

Minutes of Authority meeting held on 16 November 2022

Details:

Area(s) of strategy this paper relates to:	<p>The best care – effective and ethical care for everyone</p> <p>The right information – to ensure that people can access the right information at the right time</p> <p>Shaping the future – to embrace and engage with changes in the law, science and society</p>
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Agenda item	2
Meeting date	25 January 2023
Author	Debbie Okutubo, Governance Manager

Output:

For information or decision?	For decision
Recommendation	Members are asked to confirm the minutes of the Authority meeting held on 16 November 2022 as a true record of the meeting
Resource implications	
Implementation date	
Communication(s)	
Organisational risk	<input type="checkbox"/> Low <input checked="" type="checkbox"/> Medium <input type="checkbox"/> High

Minutes of the Authority meeting on 16 November 2022

Members present	Julia Chain Catharine Seddon Jason Kasraie Frances Flinter Zeynep Gurtin Alison Marsden	Guhrun Moore Alex Kafetz Graham James Alison McTavish Jonathan Herring
Apologies	Tim Child	Geeta Nargund Frances Ashcroft
Observers	Steve Pugh (Department of Health and Social Care – DHSC) Maria Nyberg DHSC Amy Parsons DHSC	
Staff in attendance	Peter Thompson Richard Sydee Clare Ettinghausen Rachel Cutting Paula Robinson	Debbie Okutubo Shabbir Qureshi Neil McComb Sharon Fensome-Rimmer

Members

There were 11 members at the meeting – eight lay and three professional members.

1. Welcome and declarations of interest

- 1.1. The Chair opened the meeting by welcoming Authority members and DHSC colleagues both in person and online. The Chair also welcomed observers who were online and stated that the meeting was audio recorded in line with previous meetings and for reasons of transparency, and that the recording would be made available on our website to allow members of the public hear it.
- 1.2. A declaration of interest was made by:
 - Jason Kasraie (PR at a licensed clinic).

2. Minutes of the last meeting

- 2.1. Members agreed that the minutes of the meeting held on 14 September 2022 were a true record and could be signed by the Chair.
- 2.2. The status of all matters arising was 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 conferences and the decision-making committees of the Authority.
- 3.2. Members were advised that following the cabinet reshuffle Steve Barclay MP has been re-appointed as the new Secretary of State for Health and Social Care. We also have a new team of ministers at the Department and Maria Caulfield MP had taken on the HFEA brief.
- 3.3. The Chief Executive (CE) provided an update on the key external activities that he had been involved in since the last Authority meeting.

- 3.4.** Members were advised that amongst other meetings, he was in dialogue with the bio-science community and that there were several developments in this area pertaining to our sector which had led to discussions taking place at the Scientific and Clinical Advances Advisory Committee (SCAAC) meetings.
- 3.5.** The Chief Executive continued that he was yet to meet the new Minister, but he hoped that discussions would centre around Government new priorities and HFEA concerns including early access to primary care for fertility patients. The cost-of-living crisis was also an issue and we were keeping an eye on the effect on fertility treatment as people's disposable income reduced.
- 3.6.** Members were advised that the Public and Commercial Services Union (PCS) had balloted their members for strike action across the civil service. The PCS recently notified the Chief Executive that PCS members who worked for the HFEA would not be joining the strike action as not enough voted to reach the required threshold.
- 3.7.** Members asked about the CE peer meetings that took place with other ALB CEOs and if the issue of proportionality and government expectations had been discussed. The Chief Executive responded that it was mentioned but it did not form a major part of the discussion.

