

# Minutes of the Authority meeting on 12 March 2025 held at 2 Redman Place, London

Members present	Julia Chain (Chair) Tim Child (online) Frances Flinter Tom Fowler Zeynep Gurtin Graham James Alex Kafetz	Alison McTavish Geeta Nargund Catharine Seddon Rosamund Scott Anya Sizer Stephen Troup
Apologies	Christine Watson Steve Pugh, Department of Health and Social Care (DHSC)	
Observers		
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) Sophie Tuhey (Head of Planning and Governance) Joanne Anton (Head of Policy) Annabel Salisbury (Regulatory Policy Manager) Shabbir Qureshi (Risk and Business Planning Manager) Alison Margrave (Board Governance Manager)	

#### Members

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

# 1. Welcome, apologies and declarations of interest

- 1.1. The Chair opened the meeting by welcoming Authority members and HFEA staff.
- **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. 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 and licence holder)
  - Anya Sizer (freelance advisory work with a licensed clinic)
  - Stephen Troup (consultancy work within the fertility sector)
  - Catharine Seddon (appointed to the Board and Audit Committee of the Health and Care Professions Council (HCPC) for a three-year term to February 2028)

# 2. Minutes of the last meeting and matters arising

**2.1.** The minutes of the meeting held on 22 January 2025 were agreed as a true record of the meeting and could be signed by the Chair.

### Matters arising

- **2.2.** The Chair introduced the report and informed members that the items had been actioned through the HFEA's quarterly accountability meetings with DHSC.
- **2.3.** Members noted the matters arising report.

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

- **3.1.** The Chair gave an overview of her engagement with key stakeholders and her attendance at decision-making committees of the Authority.
- 3.2. The Chair informed members that together with the Chief Executive they attended the DHSC ALB senior leaders meeting for all Chairs and CEOs, which was held on 28 January. The Secretary of State for Health and Social Care joined this meeting and spoke about the Government's agenda and 10-year Health Plan.
- **3.3.** The Chair informed members that she and the Chief Executive will be meeting with Baroness Merron, Parliamentary Under-Secretary of State for Patient Safety, Women's Health and Mental Health, and the HFEA's sponsor minister the next day to discuss the HFEA's proposals for law reform and our response to the Government's consultation on the 10 year-plan.
- **3.4.** The Chief Executive reminded members that the Authority meetings in November 2024 and January 2025 had discussed several scientific developments in the fertility sector and this had generated some press coverage. On 28 January he gave an interview on the Today programme (Radio 4) on in vitro derived gametes and there maybe further public interest in these issues..
- 3.5. The Chief Executive informed members that he had spoken at the ACE-PCF Annual Conference on Public Bodies data, technology and innovation. He commented that the HFEA's strategy of ensuring strong and effective data through programmes such as PRISM and the Epicentre replacement project before implementing AI tools was reinforced as the correct strategy through hearing other's experiences at this event.
- **3.6.** A member commented that there are different types of AI tools, some which affect and improve wider systems and the use of data, and other tools which can be used, for example, in the production of briefings, minutes of meetings and reports.
- 3.7. The Chief Executive responded that some ALBs have started working with some AI tools and the HFEA will look at how these have been adopted and lessons learnt before progressing with any implementation. The Director of Strategy and Corporate Affairs stated that the Government Communication Service had introduced an AI tool and we would review if the HFEA communications team could find them beneficial.
- **3.8.** The Chief Executive informed members that the round table event planned for 10 March on stem cell based embryo models at Nuffield Council on Bioethics was cancelled due to a Ministerial diary clash.

