Minutes of the Authority meeting on 19 November 2025 held at 2 Redman Place, London

Members present	Julia Chain (Chair) Tim Child Frances Flinter Tom Fowler Graham James Alex Kafetz	Alison McTavish Geeta Nargund Catharine Seddon Rosamund Scott Anya Sizer Stephen Troup
Apologies	Zeynep Gurtin Christine Watson Tom Skrinar (Director of Finance, Planning and Technology) Steve Pugh, Department of Health and Social Care (DHSC)	
Observers	Samatha West, Department of Health and Social Care (DHSC) Jacky Cooper (online) DHSC) Amy Parsons (online) (DHSC)	
Staff in attendance	Peter Thompson (Chief Executive) Rachel Cutting (Director of Compliance and Information) Clare Ettinghausen (Director of Strategy and Corporate Affairs) Molly Davis (Policy Manager) Sharon Fensome-Rimmer (Chief Inspector) Angharad Thomas (Head of Communications) Sophie Tuhey (Head of Planning and Governance) Shabbir Qureshi (Risk and Business Planning Manager) Alison Margrave (Board Governance Manager)	

Members

There were 12 members at the meeting – 7 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 to the 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. 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 (International Advisory Board member for Lancet Obstetrics, Gynaecology and Women's Health)
- Tim Child (consultancy work within the fertility sector overseas)
- Anya Sizer (freelance advisory work within the fertility sector)
- Stephen Troup (consultancy work within the fertility sector)

2. Previous minutes and matters arising

2.1. The Chair introduced the minutes from the meeting held on 25 September and thanked the members who had assisted with providing feedback on the draft minutes.

2.2. The minutes of the meeting held on 25 September 2025 were agreed as a true record of the meeting and could be signed by the Chair.

Matters arising

2.3. The Chair informed members that the matters arising from the previous meeting had been actioned as detailed in the report.

2.4. 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 on 26 September she attended the Robert Edwards Centenary celebrations held in Cambridge. These celebrations marked the achievements of Mr Edwards as one of the IVF pioneers with presentations on both the history and future developments.

3.3. The Chair informed members that she had participated as a speaker in a workshop held by the Nuffield Council on Bioethics on the theme the "agile regulatory frameworks needed to responsibly govern fast emerging technologies".

3.4. The Chair informed the meeting that the previous day Authority members met for their annual strategic away day and discussed the results of the Board Effectiveness Review (BER). The Chair explained the process for the BER and thanked the members for their engagement in this review.

3.5. The Chief Executive referred to the quarterly accountability meeting held with DHSC in October. This was a positive meeting and it was noted that the HFEA was meeting all its business plan requirements.

3.6. The Chief Executive summarised the quarterly meeting of the Health and Social Care Regulators Forum that he had attended in October. This forum brings together leaders from the health sector to consider common issues.

Decision

3.7. Members noted the Chair and Chief Executive's report.

4. Committee Chairs' report

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 continues to meet monthly and informed the Authority that the minutes from the October 2025 meeting had now been approved.

4.3. The SAC Chair informed the Authority that since the peer-reviewed papers published in the New England Journal of Medicine on mitochondrial donation treatment, the committee has seen an increase in applications from those seeking mitochondrial donation treatment. The Authority were reminded that the law requires that the licence is issued per patient seeking treatment.

4.4. The SAC Chair reminded the Authority that the committee considers Special Directions for import and export and that sometimes the information provided by a centre is not sufficient for the committee to make a decision and further information is then requested.

4.5. In response to a question regarding resources and whether the committee had enough members and expert advisers to support the increased workload of the committee, the SAC Chair responded that the committee is meeting their KPIs as detailed in the performance report. The Chair thanked the secretariat for the high-quality papers which are prepared for the committee, including the expert peer review and statement from the Genetic Alliance. Several committee members spoke about the importance of the information provided by Genetic Alliance in hearing the patients voice about the impact of the conditions being discussed. Committee members thanked the SAC Chair for her skills in chairing the meetings.

4.6. The Director of Strategy and Corporate Affairs informed the Authority that a paper will be brought to the March 2026 Authority meeting from the Head of Licensing regarding a summary of items which are brought to SAC and whether some items could be managed differently.

4.7. The Licence Committee Chair (Graham James) commented on the high quality of the papers and minutes produced for the committee.