Decision

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

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) noted that a number of recent cases were very complex. One particular case involved a complex licence renewal following a history of non-compliance, where the clinic had since improved to the extent that it now met the required standards. The committee also carried out their annual committee effectiveness review.
- 4.3.** The Statutory Approvals Committee (SAC) Chair, (Jonathan Herring) noted that there had been three meetings since the last Authority meeting. SAC had considered various PGT-M applications and requests for Special Directions. He then went on to give a synopsis of the discussion that took place on a particular special direction case.
- 4.4.** The Scientific and Clinical Advances Advisory Committee (SCAAC) deputy Chair (Jason Kasraie) gave an update in the absence of the Chair (Tim Child). At the meeting they had discussed public health developments relevant to fertility treatment and embryo research and the treatment add-ons review and agreed that the primary outcome for ratings will remain live births. SCAAC also asked the Executive to consider developing a framework to identify artificial intelligence (AI) models falling within HFEA remit.
- 4.5.** The Audit and Governance Committee (AGC) Chair (Catharine Seddon) gave an overview of the last meeting held in October. It was noted that actions were agreed in three key areas:
- closing of internal audit reviews once completed.
 - escalation of concerns; and
 - deep dives to be scheduled in conjunction with internal audit reviews.
- 4.6.** She continued that the committee had pressed for a clearer timetable for the completion of post PRISM activities like CaFC to be presented to the December meeting. The December meeting would also involve training for AGC members on the analysis of financial reports and it was open

to Authority members who wanted to attend. An e-mail will be going out to that effect from the Governance Manager.

Action

- 4.7.** The Executive to consider developing a framework to identify artificial intelligence (AI) models falling within HFEA remit.
- 4.8.** An email inviting Authority members to the AGC training at the December meeting to be circulated by the Governance Manager.

Decision

- 4.9.** Members noted the Committee Chairs' updates.
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5. Performance report

- 5.1.** The Chief Executive commented on the recent results from the staff survey carried out and shared headline indicators with the Authority. Members were advised that the general results were positive.
- 5.2.** There were a few areas where the results were less good than hoped for, notably on issues on diversity & inclusion and staff feeling unable to do their work because they did not have the right tools, though it was not clear exactly what factors were driving these results.
- 5.3.** It was noted that the Corporate Management Group (CMG) will take this forward and an action plan will be developed with further discussion held at the December AGC meeting.
- 5.4.** The Chair commented that given the difficulties with the rising cost of living, the responses were positive but that the areas of concern needed to be addressed.
- 5.5.** The Chief Executive updated the Authority on progress with PRISM. AGC had oversight on the roll out of PRISM. PRISM had been deployed across all clinics including those with third party suppliers. Our attention was therefore now on re-establishing links with the Register for reporting purposes, including giving the OTR team the tools to do what they need to do in good time before the impact of the removal of donor anonymity is felt in 2023.
- 5.6.** Members commented that regarding PRISM there was tremendous improvement over the last six months and it was good to see issues being fixed and that this showed good leadership.

Strategy and Corporate Affairs

- 5.7.** The Director of Strategy and Corporate Affairs presented this item.
- 5.8.** It was noted that a report looking in detail at egg and sperm donation in the UK will be published soon.
- 5.9.** The persons responsible (PR) event took place on 31 October and feedback had been positive. The Director of Strategy and Corporate Affairs thanked Alison McTavish, Zeynep Gurtin, Geeta Nargund and Tim Child who all presented at the event and Jason Kasraie for chairing sessions.
- 5.10.** Members were advised that because of the volatile political situation in recent months, we will be publishing the consultation on proposed changes to the Human Fertilisation and Embryology Act in the new year.

- 5.11.** Members were advised that the two winter stakeholder meetings were taking place – the Patient Organisation Stakeholder group (POSG) and Professional Stakeholder group (PSG). Updates on our work on ethnic disparities in fertility treatment and the new treatment add-ons rating system would be outlined as well as discussions relating to Opening the Register (OTR). These meetings were useful for getting feedback on our work and hearing developments from patient and professional groups.
- 5.12.** Members were also informed that in preparation for the SCAAC review of add-ons early in 2023 (using the new rating system) work was underway to design and user test new webpages.
- 5.13.** The Chair commented that we had gone through a number of political changes recently, including Prime Ministers and Secretaries of State for Health and Social Care, and it was therefore only right to allow things to settle down and that in the new year we would go out to consultation. Members were assured that this work remained a priority.
- 5.14.** Continuing, the Chair said that in terms of the PR event, we were going to do some analysis on feedback received from attendees and that she intended to continue visiting clinics and invited other members to join her.

