a decision to be made about the OTR support services.
- 8.2. The Policy Manager introduced the paper and provided a recap of the current provision of support services which are in place until September 2024.
- 8.3. It was noted that the HFEA has no statutory responsibility to provide this service and given the pressures on the HFEA's core budget it was no longer sustainable to provide this service. Members were assured that specialist counselling and counsellor-facilitated meetings could be organised privately by those donor conceived individuals interested and that take-up to date had been variable. These were a significant factor in the decision-making process, and it was noted that any future model of support needs to be financially sustainable.
- 8.4. The Policy Manager spoke about the methodology of the review including international comparison, funding options, stakeholder roundtable meetings, survey and costing analysis. The results of the review are now brought to the Authority for a decision on the way forward.
- 8.5. The proposed options were then discussed, and members congratulated the team for the quality of the paper presented to them.
- 8.6. Much of the discussion focused on option four to end the funding for a commissioned support service and improve and expand information and signposting. The HFEA is already seen as a credible source of high-quality information and could collaborate with other organisations to help to improve and strengthen website signposting. Members discussed whether a support App could be developed or a user generated forum moderated by the HFEA.
- 8.7. The Director of Compliance and Information stated that the HFEA website is a good starting place and that this should be utilised fully first and further developments could be considered over time. Any future development work not included in the paper presented to the Authority would need to be costed.
- 8.8. The Director of Strategy and Corporate Affairs spoke against the idea of moderating social media, such as forums as it is not within the HFEA's remit and additional resourcing with specific skills would be required.
- 8.9. Continuing, Members discussed options four and five to end funding for a commissioned support service and bring the letterbox service in-house. Members questioned the uptake for the letterbox service and if it was brought in-house the need to future proof it, perhaps by having a one-year trial.
- 8.10. Members questioned whether it was possible to obtain data from the Hewitt Centre as to the number of letter-box users and why they had used this service rather than alternative ones. Members were cautious about increasing the HFEA's workload when the demand for this service might not be present.
- 8.11. The Chair drew the discussion to an end noting that options one, two and three were not supported by the Authority. Members were then asked to decide on options four and five.

Decision

- 8.12.** Members agreed to proceed with option four as presented in the paper to end funding for a commissioned support service effective September 2024 and improve and expand information and signposting.
- 8.13.** Members agreed that further information regarding the letterbox service (option five) should be sought and brought to the Authority for decision via correspondence.

Action

- 8.14.** Executive to proceed with option four to end funding for a commissioned support service effective September 2024 and improve and expand information and signposting.
- 8.15.** Executive to gather further information from the Hewitt Centre on the letterbox service and circulate this to members for decision via correspondence.

9. Public Body Review 2023

- 9.1.** The Chair introduced this item reminding members that the Public Bodies Review programme was announced in April 2022 and that the HFEA was the second Arm's Length Bodies (ALB) of the Department of Health and Social Care (DHSC) to be reviewed with the final report being published in November 2023. This meeting was the first opportunity for the report to be discussed since publication.
- 9.2.** The Chief Executive informed members that the Cabinet Office guidance sets out the process that departments are expected to follow then conducting public body reviews. ALBs are scrutinised against four main quadrants of accountability, efficacy, efficiency and governance.
- 9.3.** The HFEA completed a self-assessment exercise and the Review decided that the primary focus would be on accountability, efficacy and efficiency, as well as looking at the adequacy of the legal framework given the focus of law reform work at the time of the review. The review considered the HFEA to have good governance arrangements so this was not a focus for the review.
- 9.4.** The Chief Executive highlighted the following quotes from the report:
- “HFEA performs important functions. It regulates a discrete and specialised area of medical practice and scientific research, which can raise sensitive clinical, legal and ethical issues.”
 - “HFEA has a small, highly experienced and capable executive management team to support its chair and members. The effectiveness of HFEA is dependent upon the breadth of skills and experience its members bring as well as the quality of support they receive from the management team.”
- 9.5.** The Chief Executive informed members that the central conclusion of the review was that the HFEA should remain an executive non-departmental public body.
- 9.6.** The Director of Strategy and Corporate Affairs informed members that of the 19 recommendations arising from the review, five of these were applicable to the Department.
- 9.7.** The Director of Strategy and Corporate Affairs presented each recommendation applicable to the HFEA, the Executive's response and proposed timing. She informed members that the Executive

would report progress against each recommendation via the quarterly accountability meetings held with the Department.

- 9.8.** A member questioned whether the HFEA should be more ambitious about using the data from PRISM regarding recommendation eight of the review. The Director of Compliance and Information responded that the HFEA is bound by current legislation, which states that an inspection must be conducted within a two year period. The HFEA would like to use the data to influence the type and frequency of inspection, and this would be considered alongside the proposed law reform proposals.
- 9.9.** Those professional members who use the Code of Practice spoke in favour of retaining the current format of the code and did not see the benefit of a shorter, slimmed down version as presented in recommendation nine.
- 9.10.** Members noted that whilst recommendation 15 refers to working with NHSE, the HFEA regulates UK wide. Members discussed whether the HFEA could be a catalyst for change within wider health priorities and that the disparities highlighted by the ethnic diversity report should be reinforced in the HFEA's response to this recommendation and further closer working with NHSE on related issues should be encouraged.
- 9.11.** A member suggested that the HFEA, and especially the Authority members, could develop a relationship with Geonomics England.
- 9.12.** The Chair drew the discussion to a close and thanked the Executive for the work they completed for this review, in an already busy work environment. The Chair also thanked those Authority members who were interviewed by the Public Body Review team.

Decision

- 9.13.** The members noted the recommendations arising from the Public Body Review and the HFEA's response to each as detailed in the paper presented to the Authority and amendments to the actions as agreed.

10. Any other business

- 10.1.** The Chair thanked all for their active participation in the meeting.
 - 10.2.** There being no further items of any other business the Chair reminded members that the next meeting will be held on 20 March 2024, in person, at the HFEA's offices at 2 Redman Place.
-

Chair's signature

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

Signature



Chair: Julia Chain

Date: 20 March 2024