

Minutes of the Authority meeting on 17 May 2023

Members present	Julia Chain Jason Kasraie Frances Flinter Zeynep Gurtin Tim Child Alison McTavish	Guhrun Moore Alex Kafetz Graham James Jonathan Herring Geeta Nargund Catharine Seddon Christine Watson
Apologies	Alison Marsden	
Observer	In person Steve Pugh (Department of Health and Social Care – DHSC) Roland Green – (DHSC)	Online Amy Parsons (DHSC) Clare Lane (DHSC) Cassian Maciejewski (DHSC)
Staff in attendance	In person Peter Thompson Richard Sydee Clare Ettinghausen Rachel Cutting Rachel Cooper Ana Hallgarten Debbie Okutubo Shabbir Qureshi Beth Rowbottom	Online Paula Robinson

Members

There were 13 members at the meeting – Eight lay and five professional members.

1. Welcome and declarations of interest

- 1.1.** The Chair opened the meeting by welcoming Authority members and DHSC colleagues present. The Chair extended a warm welcome to Professor Christine Watson as this was her first Authority meeting since becoming a member.
- 1.2.** The Chair also welcomed staff who were present and observers online and stated that the meeting was audio recorded in line with previous meetings and for reasons of transparency the recording would be made available on our website to allow members of the public hear it.
- 1.3.** Declarations of interest were made by:
 - Jason Kasraie (PR at a licensed clinic)
 - Alison McTavish (Trustee at Progress Educational Trust (PET) and British Fertility Society (BFS))
 - Frances Flinter (Trustee at PET)
 - Tim Child (PR at a licensed clinic) and
 - Geeta Nargund (Clinician at a licensed clinic).

2. Minutes of the last meeting and matters arising

- 2.1.** Members agreed that the minutes of the meeting held on 22 March 2023 were a true record and could be signed by the Chair.

Matters arising

- 2.2.** Re: 8.6 – Members were advised that a full communications plan relating to donor information was in place and had a number of different aspects including videos where relevant.
- 2.3.** Re 3.6 – On member training, the Chair requested that members who were yet to complete their mandatory training on cyber security and equality, diversity and inclusion training modules should please do so.
- 2.4.** Members were advised that item 5.18 - backlog on OTR and item 5.7 - PGT-M being out of target of the 75 working days would form part of the performance report to be presented at the meeting.

Decision

- 2.5.** The status of all other matters arising were noted.

3. Chair and Chief Executive's report

- 3.1.** The Chair gave an overview of her engagement with key stakeholders, her attendance at sector related events and the decision-making committees of the Authority.
- 3.2.** The Chair commented that member appraisals had started. The Chair and Chief Executive attended the annual accountability review meeting with our sponsors at the Department of Health and Social Care (DHSC), who had given positive feedback on the performance of the HFEA over the last year.
- 3.3.** The re-appointment of Authority members also formed part of the discussion.
- 3.4.** Following the accountability meeting the Chair had her own appraisal. The Chair stated that she will be sharing her objectives with members in due course and that this will form part of the discussion at the next away day under the review of board member effectiveness.
- 3.5.** The Chair had visited a number of clinics in Scotland, accompanied by Alison McTavish, where they were well received. At one of the clinics, a clinician commented that the relationship between themselves and the Regulator was getting better and the same applied to the inspection regime.
- 3.6.** The Chief Executive provided an update on the key external activities including his informal visits to a number of licensed clinics.
- 3.7.** Members were assured that the process to appoint the Director of Finance and Resources successor was underway. As part of the selection process, the preferred candidate had a discussion with the Chairs of the HFEA and Human Tissue Authority (HTA) audit committees, as this was a joint appointment. Members were advised that there will be a gap between when the Director leaves and before his successor starts and that the time in-between will be managed by the Chief Executive and Head of Finance.

