

## Minutes of the Authority meeting on 15 May 2024

Members present	Julia Chain Frances Flinter Zeynep Gurtin Jonathan Herring Alex Kafetz Graham James	Alison McTavish Gudrun Moore Geeta Nargund Catharine Seddon Christine Watson
Apologies	Tim Child Steve Pugh (Department of Health and Social Care – DHSC) Farhia Yusuf (DHSC)	
Advisers	Jason Kasraie, Special Adviser	
Observers	Adrian Thompson, Board Apprentice	
Staff in attendance	Peter Thompson Clare Ettinghausen Rachel Cutting Tom Skrinar Paula Robinson	Shabbir Qureshi Amanda Evans Kazuyo Machiyama Annabel Salisbury 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 and HFEA staff to the Authority Meeting, which was being held online. She informed the meeting that DHSC colleagues had sent their apologies for this meeting.
- 1.2. The Chair also welcomed observers 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)
  - Jason Kasraie (PR at a licensed clinic)

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

- 2.1. A member proposed that minute 9.4 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 20 March were a true record and could be signed by the Chair.

### Matters arising

- 2.3.** Members were advised that the matters arising items had been actioned as detailed in the paper presented to the meeting.
- 2.4.** The Chair referred to action 9.16 from the March 2024 Authority meeting regarding implementing the decisions concerning donation compensation rates. She informed members that the Executive is requesting that the Authority delegate responsibility for signing off on the amended Direction 0001 to the Chair.

### Decision

- 2.5.** The Authority agreed to delegate responsibility for signing off on the amended Direction 0001 to the Chair.

### Action

- 2.6.** The Chair to sign off on the amended Direction 0001.

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## 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 that in early May she spoke at the SHREG (Scottish Reproduction and Embryology Group) Conference in Dundee, and her presentation had been very well received.
- 3.3.** The Chair informed members that she had participated in interviews for the recruitment of four new Authority members, with the skill sets of embryology, genetics/statistics, legal/ethical and as a patient voice or advocate. This is an ongoing process that is run by the DHSC as members are appointed by the Secretary of State for Health and Social Care.
- 3.4.** The Chief Executive provided an update on the key external activities contained in the paper presented to the Authority and spoke about the work underway to prepare for the year-end accounts and annual report which will be presented to the Audit and Governance Committee in June.

### Decision

- 3.5.** 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 (Graham James) gave an overview of recent meetings and informed members that the committee had renewed the suspension of a licence, and this had received some additional press coverage. He spoke about how the committee uses its powers to ensure consistent improvements and gave an example of a clinic who had previously had a long history of poor compliance but was now showing marked improvement.

- 4.3.** The Statutory Approvals Committee (SAC) Chair (Jonathan Herring) spoke about the busy workload of the committee and its work to review outdated terminology to ensure that language used is appropriate.
- 4.4.** It was noted that the next meetings of the Scientific and Clinical Advances Advisory Committee (SCAAC) and the Audit and Governance Committee (AGC) are being held in June and a report will therefore be given at the July Authority meeting.

#### Decision

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

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## 5. Annual Performance report 2023-2024

