

Minutes of the Authority meeting on 20 March 2024

Members present	Julia Chain Tim Child Frances Flinter Zeynep Gurtin Jonathan Herring Alex Kafetz	Alison Marsden Gudrun Moore Geeta Nargund Catharine Seddon Christine Watson
Apologies	Graham James Alison McTavish	
Advisers	Jason Kasraie, Special Adviser	
Observers	Adrian Thompson, Board Apprentice Steve Pugh (Department of Health and Social Care – DHSC) Farhia Yusuf (DHSC)	
Staff in attendance	Peter Thompson Clare Ettinghausen Rachel Cutting Tom Skrinar	Paula Robinson Shabbir Qureshi Joanne Anton Mina Mincheva Alison Margrave

Members

There were 11 members at the meeting – 8 lay and 3 professional members.

1. Welcome and declarations of interest

- 1.1. The Chair opened the meeting by welcoming Authority members, HFEA staff and DHSC colleagues present. Members were informed that Alex Kafetz would join online during the course of the meeting,
- 1.2. The Chair also welcomed observers online and stated that the meeting was being recorded in line with previous meetings and for reasons of transparency. She stated that the recording would be made available on our website to allow members of the public to hear it.
- 1.3. Declarations of interest were made by:
 - Geeta Nargund (Clinician at a licensed clinic)

2. Minutes of the last meeting and matters arising

- 2.1. A member proposed that the minute 8.3 be amended so that it now reads:

It was noted that the HFEA has no statutory responsibility to provide this service and given the pressures on the HFEA's core budget it was no longer sustainable to provide this service.

Members were assured that specialist counselling and counsellor-facilitated meetings could be organised privately by those donor conceived individuals interested and that take-up to date had been variable. These were a significant factor in the decision-making process, and it was noted that any future model of support needs to be financially sustainable.

- 2.2.** With this amendment members agreed that the minutes of the meeting held on 24 January were a true record and could be signed by the Chair.

Matters arising

- 2.3.** Members were advised that the matters arising items had either been actioned as detailed in the paper presented to the meeting or that an update would be presented to members under the Directors' report in agenda item 5 and the Opening the Register (OTR) report in agenda item 6.

3. Chair and Chief Executive's report

- 3.1.** The Chair gave an overview of her engagement with key stakeholders and her attendance at the decision-making committees of the Authority.
- 3.2.** The Chair informed the Authority that she attended the Scientific and Clinical Advances Advisory Committee (SCAAC) in early February and conducted interviews for new SCAAC members towards the end of February. Ying Cheong, Peter Rugg-Gunn, and Veronique Berman have been appointed to the committee. The SCAAC Chair (Tim Child), spoke of the high calibre of candidates which reflected the high regard in which the work of the HFEA and SCAAC is held by professionals.
- 3.3.** The Chair updated the Authority on the progress of recruitment for the four new Authority members, with the skill sets of embryology, genetics/statistics, legal/ethical and patient experience. It was reported that there is a strong short list of candidates and interviews are being held next week. The Chair reminded members that both ministerial and Number 10 approval are required for Authority members appointments.
- 3.4.** The Chief Executive provided an update on the key external activities contained in the paper presented to the Authority.
- 3.5.** The Chief Executive spoke about the Nuffield Council on Bioethics (NCOB) launch of their new strategy which was held at the end of January. He informed members that at the heart of this strategy was a move to shorter, more policy focussed reports.
- 3.6.** The Chief Executive informed members that the HFEA will be working with NCOB on a new project exploring the ethical and regulatory questions surrounding embryo models. He spoke about the potential opportunities of this partnership and the benefits of working together on common issues. Members spoke in support of this partnership and asked that further information be sent to them on the project.

Decision

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

Action

- 3.8.** Chief Executive to send members further details about the NCOB project on embryo models.

4. Committee Chairs' reports

- 4.1.** The Chair invited Committee Chairs to add any other comments to the presented report.