Compliance and Information

- 5.15.** The Director of Compliance and Information commented on the performance data for the OTR service. The service remained busy with 81 applications being closed in September. The number of closed applications fell in October due to a vacant post. However, recruitment was ongoing and the structure of the team had been improved to enable more staff to be able to carry out final checks. It was hoped that the new structure would also help with staff retention.
- 5.16.** When OTR applications are received, they are considered for their complexity. Less complex requests can be responded to with less resource and on average take 30 working days to complete. This had come down from 77 working days at the start of the year. More complex applications require significant input from clinics, increased checking and therefore take much longer.
- 5.17.** A Licenced Centres Panel (LCP) meeting was held on 2 November 2022 with the focus being the challenges of 2023. Members were advised that the Head of Information gave a presentation to outline the OTR service. There was also discussion about how best to support those affected by donor conception.

Finance and Resources

- 5.18.** The Director of Finance and Resources commented on the financial indicators in the performance report. Members were advised that the HFEA accounts were laid before parliament in October.
- 5.19.** In year efficiencies have been asked for by the DHSC but we were not yet clear to what extent. We would report back to the January Authority meeting once we have more details.
- 5.20.** Debtor days and collection rates had been affected by income estimation in the switch over to PRISM but these had now been reconciled and the trajectory was showing that by this financial year-end we will have an underspend which would mainly be as a result of unspent staff costs.

Decision

- 5.21.** Members noted the performance report.

6. Strategic risk register & Risk Strategy review

- 6.1. The Risk and Business Planning Manager presented this item. The Authority was asked to note the risk review which looked at the risk structure and background, the new risk strategy and associated risk registers and to discuss the underlying risk appetite which formed part of the risk strategy.
- 6.2. It was noted that the application of our risk appetite will be dynamic and overseen by AGC.
- 6.3. Three options for a risk appetite statement were discussed in detail by members.
- 6.4. Members commented that the difference between risk appetite and risk tolerance and should be more clearly differentiated. It also needed to be taken into consideration what risk appetite best served our strategic objectives.
- 6.5. Continuing, Members commented that option three provided a number of categories but they were not all of equal weighting, however, option two seemed proportionate and afforded the opportunity to group together risk areas for which our risk appetite was similar.
- 6.6. Following further discussion, the majority of members agreed that we would proceed with option two and discuss this in detail at the AGC meeting in December. The risk appetite statement would be reviewed in a year's time to see how it was embedding and to consider whether option three (the most detailed option) might then be preferable.

Decision

- 6.7. The Authority agreed on option two and that this be reviewed at the November 2023 Authority meeting.

7. Business planning 2023/24

- 7.1. The Head of Planning and Governance presented this item. Members were advised that a draft of the business plan will be brought back to the January 2023 Authority meeting for approval prior to submission to our sponsors at the DHSC.
- 7.2. In discussion, one member commented that a fees review should be a priority area due to the centrality of resources on all of our ambitions, including crucially OTR work.
- 7.3. Some members felt that we could be criticised if we did not prioritise regulatory transparency and suggested that we deprioritise another area – possibly further work on ethnic disparity in fertility treatment, with a view to looking at this in a wider sense as part of a new broad priority on inequalities under the next strategy.
- 7.4. Members asked if we knew what patients would want to see as our priorities. The Director of Strategy and Corporate Affairs responded that it depended on who we spoke to, for instance some patients saw ethnic disparities as an area to be prioritised, while others would have different priorities depending on their own perceptions and experiences.
- 7.5. The Director of Compliance and Information responded that at LCP, the priority was seen as OTR and donor related work as these were the areas, they wanted to see the Authority focus on.
- 7.6. The Chair commented that regarding the Legislative Reform work, we are focused on putting patients at the heart of any law reform and therefore this should remain a priority.