- 5.1.** The Chief Executive introduced the annual performance report for 2023-2024 and spoke about the metrics for measurement of performance. He commented that over the past year there had been a marked reduction in the number of red indicators, and he thanked the staff for their work in this regard during a particularly busy year.
- 5.2.** The Chief Executive gave a brief overview of PRISM activities, including the large task of validating data for Choose a Fertility Clinic (CaFC). The updated CaFC is due to be published in the Autumn and the Chief Executive reminded members that regular reports on PRISM are given to the AGC.
- 5.3.** The HR indicators used throughout the year to measure and report to the Authority are sickness and turnover rate of staff.
- 5.4.** The Chief Executive stated that the target range for staff sickness is below 2.5%, and throughout the year this rate had declined from a high of 7.3% to 3.6%. If long term sick leave was removed, then the figure would be below the target of 2.5%. The Chief Executive remarked that he is comfortable with this figure, especially when comparison is made to other ALBs.
- 5.5.** The Chief Executive said that the target range for turnover is between 5-15% and whilst this has been exceeded, it is still manageable. As a small organisation that has to operate within the constraints of public policy on pay the HFEA is impacted by staff leaving for promotion and better pay.
- 5.6.** The AGC Chair commented that the HFEA has not been complacent regarding staff turnover and had looked at how it could improve its non-reward package to staff and had implemented wellbeing days. It was noted that the annual staff survey shows that staff morale is good.
- 5.7.** The Chief Executive informed members that the recruitment process had been improved so that vacancies were filled quicker than previously. This was not only beneficial to the HFEA but also to staff covering vacancies who could more easily manage their workload.
- 5.8.** A member commented that there may be additional media spikes and interest throughout the next year, especially regarding the law reform proposals, and they questioned where the resources would be to deal with these. The Chief Executive responded that when faced with such spikes other work is paused.
- 5.9.** In response to a question the Chief Executive confirmed that exit interviews are held when staff leave, and most people are leaving for a promotion which is not otherwise available to them in a small organisation like the HFEA.

## Compliance and Information

- 5.10.** The Director of Compliance and Information informed members that over the past year the workload for inspectors had remained high with both scheduled inspections and extra unplanned inspections required for increased regulatory oversight. Workload had also been impacted by long term absence and turnover, and thanks were given to the team for managing this so that licences were issued on time.
- 5.11.** The Director of Compliance and Information spoke about the robust process which inspection reports to Committees are subject to, to ensure that consistent decisions regarding regulatory actions can be taken. This means that sometimes due to extra compliance and enforcement meetings and communication with a PR the KPI will be breached
- 5.12.** The past 12 months have also been challenging for the Opening the Register (OTR) team with a greater number of applications than in previous years, especially around increased media awareness prompted by the documentary Born from the Same Stranger.
- 5.13.** Members were informed that the introduction of the new IT system, (Microsoft dynamics) and register tools, has worked well and allowed the OTR team to develop new workstreams for different application types. 137 applications were closed in April and already 58 applications had been closed in May, so inroads were being made into the waiting list. The new systems and procedures would form the basis of the new KPIs which are being developed by the team.
- 5.14.** The Director of Compliance and Information stated that she attended the Donor Conceived Network (DCN) Conference on 4 May and had spoken about aspects of the OTR service and this had been well received.
- 5.15.** Members were informed that the infrastructure penetration test commenced on 7 May with an expected finish date of 17 May. The Government Internal Audit Agency (GIAA) conducted an audit of our business continuity plan in January, and the recommendations arising from the audit will be implemented over the coming months. The DSPT audit commenced this week, and the report is expected to be finalised at the end of June.
- 5.16.** Approval was recently received from the DHSC Digital and Technology Assurance team to proceed with the Epicentre replacement project; funding has been allocated and the project specification is undergoing further review before the tendering and procurement process can commence.
- 5.17.** The Chair recorded the Authority's thanks to both the inspection and OTR teams for their work during the past 12 months. The Chair stated that during the pandemic a hybrid method of inspections was introduced and given that inspections and regulatory work are the cornerstone of the HFEA's work she asked what the review period of assessing the inspection process was.
- 5.18.** The Director of Compliance and Information responded that the inspection process is reviewed by PR feedback and GIAA audits and improvements are made where possible.
- 5.19.** In response to a question the Director of Compliance and Information stated that OTR applications will see a year-on-year increase, but it is difficult to predict spikes arising from media interest.

