

Minutes of Authority meeting 24 March 2021

Details:

Area(s) of strategy this paper relates to:	The best care – effective and ethical care for everyone The right information – to ensure that people can access the right information at the right time Shaping the future – to embrace and engage with changes in the law, science and society
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Agenda item	2
Meeting date	12 May 2021
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 24 March 2021 as a true record of the meeting

Resource implications

Implementation date

Communication(s)

Organisational risk	<input checked="" type="checkbox"/> Low	<input type="checkbox"/> Medium	<input type="checkbox"/> High
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Annexes

Minutes of the Authority meeting on 24 March 2021 held via teleconference

Members present	Sally Cheshire, Chair Margaret Gilmore Anita Bharucha Anne Lampe Jason Kasraie Catharine Seddon Emma Cave	Jonathan Herring Gudrun Moore Ruth Wilde Yacoub Khalaf Ermal Kirby Kate Brian Tim Child
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Apologies

Observers	Julia Chain, incoming Chair Alison Marsden, Incoming Authority member Marina Pappa (Department of Health and Social Care - DHSC) Steve Pugh, DHSC Csenge Gal, DHSC
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Staff in attendance	Peter Thompson Clare Ettinghausen Richard Sydee Rachel Cutting Catherine Drennan	Paula Robinson Debbie Okutubo Helen Crutcher Dina Halai
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Members

There were 14 members at the meeting – nine lay and five professional members.

1. Welcome and declarations of interest

- 1.1. The Chair opened the meeting by welcoming Authority members, observers and staff present online. She stated that this was her last Authority meeting as her term of office ended at the end of the month along with Kate Brian whose term of office would also be ending.
- 1.2. She welcomed the incoming Chair, Julia Chain, who was observing the meeting as well as Alison Marsden and informed all present that both appointments would start on 1 April 2021.
- 1.3. The Chair stated that the meeting was audio recorded in line with previous meetings and the recording would be made available on our website to allow members of the public who were not able to listen in during our deliberations to hear it afterwards.
- 1.4. Declarations of interest were made by:
 - Yacoub Khalaf (clinician at a licensed clinic)
 - Tim Child (PR at a licensed clinic)
 - Ruth Wilde (counsellor at licensed clinics)
 - Kate Brian (working at Fertility Network UK)
 - 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 27 January 2021 were an accurate record of the meeting and could be signed by the Chair.
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3. Chair's report

- 3.1.** On 2 February, the Chair participated in the arms-length body (ALB) chairs roundtable discussion led by Minister of State Edward Argar MP.
- 3.2.** On 8 February, the Chair attended the Scientific and Clinical Advances Advisory Committee (SCAAC) meeting where a number of issues were discussed and commented that the SCAAC Chair would give a summary during the course of this meeting.
- 3.3.** The Chair thanked the committee secretaries for their hard work and support given to her during her tenure as both Chair of the Audit and Governance Committee and later Chair of the Board.

Licence Committee

- 3.4.** Kate Brian was invited to give a summary as the outgoing chair of the Licence Committee. She reflected on her experience as Chair and stated that Jonathan Herring was now the Chair of the Committee. She sent her appreciation to the Inspection team who provided the reports and Licensing staff who supported her during her term in office.
- 3.5.** Jonathan Herring gave a brief summary of the last Licence Committee meeting.

Audit and Governance Committee (AGC)

- 3.6.** The AGC Chair (AB) gave a summary of the meeting held on 16 March. The AGC Chair welcomed the progress being made by the teams and clinics on the digital programme. Members were reminded that at the January meeting the decision had been taken to delay go live as a result of lockdown and pressures on clinics. The agreed time to go live was in May/June since this seemed to be the best option in order to maximise clinic engagement. Members noted that the AGC would continue to meet monthly to review progress.
- 3.7.** An update from internal audit on completed reports was presented and there were two reports that had received the top rating, one on financial processes and the other on virtual inspections. The committee was very pleased to see these positive ratings.
- 3.8.** The strategic risk register was reviewed and the committee agreed that it would be timely to review the risk policy and risk appetite statement in the near future.
- 3.9.** An update on business continuity, resilience and cyber security was received. The committee particularly welcomed the recent update of choose a fertility clinic (CaFC) data.

Scientific and Clinical Advances Advisory Committee (SCAAC)

- 3.10.** The SCAAC Chair (YK) summarised the items presented at the meeting held in February. He commented that the effects of Covid-19 on fertility, assisted conception and early pregnancy would continue to be monitored.
- 3.11.** The committee suggested changes to the 2021/22 SCAAC workplan and recommended some external speakers for priority topics.

