

Minutes of the Authority meeting on 13 September 2023

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

Members

There were 11 members at the meeting – 7 lay and 4 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. 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:
 - Frances Flinter (Trustee at Progress Educational Trust)
 - Alison McTavish (Trustee at Progress Educational Trust and British Fertility Society)
 - 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 12 and 17 July 2023 were a true record and could be signed by the Chair.

Matters arising

- 2.2. Members were advised that matters arising were either being actioned or were on the agenda as a separate item.

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 of her introductory meeting with the HFEA's new sponsor from the Department of Health and Social Care (DHSC). During this meeting it has been agreed to hold monthly meetings with the sponsor to further enhance the working relationship with DHSC.
- 3.3. The Chief Executive provided an update on the key external activities and informed the Authority that the Annual Report and Accounts was laid in July just before recess. He expressed his thanks to members of the Audit and Governance Committee and the Head of Finance for their work in this regard.
- 3.4. He informed the Authority that HFEA's proposed pay settlement for all staff below Director level had been agreed by DHSC and would now be implemented. The settlement was in line with government guidelines. The Remuneration Committee will be meeting later this month to discuss the pay settlement for the senior management team.
- 3.5. Discussions are continuing with regard to the public body review, but this should be concluded in the Autumn.

Decision

- 3.6. 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 were several cases of notable compliance improvements. The committee had experienced higher than normal workload recently and he thanked the Chair and all committee members for their efforts in managing this workload.
- 4.3. The Statutory Approvals Committee (SAC) Chair (Jonathan Herring) provided further insight to the work of the committee and stated that the rotation system of Authority members is working well. A special direction for export had been refused as the receiving clinic had not provided any evidence on their quality management system; this in turn had led to the committee discussing what documentation was required to satisfy assurance of a quality management system.
- 4.4. In the absence of the Scientific and Clinical Advances Advisory Committee Chair (Tim Child), the Deputy Chair (Jason Kasraie) gave an update on the work of the committee. He spoke about the presentation given by the team at Newcastle Fertility Centre at Life on the mitochondrial donation programme and provided further information about the committees' discussions regarding the new ratings for treatment add-ons.
- 4.5. The Audit and Governance Committee (AGC) Chair (Catharine Seddon) informed the Authority that the committee will meet in early October. The two external members had retired from the

committee as their maximum term of service had been reached and a new external member had been appointed. She provided further information about the new member's experience and background. The committee will undertake an effectiveness review and skills audit later in the year and this will help to determine whether a second external member will be recruited.

- 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.

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. The staff sickness rate continues to be red, and this can be attributed to four employees on long-term sick; all are distinct cases and are not related to stress or workload. Staff turnover has been declining from a historic high but is rising once more, which can be attributed to public pay not keeping pace with cost of living and limited promotion opportunities in a small organisation like the HFEA.
- 5.2.** Noting that the Director of Compliance and Information had sent apologies as she was speaking at a conference, in response to a question, he stated that whilst inspection KPIs are not currently on target all licences have been issued on time. He expected these KPIs to improve once the new inspectors are fully trained and can undertake inspections independently.
- 5.3.** On PRISM, activity levels were now stable with an error rate of just 3.3%. On Choose a Fertility Clinic (CaFC), the team are continuing to encourage clinics to address errors and it was felt that the previously agreed timescales are achievable. It was noted that all but three clinics are using the new system.
- 5.4.** Members were informed that the opening the register (OTR) team had been diverted from their workstreams to test the new IT system. With testing now complete it is anticipated that the team will be able to manage and move through the backlog of work. Members noted that a fuller report will be brought to the next meeting and asked that this include anticipated levels of productivity. Members spoke about the importance of holding, managing, and integrating data and the level of additional information and reports this system will be able to provide.
- 5.5.** The Chief Executive referred to the two data breaches that had recently come to light in other public bodies which had been reported in the media. He informed members that the HFEA's Head of IT had reviewed both to consider any issues relevant to the HFEA. A future Clinic Focus article will provide any relevant updates to the sector.

Strategy and Corporate Affairs

- 5.6.** The Director of Strategy and Corporate Affairs informed members that the State of the Sector Report was released yesterday and provided further insight to this. Work continues on the Ethnic Disparities in Fertility Treatment report, and this is on track to be published later on in the year.
- 5.7.** Further insight into the data dash boards was provided and information about the testing with various groups which had taken place; feedback received was positive. A member spoke about the importance of this tool for the HFEA.

- 5.8.** Information was provided about the planned communication work regarding OTR and the treatment add ons.
- 5.9.** Members were informed that the Code of Practice update, which had been agreed previously by the Authority is on track to be published by the end of the calendar year.

Finance

- 5.10.** The Director of Finance and Resources referred to the report and stated that 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; income is as expected at this point in the year.

Decision

- 5.11.** Members noted the performance report.