## Strategy and Corporate Affairs

- 5.20.** The Director of Strategy and Corporate Affairs spoke about the achievements of the Strategy and Corporate Affairs Directorate over the past 12 months. The HFEA had arranged and serviced over 60 formal committee meetings.
- 5.21.** During the year the Statutory Approvals Committee had approved 200 conditions that had been added to the approved list of PGT-M conditions.
- 5.22.** Throughout the year improvements had been made to the HFEA's Strategic Risk Register and associated documents and thanks were given to the Risk and Business Planning Manager for driving this work forward.
- 5.23.** The Director of Strategy and Corporate Affairs reported that the team had dealt with 2,000 public enquiries throughout the year, and it was noted that some parliamentary questions and freedom of information requests can require complex data.
- 5.24.** Members were informed that over the year a 30% increase in media coverage had been achieved and the HFEA dashboard was introduced, the Director of Strategy and Corporate Affairs stated that more information about the data we publish would be given under agenda item 6.
- 5.25.** The Directorate had also successfully managed two GIAA audits for the Code of Practice and the Register Research Panel, both of which had very positive outcomes.

## Finance

- 5.26.** The Director of Finance and Resources informed the members that the Finance team is a small team and had carried a vacancy for a large part of the year, this had now been filled and the team was at full capacity. He thanked the team for their work.
- 5.27.** Members were informed that the year end books had been closed and the audit had commenced. The provisional year end position shows an underspend on staff and legal although IT spend had been higher than budgeted. The Director of Finance and Resources cautioned that there would be some movement of figures during the external audit and the accounts and annual report would be presented to the June AGC meeting.
- 5.28.** The Chair thanked the members of the Senior Management Team for the overview of the year and remarked that this is an opportunity for the Authority to look strategically at the performance of the HFEA over the past year.
- 5.29.** The Chair thanked the HFEA team for their work and performance throughout the year and for delivering on extra projects such as the public body review and the law reform proposals.
- 5.30.** A member thanked the Executive for the transparent and detailed report and asked whether any consideration had been given to reporting on the impact of the HFEA's work. They offered to send examples of such reporting by other public bodies to the Chief Executive.
- 5.31.** The Director of Compliance and Information reminded members of the annual State of the Sector report which details compliance and non-compliance and looks year-on-year at how the sector has performed.
- 5.32.** There being no further comments the Chair drew the discussion on the annual performance report to a close.

## Decision

**5.33.** Members noted the annual performance report.

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## 6. The Register Research Panel

- 6.1.** The Head of Research and Intelligence introduced the paper and reminded members that the HFE (Disclosure of Information for Research Purposes) Regulations 2010 allow the disclosure of information for research purposes and that the Authority has delegated authorisation for this to the Register Research Panel (RRP).
- 6.2.** The HFEA holds a statutory register of all patients, partners, donors, treatments and children born as a result of fertility treatment and it is believed to be the largest database of assisted reproduction treatment in the world.
- 6.3.** One of the HFEA's key strategic aims is to ensure that people can access the right information at the right time.
- 6.4.** The Head of Research and Intelligence spoke of the reason why the HFEA collects data and how it can be used to have an oversight of the fertility sector and to look for trends and where improvements can be made. Reference was made to making data available to researchers conducting important research and the range of data reports which the HFEA publishes.
- 6.5.** The main data publications released in 2023-2024 were Fertility treatment 2021: preliminary trends and figures and Ethnic diversity in fertility treatment 2021. Members were reminded that a call to action was also published at the same time as the ethnic diversity in fertility treatment report. Presentations on these reports were given at Fertility 2024, ESHRE and other academic conferences.
- 6.6.** Members were informed about the purpose of the HFEA dashboard and that in the first two months since launch it had been viewed over 30,000 times. There has been positive feedback from stakeholders and wide media coverage had been obtained. The Head of Research and Intelligence informed members that the HFEA had been invited to present the dashboard at the Royal Statistical Society Conference in September.
- 6.7.** During the year over 200 data related enquiries had been received including freedom of information requests and parliamentary questions. Members were informed that a third of recent requests were signposted to the HFEA dashboard, therefore reducing the workload of the team.
- 6.8.** The Senior Research Manager informed members that since the last annual update the RRP had met five times and reviewed 11 project applications, including five new applications. During the period under review two projects had been fully approved by the panel and members were given a brief overview of these projects.
- 6.9.** There are 10 projects currently active and individual project webpages had been created for each project. The aim of this was to provide a lay summary and public benefit statements which in turn would increase the transparency of the HFEA's data use.
- 6.10.** Members were informed that one of the key outputs from the RRP publications is that since 2010 there have been 24 peer-reviewed papers from RRP projects and 26 peer-reviewed papers using anonymous HFEA data. Members were given a brief overview of the papers recently published