### Decision

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

# 4. Committee Chairs' reports

- **4.1.** The Chair introduced the report and invited Committee Chairs to add any other comments to the presented report.
- **4.2.** The Statutory Approvals Committee (SAC) Chair (Frances Flinter) stated that the committee had considered PGT-M applications and approved the majority of these as detailed in the paper. The committee had considered and approved a PNT application from the Newcastle Fertility Centre at Life.
- 4.3. The Audit and Governance Committee (AGC) Chair (Catharine Seddon) informed members that the AGC had met just last week and had received reports from both internal and external auditors. The Internal Audit plan for 2025/26 had been agreed. The AGC Chair spoke of the auditors' view on revenue recognition and she assured the Authority that the committee will keep this under review and work with the staff and auditors on this matter. The AGC were informed of the review of the strategic risk register (SRR) against the recently adopted new strategy for 2025-2028, noting that the full revised SRR will come to the June AGC meeting. The AGC had received a deep dive report on implementation of the Government Functional Standards and were informed that the ALB oversight team had stated that the HFEA's approach was sufficient and proportionate. The AGC had received reports on PRISM and the Epicentre replacement project.
- 4.4. The SCAAC Chair (Tim Child) informed members that the minutes from the SCAAC meeting held on 3 February 2025 have been published on the HFEA website. The committee had discussed health outcomes in children conceived by ART, the impact of stress on fertility treatment outcomes and mitochondrial donation: polar body transfer. The committee also discussed the prioritisation of horizon scanning topics and the workplan for 2025/26. The SCAAC Chair reminded the Authority that the committee was recruiting for two new external advisers, and he encouraged members to forward details to suitable candidates.
- **4.5.** The Licence Committee Chair (Graham James) stated that the new format of the committee report provided greater oversight of the work of the Executive Licensing Panel and he referred to the applications considered by this committee as detailed in the paper. He informed the Authority that the minutes of the Licence Committee meeting from 16 January 2025 had been approved, and he explained the rationale for reserved decision outcomes.
- **4.6.** The Chair thanked all Committee Chairs for the reports and stated that committee papers and minutes are published on the HFEA website.

### Decision

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

# 5. Performance report

- 5.1. The Chief Executive introduced the performance report and reminded members that the Key Performance Indicators (KPIs) measure various operational aspects of the business conducted by the HFEA.
- **5.2.** The HFEA now has 19 KPIs and two new KPIs relating to Opening the Register (OTR) have been added since January 2025. The Chief Executive stated that performance continues to be consistently strong across the KPI indicators with 12 green, two red, two amber and three neutral

- indicators. He spoke to the two red KPIs and commented that sometimes an inspection report will be more involved than envisaged and the KPI will be missed due to the need to gain further information and have further discussions with a PR before finalising the report.
- **5.3.** The Chief Executive referred to the HR KPIs and commented that whilst seasonal viruses have contributed to an increase in staff sickness, this remains under target.
- **5.4.** Staff turnover remains green at 6.5% and is well within the 5-15% target band. The Chief Executive remarked that whilst this percentage is set to increase, the turnover is manageable and the HFEA does not currently struggle to recruit the right staff.

### Compliance and Information

- 5.5. The Director of Compliance and Information explained that inspection KPIs are a guide and where complexities need follow up after inspection this may mean that occasionally a KPI is breached. It is important to take this extra time in some cases, as it is beneficial in terms of regulatory outcomes to gain additional information and have further discussions with a PR before finalising the report.
- **5.6.** Members were informed that one inspection report exceeded the KPI due to the need to gain further information regarding an incident prior to finalising it.
- **5.7.** The Director of Compliance and Information informed members that all planned inspections have been scheduled up to March 2026 and inspector teams have currently been allocated up until November 2025.
- **5.8.** For the new financial year (April 2025 to March 2026) there are 94 inspections on the schedule, with an average of 8 per month although the Director of Compliance and Information stated that this number will likely increase in-year, due to extra inspections such as those required for new centres, or targeted visits following incidents or whistleblowing allegations.
- **5.9.** The Director of Compliance and Information informed members that the number of OTR requests processed in the last few months was a little less than usual, due to different work requests affecting a proportion of the OTR team members' time.
- **5.10.** Continuing, the Director of Compliance and Information stated that the OTR waiting list is currently at its lowest level for the past 12 months at 926. Progress is being made to reduce the waiting list each month and the team is closing more applications than are being received. The number of OTRs being worked on, including those ready for checking, stands at 305.
- **5.11.** Members were informed that almost 1,600 people have received information from the OTR service within the last 12 months.
- **5.12.** A member congratulated the team for the implementation of the OTR KPIs but questioned why the OTR waiting list and change each month had only been set at 40 per month as with this target it would take two years to close the current waiting list.
- **5.13.** The Director of Compliance and Information reminded members of the new systems and procedures which had been implemented for the OTR team and the time it takes to fully train staff on these. The Senior Management Team had felt that 40 per month was a sensible and realistic target but this will be kept under review.