4.8. The Licence Committee Deputy Chair (Alison McTavish) commented that the committee had recommended that all members should have the opportunity to observe an inspection. Members noted that the inspection process was thoroughly explained to members during their induction process. The Chair stated that one recommendation arising from the BER is that members should have the opportunity to visit clinics.

4.9. The Scientific and Clinical Advances Committee (SCAAC) Chair (Tim Child) informed the Authority that SCAAC welcomed Professor Laura Shallcross as a new External Adviser to their October 2025 meeting and that she brings expertise in public health and translational data science.

4.10. The SCAAC Chair reported that following the recommendations made by the committee in June 2025 the HFEA website had been updated to highlight MHRA guidance on using GLP-1 medicines when trying to conceive; the use of intrauterine and intraovarian platelet rich plasma (PRP) as an adjunct to treatment and patient information around the potential risks associated with the use of donor eggs and for surrogates, and the role of preconception health for ART patients.

4.11. The SCAAC Chair reported that at the October 2025 SCAAC meeting the committee discussed several papers relevant to public health and research findings, including two papers published by the Newcastle Fertility Centre reporting progress on the mitochondrial donation programme; a paper on IVF outcomes in same-sex female couples using partner vs. own eggs; the publication describing the development of human oocytes from adult somatic cells; and an abstract review describing the role of riVM and riCSI.

4.12. The SCAAC October 2025 meeting also discussed research developments in two horizon scanning topics: alternative methods to derive embryonic and embryonic-like stem cells, and testicular tissue transplantation to restore fertility in males. The SCAAC Chair reminded members that there is a joint statement between the HFEA and the Human Tissues Authority (HTA) in place to clarify the regulatory roles regarding tissue transplantation.

4.13. Members were informed that SCAAC had agreed add-on ratings for both intrauterine and intraovarian platelet-rich plasma (PRP). The committee had agreed that red ratings should be given due to the insufficient quality of evidence indicating that treatment was effective and a concern regarding the lack of research into the safety of the treatments.

4.14. The SCAAC Chair informed the Authority that the Executive are currently recruiting for a pool of expert biostatisticians, with experience in systematic review and evidence assessment using the GRADE methodology. These experts will be used to assist SCAAC with their add-ons review process. A committee member spoke of the rich discussions held during committee meetings and the extra dynamic that external experts bring to the table.

4.15. In response to a question, the SCAAC Chair explained the process for treatment add-ons being reviewed by SCAAC and stated that the process is set out on the HFEA website.

4.16. The Audit and Governance Committee (AGC) Deputy Chair (Alex Kafetz) informed members that all outstanding non-DSPT audit recommendations have been completed and congratulations were given to the Executive in achieving this.

4.17. The Authority were informed that the AGC received a deep-dive paper on clinic whistleblowing at the October 2025 meeting and assurances were given on the processes in place.

4.18. At the October 2025 meeting, the AGC received progress reports on the HFEA's two IT projects. The committee was pleased to note that PRISM is rolled out across the sector and that the HFEA is now able to utilise the data from PRIMS in a variety of ways. The committee had discussed the update to Choose a Fertility Clinic (CaFC) and had made a recommendation to the Authority on what should be done with aged data. This was presented to the Authority at the meeting held on 5 November 2025.

4.19. The AGC Deputy Chair informed members that the next AGC meeting is being held on 3 December 2025 and includes an afternoon training session on external audit. An invitation was extended to members to attend the training.

4.20. The Chair thanked all Committee Chairs for the reports and expressed thanks to the committee members and the staff who service the various committees for their hard work. The Chair stated that committee papers and minutes are published on the HFEA website.

4.21. Members noted the Committee Chairs' reports.

5. Performance Report

5.1. The Chief Executive introduced the performance report and reminded members of the Key Performance Indicators (KPIs) which are used to measure performance.

5.2. The Chief Executive stated that the HFEA's performance across all 19 KPIs had been variable in October, with 11 indicators rated Green, three Neutral, two Amber and three rated Red. For those KPIs which are rated red there are particular reasons for this, rather than structural issues, and these will be explained in the Directors' reports.

5.3. The Chief Executive referred to the HR KPIs and stated that sick leave has increased, due to pregnancy related sickness and this KPI is now showing red. Whilst the turnover KPI remains within target, it is now at the upper end of the threshold, but it is anticipated that this will stabilise and decrease.

