

## Minutes of the Authority meeting on 25 September 2024

Members present	Alex Kafetz Graham James Alison McTavish Gudrun Moore	Geeta Nargund Catharine Seddon Christine Watson
Apologies	Julia Chain Tim Child Zeynep Gurtin Frances Flinter Jonathan Herring	
Advisers	Jason Kasraie, Special Adviser	
Observers	Adrian Thompson, Board Apprentice Steve Pugh (DHSC) Farhia Yusuf (DHSC)	
Staff in attendance	Peter Thompson (Chief Executive) Clare Ettinghausen (Director of Strategy & Corporate Affairs) Rachel Cutting (Director of Compliance & Information) Tom Skrinar (Director of Finance & Resources) Paula Robinson (Head of Planning and Governance) Rebecca Taylor (Scientific Policy Manager) Alison Margrave (Board Governance Manager)	

### Members

There were 7 members at the meeting – 5 lay and 2 professional members.

## 1. Welcome and declarations of interest

- 1.1. The Deputy Chair opened the meeting by welcoming Authority members and HFEA staff to the Authority Meeting.
- 1.2. The Deputy Chair also welcomed observers and stated that the meeting was being recorded in line with previous meetings and for reasons of transparency. The recording would be made available on the HFEA website to allow members of the public to view 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. The Deputy Chair proposed that minute 7.18 be amended to:

“The Chair drew the discussion to a close noting that the principles for the review were agreed; that options B ‘**status quo plus (mixed activity driven)**’ and E ‘**banded flat annual fee**’ as presented in the paper were currently favoured by the Authority and warranted further development; and that if possible the decoupling of the HFEA’s fee as a perceived ‘treatment tax’ levied on patients by clinics was welcomed.”

- 2.2.** With this amendment the minutes of the meeting held on 3 July 2024 were agreed as a true record of the meeting and could be signed by the Chair.

#### Matters arising

- 2.3.** Members were advised that the matters arising item had been actioned as detailed in the paper presented to the meeting.
- 2.4.** Members noted the matters arising report.

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

- 3.1.** The Chief Executive gave an overview of the Chair's engagement with key stakeholders and her attendance at decision-making committees of the Authority.
- 3.2.** Members were informed that the Chair had attended and participated in the all-staff event held on 15 July at the HFEA's office and the Chief Executive spoke of the valuable experience in bringing all the HFEA staff together. He spoke about the stability of the workforce and generally high staff morale.
- 3.3.** The Chief Executive informed members that together with the Chair and Director of Strategy and Corporate Affairs he had an introductory meeting with the HFEA's new sponsor minister, Baroness Merron, and that this was a very positive early meeting with open and enthusiastic dialogue. The HFEA had taken the opportunity to highlight the law reform work and the key challenges over the next 5 to 10 years.
- 3.4.** Members were informed that the Chair had met with the Scottish Minister of Health, Jenni Minto MSP, on 17 September. The Chief Executive reminded members that the HFEA is a UK wide regulator and, although reports to the Westminster Government, positive continued relationships with the devolved administrations are welcome.

#### Decision

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

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### 4. Committee Chairs' reports

- 4.1.** The Deputy 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 of the decision to lift a clinic suspension and the stimulating discussion regarding a licence for a research centre. On behalf of the committee, he thanked outgoing member, Gudrun Moore, for her expertise, warmth and humanity which she brought to the committee.
- 4.3.** The Statutory Approvals Committee (SAC) Deputy Chair (Gudrun Moore) provided a brief overview of the three meetings which had been held since the Authority last met noting that they had approved most applications and special directions.

- 4.4.** The Audit and Governance Committee (AGC) Chair (Catharine Seddon) informed members that the HFEA's Annual Accounts and Report were laid in Parliament on 25 July. Thanks were given to all staff involved in the production of the accounts. Members were informed that the next meeting of the AGC is being held virtually on 1 October and that a training session on assurance mapping would be held after the meeting on 6 December.
- 4.5.** The Deputy Chair informed members that the Scientific and Clinical Advances Advisory Committee (SCAAC) next meeting is being held on 7 October and that a separate agenda item on the HFEA's horizon scanning function is being brought to this Authority meeting.