Strategy development

- 3.8.** The options for strategy development were discussed. The Head of Planning and Governance presented this item and reminded members that our current strategy is due to end in April 2024. Members were advised that it was not straightforward to agree a timeline for the development of the next strategy because of a number of current unknowns which would make it difficult to agree clear strategic objectives. In particular, it was not yet known how the recommendations on modernising the Act would be received; and the outcome and recommendations that would arise from our ongoing Public Body Review were not yet known.
- 3.9.** Options were presented and discussed, and members were advised that a further paper would be brought to the July Authority meeting. The options considered were:
- To develop a new strategy now, trying to work around the unknowns
 - To extend the current strategy by one year, and delay the development of the new strategy
 - To have a one-year gap between strategies, and delay the development of the new strategy.
- 3.10.** Members asked if the current strategy, which began in 2020, was out of date and whether we had received guidance from the DHSC on the timeline to get a new strategy approved. The Head of Planning and Governance responded that the majority of the content of the current strategy remained valid, although some of the envisaged activities had not been possible due to Covid and subsequent related pressures on the primary care system. The Chief Executive explained that the DHSC did not request a particular timeline in relation to strategy development; instead they maintain an overview of our performance through the annual business plan.
- 3.11.** Members supported option two, a one-year extension, as this would give us time to know the outcomes of certain key activities. It was agreed that we should communicate a clear narrative on the need for the extension and what work would be done meanwhile, in the additional year.
- 3.12.** A paper would be brought to the July meeting setting out an interim plan for the year, based on the existing vision and aims. The aim would be to then publish this with an explanation of our current thinking and plans.

Decision

- 3.13.** Members noted the Chair and Chief Executive's report.
- 3.14.** Members agreed a one-year extension to the current strategy, which was to retain the vision and aims from the current strategy for an additional year, and delay development of the new strategy.

4. Committee Chairs' reports

- 4.1.** The Chair invited Committee Chairs to add any other comments to the presented report.
- 4.2.** In the absence of the Licence Committee Chair (Alison Marsden), the Deputy Chair, Graham James, gave an overview of the last committee meeting. He commented that there was a high volume of work at this present time with more frequent meetings than usual and that there had been an Appeal hearing. He encouraged other members to read the papers from the Appeal hearing which are available on the HFEA website.

- 4.3.** The Statutory Approvals Committee (SAC) Chair (Jonathan Herring) stated that the meetings were challenging but effective. Meetings covered a breadth of areas and the diverse skill set on the committee enabled them to address all the issues raised.
- 4.4.** The Audit and Governance Committee (AGC) Chair, Catharine Seddon commented that the committee had not met since the last Authority meeting but that they were in the process of recruiting to the two vacancies of the non-Authority members on the committee. Five candidates had been shortlisted and interviews will be taking place in June and that the final decision would be a delegated decision of the Authority Chair. The new members will take up position on 1 October 2023.
- 4.5.** Members were advised that the SCAAC meeting scheduled for June had been postponed to the end of July and will be reported back to the September Authority meeting.

Decision

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

5. Performance report

- 5.1.** The Chief Executive commented on staff sickness and turnover. Members were advised that sickness levels were higher than usual as there had been a number of employees absent for various short-term reasons and two employees remained on long term sick leave. The Chief Executive stated that there was nothing structural to be concerned about as our figures were largely as expected for this time of year. Turnover was on target.
- 5.2.** Members asked how sickness was being measured. The Chief Executive responded that it was measured across the organisation and they were mainly winter related illnesses of coughs and colds apart from the two staff members on long term sick leave.
- 5.3.** On PRISM, the Chief Executive commented that the system was working well. The data was in the papers presented and the detailed report formed part of the AGC meeting item. There are three clinics remaining who are yet to use PRISM but that should be resolved soon.
- 5.4.** At the June AGC meeting we would be in a position to report that over 400,000 units of activity had been entered into PRISM with an average 4% error margin. The Chief Executive thanked the clinics who were dealing with backdated errors and commented that Choose a Fertility Clinic (CaFC) should be ready to be updated before the end of the year.
- 5.5.** Members asked about the errors reported. The Chief Executive responded that the errors were typically incomplete information inputted, which could occur during data transfer. Members were assured that we were not missing any major data and that the public were not given misleading information.
- 5.6.** In response to a question, it was explained that the 10-family limit was the policy adopted that a maximum of 10 separate families can be created from any one donor.
- 5.7.** Members were advised that the annual performance report will be presented to the July Authority meeting.

Compliance and Information

- 5.8.** The Director of Compliance and Information gave an update. Members were reminded that inspections were deferred when restrictions on travel were in place during the Covid-19 pandemic and licences were extended. This has resulted in a significant increase in the number of inspections on this year's schedule. Alongside this, staff absences and turnover had placed the team under significant pressure.
- 5.9.** Members commented that the number of inspections alone did not reflect the work done by the team and support given to centres before, during and post inspections.
- 5.10.** The Chair commented that feedback from recent visits to clinics was that they welcomed the hybrid method of inspections which was now part of the inspection regime. The Chair requested that the Director of Compliance and Information take back the Authority's thanks to staff for their hard work.
- 5.11.** The OTR backlog is still significant but there is stability in the team now and good progress is being made on the integration of the new case management system which will make the process more time efficient.