5.4. The Chief Executive informed members that the annual staff survey had recently closed with a response rate of 88%, which is extremely good for the public sector. The results of the survey will be reported at the all-staff event in early December 2025 where the Executive will focus on what actions could be taken arising from the survey. The December 2025 AGC meeting will also receive the bi-annual HR report, including the results of the staff survey. Members congratulated the Chief Executive for the high staff survey response and the range of questions contained in the survey.

Strategy and Corporate Affairs

5.5. The Director of Strategy and Corporate Affairs informed members that following the decisions taken by the Authority in September 2024 regarding communicating licensing, regulatory activity and incident information as of January 2026, the information provided on the HFEA website regarding the latest decisions on clinics will be updated weekly.

5.6. As mentioned by the SAC Chair, applications to the committee had been increasing, but this is now stabilising.

5.7. Members were informed that the Autumn stakeholder meetings for the Patient Organisation Stakeholder Group (POSG) and the Professional Stakeholder Group (PSG) had been completed. There was a similar agenda for both meetings which included an update on HFEA activities since Spring 2025; future items coming to Authority meetings; a presentation on the HFEA's horizon scanning function and the Fertility Sector report which had been published the week before.

5.8. The Director of Strategy and Corporate Affairs stated that press interest in egg donation and unlicensed sperm donation continues, with widespread national coverage on these topics in recent weeks.

5.9. Members were informed that the House of Commons Women and Equalities Select Committee has a call for evidence on egg donation and freezing. The HFEA will provide evidence.

5.10. ESHRE has started a consultation on family limits and how these could be applied through the European Union. Whilst the UK is no longer in the EU, the HFEA will review any guidelines published.

5.11. The Director of Strategy and Corporate Affairs stated that the annual committee effectiveness reviews are underway with the results coming to the Authority in March 2026. Thanks were given to all those members who had participated in the reviews.

5.12. Following the earlier November 2025 Authority meeting regarding the future publication of the full Choose a Fertility Clinic (CaFC), the team has started to implement the Authority's decisions. The PRISM team is working with clinics on the verification of data, a letter from the Chief Executive has been sent to all PRs and there will be an article in Clinic Focus in November 2025. There will also be further information provided for both clinics and the public. Members were reminded that the paper and recording of the meeting is available on the HFEA's website.

5.13. The Director of Strategy and Corporate Affairs informed members that National Fertility Awareness week took place in November 2025, and the HFEA participated in a number of activities during this week. Thanks were given to Authority members for their help with media work.

5.14. The Director of Strategy and Corporate Affairs informed members that a Persons Responsible (PR) event will be held in April 2026 and invitations have been issued to all PRs in the UK. The Chair remarked that she felt that the PR event will be very well received and whilst the initial event letter has only been out for a week, several agenda items had already been suggested.

5.15. The Chair offered the assistance of members in producing the HFEA's evidence for the Women and Equalities Select Committee inquiry.

5.16. In response to questions, the Head of Communications noted that whilst the HFEA can track referral sources to the website (e.g. LinkedIn, Facebook, X), we cannot identify individual visitors or demographics. The recent decline in website sessions may relate to increased use of AI chatbots, and work is underway to optimise the website. Similar trends are being reported by other organisations, and the Head of Communications is engaging with other public bodies for shared learning.

Compliance and Information

5.17. The Director of Compliance and Information reported that the Opening the Register (OTR) waiting list continues to reduce, with a slight slow down in October 2025 due to a few complex cases. Thanks were given to the OTR team for their continued efforts in reducing the waiting list.

5.18. The Director of Compliance and Information reported an issue with some clinics failing to respond to the OTR team's requests for checks, leading to significant delays and escalations. The Director of Compliance and Information confirmed that she writes to the PR of any non-responsive clinic to remind them of their legal requirement to respond to information requests from the HFEA. Discussions with inspectors will take place in the New Year to consider how this could be linked with regulatory compliance and it may be necessary for the HFEA to adopt a tougher stance to ensure requests are dealt with in a timely manner.

5.19. As previously reported to the Authority, the HFEA's Head of Information left the organisation in September 2025 and members were informed that this vacancy has now been filled and the post-holder will start later this year.

5.20. The Director of Compliance and Information noted that it continues to be a busy time for the Inspection Team, with an increase in the number of inspections from the previous year. In addition, inspectors are supporting the Phoenix IT programme and other projects.