#### Decision

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

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## 5. Performance report

- 5.1.** The Chief Executive introduced the performance report and informed members that the report includes data up to the end of August. Performance continues to be good across the KPI indicators with ten green, three amber, one red and three neutral indicators. He expressed thanks to all the HFEA staff for their continued hard work.
- 5.2.** The Chief Executive referred to the HR KPIs contained in the paper and the positive downwards trend in both sickness and turnover. Since May the turnover rate for staff has been moving towards target which has provided a period of stability for the organisation and a solid resource base to continue work and development.
- 5.3.** The Deputy Chair commended the Chief Executive and the Senior Management Team for their leadership and support of HFEA staff which is evidenced via staff surveys.

#### Compliance and Information

- 5.4.** The Director of Compliance and Information stated that the new members of the inspection team are integrating well into the team and that there has been a significant, sustained improved in the KPIs. Thanks were expressed to the whole team for this work.
- 5.5.** Members were informed that following the recently published reports on [CQC](#) and [Ofsted](#) the HFEA had reflected on its own inspection regime's strengths and weaknesses. An opportunity had been identified to strengthen inspectors' training and specialised training had been arranged for later in the year. Members were informed this training would cover aspects such as handling difficult situations whilst on inspection; identifying those individuals who may be experiencing stress due to the inspection and how to handle these individuals calmly, confidently and with sensitivity/empathy to ensure they are properly supported during the inspection process.
- 5.6.** The Director of Compliance and Information informed members that the Data Security Protection Toolkit (DSPT) is undergoing significant changes and will eventually be replaced by the Cyber Assessment Framework (CAF). Whilst the HFEA is still evaluating this change, it is likely that this will involve more work for the IT team.
- 5.7.** Members were informed that the team is working through the recommendations arising from the infrastructure penetration test and that the application pen test will be scheduled imminently.
- 5.8.** Members were informed that the tender process for the Epicentre replacement is currently open, with the team responding to clarification questions from prospective suppliers. The closing date

for receiving tenders is early October and it is anticipated that the contract will be awarded by the end of October following a scoring and shortlisting process.

- 5.9.** The Opening the Register (OTR) team is now fully staffed and trained with the new case management system and were able to process over 800 applications in the last 6 months, which is more than were processed in the entirety of 2023.
- 5.10.** Members were informed that currently there is a low number of OTR applications relating to post 2005 identifiable donors. This could be attributed to the number of children conceived with an anonymous donor after April 2005 and a gradual change in the culture of 'telling' after the law change, which will affect how many of those eligible to access donor information know that they are donor-conceived.
- 5.11.** The Deputy Chair thanked the HFEA team for their reflection on its inspection process following the publication of the CQC and Ofsted reports. This clear commitment to continuous reflection and learning is very welcomed.
- 5.12.** The Chief Executive spoke of the requirements for DSPT and the increased level of corporate reporting to Government, which for a small ALB are not proportionate to the organisation's resources. He cautioned that the Authority may need to address priorities in the future if requirements of corporate reporting increase still further.
- 5.13.** A member spoke of the good progress which the HFEA had made with DSPT and cautioned that DSPT was designed for large organisations such as NHS bodies. The new standards should be appropriate for all organisations, no matter their size.
- 5.14.** In response to a question regarding the number of planned and delivered inspections, the Director of Compliance and Information stated that some inspections may be pulled forward and gave some examples of why this might happen.

### Strategy and Corporate Affairs

- 5.15.** The Director of Strategy and Corporate Affairs remarked that the summer period had continued to be busy and referred to the number of licensing activities undertaken during this period.
- 5.16.** Members were informed that the Fertility Trends report had been published and gained widespread coverage online, in print, TV and radio. The State of the Sector report would be published in October and an update on the Family Formation report later this year.
- 5.17.** The Director of Strategy and Corporate Affairs spoke of the fieldwork being undertaken for the national patient survey, which is conducted every three years. The HFEA is keen to increase responses from Black and ethnic minority patients and Authority members were encouraged to promote the survey where possible.
- 5.18.** Members were informed of the patient organisation and professional body stakeholder meetings which were taking place in the Autumn and how these will be used to inform and update people on the work of the HFEA and get views on areas such as the new HFEA strategy and the multiple birth rate.
- 5.19.** The Director of Strategy and Corporate Affairs updated members on the continuing work regarding proposed law reform, noting that the November Authority meeting will receive papers on patient protection and safety, and scientific developments.

- 5.20.** Members were informed that the SCAAC meeting in October will be discussing scientific developments, and the papers prepared for that meeting are of an extremely high calibre and would be available on the HFEA's website.
- 5.21.** Members were informed that members of the senior management team had undertaken several speaking engagements at conferences and events including a joint training day at the British Fertility Society study week.