6. Opening the Register - update

- 6.1.** The Director of Strategy and Corporate Affairs presented the update on Opening the Register (OTR) noting that an update on the workstream was also provided under the Performance Report.
- 6.2.** It was reported that the new IT system for managing applications had gone live at the beginning of August, which was earlier than scheduled.
- 6.3.** The post donation support questionnaire closed yesterday, with a positive number of responses received with a good representation across those impacted by donation. An overview of the work to date on the future of support services workstream would be brought to the November Authority meeting.
- 6.4.** Further information was provided about the planned communication workstream, noting that several targeted public-facing communications will begin shortly. A member commented that the presentation given by the Director of Compliance and Information to clinics was very well received and consideration should be given to include further details of this in a Clinic Focus.
- 6.5.** The ongoing risks associated with OTR were also noted.
- 6.6.** In response to a question the Chief Executive stated that the backlog of enquiries was composed of several different types of information requests and it may be necessary to prioritise these to manage expectations and reduce the backlog.
- 6.7.** The Chair thanked the various teams working on the three OTR related workstreams for their work. It was noted that further information would be brought to the next meeting which may provide insight into the efficiencies gained from the new IT system on processing applications.

Decision

- 6.8.** Members noted the update on OTR.

7. Law Reform Proposals

- 7.1.** The Chair introduced this agenda item, reminding the members of their previous discussions and decisions taken in July on this important work and that the report presented to them today focuses

on the three outstanding proposals on consent, access to donor information and scientific developments.

- 7.2.** The Director of Strategy and Corporate Affairs introduced the report and informed members that nearly 7,000 responses were received for the public consultation and the team had reviewed and considered each of these and all points contained within. She expressed her thanks to those individuals and organisations who had participated in helping to shape this work.
- 7.3.** The risks which were outlined in the May 2022 Authority meeting remain current and whilst the majority of the proposals received widespread support, some of the proposals will go too far for some and not far enough for others. The Authority will therefore need to be content with a level of criticism from those that would like a different proposal or outcome.

Consent

- 7.4.** The Chief Executive spoke to the issue of consent and reminded the members of the decisions they had taken in July and the further work which they had requested be brought to this meeting.
- 7.5.** He stressed that the issue of consent referred to throughout is that which is required by the HFEA Act and that any consent taken by either NHS or private clinics relating to medical consent to treatment are entirely separate and not within the scope of this work.
- 7.6.** The general concern is that the current system is complex and needs to be simplified, yet the opt-out proposal did not generate widespread consensus during the consultation process. The range of consents required for some people is simpler than others so a possible model where those people could chose a simplified model of consent might be possible.
- 7.7.** The current system of consent also does not appropriately reflect the range of modern family formulations and any revised consent regime should focus on the intention to be the legal parent.
- 7.8.** The Chief Executive reiterated the principles of consent outlined in the paper to frame any new system..
- 7.9.** Members spoke about the distinction between an ‘opt out’ option and ‘deemed’ consent and whether it was possible to offer a ‘package’ of possible consent models for future discussion with relevant stakeholders. The Chief Executive responded that a framework of options to open and facilitate future discussion may be helpful.
- 7.10.** Members suggested considering whether it was possible to future proof the issue of consent by including options for future scientific improvements.
- 7.11.** Members suggested consideration in any new system of secure digital storage.

Decision

- 7.12.** Members agreed the proposal that the HFEA recommend a thorough overhaul of the consent regime, and that this should be carried out together with interested parties among professional bodies, patient groups and licensed centres within the fertility sector.
- 7.13.** Any revised consent regime, should uphold the following principles:
- Reflect current best practice and guidance, for example, the GMC principles of consent.
 - The importance of free consent
 - Dynamic consent

- Simplification
- Recognition of modern families
- The special status of the embryo

Access to donor information

- 7.14.** The Director of Strategy and Corporate Affairs spoke to the issue of access to donor information and reminded members of the decisions they had taken in July and the further work which they had requested be brought to this meeting.
- 7.15.** The Director of Strategy and Corporate Affairs spoke to the principles which would be upheld in any new system and outlined a number of items for further consideration as detailed in the paper.
- 7.16.** Members discussed the issue of capacity and competency, and at what age limit it could or should be applied to a child. It was noted that a primary purpose of removing anonymity is for the benefit of the donor conceived child.
- 7.17.** Members expressed a view that any proposals may have an impact on donor numbers, noting that some patients are seeking treatment abroad to ensure an anonymous donor or to provide greater ethnic choice.
- 7.18.** In response to a question the Chief Executive confirmed that the 10-family limit policy is applied to any imported donations into the UK, but that the HFEA does not have any jurisdiction on donations used outside of the UK.
- 7.19.** Members discussed the timing of removing anonymity noting that access to information is already available through DNA testing websites and other means and therefore a long timescale for this aspect of the work should not be considered.