5.21. Members where informed that inspection KPI breaches are due to individual case complexities - such as multiple meetings with PRs, involvement of the HFEA legal team, or delays in receiving information when staff are on leave – rather than HFEA staff capacity. Members were assured that current KPI targets remain appropriate and do not need to be revised.

Finance, Planning and Technology

5.22. The Chief Executive stated that there are three finance KPIs, two of which are green and one is red. As detailed in the performance report, the red KPI relates to collection of debt within 40 days. Whilst 90% of debt is collected within 60 days, there are several invoices relating to a couple of clinics which means this KPI is not met.

5.23. Members were reminded that the Executive is forecasting a fairly significant year-end deficit. While various actions have been taken to reduce this deficit, a few additional pressures – mainly linked mainly to IT and the Phoenix Programme - have been identified.

5.24. The Chief Executive commented that the HFEA has several staff on maternity leave and due to increased work pressures this year, linked to inspections and the Phoenix programme, it has been necessary to find cover to back-fill the posts.

5.25. The Chief Executive advised that it is unlikely the HFEA will reduce its deficit to zero by year-end and this has been discussed with the Department. In its six-month submission, the HFEA proposed a revised year-end deficit target of £200k and is working towards this whilst awaiting the Department's response. The Chief Executive noted that the HFEA recognises the financial pressures currently facing the Department.

5.26. At the end of October 2025, the forecast year-end deficit remains high at £411k, driven by an income shortfall of £286k and an overspend against expenditure of £125k. The Chief Executive outlined actions to reduce costs, including reviewing recruitment timings and leaving temporary gaps in posts where possible. All financially consequential decisions are being scrutinised by the Senior Management Team, and it is anticipated that planned expenditure reductions will be achieved by year-end.

5.27. A member questioned whether DHSC colleagues could help with the purchasing of the relevant IT licenses, as other health ALBs must be in the same position and the Department might be able to negotiate a discount. The Chief Executive undertook to raise this with the Department.

5.28. In response to a question, the Chief Executive referred back to the key points arising from the staff survey and the high response rate received; currently these do not show that staff feel they are under extra pressure but the Executive will keep this under review to ensure staff morale is maintained.

5.29. The Chair drew the discussion to a close, noting that there is a robust plan in place to achieve savings where possible and that the Executive where mindful of pressure on existing staff.

Decision

5.30. Members noted the performance report.

6. 2026-27 Budget Proposal

6.1. The Chief Executive introduced the paper and reminded members that the HFEA is funded by a mixture of fees and Grant-in-Aid (GIA), with 95% of income coming from fees and 5% from GIA. ALBs are not expected to make a profit or loss, and income received should be sufficient to cover all the required statutory duties.

6.2. The income side of the budget can be volatile as it is based on clinic activity which can create problems with forecasting. The volume forecasts for this year are currently within an acceptable range of accuracy, but the HFEA has had to revise its assumptions about the value of fees received.

6.3. The Chief Executive remarked that some clinics are still providing catch-up data to PRISM and therefore a proportion of invoices relate to activity in previous years and are therefore charged at a lower rate. An assumption has been made that 5% of invoices in 2026-27 will be charged at the previous year's rate, and that activity will remain similar to that of 2025-26.

6.4. To deliver all its duties in 2026-27 and complete the IT transformation programme, the HFEA expects overall expenditure to increase by around 5%. The increase is mainly due to inflationary growth in core staff and IT costs, as well as several fixed-term posts providing maternity cover.

6.5. The Chief Executive noted that the growth figure is further complicated by the fact that the budget which was set for 2025-26 was in hindsight not high enough to meet actual expenditure, so therefore the HFEA is already starting from a very low base.

6.6. The Chief Executive noted that when the Phoenix Programme ends next year, a full review of the HFEA's IT spend requirements, particularly regarding licence costs, will be undertaken with an aim to reduce costs as far as possible.

6.7. The Chief Executive introduced the three scenarios contained in the paper which are based on different levels of GIA being received from the Department and explained each scenario in detail. The first scenario is based on the minimum GIA requirement, being the funds required for the OTR service. The other two scenarios are based on the Spending Review (SR) bids which were made in 2025.