Strategy and Corporate Affairs

- 5.12.** The Director of Strategy and Corporate Affairs commented that ongoing planning for upcoming publications was continuing, including the Fertility Trends report in June and accompanying data dashboards later in the year.
- 5.13.** The Code of Practice update previously agreed by the Authority would be finalised shortly. It was also noted that as far as we understood at present (according to the DHSC), the Windsor Framework would not require any changes to the Code of Practice.
- 5.14.** The news resulting from a Freedom of Information request relating to mitochondrial donation had been widely reported on recently in news outlets and on social media.
- 5.15.** The Chair commented that when we launched the consultation on modernising the Act there had been a lot of media interest, particularly in the areas relating to donor anonymity.
- 5.16.** Members congratulated the team on the handling of HFEA activity in the media and noted the widespread national and international interest in mitochondrial donation.

Finance and Resources

- 5.17.** The Director of Finance and Resources commented that at the end of the 2022/23 financial year, we posted a surplus against budget of £252k. This was the interim report but overall, we were in a good position. There were two red indicators which are F1 – debt collection, which was as a result of delays in credit control due to prioritising year end and audits which affected collection; and F2 – debtor days as collection was impacted by year-end preparations for clinics which increased response times.
- 5.18.** Members were assured that there had never been a case where clinics did not pay their fees in time. In terms of finalising the accounts there could be some changes of reduction in debt but at this stage there are no overall concerns.

Decision

- 5.19.** Members noted the performance report.

6. Strategic risk register

- 6.1. The Risk and Business Planning Manager presented the strategic risk register. The Chair commented that the new risk register had been driven by the AGC and thanked the committee for their leadership to date and also thanked the Head of Planning and Governance and the Risk and Business Planning Manager who had done the work.
- 6.2. The Risk and Business Planning Manager noted that all the closed risks will be removed from future Authority papers on risk, for brevity, but would continue to be presented to AGC regularly.
- 6.3. In response to a question, the Chief Executive commented that we aim to be transparent about strategic and operational risks. One example was PRISM which has had a huge operational impact in terms of opportunity costs - for example the development of a replacement for Epicentre has been delayed due to the focus on PRISM.
- 6.4. Members commented that we need to be careful how we gauge residual risk levels and gave the example of financial risk being described as below tolerance and suggested that this was perhaps understated. Also, the governance risk being at tolerance might not reflect our view given the need to modernise fertility law, and until that is done, there are associated risks. Members further commented that it was important to look at mitigations alongside the risk itself.
- 6.5. The Director of Finance and Resources commented that in terms of financial risk we will not know with certainty where we will be until after the first quarter, but we are not breaching controls.
- 6.6. The Chair asked if we were mapping the new risk categories against the areas identified in our law reform work. The Chief Executive commented that the risk register was framed against the powers we currently have and mitigations were based on what we currently do. Following the discussion, it was agreed that AGC will explore this further.
- 6.7. Members commented that we need to avoid over complicating our expression of risks. For instance, the section on legal risks had been moved into operational risks for the time being, but on reflection the strategic risk register should possibly have a legal risk category. Members were assured that under the new risk system which was dynamic, if legal (or other) risks that had been closed became a live issue again, the register was designed to enable such risks to be re-opened. It was reiterated that as a regulator we are always open to legal challenges.
- 6.8. Members commented that under the technology risk category, in terms of shaping the future there was no specific mention of artificial intelligence (AI), which was an area we were monitoring through SCAAC, since it could have an impact on the fertility sector.
- 6.9. The Chief Executive commented that we were trying to move away from having ever-present risks which form part of our business as usual. AI remained an upcoming issue so it was difficult for the HFEA to take any action to actively mitigate the potential risks. The strategic risk register however was an active live dynamic document, and risks are closed, re-opened, or introduced as needed.
- 6.10. The Chair of SCAAC commented that AI was mentioned as part of horizon scanning during their committee meetings so it had been considered and that the committee will keep the watching brief on this. Members further commented that human genome work was also being developed.
- 6.11. The Chair stated that this is a live document and would continue to be reviewed regularly.