#### Finance

- 5.22.** The Director of Finance and Resources informed members that the HFEA's annual report and accounts were laid in parliament on 25 July, and he expressed his thanks to the team for all their work in this regard.
- 5.23.** The Director of Finance and Resources referred to the paper and stated that whilst the August data is showing a surplus of £30,000 a full review will be undertaken at the end of quarter two.
- 5.24.** Members were appraised of the potential spend on IT investments and when this might happen.
- 5.25.** The Director of Finance and Resources spoke on the debt KPIs and commented that these were being influenced by long-term debt, with a couple of clinics affecting the overall results. The Chief Executive commented that the HFEA does not have a structural problem in collecting debt but there are a few historical problems which the team are working to resolve.

#### Decision

- 5.26.** Members noted the performance report.

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## 6. HFEA's horizon scanning function

- 6.1.** The Scientific Policy Manager introduced the paper and reminded members that the HFEA established its horizon scanning function in 2004 to identify developments in research and technology that could have an impact on the field of assisted reproduction or embryo research.
- 6.2.** Members were informed that horizon scanning is an annual cycle that feeds into the HFEA's strategic business planning, the Scientific and Clinical Advances Advisory Committee's (SCAAC) workplan and the Authority's consideration of scientific and ethical issues and standards.
- 6.3.** Through this horizon scanning function the HFEA can build knowledge, build relationships in the sector and then use that knowledge to help shape its current and future work.
- 6.4.** The Scientific Policy Manager explained how horizon scanning topics are identified through annual literature reviews, attendance at conferences, the annual HFEA horizon scanning meeting held at the European Society for Human Reproduction and Embryology (ESHRE) Conference and when papers are brought to the HFEA's attention by SCAAC members.
- 6.5.** In February 2024 SCAAC had prioritised 14 topics for their 2024/25 workplan into high (10), medium (2) and low (2) priority categories. Further information was provided on several of the high priority topics and how these were considered by SCAAC.
- 6.6.** The Scientific Policy Manager showed the range of topics which had been discussed at the horizon scanning meetings from 2019 to 2023 and spoke about how the HFEA's focus changed as these topics advanced and developed. New topics can arise as a result of new research or

technology. Stem cell based embryo models was a new horizon scanning topic in 2021 and now in 2024 they are being considered from a regulatory perspective.

- 6.7.** Continuing, the Scientific Policy Manager spoke about how the different horizon scanning activities feed into each other and gave the example of AI, which was first raised at a horizon scanning meeting in 2018, made a high priority topic in 2019 and then became part of the HFEA's organisation strategy in 2020. At first the HFEA was monitoring AI regarding its use in fertility treatment but since 2023 this has developed to also include AI in regulation.
- 6.8.** The Scientific Policy Manager spoke of the annual HFEA horizon scanning meeting which is held at the ESHRE annual conference. This year's meeting had discussed early embryo genetic screening with PGT-P; organoids; AI in the IVF lab and ovarian rejuvenation.
- 6.9.** The Deputy Chair thanked the Scientific Policy Manager for the interesting presentation and commented that as the Authority needs to carefully balance scientific developments with ethical debate, the horizon scanning work is extremely useful in helping to find this balance.
- 6.10.** A member spoke of the important topics being discussed by the October SCAAC meeting some of which will be brought to the November Authority meeting for discussion and decision. The member spoke of the scientific developments being made in the fertility sector and how the Authority might respond to them.
- 6.11.** The Director of Strategy and Corporate Affairs reminded members that SCAAC brings together expertise within the field and its role is to advise to the Authority. The papers for the SCAAC meeting will be published on the HFEA website shortly after the meeting. There has been public dialogue on the 14-day rule and the Nuffield Council of Bioethics will be publishing a report on embryo models in November.
- 6.12.** In response to a question on topic prioritisation and the SCAAC workplan, the Scientific Policy Manager explained that those topics which are a high priority come more frequently for discussion at SCAAC meetings.
- 6.13.** A member referred to the slide which had shown what topics had been discussed at horizon scanning meetings since 2019 and commented that this shows the changing importance of these topics over time.
- 6.14.** The Chief Executive commented on how the horizon scanning function allows the HFEA to monitor topics and develop work streams as the individual topics develop momentum. The horizon scanning function allows the HFEA to put priorities around where it focuses its attention on items which are developing.
- 6.15.** A member commented that topics which are discussed under horizon scanning are not just scientific topics, but also those which are patient centred.
- 6.16.** Members reflected how quickly the sector is changing and the increasing pace of change. They felt that the HFEA's horizon scanning function was crucial to ensure that the HFEA was front and centre in keeping up with such developments and that as an Authority it could continue to balance the ethical needs of research and a patient focus.
- 6.17.** The Deputy Chair drew the discussion to a close thanking all members for their active participation on this important topic.
- 6.18.** The Authority noted the report.