6.8. The Chief Executive commented that it would be prudent to assume that the lowest level of GIA would be received and therefore a 20% increase on IVF activity fees and 12.5% increase on DI fees would be required. The Chief Executive commented that historically the HFEA has been very successful at limiting free increases but that the proportion of core spend which is covered by GIA has dropped considerably over the past few years.

6.9. The Chief Executive concluded his presentation by stating that the Authority is being asked for approval to commence discussions with the Department and HM Treasury (HMT), based on a prudent increase of 20% on IVF activity fees and 12.5% on DI fees. When the level of GIA support is announced, the HFEA will revise its budget accordingly.

6.10. Members spoke in favour of the increase, noting that it was a below inflationary increase and that the HFEA had maintained fees levels for as long as possible, but that this increase is required so that the HFEA can maintain public protection through its regulatory actions.

6.11. Members noted that in relative terms the proposed increase is small compared to the overall cost of treatment.

6.12. A member questioned whether the proposed increase is sufficient to fully fund the HFEA. The Chief Executive responded that the HFEA fees have not kept pace with inflation and the proposed increase should be sufficient unless activities that incurs a fee decreases further. Whilst the Executive has reviewed all costs, the largest single cost to the HFEA is staffing and no savings could be made without impacting on delivering the HFEA's statutory duties.

6.13. A member noted that a full fee review is taking place and asked whether a zero-budgeting exercise will run alongside that. The Chief Executive responded that within the HMT spending review requests such budgeting exercises have been conducted.

6.14. A member noted that the communications around the proposed increase will need to be handled sensitively for both clinics and patients.

6.15. The Chief Executive reminded members that within the Act is the requirement that any fee increases must have approval from the Department, so the timeframe of this proposal is sufficient to allow for the necessary discussions with the Department and HMT, while still provide adequate

advance notice to clinics. It is anticipated that the level of GIA funding should be announced before Christmas 2025 which means that the Executive will hope to report to the January 2026 Authority meeting on the outcomes of the discussions.

Decision

6.16. Members agreed:

- the proposed HFEA operating budget for 2026-27 (noting the potential to increase the budget for additional systems investments should the HFEA receive a higher GIA settlement based on its SR bid)
- Fee levels of £120 for IVF and £45 for DI as required to fully fund the HFEA in 2026-27 (noting the potential to reduce the IVF fee to £115 should the HFEA receive a higher GIA settlement)

Action

6.17. Director of Finance, Planning and Technology to continue discussions with the Department and Treasury to implement the 2026-27 budget proposals and report back to the January 2026 Authority meeting.

7. The Fertility Sector report and review of inspection feedback

7.1. The Head of Communications reminded members that the Fertility Sector 2024-25 report was published last week. This report was formerly known as the 'State of the Sector' report. Members who contributed to the review were thanked for their input.

7.2. The main points of the report are displayed in an infographic, to make the information easier to understand and for different audiences to engage with it. The Head of Communications commented that inspiration had been taken from other regulators on how they present their information.

7.3. The Head of Communications outlined the key findings set out in the report.

7.4. Members were informed that the report was shared with the HFEA's stakeholder groups ahead of publication and has been well received. A number of patient-facing organisations shared the report once the HFEA published it.

7.5. The Head of Communications stated that within the first 48 hours there were around 1,000 views on the report on the HFEA website and this had increased to 3,000 within the first six days, which was double on the previous year. This increase could be linked to the new format and the communication team will continue to monitor the reports performance.

7.6. Social media engagement was highest on LinkedIn which showed that the report is of interest to professional audiences. There has also been a good response on Instagram which is a more patient-facing audience.

7.7. The Head of Communications informed members that the press release was issued widely with a good open rate.

7.8. The Head of Communications concluded her presentation by stating that that HFEA continues to be very transparent in the information it provides and that the communication team will continue to monitor how the report performs and use this feedback to formulate the publication for next year.

7.9. The Chief Inspector provided an overview of post inspection survey feedback. The Chief Inspector stated that the HFEA is very open to feedback and that the team encourages clinics to provide feedback via SurveyMonkey at the end of the inspection process. Processes are then reviewed against feedback received and where necessary improvements are made.

7.10. Members were informed that from April 2024 to March 2025, 88 inspections took place and 24 post inspection survey results were received. Of all the answers received 80% of responses received were positive, 10% negative and 10% neutral. The survey questions are split into three distinct sections which are pre-inspection, during inspection and post inspect.