### Strategy and Corporate Affairs

- **5.14.** The Director of Strategy and Corporate Affairs informed members that media interest remains high and it is positive that the HFEA is seen as the authoritative source for information and data. Spikes can be seen in the number of website visits, especially in January which is likely due to people planning to start treatment in the new year.
- **5.15.** Members were informed that The Guardian article on the Authority's discussions on in-vitro gametes generated significant media coverage as did a programme looking at patients in older age brackets having fertility treatment.
- **5.16.** The Director of Strategy and Corporate Affairs informed members that we would be publishing the report of the National Patient Survey in March and that work is progressing on the annual Fertility Trends report and this is due to be published in June.
- **5.17.** The Director of Strategy and Corporate Affairs spoke about the debate on Women's Health that was held in Westminster Hall and supported by HFEA Authority member Geeta Nargund. The HFEA's briefing on this is available on the HFEA website.
- 5.18. Members Tim Childs, Geeta Nargund, Alison McTavish and Stephen Troup were thanked for their contribution to the HFEA's blogs and social media posts on International Women's Day, which celebrated a few of the many pioneering women in the world of fertility. The Director of Strategy and Corporate Affairs spoke of the increased social media engagement on Instagram and LinkedIn. A member congratulated the team on their active social media engagement.
- **5.19.** In response to a question the Director of Strategy and Corporate Affairs explained that X is used as a one-way information channel and the HFEA is following Government Communications Service advice on X including looking at potential future communication channels.

### Finance, Planning and Technology

- **5.20.** The Director of Finance, Planning and Technology informed members that, as at the end of February, an overspend of £84,000 is being forecast, before taking into account any accounting adjustments such as potential reversals to two significant provisions.
- 5.21. The first provision relates to aged debt, which is likely to reduce in this year's accounts. The Director of Finance, Planning and Technology spoke of the significant work that the Finance Team had undertaken to reduce the level of debt over 96 days (which has reduced by over 50% from March 2024 to £127k, with the majority relating to one clinic). In response to a question, he provided further information about the historic debt and the plans put in place with those clinics to reduce this.
- 5.22. The second provision relates to income and identification of likely refunds to clinics. Members were reminded that errors that have arisen in clinic's IVF/DI activity submissions as part of the transition to PRISM over the past few years have resulted in some duplicate activity being recorded, which has led to duplicate invoicing (which once corrected, requires a refund to the clinic). The HFEA created a provision at the end of 2023/24 which aimed to estimate the value of refunds that the HFEA would make to clinics in 2024/25. The Finance Team is working with the National Audit Office (NAO) to evidence the value of refunds made in year and the income provision. The NAO have some concerns about the accuracy of the HFEA's income due to corrections in clinic activity data, which was discussed in some detail at AGC in March.

- 5.23. The Director of Finance, Planning and Technology referred to the 2025/26 budget contained in the meeting papers and informed members that the HFEA's Grant in Aid (GIA) from the DHSC had been confirmed. Core GIA funds the HFEA's Opening the Register Service. Additional GIA agreed by the Department will cover the completion of the current Phoenix IT project and will support the HFEA in investing in cyber security and website improvements. Other costs are covered through fees, which the HFEA does not plan to increase in 2025/26.
- 5.24. The Director of Finance, Planning and Technology explained the assumptions made when devising the 2025/25 budget regarding income and expenditure. In response to a request for an update on the current Spending Review he said that the process was due to conclude in the summer, but added that the detailed outcome of Government Spending Reviews are often announced in the Autumn statement.