- 7.7.** Continuing the Chair argued that in thinking about prioritisation, we should be clear about the distinction between what only we can do and what we can do working with others. We should look to see if anyone else is doing expert work, or whether we could partner with others to do certain activities, for instance on ethnic disparity, or AI & genetics horizon scanning.
- 7.8.** Members felt that the effects on the patient should be at the heart of our decision-making on priorities.
- 7.9.** The Chair commented that there was recognition from members on areas that needed to be prioritised and the Executive should consider the framework above, prior to discussion of a draft business plan in January.
- 7.10.** The Director of Strategy and Corporate Affairs commented that staff would go away and work out what resources are required for the prioritised areas and we would be grateful to hear from professional members and professional stakeholder bodies.
- 7.11.** The Chair commented that as the Regulator we need to understand that we do not have the resources to do everything we would like to do, and hence prioritisation was necessary.
- 7.12.** The Chief Executive commented that by the January meeting we would produce a further paper for members to help them make final prioritisation decisions. This would include looking at what work could only be undertaken by the HFEA, what can or should be done in partnership with others, and what should be done by others. There would be a further opportunity for discussion when the draft business plan was presented to the January meeting.

Decision

- 7.13.** Members agreed the course of action and noted that it would be an agenda item at the January meeting.

8. Support services for donors and donor conceived people

- 8.1.** The Head of Information presented this item regarding the OTR support service, which provides limited counselling for those affected by donation in the UK born after 1991 and who have contacted the OTR service. The service is currently delivered by the Hewitt Fertility Centre and is funded by the HFEA. The current contract expires on 31 March 2023.
- 8.2.** The HFEA was anticipating an increase in applications to the OTR service from late 2023 onwards as the first cohort of donor conceived (DC) people turned 18, following the legal change to donor anonymity in 2005.
- 8.3.** It was noted that the 1990 Act did not expressly impose an obligation on the HFEA or licensed centres to provide counselling to donors or donor conceived people. The 1990 Act provides that donor-conceived applicant must be given “a suitable opportunity to receive proper counselling about the implications of compliance with the request” before the Authority can disclose information to an applicant about their donor (s 31ZA). There is no suggestion that donors should receive counselling at the point where their identifiable information is released - although they should have received implications counselling at the time of their donation.
- 8.4.** It was put forward that the likely increase in applicants post OTR 2023 could mean that the money required to continue to fund the support service will become unaffordable under the current

arrangements. Without action, the HFEA could find itself in a position where it was unable to fund other strategic priorities and/or some of its statutory duties.

8.5. Four options were presented to members:

- Option 1 – status quo
- Option 2 - those affected by donor conception pay for any counselling support
- Option 3 - the clinic pays directly for any counselling support
- Option 4 - the HFEA charges a levy to fund a support service
- Option 4a & 4b – Continue the support service current model or commission a new multi-layered support service.

8.6. Members asked if there were charities available to offer a counselling service. The Head of Information responded that the Donor Conception Network (DCN) currently provide information and peer support. It potentially could establish this in future, but he was not sure about other charities.

8.7. Members commented on the fact that only 7.9% of applicants took up the offer of counselling in 2021 and asked if the Executive had any intelligence on the 92% that did not take up the offer and what they did instead. During discussion it was noted only a small number of people take up counselling and therefore it may be beneficial to provide further information through the website or leaflets as a supportive mechanism. This would be particularly beneficial if counselling became chargeable to those accessing it.

8.8. Members felt that the status quo was not sustainable and that some further exploration of the other options was required, in particular option 4.

8.9. Members commented on option 3 and asked what would happen if clinics were no longer in existence, who would then pay that cost?