7.11. The Chief Inspector highlighted the positive response to the question of whether the self-assessment questionnaire (SAQ) helps centre staff prepare for inspection. The purpose of the SAQ was explained. A clear majority of respondents strongly agreed or agreed that the SAQ helped prepare centre staff for the inspection. There was a mixed response to the question of whether the submission of the SAQ and the relevant application to the HFEA were simple, but more positive responses were received than negative.

7.12. The Chief Inspector reported that 100% of the respondents strongly agreed or agreed that the desk-based assessment (DBA) was clearly explained. There was also strong agreement that having the DBA issued 12 weeks in advance of the inspection was sufficient notice. Members were reminded that the DBA was first implemented as part of the pandemic response.

7.13. The Chief Inspector commented that at no point should an inspection impact the centre's operations or service to patients. One clinic responded that patients were inconvenienced by the inspection, however no clinic responded that patient care was jeopardised by the inspection. Feedback had been given to the Inspection team to remind them that inspections should not interfere on how the clinic is run.

7.14. The Chief Inspector reiterated the importance of good communication between clinic staff and inspectors. It was therefore pleasing that 15 respondents strongly agreed or agreed that there was enough time to discuss inspection findings through the day and at the end of the inspection, and only two disagreed or strongly disagreed. 85% of respondents felt that they were able to discuss inspection findings and improvement required with the inspection team.

7.15. Regarding the clarity of the inspection report, 15 respondents strongly agreed or agreed that the report was accurate and clearly presented. 15 respondents also strongly agreed or agreed that the timescales for implementation of the recommendations were reasonable with no one disagreeing. The Chief Inspector commented that there are some areas of the report which could be improved going forward.

7.16. The survey asked whether the inspection process promotes learning and improvements; 17 respondents strongly agreed or agreed that it did, with one disagreeing.

7.17. The Chief Inspector discussed the lessons learnt from the survey and highlighted planned follow-up actions. The Inspections team will continue to encourage clinics to complete the survey, with the aim of increasing the response rate. Consideration will be given to developing specific questions tailored to the type of inspection. Members were informed that a note will be added at the end of the survey to request that if PRs have any complaints or concerns, they can request to meet with the Chief Inspector. Any technical issues regarding SAQs will be directed to the Phoenix Project members.

7.18. Several members suggested that to increase the survey response rate, the survey could be sent to other members of the clinic staff and not just the PR.

7.19. A member commented that given the small sample size, firm conclusions could not be drawn from the results. The member questioned whether the response rate had been benchmarked against other regulators and whether we could learn from others who may have secured a higher response for similar surveys. It was suggested that giving people the option of providing a name when completing the survey would ensure that any feedback on their comments could be provided directly, and people should not fear inspection prejudice.

7.20. A member commented that it would be helpful to see the responses to all the questions, including any free text provided. The Director of Compliance and Information agreed to pick this up with Authority members outside of the meeting.

7.21. In response to a question, the Chief Inspector stated that some respondents felt that it was difficult to navigate and submit the current SAQ but the current IT Phoenix Programme would improve this.

7.22. The Director of Compliance and Information noted that the survey provides further insight into the inspection process, in addition to the KPIs which are reported to the Authority in the Performance Report. The response rate for the survey has increased from previous years but the team will consider how this can be increased further. The Director of Compliance and Information spoke of the proposed IT improvements that the Phoenix Programme will bring.

7.23. In response to a question the Chief Inspector confirmed that the survey is issued as soon as the inspection is finished.

7.24. A member commented that whilst 75% of respondents agreed with the inspection findings, this meant that one in four respondents didn't and concern was expressed about this. The Chief Inspector responded that unless free text responses provided more information on why the respondent didn't agree with the inspection finding then the HFEA couldn't take any action. The inspection report does give the PR the opportunity to comment in each individual inspection finding before the report is published.

7.25. A member noted that there are lots of avenues available to clinics/PRs to provide feedback to the HFEA and it would be good to ensure that all information provided, not just the survey, is triangulated. The Director of Compliance and Information commented that the HFEA has a very open relationship with the sector.

7.26. A member suggested the possibility of having a "you said, we did" feature in the Clinic Focus newsletter that is sent to all licensed clinics, so that clinic staff can see the impact of completing the survey and what actions the HFEA had taken.