**5.25.** Members noted the performance report.

### 6. Draft Business Plan 2025/26

- **6.1.** The Risk and Business Planning Manager introduced the paper and spoke about the proposed priorities for 2025/26.
- **6.2.** The Risk and Business Planning Manager stated that a major programme of work is the Phoenix programme which will replace the HFEA's inspection and licensing database (Epicentre) and the information storage system with SharePoint. This programme has just commenced with an expected completion date of Spring/Summer 2026. Members were informed that this programme has an operational impact across the HFEA teams and resources will need to be managed and allocated accordingly.
- **6.3.** The Risk and Business Planning Manager spoke about Choose a Fertility Clinic (CaFC) and stated that headline statistics are to be published in Spring 2025. Work will then continue to publish a full CaFC update in Summer 2025 and in Winter 25/26. Another planned project is the replacement of the key finance systems.
- **6.4.** The other priorities for the 2025/26 business plan include:
  - further work to progress law reform proposals
  - a fees review
  - work relating to implementing the new European Regulations on standards of quality and safety for substances of human origin intended for human application (the SoHO Regulation) for clinics in Northern Ireland
  - an update to the multiple births policy, if required following discussion at this Authority meeting
  - ongoing monitoring of the OTR service, include capacity, future demand and resources
  - potential for ongoing work to review Al use in the fertility sector and related developments
  - review of horizon scanning processes and related communications
  - using HFEA data to highlight changes in fertility treatment, particularly where inequalities occur.

- **6.5.** The Risk and Business Planning Manager informed members that if the government decides to take forward law reform then some of the activities currently listed would need to be de-prioritised.
- 6.6. In response to a question regarding law reform the Chief Executive reminded members that there are structural issues which the Authority believes can best be resolved by the law reform proposals and that we would be having ongoing conversations with the DHSC about any prospective time frame for this. If law reform is not forthcoming during the strategic period then the Chief Executive stated that we would need to have conversations about what progress could be made without law reform.
- **6.7.** The Chair reminded members that the Business Plan is an implementation tool for delivering the approved strategy; if law reform goes forward in the next few years then the Authority will need to pivot on some of the identified priorities.
- **6.8.** A member noted the inclusion of the government's 10-year health plan and the acknowledgment that when this is published in Spring 2025 the Authority will need to assess if further work is needed.

- **6.9.** Members approved the draft business plan activities section for 2025/26, noting that further development of the business plan and confirmation of the budget will follow and that Department colleagues will review the plan prior to publication.
- 6.10. Members noted the ongoing possibility that it may be necessary to reprioritise some areas of work, in the event of having a confirmed timetable for legislative changes to go through Parliament.

### 7. Effective Governance

- **7.1.** The Chair introduced the agenda item and reminded members that every year all committees were required to review their own effectiveness using a standard or bespoke framework. The importance of this review and being able to benchmark the HFEA's governance activities was emphasised considering the concern regarding governance arrangements in some other ALBs.
- 7.2. The Chair stated that between September 2024 and February 2025 this review exercise was conducted by the Licence Committee, Executive Licensing Panel, Statutory Approvals Committee, the Scientific and Clinical Advances Advisory Committee, the Audit and Governance Committee and the Register Research Panel. Thanks were given to all members who participated in the reviews.
- **7.3.** The Board Governance Manager introduced the paper and stated that the purpose of this exercise is to provide assurance over the structures established by the Authority and review the effectiveness of committees making decisions on behalf of the Authority.
- **7.4.** The Board Governance Manager stated that this review also provides assurance to the Authority that its activities are aligned with the HFEA's statutory duties, responsibilities and objectives.
- **7.5.** The feedback from the committees has been positive and several recommendations have been made to further enhance and improve the work of the committees. Members were informed that the relevant committee officers will work with their respective committee Chairs to implement these recommendations.

- **7.6.** The proposed minor changes to the standing orders were explained.
- **7.7.** A member complimented the format of the paper for showing the full extent of the reviews undertaken by the various committees and for the oversight and assurance this provides to the Authority.

- **7.8.** Members unanimously voted in favour of the changes to the standing orders.
- **7.9.** Members also noted the summary of actions contained in the annual review of committee effectiveness.