- 3.12.** The committee agreed that the HFEA should maintain a pro-vaccine stance and update the coronavirus frequently asked questions (FAQs) as British Fertility Society (BFS) and Association of Reproductive and Clinical Scientists (ARCS) guidance got updated.
- 3.13.** In terms of prioritisation of issues, it was noted that SCAAC had asked the Executive not to limit their horizon scanning to a previously agreed list of journals but instead use a more open, informed literature search.
- 3.14.** Lastly, the committee's focus on embryo culture media was de-prioritised from high to medium as it did not fall within the HFEA's regulatory remit.

Statutory Approvals Committee (SAC)

- 3.15.** The Chair of SAC (MG) addressed the Authority. It was noted that monthly meetings continued to be held.
- 3.16.** At the last meeting, the committee considered a mitochondrial donation application, a few PGD applications and one special direction.

Decision

- 3.17.** Members noted all the Chairs' updates.

4. Chief Executive's report

- 4.1.** The Chief Executive (CE) reported back on some of the engagements he had with the sector.
- 4.2.** On 18 February the Chief Executive gave evidence to the World Health Organisation (WHO) commission on human genome editing. They were nearing the end of their evidence gathering as they were looking at regulatory aspects.
- 4.3.** The Chief Executive gave a synopsis of progress with PRISM and explained that clinics were training their staff with their live data which should all lead to a smooth transition.
- 4.4.** Members commented on the recently published ethnic diversity in fertility treatment report and asked what engagement there was with clinics. The Chief Executive responded that this would be answered under the performance report item.

Decision

- 4.5.** Members noted the CE's report.

5. Performance report

Strategy and Corporate Affairs

- 5.1.** The Director of Strategy and Corporate Affairs gave a brief overview on ongoing work in the directorate.
- 5.2.** There was a recent Association of Fertility Patient Organisations (AFPO) meeting, where the HFEA received positive feedback on our engagement and our recent response to the Covid-19 pandemic. Members were also informed that our website was recently updated with new treatment add-on pages and had offered to publicise this. The Authority Chair had also attended part of the meeting so that AFPO members could say their farewells to her.

- 5.3.** On the recently published ethnic diversity in fertility treatment report, members congratulated all staff involved. Members further commented that the report showed the HFEA at its best. The report provided useful information for and from a diverse set of people. Members commented that the data gathered would be used to trigger useful conversations. There was a clarification sought that had been raised during the debate which was the 'Black and Minority Ethnic (BAME)' term and how useful it was in this context since not everyone identifies as BAME.
- 5.4.** The Director of Strategy and Corporate Affairs responded that the report had an action plan at the end and the clinics and the HFEA would be working through the plan and she would report back to Authority in due course. It was noted that the term 'BAME' was not being used internally or in this report, or going forward. It was noted that the findings would be presented at the Royal College of Obstetricians and Gynaecologists (RCOG) Race Equality Taskforce meeting in September.
- 5.5.** Lastly, on the ongoing work in the directorate, there were further EU exit related activities being carried out by teams across the HFEA. We were looking at small updates to the Code of Practice the HFEA @30 activities work was now live which included a series of blogs being launched and an event scheduled for the evening of 24 March 2021.

Compliance and Information

- 5.6.** The Chief Executive commented that in relation to the inspection resumption there was some assurance from the inspectors and clinics that the hybrid system that we intend using going forward was broadly supported. During Covid restrictions on site visits are only conducted where concerns remain. In a hybrid model going forward on-site visits would occur for each inspection but fewer hours would be spent on site.
- 5.7.** The Director of Compliance and Information gave an overview of the work in her directorate. Members were advised that every year we have inspection themes in line with the HFEA strategy that are a focus on interim inspections. The themes for 2021-2022 are
- Patient safety, feedback & emotional support.
 - Leadership, staffing & clinical governance.
 - Consent
 - Donor recruitment, selection, assessment and screening. QMS.
 - Audits.
 - Surgical procedures.
 - Pre-inspection review of data quality.
 - Pre-inspection review of the centre's history of compliance, RBATs, patient questionnaire reports, incidents and complaints and centre's websites.
- 5.8.** On 1 April a new member of staff will start in the opening the register (OTR) team to support in clearing the backlog. Processes in the team were also being reviewed so that they can be streamlined as the team continued to receive unprecedented numbers of requests. Members commented that this was a positive step as the backlog could lead to reputational damage.
- 5.9.** Members cautioned on the current system of inspections and commented that casual conversations that happened with junior staff might not happen as they were not likely to pick up the phone to speak to the Inspector. The Director of Compliance and Information commented that we would continue to speak to a range of staff.