- 4.2.** The Licence Committee Chair (Alison Marsden) gave an overview of recent meetings, including the recent decision regarding suspension of a licence due to significant concerns, and the subsequent press coverage. She spoke about the importance of the HFEA's regulatory work and the high regard that this work is held in. She took the opportunity to thank the committee and the staff who supported it for all their work during her tenure as Chair.
- 4.3.** The Statutory Approvals Committee (SAC) Chair (Jonathan Herring) provided further information on the review of autosomal deafness conditions which was brought to the committee by an expert reviewer. He reminded members of the regulatory requirement to consider such assessments and that the committee had approved those presented by the expert reviewer.
- 4.4.** The Scientific and Clinical Advances Advisory Committee (SCAAC) Chair (Tim Child), spoke about the visit to the Newcastle Fertility Centre to learn more about the mitochondrial donation programme and informed members that the Newcastle team will be invited to attend a future SCAAC meeting to update further.
- 4.5.** The Audit and Governance Committee (AGC) Chair (Catharine Seddon) gave an update on the work of the committee. She informed members that the Code of Practice audit had received a substantial rating, with no recommendations for action, and that this is the highest rating that can be achieved. The committee had agreed the 2024/25 audit plan and had considered the longer-term audit planning list. The good progress on closing outstanding audit actions was noted and a deep dive discussion on specific governmental functional standards was held.
- 4.6.** The Chair spoke about the importance of the work undertaken by the various committees and expressed her thanks to the Chairs and all members for their commitment to this work.

Decision

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

5. Performance report

- 5.1.** The Chief Executive introduced the performance report and stated that of the 17 KPIs, five are red, three amber, six green and three neutral. Members complimented the new presentation of the RAG rating.
- 5.2.** PRISM activity levels continue to be stable with an error rate of 3.5%. The targeted approach for those clinics who have an error rate higher than 4% continues. The Chief Executive informed members that the verification process for Choose a Fertility Clinic (CaFC) has commenced and he explained the process in greater detail. The benefits of PRISM and the ability to manage and share data more easily were noted.
- 5.3.** The Chief Executive spoke about the HR KPIs and stated that as a small organisation the KPI for staff sickness continues to be negatively impacted by long-term sick leave. As previously reported these are distinct cases unrelated to stress or workload.
- 5.4.** The Chief Executive informed members that the KPI for staff turnover has increased slightly above the agreed target band and he informed members that other comparable organisations have a much higher turnover rate than the HFEA. He did not have any information to indicate that this trajectory will increase further.

- 5.5.** A member asked whether it would be possible to create two new KPIs for Opening the Register (OTR) relating to the number of applications and waiting list and the average time for logging an application as completed. The member further questioned whether the Executive could predict how OTR services will be affected by the full realisation of PRISM.
- 5.6.** The Chief Executive responded that metrics which break down the total number of applications will be possible, but that any such reports need to be relevant for the team. He stated that PRISM provides the OTR team with new data management tools and now that they are being used the Executive should be able to establish a productivity rate which could be used to measure performance going forward.

Compliance and Information

- 5.7.** The Director of Compliance and Information informed members that OTR applications were extremely high in January and February due to raised awareness arising from the documentary *Born from the Same Stranger*.
- 5.8.** It was reported that the OTR team are using the case management tools to split applications into different categories and are working on how to report KPIs and application numbers in a useful, purposeful manner. It is anticipated that by June more meaningful reports will be able to be produced.
- 5.9.** The Director of Compliance and Information informed members that the Compliance team was being impacted by long-term absence. Whilst this and the extra inspections had put additional pressure on the inspection team it has not resulted in a clinic not being able to have a licence renewed. It was reported that in the period from January to September 2024 72 inspections had been scheduled.
- 5.10.** A member questioned how the inspection team was bearing up under this additional pressure. The Director of Compliance and Information responded that it had been a difficult time with a busy and demanding schedule, and she took the opportunity to thank the team for all their work. Additional resources had been allocated to recruit an additional inspector and it would be necessary to consider resourcing going forward.
- 5.11.** Turning to IT, the Director of Compliance and Information informed members that the HFEA's VPN solution was changed recently, due to a loss of confidence in the previous vendor and security vulnerabilities. The change over had been a smooth process and thanks were given to the IT team for managing this change at pace.

Strategy and Corporate Affairs

- 5.12.** The Director of Strategy and Corporate Affairs spoke about the high media interest and the increased communications activities partly arising from the *Born from the Same Stranger* documentary, the BBC iPlayer programme on egg freezing and wide interest in incidents/licensing. She thanked those Authority members who had participated in various media interviews.
- 5.13.** The success of the dashboard since its launch was highlighted. The new media centre was recently launched on the HFEA website, and thanks were given to the HFEA staff who had implemented this.