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## 7. State of the Fertility Sector report

- 7.1. The Director of Compliance and Information told members that the State of the Fertility Sector report for 2023/24 would be published shortly and she took this opportunity to provide an overview to members.
- 7.2. This report summarises the HFEA's regulatory work for the period 1 April 2023 to 31 March 2024 and covers the 135 centres which were licensed by the HFEA to provide fertility treatment, storage and/or research. The report is compiled from information gathered from inspections and from other sources including the HFEA's register of fertility treatments, incident reports and patient feedback mechanisms.
- 7.3. Members were informed that all grades of non-compliance had increased from the previous year, but this is in line with the higher number of inspections carried out. Members were reminded that information regarding the types of non-compliances are given to licensed centres via the quarterly clinical governance updates, which allows centres to reflect against their own practice and identify any improvements.
- 7.4. Members were informed that total incidents reduced by 8% compared to the previous financial year. In response to a question the Director of Compliance and Information commented that incidents area way of learning for the sector but that it was important to remember that 99% of treatment and storage cycles are completed without incident.
- 7.5. The grading of incidents was explained, and members were informed that Grade A incidents are the most serious and are rare occurrences. The Director of Compliance and Information spoke of how these incidents are dealt with by the inspection team and how the inspectors put in place enhanced regulatory oversight to ensure risks are mitigated.
- 7.6. The Director of Compliance and Information stated that the effectiveness of regulation has been under the spotlight recently with the publication of independent reports on the CQC and Ofsted. Both reports were critical of aspects of the inspection regime used in each organisation and this has led the HFEA to review its own inspection regime.
- 7.7. The Director of Compliance and Information summarised the findings of that review. The HFEA maintains a robust regulatory oversight of the sector with licensed premises being inspected every 2 years as required by law. If the HFEA had any concerns then inspections would be more frequent, and the centre would be closely monitored.
- 7.8. Members were informed that all HFEA inspectors have direct scientific or clinical expertise relating to the fertility sector.
- 7.9. Members were also reminded that the HFEA inspection methodology underwent a major overhaul in 2021/22 and the HFEA believes it provides a robust mechanism for how we regulate the sector. Feedback from clinics also suggested that the HFEA inspections promote improvement. However, as part of its continuous cycle of improvement and growth the HFEA review had identified a number of improvements in areas such as IT systems and inspector training.
- 7.10. In response to a question about publishing trend information the Chief Executive spoke about the importance of building a culture of openness and reporting. He reiterated that 99% of cycles are completed without incident.

- 7.11.** In response to a question the Director of Compliance and Information informed members that the details of non-compliance are provided in the Quartey Clinical Governance update.
- 7.12.** A member referred to the NHS patient safety incident response framework (PSIRF) and questioned how this relates to the reporting of incidents to the HFEA. The Director of Compliance and Information responded that it is a mandatory requirement under the HFE Act for all clinics to report incidents to the HFEA. Discussions had also been held with NHS England (NHSE) to ensure that centres were not overburdened with reporting functions. The Director of Strategy and Corporate Affairs suggested that a future article in Clinic Focus could explain this.
- 7.13.** The Deputy Chair drew the discussion to a close and welcomed the publication of this report which is an important element of HFEA's accountability and transparency and underpins the HFEA's strategic aim of 'best care'.