Decision

- 7.20.** Members agreed the proposal that the HFEA recommends the removal of donor anonymity from the birth of any child born from donation. Before any change to the law is implemented there would need to be in-depth discussions with interested parties among professional bodies, patient and donor groups, donors and donor conceived individuals and licensed centres within the fertility sector.
- 7.21.** Any revised system for releasing donor information, should uphold the following principles:
- That there remains a need for an official ‘record of truth’ and the law should continue to require the HFEA to collect data about children born from a donor
 - That consent should be properly obtained, and donors and recipients fully informed about the potential challenges to anonymity from DNA testing and matching services.
 - That parents should not be legally required to disclose to their children that they are donor conceived. But patients should continue to be encouraged by clinics to be open with their children about how they were conceived.
- 7.22.** Future consideration of the following consequences should be undertaken:
- Removal of anonymity should take place following legislative change with an implementation date to be agreed.

- Donor is known from time of birth if information is requested by parents but that a wholly 'open' system of donor selection is not recommended at this stage, whilst recognising that it does occur in other countries.
- Access to the donor sibling registry for non-donor conceived offspring of donors is considered as part of any further work on consequences of the changes above and views of all parties are explored.
- Continued respect of donor anonymity for pre-2005 donors and no retrospective early removal of anonymity for post-2005 donors.

Scientific developments

- 7.23.** The Public Policy Manager spoke to the issue of scientific developments and reminded the members of the decisions they had taken in July and the further work which they had requested be brought to this meeting. She stated that the purpose is to future proof the Act and provide flexibility to accommodate future scientific developments, noting that this is a sensitive area for many.
- 7.24.** Members discussed the speed of scientific changes, citing the recent developments led by the Weizmann Institute of Science on embryo models as an example of the pace and speed that this sector is experiencing. The Chief Executive drew an important distinction in relation to the model produced by the Institute, explaining that there is no evidence that it would grow into a foetus, and that it would be illegal to transplant the model into a womb.
- 7.25.** Members discussed developments taking place across the world where countries do not have the same rigor and regulations as the UK and indeed a regulatory body such as the HFEA.
- 7.26.** Members discussed issues relating to safety, innovation, and social concerns, noting that safety was not an absolute and that when thinking about medical innovation the key principle was whether the evidence suggested that something was unsafe, given the potential benefits.

Decision

- 7.27.** Members agreed the proposal that the HFEA recommend that the Act should be amended to future proof it, so that it is better able to accommodate future scientific developments/new technologies. Ongoing policy work should take place with relevant interested parties among professional bodies, scientific researchers, patient groups and licensed centres within the fertility sector to agree a set of regulatory changes to address the challenge posed by novel scientific developments.
- 7.28.** Any revised regime, should uphold the following principles:
- The need for public engagement and discussion coupled with appropriate consideration of any ethical and social concerns.
 - The ability to set bespoke regulatory rules should be retained.
 - Continuous monitoring.
 - Ongoing scrutiny.
 - Balance of different interests.

Next Steps

- 7.29.** The Executive would next implement the Authority's decisions and prepare the submission for the DHSC and for wider publication. .
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8. Business Planning and Strategy 2024-25

- 8.1.** The Risk and Business Planning Manager introduced the report and provided members with an overview of the planning cycle and key dates within this cycle. He referred to the strategic priorities contained within the report and asked whether there was any further steer from Members.
- 8.2.** The Chair commented that HFEA is a small organisation with a huge workload and stretched resources so when considering the list of priorities, it was important not only to agree what should be done but also what could not be done. She referenced the time and resource which was consumed by the Public Body Review process as one recent example.
- 8.3.** Members questioned proposed work around increasing the focus on genetics and Artificial Intelligence (AI) and whether this should be increased from a watching brief and whether there was any link to the work of other organisations such as the Nuffield Council on Bioethics. The Chair responded that the HFEA collaborates with several organisations and these relationships will continue. The Director of Strategy and Corporate Affairs confirmed that the proposed workstream on AI would be expanded from its current status of a watching brief.
- 8.4.** Members discussed several potential priorities including Epicentre replacement, aspects of the Women's Health Strategy, Law Reform and the Fees Review.
- 8.5.** Members discussed the resources required to undertake a review of fees and questioned whether additional resources, such as an analyst, could be obtained from DHSC. The Executive were asked to raise this item for discussion during the quarterly accountability meeting with DHSC.
- 8.6.** Members encouraged the HFEA to continue its work on ethnic disparities and that this should continue to be a strategic priority for the Authority.

Decision

- 8.7.** Members noted the report and that further development of the business plan for 2024/25 would now commence.
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9. Any other business

- 9.1.** There being no items of any other business the Chair reminded members that the next meeting will be held on 15 November 2023, 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

A handwritten signature in black ink that reads "Julia Chain". The signature is written in a cursive style with a large initial 'J'.

Chair: Julia Chain

Date: 15 November 2023