7.27. The Chair drew the discussion to a close, noting that there may be parts of the inspection process that clinics dislike or disagree with, particularly given that as a regulator the HFEA will highlight areas of non-compliance through the inspection process, but the Chair felt that it is still important for the HFEA to canvass opinions on the inspection process. The Chair noted that whilst the sample size is small, there are actions planned to improve the submission rate and it is anticipated that the sample size will increase for next year.

Decision

7.28. Members noted the Fertility Sector report and review of inspection feedback.

Action

7.29. The Director of Compliance and Information to circulate the full survey responses of inspection feedback to members.

8. The Regulation of AI in Fertility Treatment

8.1. The Chair introduced this item by stating that artificial intelligence (AI) is increasingly being used in the fertility sector and this paper provides a timely overview on its use and the regulatory framework and seeks the view of the Authority on its regulatory stance.

8.2. The Policy Manager introduced the paper and confirmed that this paper supports objective six of the HFEA's Strategy for 2025-28, which is to prepare for the ways in which AI and its future potential is likely to impact on the sector and HFEA.

8.3. The HFEA has been monitoring research and clinical developments in AI through its Scientific and Clinical Advances Advisory Committee (SCAAC) and its horizon scanning function since February 2019, last discussing research developments in February 2024. Following recommendations made by the Committee, the HFEA has carried out a scoping project aiming to improve understanding of how AI and other emerging technologies (including robotics and automation) are being used in fertility treatment, map the UK's regulatory landscape, and consider how the HFEA as a regulator can best support the responsible adoption of these tools across the sector in the interest of patient care.

8.4. The Policy Manager informed member that the UK Government has adopted a pro-innovation approach to the regulation of AI, seeking to balance effective oversight with flexibility to support technological development within the UK.

8.5. Within the healthcare sector the shared regulatory oversight of AI adoption depends upon a technology's intended purpose, data use, and clinical context. This Policy Manager spoke of the role of Medicines and Healthcare products Regulatory Agency (MHRA) and other regulators in relation to AI, highlighting how regulatory remits intersect across the development and deployment of an AI-enabled healthcare tool.

8.6. The HFEA, as a sector-specific regulator, is responsible for monitoring how AI technologies are being adopted in practice. This is done by ensuring that licensed clinics who are using AI-assisted tools are able to demonstrate that they are meeting the required standards and that the technology is being deployed in a way which is compliant with the Human Fertilisation and Embryology Act (HFE) 1990 (as amended) and associated guidance. However, as the Authority are not technical or product regulators, the HFEA does not have the in-house expertise to assess the underlying algorithm or technical architecture of AI tools.

8.7. The Policy Manager referred to Annex B of the paper which illustrates the current and potential uses of AI in the fertility patient pathway, such as initial engagement and assessment, clinical treatment, and post-treatment uses. Whilst AI technologies have the potential to bring great benefits to the fertility and embryology sector, there are also potential risks. Some of these risks relate to data bias, lack of transparency and explainability, overreliance on tools and the impact on clinical expertise.

8.8. The Policy Manager spoke of HFEA's regulatory position in regulating AI within licensed fertility centres, and the requirement for any new technology being deployed to be compliant with existing HFEA requirements. This includes the Code of Practice, licence conditions, General Directions, and authorised processes framework. It was noted that, if centres fail to evidence that they meet the required standards, a non-compliance can be cited on inspection.

8.9. The Policy Manager spoke of potential next steps, including:

- Continue horizon scanning to track AI use in fertility treatment and identify areas of regulatory concern; scheduled for SCAAC discussion in Feb 2026.
- Maintain and update Clinic Portal guidance on AI as needed, including signposting to external regulators.
- Engage with MHRA and other oversight bodies as their AI and Software and Medical Device requirements evolve; escalating concerns where appropriate.
- Consider how principles of responsible innovation may be extended to cover AI tools.
- Ongoing engagement with stakeholder groups to understand emerging issues. Respond to clinic requests for clearer AI-specific guidance to support consistent practice, for example interpretation of the authorised processes list, or developing patient facing information.
- Use inspection findings to monitor the use of AI tools and detect any unsafe deployment.