5.10. Members commented that it was good that on-site visits are still happening when needed. To clarify a point, the Director of Compliance and Information stated that whilst restrictions have been in place inspections have included virtual technology to look at specific items and this assured inspectors. However, when necessary, inspectors had attended the clinic in person but spent less time on site than previously.

Finance and Resources

5.11. The Director of Finance and Resources presented to the Authority. It was noted that the year-end financial position would see an underspend partly because PRISM had not been completed and we had additional funding for the project.

5.12. Regarding occupation of the new office, it was noted that the earliest we would return to the office would be in June in line with government guidance, which currently still stated that wherever possible people should work from home. In responding to a question it was noted that the office was ready for occupation.

Other issues

5.13. In response to a question on the change to a new office, it was noted that the HFEA remains a flexible employer with all Inspectors as home workers and office-based staff working from home up to two days a week. There would be a new way of working settlement when we were to attend the new office that would likely look at how many days a week staff would be required to be in the office. The CE promised to keep members updated.

5.14. On staff wellbeing, the CE commented that there were two key performance indicators that we used to measure staff well-being and these were employee turnover and sickness rates, both of which were green. The third lockdown had been harder on staff but we would be focusing on our return to the office. Also, an internal survey would be carried out to measure staff preferences on office or home working.

5.15. The Chair invited professional members to reflect on the situation in relation to their clinics.

5.16. Members working in the sector commented that the present situation was becoming the norm.

5.17. Clinics had started becoming busy both in the NHS and private clinics and even though there were more work pressures, they were more staff support related. There were safety rules in place and efforts were being made to reduce waiting time.

5.18. The CE stated that the importance of good communication with patients would continue to be highlighted to clinics.

5.19. The Chair congratulated clinic staff and HFEA staff and commented that the fertility sector was the first in the health sector to re-open following the first lockdown.

5.20. The Chair commented that all key performance measures were green except one which was for an invoice not paid on time.

Decision

5.21. Members noted the performance report.

6. Covid-19 update

- 6.1. The Director of Compliance and Information presented to the Authority.
- 6.2. Members were informed that almost all centres that had suspended treatment services in the recent lockdown had now restarted treatment.
- 6.3. Inspections had resumed and were risk based and where on-site visits were not conducted a clear rationale for this was documented.
- 6.4. As at February 2021, private centres were performing more cycles than this time last year compared to NHS centres who were at 70% of where they were last year.
- 6.5. A member suggested that the presence of partners still remained an issue in some clinics, especially where bad news had been received and the patient needed support.
- 6.6. It was noted that there was a huge increase in the number of patients coming forward for support and advice from Fertility Network UK. Fertility Network had seen further anxiety from some patients who had planned to have treatment abroad but were not able to at present. Also, patients' inability to seek treatment abroad meant that they were approaching UK clinics which were more expensive compared to those overseas which was causing a lot of anxiety.
- 6.7. It was noted that most patients were aware of the efforts clinics were making and were grateful for this.

Decision

- 6.8. Members noted the Covid-19 update.
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7. Effective governance

- 7.1. The Chair suggested that due to time constraints, the report should be taken as read and members should focus on the changes to Standing Orders recommended.
- 7.2. At 5.1.1 in Standing Orders there was a proposed correction to an anomaly in the reserved matters list. It was recommended that in Annex 1, section 5.1 (p) we remove the word 'annual' and replace 'approval of' with 'consider all proposed updates to'.
 - (p) Consideration of all proposed updates to the Code of Practice and general directions, while retaining the power to delegate revisions where necessary, provided this is done in accordance with paragraph 6.6 of Standing Orders.
- 7.3. There was a proposal to increase the delegated powers to the Chair so that decisions could be made in a more agile way. It was recommended that section 5.2.4 should read:
 - The Chair of the HFEA may, alternatively, form a sub-group of members to make decisions outside the cycle of meetings in the event of urgent or business critical issues arising.
- 7.4. In annex A, section 2 there was a proposal to increase the membership of the Audit and Governance Committee. A member also asked if we could include the words 'if required' in relation to the two non Authority places on the committee. It was further suggested that the committee's quorum be updated to reflect that at least two Authority members should be present. The recommended changes were:

- The Audit and Governance Committee shall consist of up to **six members** including:
 - a Committee Chair (who shall be an Authority member)
 - a Deputy Committee Chair (who shall be an Authority member)
 - up to two other Authority members
 - two persons who shall not be Authority members and who have relevant legal, financial, public sector or other corporate governance expertise (if required).
- The quorum for a meeting of the Audit and Governance Committee shall be three, providing that two are Authority members, including the Committee Chair or deputy Committee Chair.