- 5.14.** The Director of Strategy and Corporate Affairs commented that the busy period for the inspection team has a knock-on effect on the licensing team, especially the Executive Licensing Panel and the actions taken to manage this work was explained.
- 5.15.** It was reported that planning for the new business year was well advanced and includes projects such as setting out what a workstream on AI will look like, further development of the dashboards, further work on two aspects of our work on law reform and preparation for the fertility trends report and next national patient survey.
- 5.16.** The Director of Strategy and Corporate Affairs informed members that she had attended the Institute for Regulation annual conference, and it was a good opportunity to hear from other regulators how they are addressing similar issues to those that the HFEA are facing.
- 5.17.** Members were informed that planning is underway for the next patient and professional stakeholder groups which are being held in April/May.

Finance

- 5.18.** The Director of Finance and Resources referred to the paper and stated that as previously reported the HFEA is currently operating with a deficit of around £100k which can be attributed to increases in IT costs, the unplanned non-consolidated bonus for staff which was agreed by the Government but needed to be met out of the HFEA's current budget, as well as a reduction of Grant in Aid (GIA) of £100k that had not been recognised at the beginning of the year. This position is likely to change as year-end is approached and various accounting adjustments may be made due to the audit process. He reported that there is a good exchange of information and communication with the finance business partners in the Department who have not requested that HFEA undertake any specific action to reduce the deficit.
- 5.19.** Members were informed that communications had been issued to clinics regarding the fee increase.
- 5.20.** The Director of Finance and Resources informed members that the bid for the Epicentre replacement had been submitted to the Department and a response was expected by the end of the month. He spoke about the consequences and actions required if the bid was unsuccessful and stated that this had also been communicated to clinics.
- 5.21.** In response to a question regarding the reduction in IVF cycles the Chief Executive stated that it is not yet clear why but there is always an adjustment in figures before year end and past experience suggested that the number is likely to increase somewhat. The majority of IVF cycles in England and Wales are conducted privately so it could be assumed that this may have been affected by the increased cost of living, whereas cycles in Scotland are fully funded.

Decision

- 5.22.** Members noted the performance report.

6. Opening the Register - update

- 6.1.** The Chair introduced this agenda item and reminded members that as this was a critical year for Opening the Register (OTR) it had been agreed that this would be reported as a standalone agenda item, but members had agreed at the January meeting that further monitoring of OTR from April onwards would be through the performance report.

- 6.2.** The Director of Strategy and Corporate Affairs presented the paper reminding members of the three workstreams contained in the report of OTR services/infrastructure, future of support services and communications.
- 6.3.** The Director of Compliance and Information spoke positively about the benefits of the new IT systems and the reports it can produce for the OTR team; this has made training of new team members easier. The updating of SOPs is still being worked on to ensure that complex scenarios and the procedures to follow are fully captured.
- 6.4.** The Director of Compliance and Information reminded members of the decision taken at the last meeting regarding support services and the agreement to improve and expand all the HFEA's information and signposting for donor conceived people and donors. This work will be conducted throughout 2024.
- 6.5.** As agreed at the last meeting, options regarding the Letterbox service had been issued to members via email and members had agreed that the Letterbox service should not be brought in-house and that the HFEA should issue information and advice to donor conceived people on making initial contact with their donor or donor sibling.
- 6.6.** The Director of Strategy and Corporate Affairs spoke about the success of the #WholsMyDonor campaign and the need to pause some of the activities to avoid overloading the team. In February the Corporate Management Group (CMG) has agreed to covert content from that campaign to ongoing business as usual (BAU) activities. Members were informed about the successful Instagram live Q&A session which targeted donor conceived individuals (DCIs) and donors.
- 6.7.** The Director of Strategy and Corporate Affairs spoke about the remaining risks as identified in the paper and stated that reputational risks remain, as the HFEA manages the increasing waiting list of applications and the expectation of how long it takes to process an application.
- 6.8.** Members were informed that each workstream will be completed by the end of the business year, with some aspects being taken forward through BAU activities.
- 6.9.** In response to a question regarding managing the waiting list the Director of Compliance and Information stated that the number of applications received January-March were more than three times the average. An additional member of staff had been recruited to support the OTR team and applications were now being streamed into different categories so they can be managed in a more efficient way.
- 6.10.** In response to a question the Director of Compliance and Information informed members what constitutes repeat applications.
- 6.11.** The Chair drew the discussion to a close noting that future reporting will be in the performance report and requested that this includes information about managing the waiting list.