### Action

**7.10.** The Board Governance Manager to publish the revised standing orders.

# 8. Multiple Birth Target

- **8.1.** The Chair introduced the agenda item and stated that the dramatic reduction in multiple births from IVF over the past decade has been a real public policy success. With many clinics below the 10% target, it makes sense for the Authority to consider whether any revision is needed to the target.
- **8.2.** The Regulatory Policy Manager reminded members that in 2007 the HFEA, with professional bodies and patient groups, launched the One at a Time campaign, and in 2012 the HFEA set the maximum multiple birth rate at 10%. This target was reached for the first time in 2017 and is still in place. Practices to reduce multiple births, such as elective single embryo transfer, have become commonplace in the sector.
- **8.3.** Members were reminded that the multiple births target was last discussed by Authority at the September 2021 meeting, where members agreed:
  - to maintain the 10% multiple births target for now and continue to monitor on inspection;
  - to encourage clinics to be mindful of their multiple birth minimisation strategy in relation to patients from ethnic groups;
  - a report should be published outlining the data presented to the Authority to stimulate further discussion and following that;
  - discussions should be opened over time with key stakeholders, patients and clinics, with the aim of considering a future review of the 10% rate;
  - that the four clinics that were outliers, should be asked why this was the case.
- **8.4.** The Regulatory Policy Manager stated that whilst the multiple births policy has been a success there continues to be a small number of clinics who consistently exceed the maximum rate. Currently the HFEA does not have the necessary enforcement powers to directly address this problem and this will remain the case unless and until the HFEA has new powers from changes to the law.
- **8.5.** The Regulatory Policy Manager introduced the proposed options and explained that stakeholder views on options for the multiple births policy had been sought from the Licensed Centres Panel (LCP), the Professional Stakeholder Group (PSG), and the Patient Organisation Stakeholder Group (POSG). The Multiple Births Foundation was also represented on both PSG and POSG.

- **8.6.** In response to a question the Director of Strategy and Corporate Affairs confirmed that the report includes both fresh and frozen embryo transfer outcomes.
- **8.7.** The Regulatory Policy Manager introduced option one ("BAU" i.e. business as usual) and explained that this option would keep the existing maximum multiple birth rate at 10% until the HFEA might have new enforcement powers following law reform. The pros, cons and resource implications for this option were explained.
- **8.8.** Authority members discussed how successful the campaign has been and that at the time of implementation the 10% target was viewed as ambitious. Yet now the target is widely accepted, and many clinics are well below this target.
- **8.9.** A member cautioned that any new target should not risk patients' success rates. It was noted that the 10% multiple births target had not affected the birth rate, and that the birth rate had continued to increase whilst multiple births have decreased.
- **8.10.** Members noted that multiple births are the single greatest health risk of fertility treatment. A member commented that the HFEA's multiple births campaign has also helped to protect the public purse as the NHS bears the cost of adverse health outcomes following multiple births.
- **8.11.** Members discussed those clinics that were outliers and how the HFEA could address those clinics which are offering unsafe clinical practices. Some members felt that more emphasis should be given to the outliers so they could be persuaded to meet the 10% target.
- **8.12.** In response to a question the Director of Strategy and Corporate Affairs informed members of the resources that could be required to implement a new target, including an equalities impact assessment; consultation with the sector and patients; updating the Code of Practice, General Directions and other regulatory tools; what inspectors would focus on during inspections and a range of communication activities.
- **8.13.** The Regulatory Policy Manager introduced option 2, which is to leave the rate at 10% and change how multiple birth rates are reported. The pros, cons and resource implications for this option were explained.
- **8.14.** Members considered the option of reporting by exception and highlighting those clinics that have a higher than 10% multiple birth rate. It was discussed whether patient facing communications could highlight further the negative effects of multiple births.
- **8.15.** A member commented that the "one at a time" policy is well accepted within the sector and noted that the British Fertility Society (BFS) had not updated its guidance on elective single embryo transfer as this practice is now so well adopted in the sector.
- **8.16.** Members discussed whether this option could be combined with another of the options and presented as part of an ongoing journey to a lower target.
- **8.17.** The Regulatory Policy Manager introduced option 3, which is to lower the target rate. The pros, cons and resource implications for this option were explained.
- **8.18.** A member spoke in favour of reducing the target to further improve patient safety and increase potential cost savings for the NHS.
- **8.19.** Members discussed that 92% of clinics are operating below the 10% target and reducing the target could be perceived as over regulation of those clinics who are already adhering to the policy. The collaborative approach to working between the HFEA and clinics was noted.