Decision

6.12. Members noted the strategic risk register.

7. Opening the Register - update

- 7.1.** The Directors of Compliance and Information and Strategy and Corporate Affairs presented the update on Opening the Register (OTR).
- 7.2.** Following the presentation members asked whether we knew if donors had updated their details in response to a recent media story that we had run to cover this. The Director of Strategy and Corporate Affairs responded that most donors would likely contact the clinic they donated at in the first instance.
- 7.3.** In response to a question on the exploration of funding options for the support service, the Director of Compliance and Information responded that an options paper would be brought to the Authority later in the year.
- 7.4.** A member raised the concern that there may be an increased risk of cyber-attack due to increased publicity and risk of fraud, for example someone setting up a website 'otr.com' to take payments and give out false information. The Executive responded that we would revisit this in the risk register.
- 7.5.** The Director of Strategy and Corporate Affairs commented that although the OTR team had increased in number and new systems are being integrated, demand may continue to increase exponentially and this was a concern. There was also a resource concern on the communication workstream as there was ongoing and significant media interest in this area.
- 7.6.** The Director of Compliance and Information noted that in the workstream looking at support services, a number of roundtables would be held to get feedback on what future support might look like.
- 7.7.** Members asked if we knew how many donor conceived individuals (DCIs) approached clinics for counselling. The Director of Compliance and Information responded that we would only know about those who apply through the HFEA OTR service and take up counselling services through the Hewitt, as that was data we received. The Chair commented that this maybe a worthwhile piece of research to be considered.
- 7.8.** A member commented that they understood that for adoption services there was no fee to find out if people were adopted and wondered how that service was funded and whether that could be considered as a funding model.
- 7.9.** Members also asked what happened if someone rang in to say they believe they were donor conceived. The Executive responded that they would be advised to apply through the OTR service, and this information could be provided by checking the register.
- 7.10.** The Chair thanked the team for their work to date, commented that the team was stretched and also that when we launched the law reform consultation, donor conception was an area of great public interest. An update would be received at the July Authority meeting.

Decision

7.11. Members noted the update on OTR.

8. OTR Donor Contact

- 8.1.** The Director of Compliance and Information and the Legal Adviser presented this item. It was noted that the HFEA has a power (not an obligation) to contact donors to let them know that identifying information about them had been requested.
- 8.2.** Three options were presented to members:
- Option A: Contact donors using the most recent postal address recorded on the Register/clinic's files. Provide this same address to the DCI making the OTR request
 - Option B: Contact donors using an address obtained through an NHS database (PDS). If the donor confirmed this was their correct address and consented to the Register being updated the updated address would be provided to the DCI. In all other cases, the most recent address (between the Register and clinic notes) would be disclosed to the DCI
 - Option C: Contact donors using PDS address only where the addresses match the Register address (or that on the clinic's notes). Provide the address on the Register/clinic records to the DCI (even where it does not match the PDS address).
- 8.3.** Members were informed that we planned to attempt to contact donors using the latest contact details provided by them. This had been consistently communicated to the sector since 2004 (for example in a 2004 Chair's letter and as guidance in the Code of Practice) and licensed clinics should have explained this to donors as part of their informed consent process. However some stakeholders had raised concerns about the passage of time since donation and the accuracy of the donor's address on the register.
- 8.4.** The HFEA had investigated whether we could use a third-party database to proactively search for an updated address but found that there were several difficult legal and reputational risks to consider when appraising the options.
- 8.5.** A discussion ensued. Members commented that in terms of reputational risk the Authority needed to measure what was the greater risk, using a third-party database for updating addresses or sending sensitive information to non-verified addresses.
- 8.6.** The Director of Strategy and Corporate Affairs commented that donors were informed that their identity could be released and that they may be contacted, but donors were under no obligation to update their details. The issue was that the law predated modern forms of communication and required us to provide a postal address.
- 8.7.** In response to a question the Director of Compliance and Information stated that using the special delivery service at the Royal Mail meant we could track and trace letters. A member asked whether we could send a letter requesting that they contact the HFEA without mentioning this was about donation. However, having the HFEA on a letterhead would still provide a clear indication that this was in connection with fertility treatment in some way. This method would be resource intensive, impractical and had other risks.
- 8.8.** Members commented that some fertility clinics were standalone centres and therefore updating information with GPs would not filter through to fertility clinics. Private clinics do not have access to NHS systems.
- 8.9.** A member commented that it should be accepted that some donors might not want to be contacted and may actively choose not to update their contact details.