Decision

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

7. Authorised Processes Review

- 7.1.** The Policy Manager introduced the paper and stated that the HFEA has a statutory responsibility to have an approval process for processes that fall within its regulatory remit which may affect the

quality of tissues and cells. The authorised processes (AP) list describes the processes clinics can use to carry out the licensable activities set out in the HFE 1990 Act.

- 7.2.** The proposed updates to the AP list aim to bring the list in line with up-to-date practice and terminology; ensure that the list is clear and consistent and future proof the list such that small modifications to procedures/techniques fall under the umbrella term.
- 7.3.** The application process which a centre must follow if they wish to use a process which does not appear on the AP list was explained.
- 7.4.** The Policy Manager reminded members that currently the Authority has delegated the authorisation of processes to SAC, who are advised on the matter by SCAAC. The roles of both SCAAC and SAC was explained in more detail.
- 7.5.** The proposal is to move the AP decision making powers to SCAAC. It was reported that both committees have been consulted on and support this proposal. It was noted that the required changes to the standing orders were explained in detail in the Effective Governance paper.
- 7.6.** The Chair of SCAAC stated that the current process is complicated as two committees consider the same matter. This proposal improves efficiency. He reiterated that both committees are fully supportive of the proposals contained in the paper.
- 7.7.** The required updates to the decision tree were explained and the proposal is that the Executive develops the new decision tree and guidance in collaboration with SCAAC with final agreement and approval of these documents being given by SCAAC.
- 7.8.** In response to a question the Chief Executive confirmed that the Authority had the power to delegate within the existing legal framework. The composition of SCAAC was discussed noting that it was only Authority members who had voting power.
- 7.9.** The name of SCAAC was discussed and it was agreed that it was still relevant and suitable as almost all of the committee's work was of an advisory nature.

Decision

- 7.10.** Members agreed the proposed updates to the AP list.
- 7.11.** Members agreed the proposal to divert the decision-making powers relating to AP from SAC to SCAAC via changes in the standing orders.
- 7.12.** The development of a new decision tree and accompanying guidance for decisions relevant to AP and that SCAAC be given authorisation to approve these documents.
- 7.13.** Members agreed to delegate authority to the Chair for approving changes to GD 0008.

Action

- 7.14.** The Executive to implement the Authority's decisions on Authorised Processes.

8. Effective Governance

- 8.1.** The Chair introduced the agenda item and reminded members that on an annual basis all committees were required to review their own effectiveness using a standard and/or bespoke framework. Between September 2023 and early March 2024 this 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.

- 8.2.** The Board Governance Manager introduced the paper and informed the Authority that all committees stated that the meetings and papers were well prepared and that they had sufficient information necessary to take decisions.
- 8.3.** Each committee had made a number of recommendations for improvement and the proposed actions against these recommendations are shown in the paper.
- 8.4.** The proposed changes to the standing orders were explained, noting that the Authority had agreed in the previous agenda item to divert the decision-making powers relating to AP from SAC to SCAAC and these changes were shown in Annex B of the paper.
- 8.5.** The Chair expressed their appreciation of the team that supports the various committees in their work.
- 8.6.** The Chair noted that with the appointment of four new Authority members the composition of committees will need to be reviewed. It may also be appropriate to review the terms of reference of all the committees during the next business year.

Decision

- 8.7.** The members unanimously voted in favour of the changes to the standing orders.
- 8.8.** Members also noted the summary of actions contained in the annual review of committee effectiveness.