- **8.20.** A member stated that fertility clinics in the USA are using pre-implantation genetic testing for aneuploidy (PGT-A) as a tool for reducing multiple births and there is a concern that more UK clinics follow suit. It was noted that PGT-A is currently rated red for increasing chances of having a baby for most fertility patients on the HFEA's website.
- **8.21.** Members noted the proposed law reforms proposals regarding patient safety and how this reform could give the HFEA the power to address those outlier clinics.
- **8.22.** The Regulatory Policy Manager introduced option 4, which is to change the target to an upper limit. The pros, cons and resource implications for this option were explained.
- **8.23.** A member spoke about the possibility of having a range of standard variations against the national average target.
- **8.24.** Members discussed how the sector had responded well to the target and that 52% of clinics are now under 4%. Members discussed the need to target those clinics which are not adhering to the policy.
- **8.25.** After further discussion regarding the proposed options and whether a combination of the options could be progressed the Chair drew the discussion to a close.

- **8.26.** The Authority agreed to implement option two (leave the rate at 10% and change how multiple birth rates are reported) and, over time, option four (change the target to an upper limit).
- **8.27.** The Authority further agreed that the Executive should bring to the Authority in November 2025 further information on the work that would be needed to implement option three (lowering the target rate). This did not commit the Authority to this option in future.

### Action

- **8.28.** The Executive to implement the Authority's decisions regarding leaving the multiple birth rate target at 10% and changing how multiple birth rates are reported; and over time changing the target to an upper limit.
- **8.29.** Further information should be brought to the Authority in November 2025 to enable members to take a view on the resource implications for implementing option three (lower the target rate).

# 9. Update on Public Body Review

- **9.1.** The Director of Strategy and Corporate Affairs introduced the paper and reminded the Authority that the HFEA's Public Body Review (PBR) report was published in November 2023.
- **9.2.** In January 2024, the Authority discussed the recommendations from the review and the proposed actions in response. The Authority agreed responses to the recommendations from the review, and these have been discussed at the quarterly accountability meetings with the HFEA's DHSC sponsor team.
- **9.3.** The Director of Strategy and Corporate Affairs informed the Authority that the sponsor team had agreed that the PBR need not be on the agenda for the quarterly accountability meetings going forward after January 2025.

**9.4.** The Director of Strategy and Corporate Affairs informed the Authority that it is proposed that any further reporting updates be incorporated into existing reporting structure such as the Audit and Governance Committee or the Scientific and Clinical Advances Advisory Committee.

### Decision

**9.5.** The Authority noted the update to the PBR recommendations set out in the paper and agreed to close future reviews of the actions from this meeting.

# 10. Any other business

- **10.1.** The Chair thanked everyone for their active participation in the meeting which had considered a full and detailed agenda.
- **10.2.** The Chair welcomed Sophie Tuhey, Head of Planning and Governance to the Authority and informed the Authority that this was the last meeting for Paula Robinson, Head of Planning and Governance, who would be retiring from the HFEA at the end of the month.
- **10.3.** On behalf of the Authority the Chair expressed her sincere thanks to Paula Robinson for her commitment and dedication to the HFEA. The Chair wished Paula a long and happy retirement.
- 10.4. Paula Robinson reflected on her time at the HFEA and what had been achieved. She spoke of the high calibre of discussions at Authority Meetings and thanked all for their work, co-operation and support.
- **10.5.** There being no further items of any other business the Chair closed the meeting and reminded members that the next Authority meeting will be held on 21 May 2025.

# Chair's signature

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

Signature

Chair: Julia Chain

Date: 21 May 2025