7.5. Changes to the terms of reference for the Scientific and Clinical Advances Advisory Committee (SCAAC) (Annex A, paragraph 6.3) were also recommended. The proposed changes are:

- The Scientific and Clinical Advances Advisory Committee shall consist of **at least three** Authority members, including:
 - a Committee Chair (who shall be an Authority member)
 - a Deputy Committee Chair (who shall be an Authority member), and
 - **up to three** other Authority members.

7.6. The proposed changes to the Register Research Panel membership in Annex A, section 8 to ensure it remains fit for purpose were:

- The Register Research Panel shall consist of a **Chair and Deputy Chair (or Deputy Chairs) and a pool of suitable employees, appointed by the Chief Executive from amongst the employees of the Authority. In the absence of the Chair of the Panel, a Deputy Chair or other person nominated by the Chair of the Panel may act as Chair of the Panel.**
- The quorum for a meeting of the Register Research Panel shall be **five**, and there shall be due consideration to the balance of membership to ensure a fair and robust appraisal of any research applications and decisions. All decisions and minutes must be signed off by the Chair.

7.7. To correct an anomaly to the Executive Licensing Panel (ELP) delegations and make it clearer which licences ELP can vary, the following change was proposed:

- **The following variations of licences on application:-**
 - change of Person Responsible (under section 18A(1) of the Act)
 - changes to licensed activities (under section 18A(2) of the Act), and
 - change of a centre’s premises (under section 18A(2) of the Act).

7.8. There was a request from the Chair of the Statutory Approvals Committee also to update Standing Orders to read:

- The Statutory Approvals Committee shall operate from a pool of members, with no more than **five** members attending each meeting.

7.9. Members were invited to ask questions.

7.10. In response to a question about the Remuneration Committee, it was noted that the Authority Chair doubled as the Remuneration Committee Chair since all staff pay was governed by a government framework which limited the committees role in deciding staff pay.

Standing Orders

7.11. Members were invited to vote on the proposed changes.

Decision

7.12. Members noted the annual reviews of committee effectiveness and the action points for each committee.

7.13. Members unanimously agreed the changes to Standing Orders, effective from 1 April 2021.

8. Business plan

8.1. The Chair invited the Risk and Business Planning Manager to present this item. Members were reminded that at the November Authority meeting, they approved the draft activities section of the business plan.

8.2. The business plan for 2021-22 built on the extraordinary work of 2020-21 and had been developed following conversations both within teams and amongst the corporate management group. It was noted that despite the challenges of the pandemic, a lot was achieved in the preceding year as we delivered on core activities such as inspections and licensing, implementation of changes from EU exit, progressing PRISM and producing publications.

8.3. The Chair invited members to ask questions.

8.4. Members welcomed the plan and suggested that the wording could be more specific about collaborative and partnership working. Also, as it was an ambitious plan, it would be important to monitor it to ensure that it remained deliverable.

8.5. Members also commented that the work done in 2020-21 would give the HFEA a good grounding for the coming year and would enable the provision of evidence when it was needed for future work on the Act. This would also feed into ongoing improvements in standards.

8.6. Members asked what clinics were required to put on their own clinic website in relation to add-ons. Staff commented that we would continue to review and it would form part of the conversation with clinics.

8.7. In terms of the relocation to Stratford, members suggested that we change the term 'snagging' to 'optimise the use of the premises'.

8.8. The Chair thanked staff and members for their contribution.

Decision

8.9. Members approved the business plan for 2021-2022 subject to incorporating the suggested comments and noted that year-end information would be added in April 2021.

9. Treatment add-ons update

9.1. An update on progress to treatment add-ons since the last Authority update in November 2020 was noted. Members were reminded that addressing treatment add-ons was a key feature of our strategy for 2020 to 2024.

- 9.2.** It was noted that the information on the website was updated to ensure it was clear to patients that it was their choice whether to opt for a treatment add-on, since this was over and above routine IVF cycles and there was an added cost.
- 9.3.** Members were also informed that all the actions agreed at the November 2020 Authority meeting had been completed.
- 9.4.** Members commented that clinic websites needed to be updated to ensure that there was no misleading data.
- 9.5.** To improve patient understanding about treatment add-ons, the HFEA collaborated with the Fertility Network UK to develop a list of questions and a checklist that patients could refer to when having a discussion with their clinicians about treatment add-ons.
- 9.6.** Members were advised that the information on complementary and alternative therapies was in draft form and would go live on the HFEA website in the coming weeks.
- 9.7.** The Chair thanked the Scientific Policy Manager and the team for the work completed to date.