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## **8. Communicating licensing, regulatory activity and incident information**

- 8.1.** The Director of Strategy and Corporate Affairs introduced the paper and spoke of the HFEA's ambition to increase the transparency of the information it holds, noting that most of the information which the HFEA publishes is written for governance/licensing purposes rather than for patients.
- 8.2.** The Director of Strategy and Corporate Affairs explained the HFEA's current position regarding publishing information relating to licensing, compliance and incidents. Some shortcomings of the established position had been exposed in the last year in light of some licensing decisions. The reactive [statement](#) regarding Guy's and St Thomas ACU and the proactive [statement](#) on the Homerton Fertility Centre were discussed.
- 8.3.** The risks and benefits of publishing more information which is shown in Annex A of the paper presented to the Authority was discussed. It was noted that the CQC routinely publishes its press notices on the outcomes of their inspections, reviews and ratings, and posts these on social media.
- 8.4.** The Director of Strategy and Corporate Affairs spoke to the proposed changes regarding publishing of licensing decisions and the revised Committee Chair's report which would come to each Authority meeting and be published on the HFEA website.
- 8.5.** Continuing, the Director of Strategy and Corporate Affairs spoke of how clinic level incident information is currently published in the annual State of the Sector report and the quarterly clinical governance report. This governance report gives an overview of non-compliances found on inspections and through incident investigations so that learning can be shared with HFEA licensed centres via the monthly Clinic Focus newsletter. Members were informed that the HFEA has faced criticism from journalists that this information is difficult to find on the HFEA website.
- 8.6.** Members were informed of how NHSE publishes incident information via 'never event' and other reports and the information which these reports contain at provider level. The HFEA is now proposing that details of incidents by type and grade by clinic should be published as part of the underlying data set with the annual State of the Sector report.
- 8.7.** A member spoke of the need to continue to nurture the culture of reporting, and any changes should be framed to ensure that this culture is still supported and encouraged.



- 8.8.** A member welcomed the increased information which would be provided on licensing decisions as they felt that many people didn't realise the steps, processes and support which the HFEA undertakes with the licensed centres. The member also advocated for using language in incident reporting that could be understood by patients rather than just professionals. Stakeholder groups could perhaps be used to assist with this.
- 8.9.** Members were supportive of increasing the transparency of the information which the HFEA holds, noting that this may have a resource implication if it leads to a greater number of freedom of information requests and enquiries.
- 8.10.** Members discussed best practice in other regulatory organisations, noting that many of them publish information across all media outlets at the same time, including social media. Members cautioned that any social media posts must adhere to the information contained in the official press release and not be an edited version of that.
- 8.11.** In response to a question the Chief Executive confirmed the HFEA's intention is to make information more readily available on the HFEA's website and that it was important to reach the general public on whatever platform they seek information, be it websites or social media. The Chief Executive also commented that the recommendations brought forward to this meeting will set out the HFEA's current direction of travel and these can be amended, if required, over time.
- 8.12.** In response to a question regarding digitally excluded people the Chief Executive commented that Ofcom data shows that the age range of people looking for fertility treatment would generally have internet access and mobile phones.
- 8.13.** Members questioned whether it would be possible to distinguish between those centres that have been refused a licence for administrative reasons, rather than because they were deemed to offer unsuitable or unacceptable services or facilities.

### Decision

- 8.14.** The Authority unanimously agreed the following recommendations:
- When a licence committee suspends or revokes a clinic licence, or adds additional conditions, a summary of the decision should be publicised through a news release; social media posts; and information on the clinic's CaFC pages. This includes removing the rating for the duration of the suspension to avoid causing confusion for patients. This would always follow the PR and Licence Holder being notified about the decision.
  - Where a suspension takes place with immediate effect then this should be publicly communicated before the minutes are published.
  - Information about licensing decisions should be made more easily publicly available through Authority papers and separately on the HFEA website.
  - Details of incidents by type (e.g. administrative, clinical, laboratory) and grade by clinic should be published as part of the underlying data set with the annual State of the Sector report.

### Action

- 8.15.** The Executive to implement the decisions regarding communicating licensing, regulatory activity and incident information.

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## 9. Any other business

- 9.1.** The Deputy Chair thanked all for their active participation in the meeting. As this was the last meeting for Jason Kasraie, Gudrun Moore and Jonathan Herring she expressed the Authority's appreciation for the rich and diverse experience and perspective they brought to all discussions and for their dedicated work over several years on many of the HFEA committees.
- 9.2.** The Deputy Chair reminded members that they had been sent information about the conference at Girton College, University of Cambridge on 30 October to mark Mary Warnock's 100th birthday.
- 9.3.** There being no further items of any other business the Deputy Chair reminded members that the next Authority meeting will be held on 20 November 2024 with a Board strategy session being held on the afternoon of 19 November.
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## Chair's signature

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

Signature



Chair: Julia Chain

Date: 20 November 2024