8.10. The Chair thanked the Policy Manager for the informative paper and presentation and invited comments from members.

8.11. The SCAAC Chair informed member that developments in AI, robotics and automation have been discussed at the SCAAC meeting on several occasions and highlighted that AI is beginning to be widely adopted within clinics. SCAAC have considered the use of AI in the context of embryo grading/time-lapse imaging incubators, rating this as a treatment add-on. The committee noted that, despite there being some high-quality research, there appears to be no benefit on live-birth rate when used for this application resulting in a 'black' rating. A member supported the position that AI should not be defined as a treatment add-on under the current parameters, due to its potential to become a routine part of treatment.

8.12. The SCAAC Chair highlighted that there are touchpoints for AI applications throughout the patient's treatment pathway and provided examples of these to members. Whilst the MHRA is responsible for regulatory oversight of AI-integrated medical devices, there remains confusion around the regulatory landscape and the pace at which both the technology and regulation is adapting. The SCAAC Chair offered his support in producing further information as required and utilising the infographic on Annex B.

8.13. A member commented that there are generalised concerns with AI technologies that are not specific to the use of AI in fertility treatment, however issues with data-bias could be very alarming for fertility patients.

8.14. A member commented that awareness around the use of AI tools for patient communication and how this may benefit or challenge different patient groups, such as neurodiverse patients, should be noted. Members discussed developing patient information about the use of AI in fertility treatment, highlighting that this is a fast-moving area so the information should be monitored and refreshed as required.

8.15. Members noted that that not all AI applications within fertility treatment fall within the same application, and it may first be appropriate to tease out the different applications so that specific use concerns can be recorded.

8.16. The SAC Chair commented that the committee had considered whether AI could be used to help with the review of the PGT-M licenced conditions but on a third of the conditions it was incorrect in identifying the genetic inheritance patterns of recessive conditions and the disease specialisms. The SAC Chair commented that people could be asked to proactively alert developers when AI is providing incorrect information so that this could be rectified. The HFEA may have a role in warning users of identified errors.

8.17. Members noted the numerous different agencies involved in the regulation of AI and a member suggested that there could also be a role for the Advertising Standards Authority (ASA) when unjustified marketing claims regarding fertility treatment are being made.

8.18. A member noted that the NHS has two clinical risk management standards (DCB0129 and DCB0160) to support developers and adopters of digital technologies. It was noted that the HFEA could have role in sharing such guidance and best practice to clinics via Clinic Focus. The potential to use the forthcoming PR event to discuss use of AI was discussed. It was also suggested that the HFEA could formally write to the new National Commission about its concerns with AI-based medical devices being used within the fertility sector specifically, to ensure that this is on their agenda to be addressed.

8.19. Members discussed the use of AI as a medical device and the work of MHRA in recognising and classifying such devices. The potential role of inspectors checking that such medical devices meet the required standards, such as DCB0160, was discussed.

8.20. Members discussed segmenting the patient pathway into key areas of regulatory interest and different AI methods used so that the HFEA can take action to address its most pressing concerns and align them with the HFEA's strategy and available resources.

8.21. The AGC Chair suggested that the Executive could consider adding a risk to the strategic risk register, not only about the risks of adoption of AI within the sector, but also for the HFEA in terms of keeping up with developments in or appetite for further development of AI both within the sector and government.

8.22. The Chair drew the discussion to a close and summarised the main points as:

- The regulation of AI in fertility treatments needs to be considered now, whilst being mindful of the limitations introduced by interdependencies and movement within this area.
- Further work should be undertaken to prioritise the HFEA's focus, with clinical and laboratory applications being the focus of SCAAC discussions.
- The HFEA could develop patient-facing information, keep up to date information for the sector, and consider implications for the future inspection regime (against the Authority's priorities for 2025-28 and resource availability).
- The HFEA Executive should develop a plan for addressing this across the next few years, in alignment with the organisational strategy.
- Anticipate that this topic will be returning to the Authority with further progress updates on specific items and not a general AI overview.

9. Any other business

9.1. The Chair thanked members for their contributions over the past two days, firstly at the strategic away day and then at the Authority meeting.

9.2. The Chair noted that this was the last Authority meeting for the calendar year and therefore extended season's greetings to all.

9.3. The Chair thanked everyone for their active participation in the meeting and for the high quality of papers before the Authority. There being no further items of any other business, the Chair closed the meeting and reminded members that the next full Authority meeting is being held on 21 January 2026. Details of this meeting, including how to request to observe, is posted on the HFEA website.

Chair's signature

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

Signature

Chair: Julia Chain

Date: 21 January 2026