- 8.10.** Members commented that it was challenging to keep patient details up to date as they often do not stay in touch with a centre even when they have material in storage. This probably meant donors were less likely to stay in touch and update their details.
- 8.11.** Amongst the options presented to members, one member felt that option B was a better option because it allowed the provision of more accurate information as well as keeping information confidential. It might cost more but would involve less reputational damage. However, this was not in line with what the donor would have been told at the time of donation, which was problematic.
- 8.12.** Members commented that as the name and date of birth were released alongside the address, it was likely that by using internet searches a donor would be found, even if the address was now incorrect.
- 8.13.** Some members also felt that since the HFEA did not currently have access to the NHS database, the treating clinic should be contacting the donor. However, private clinics do not have access to the NHS systems and they would be hesitant to send letters to donors at out-of-date addresses in case a breach of confidentiality occurred.
- 8.14.** In response to a question regarding method of contact, the Director of Compliance and Information commented that in law the donor conceived individual had to be provided with the last known postal address, but a donor could also give other contact details such as an email or phone number which could also be passed to the donor conceived individual and a preferred method could be stated.
- 8.15.** The majority of members were in favour of option A as they felt that it was the simplest option with the least burden on clinics and the lowest risk. It was also preferred as it reflected the law and was in line with what information was provided to the donor at the time of donation.
- 8.16.** Members highlighted that communication with the DCI should come with clear warnings that the postal address of the donor may be out of date owing to the passage of time since it was recorded.
- 8.17.** The Chair commented that our legal duty needed to be borne in mind. Contacting the donor may be the right thing to do but it was not a legal duty. We however have a legal duty to DCIs, to provide them with defined information and we need to be careful not to compromise that statutory duty.

Decision

- 8.18.** Following the discussion 12 members voted in favour of option A as they felt it was the best option given our current powers:
- Contact donors using the most recent postal address recorded on the Register/clinic's files.
 - Provide this same address to the DCI making the OTR request.
- 8.19.** One member voted in favour of option B.
- Contact donors using an address obtained through an NHS database (assuming access could be enabled) provided it was more recent than the latest address provided by the donor at the time of donation.
 - If the donor confirmed this was their correct address and consented to updating the Register accordingly, this address could then be provided to the DCI.

- In all other cases, - the most recent address (between the Register and clinic records) would be disclosed to the DCI.

8.20. Option A was therefore agreed. However, it was also agreed that the Executive would be mindful of the points made by the member who voted in favour of option B.

9. Modernising Fertility Regulation - update

- 9.1.** The Director of Strategy and Corporate Affairs, Social Research Manager and the Public Policy Manager presented a preliminary analysis of the responses to the consultation.
- 9.2.** The consultation provided valuable qualitative and quantitative feedback and we had begun to analyse the responses. It was noted that the consultation was not a public vote but was helpful in hearing a range of views before the Authority finalised its proposals to the DHSC.
- 9.3.** There was broad support for the majority of the proposals, but Members were advised that four areas required more consideration following the analysis of responses received; these were:
- Elements of our regulatory powers, most notably the regulation of allied services
 - Changes in donor information provision
 - Ways in which to simplify the current consent process and
 - The potential use of secondary legislation and other mechanisms for changes to the regulation of scientific developments.
- 9.4.** Members commented that these changes were developed through a series of discussions with the Authority and from a range of expert groups including the Legislative Reform Advisory Group.
- 9.5.** Some members felt that more analysis of the responses to the consultation will help with the four areas set out above.
- 9.6.** Members noted that this consultation was never going to be fully representative of a balanced set of views and may not be typical of the wider population.
- 9.7.** Following the discussion, the Chair summarised and commented that a majority of members were in favour of moving forward to develop proposals for discussion at the July Authority meeting.

Decision

- 9.8.** Members agreed that recommendations for law reform should be considered in July with the aim of submitting to DHSC and publicised more widely in due course.

10. Any other business

- 10.1.** The Chief Executive commented that this was the last meeting of the Director of Finance and Resources, Richard Sydee, as he would be leaving the HFEA in June. Richard was thanked for his leadership and advice over the last six and a half years. The Chair reiterated this on behalf of the board.
- 10.2.** The Chair commented that there will be an away day later in the year asked that members please make themselves available. Dates to be sent out shortly.
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Chair's signature

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

Signature

A handwritten signature in black ink that reads "Julia Chain". The signature is written in a cursive, flowing style.

Chair: Julia Chain

Date: 12 July 2023