8.10. It was suggested that fertility counsellors may not be trained to counsel 18-year-old donor conceived children and that the DCN still appeared to be the best place to offer this service. The Director of Compliance and Information responded that the DCN offered peer support and not counselling but this was also an example of how support could be offered.

8.11. It was felt that a multi layered support service appeared to be what was required and stakeholders needed to be involved in this discussion. Likewise, who receives counselling needs to be decided on a pragmatic level as family members might also wish to access the service. A majority of members felt that donor conceived individuals should be prioritised over others who might be affected.

8.12. A majority of members agreed that the viable option was to explore how costs could be met by making the support service a chargeable service. It was agreed it was not sustainable for the HFEA to continue to fund the service in the current model.

8.13. A member asked about other forms of counselling including grief counselling and raised the point that GPs refer patients on to specialist counsellors and asked why that was not the same for donor conceived people.

8.14. Other members responded that in theory it should work that way but there may be long waiting lists and there may not be access through this route to this highly specialist type of counselling.

- 8.15.** The Executive commented that post autumn 2023, counselling required would be different due to the complexities of identifiable information being released.
- 8.16.** Members felt that the focus for counselling was very important. There are differences between implications counselling and therapeutic counselling, and it was important both aspects are considered.
- 8.17.** Members also commented that if a fee were raised from clinics by charging per treatment the fee would be passed to patients. The Director of Finance commented that as a Regulator we do not charge patients. The Director of Finance also commented that should we decide to raise a charge to cover the costs for this service we would need to be careful where the funds sit.
- 8.18.** The Chair summarised the discussion and commented that we would engage with stakeholders and explore options, also noting that the number accessing the service would be different every year which would have its own inherent risks.
- 8.19.** The Chief Executive noted that the Authority did not wish to continue the status quo and that we would talk with the Hewitt Centre with the aim of extending the existing service for a year.

Decision

- 8.20.** Members agreed that the Executive should talk with the Hewitt Centre with the aim of extending the service for a 12-month period and undertake further work to consider the future model of support.

9. State of the sector 2021/22 & inspection themes

- 9.1.** The Chief Inspector presented this item. The state of the sector report was issued on 3 October 2022. It was noted that this was the annual report which summarised what we have seen through regulatory work conducted during the previous 12 months.
- 9.2.** The presentation highlighted the inspection themes to be focussed on during interim inspections.
- 9.3.** Following the presentation, members commented that clinics had reported that at the conclusion of the inspection feedback was often positive, but when they received the draft report, it was not always as positive as they had felt on inspection.
- 9.4.** The Chief Inspector responded that this had also been fed back to the Inspection team and they are creating guidance for inspectors to be used during the closing meeting. This will allow a more standardised format for reporting back to clinics in order to manage expectations and improve consistency.
- 9.5.** On the data quality review members suggested that this be brought back in due course.
- 9.6.** In response to a question on capturing examples of best practice in the quarterly clinical reports the Chief Inspector commented that at present only non-compliances are reported.
- 9.7.** The Director of Compliance and Information responded that we have a code of practice to highlight best practice and there is also published professional body guidance. As a consequence, we need to tread with caution to ensure that any best practice we highlight is not at odds with that professional guidance. As a regulator we highlight best practice through events that we organise or attend and gave the example of the recent PR event.

- 9.8.** The Chief Executive commented that we are a regulatory licensing body and that needed to be our primary focus during inspections.

Decision

- 9.9.** Members noted the State of the Sector 2021/22 and inspection themes.
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10. Any other business

- 10.1.** The Chair commented that this was the last Authority meeting in 2022 and wished everyone compliments of the season and a very happy new year in advance.
- 10.2.** The next meeting was scheduled for Wednesday, 25 January 2023.
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Chair's signature

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

Signature

A handwritten signature in cursive script that reads "Julia Chain".

Chair: Julia Chain

Date: 25 January 2023