Decision

- 9.8.** Members noted the progress made in relation to treatment add-ons.

10. HFEA response to CMA/ASA guidance

- 10.1.** The Director of Strategy and Corporate Affairs presented this item. Members were advised that the Competition and Markets Authority (CMA) and the Advertising Standards Authority (ASA) had been working with the HFEA for a while now with both regulators publishing their guidance in the weeks ahead.
- 10.2.** The work these regulators had undertaken had raised some important issues for us. There were some issues to note including the overall HFEA response, changes to the Code of Practice, developing a memorandum of understanding (MoU) and protocols, and training for inspectors.
- 10.3.** There were also some issues for discussion including further references in the Code beyond success rates current non-compliance with the Code on publication of information about success rates, treatment add-ons and whether text should be added to the role description for Persons Responsible (PRs).
- 10.4.** The Chair commented that when developing the MoUs we needed to be clear on what the roles of the different regulators were. Some of the professional members who were PRs commented that PRs should already be aware of their position of overall responsibility. However, guidance might be necessary to ensure consistency across all clinics.
- 10.5.** Members supported having written guidance as it would ensure that all clinics understood their obligations. It would also be used for clinic engagement so as to make a tangible difference.
- 10.6.** The Chair thanked the CMA, ASA, all staff involved and members for their contributions.

Decision

- 10.7.** Members approved the overall HFEA response, the additions to the Code of Practice and the development of the MoU and protocols.
- 10.8.** Members noted that there will be a further discussion with the Authority later in the year.

11. Compliance and Enforcement Policy post consultation

- 11.1.** The Director of Compliance and Information presented this item. Members were also informed that the Head of Legal had played a significant role in the development of the policy.
- 11.2.** The new draft policy sets out the Authority's regulatory aims which underpinned all our compliance and enforcement activities. The policy would only be used in circumstances that warranted regulatory action.
- 11.3.** Members were advised that the draft policy was consulted on in January 2021 with helpful and insightful comments received from both the NHS and the private sector which had been incorporated where applicable.
- 11.4.** It was noted that once approved, the policy would come into effect in June 2021 since time was needed to train inspectors in its usage.
- 11.5.** In response to a question, it was noted that non compliances are used to form the quarterly Governance Summary which is shared through our Clinic Focus.
- 11.6.** Members suggested a six-month interim review/audit follow up meeting following an intervention to ensure the clinic was on track. The Director of Compliance and Information agreed to follow this up with the Director of Finance and Resources.
- 11.7.** The Chair thanked everyone involved including the Inspectors for their work in getting this policy completed.

Decision

- 11.8.** Members approved the final version of the Compliance and Enforcement policy and the proposed timeline for implementation.
- 11.9.** Members agreed to delegate sign-off of the revised guidance on licensing to the Chair and Deputy Chair of the Licence Committee.

12. Any other business

- 12.1.** The Chair, Sally Cheshire gave some parting words and emphasised that patients were central to our work at the HFEA. She thanked everyone who had contributed to her success whilst in post over the last 15 years, since she became involved in the HFEA.
- 12.2.** The Chair went on to pay tribute to Kate Brian as it was also her last meeting and commented that Kate had been an effective voice for patients.
- 12.3.** Kate thanked everyone present and stated that it was an absolute privilege and honour to work alongside all Authority members and staff, and in particular thanked the committee staff and inspection team.
- 12.4.** Margaret Gilmore, deputy Chair, on behalf of members, thanked Kate Brian and Sally Cheshire for their dedication to the HFEA.
- 12.5.** The Chief Executive commented that it was a privilege to work alongside Sally as she provided leadership, challenge and support ensuring that we improved as an organisation. He commented on Sally's approachability and visibility to staff.

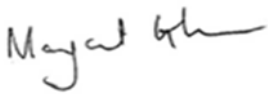
12.6. Marina Pappa on behalf of the DHSC also thanked Sally for her work over the years and huge contribution to the work of the HFEA.

12.7. Sally commented that the HFEA was a collective place with mutual respect, and of all the places she had worked in the public sector, the HFEA was one of the best, that she would remember with fondness.

Chair's signature

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

Signature

A handwritten signature in black ink, appearing to read 'Margaret Gilmore', written on a white background.

Chair: Margaret Gilmore

Date: 12 May 2021