Action

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

9. Donor Compensation

- 9.1.** The Head of Policy introduced the paper and stated that there have been no changes to the compensation rates for donors since they were agreed by the Authority in 2011. When the rates were agreed in 2011 the Authority felt that the compensation amounts struck the right balance between covering donor expenses and donors feeling valued but were not enough to remove the altruistic motivations behind donating gametes and embryos.
- 9.2.** The Head of Policy stated that the impact of inflation, particularly since 2020-21, means that in 2024 the donor compensation rates are not reflective of the intended monetary value when the rates were set in 2011. The proposal is to uprate the level of compensation for UK sperm donors to £45 per clinic visit and UK egg donors to £985 per donation cycle.
- 9.3.** The proposed review period was explained with the recommendation that the Executive reviews every five years, or when the GDP deflator has shown a 10% increase in inflation, whichever occurs sooner. This would ensure that the value of donor compensation remainder broadly equivalent over time.
- 9.4.** The Head of Policy informed members that during the 2011 review the compensation rate for donations that had taken place abroad and imported into the UK had not been addressed and the proposal now is that that these be brought in line with UK rates. The Head of Policy explained that

it is not practical to introduce individual compensation rates for every country and to monitor and adjust these limits as currencies and economies change over time.

- 9.5.** In response to a question regarding excess expenses the Head of Policy stated that these are set out in the Code of Practice and General Directions. It is the responsibility of clinics to record and document any such expenses and make these available for inspectors to review.
- 9.6.** In response to a question regarding monitoring the rates of donor compensation in Europe the Chief Executive stated that it has been looked at, and the rates set by the HFEA are in the middle of the range.
- 9.7.** A member expressed concern that if the compensation rates are increased by inflation this might be taken as incentivising donations during a cost-of-living crisis. The member questioned whether this could be considered as removing altruistic motivation. The Chief Executive spoke about the principles of the value agreed by the Authority in 2011 and how, due to inflation, that value is considerably less than when it was agreed in 2011. The proposal contained in the paper seeks to maintain that value in principle.
- 9.8.** A member question whether it would be possible to look at the number and profile of donors post the implementation of any increase to see whether it affects the profile of donors. The Director of Strategy and Corporate Affairs referred to the report on trends in egg, sperm and embryo donation in 2020 which was published in November 2022 and undertook to recirculate this report to members.
- 9.9.** Several members spoke in favour of the proposals noting that egg donation is an invasive and complex procedure.
- 9.10.** In response to a question the Head of Policy stated that the communication issued to clinics can reinforce the requirement that donors must be offered counselling.
- 9.11.** The Director of Strategy and Corporate Affairs reminded members that whilst the HFEA is a UK wide regulator, the Scottish Government has decided that no donor compensation is given to donors via the NHS in Scotland.
- 9.12.** The Chair drew the discussion to a close and asked members to vote on each recommendation contained in the paper.

Decision

- 9.13.** Members agreed that the compensation rate for UK based gamete donors be updated to take account of inflation, to a new rate of UK sperm donors £45 per clinic visit and UK egg donors £985 per donation cycle.
- 9.14.** Members agreed that the compensation rate for overseas donors being imported into the UK is brought in line with UK rates.
- 9.15.** Members further agreed that donor compensation rates are reviewed by the HFEA Executive every five years, or when the GDP deflator has shown a 10% increase in inflation, whichever occurs sooner.

Action

- 9.16.** The Executive to implement the Authority's decisions regarding donor compensation rates.

- 9.17.** The Director of Strategy and Corporate Affairs to recirculate the report on trends in egg, sperm and embryo donation in 2020 to members.

10. Any other business

- 10.1.** The Chair thanked all for their active participation in the meeting. She informed members that whilst the HFEA's standing orders do not allow for proxy voting, Alison McTavish had sent via email her support for all the proposals contained in the papers. The Chair asked that this be recorded in the minutes.
- 10.2.** The Chair informed members about the potential of an Authority away day in November and she asked members to reserve the 19 November 2024 for this.
- 10.3.** The Chair informed members that Alison Marsden's term will finish at the end of March, and this was her last Authority meeting. On behalf of the HFEA the Chair thanked Alison for her contribution and especially for her work as Chair of the Licence Committee. The HFEA was very fortunate to benefit from her skills and her contribution will be greatly missed.
- 10.4.** There being no further items of any other business the Chair reminded members that the next meeting will be held on 15 May 2024.
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Chair's signature

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

Signature



Chair: Julia Chain

Date: 15 May 2024