and were informed that the HFEA's data is not only being used in high-impact factor academic journals but is also informing clinical practice and policies in the fertility sector.

- 6.11.** Members were reminded that during the RRP update presented in January 2023 they had agreed to recommend updates to the 2010 regulations on data use for research purposes and the HFEA had subsequently submitted a brief on this to the Department of Health and Social Care.
- 6.12.** The Senior Research Manager informed members that the RRP had been audited by GIAA and had achieved the highest rating possible. The audit report had also acknowledged the significant work to improve the RRP in recent years.
- 6.13.** Turning to work in 2024-2025, members were informed of the planned work to engage with researchers through a new research newsletter, webinars, presentations at academic conferences and round tables. The team will also continue to streamline the RRP processes by providing more information to researchers on application requirements, as well as quality and completeness of data held on the Register.
- 6.14.** Members expressed their appreciation for the informative presentation and the reports which had been published and promoted. The accompanying call to action on ethnic diversity in fertility treatment was especially welcomed.
- 6.15.** Members welcomed the planned work for 2024-2025 and discussed several aspects relating to some of the proposed activities.
- 6.16.** Members discussed the possibility of collaborating with other organisations on research projects. Several members undertook to send the HFEA staff a list of MSc courses that cover fertility to see whether there was any potential for research synergy beneficial to the HFEA.
- 6.17.** There being no further comments the Chair drew the discussion to a close.

#### Decision

- 6.18.** Members noted the annual report of the RRP.

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## **7. Proposed legislative changes on posthumous storage and screening**

- 7.1.** The Regulatory Policy Manager introduced the paper and stated that the Government has proposed two areas of legislative change, which if passed by Parliament will affect the fertility sector.
- 7.2.** The paper presented to the Authority set out in detail the changes to the posthumous storage of gametes and embryos and the screening for reciprocal IVF, also referred to as shared motherhood, and known donation from those who have HIV with an undetectable viral load.
- 7.3.** Members were informed that the final text relating to the posthumous storage of gametes and embryos has been published and the law came into force on 10 May 2024. The final text relating to the other area of change has also been published, but the timetable for implementation depends on the DHSC and the parliamentary timetable. The HFEA is planning for the consequences of these changes to ensure that it is prepared and can provide information to clinics and patients as relevant.

- 7.4.** The Regulatory Policy Manager spoke to the recommendation that the Authority delegates responsibility to the Chair to sign off the requirement documents.
- 7.5.** The Director of Strategy and Corporate Affairs informed members that the statutory instrument for posthumous storage was laid in Parliament last Friday and the statutory instrument for screening had been laid today.

### Decision

- 7.6.** The Authority agreed to delegate responsibility to the Chair to sign off:
- Updated Standing Licence Conditions (SLCs) for Great Britain and Northern Ireland.
  - Updated General Direction 0007, listing a new consent form.
  - Other guidance if needed, in line with the proposed changes set out in the paper presented to the May Authority meeting.

### Action

- 7.7.** The Chair to sign the updated documents relating to the legislative changes on posthumous storage and screening.

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## 8. Any other business

- 8.1.** The Chair thanked all for their active participation in the meeting.
- 8.2.** There being no further items of any other business the Chair reminded members that the next meeting will be held on 3 July 2024.
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## Chair's signature

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

### Signature



Chair: Julia Chain

Date: 3 July 2024