

Minutes of Authority meeting

23 March 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	18 May 2022
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 23 March 2022 as a true record of the meeting

Resource implications

Implementation date

Communication(s)

Organisational risk Low Medium High

Annexes

Minutes of the Authority meeting on 23 March 2022 held via teleconference

Members present	Julia Chain Margaret Gilmore Anne Lampe Catharine Seddon Jason Kasraie	Jonathan Herring Gudrun Moore Alison Marsden Tim Child
Apologies	Ermal Kirby Ruth Wilde	
Observers	Graham James Zeynep Gurtin Alison McTavish Frances Flinter Alex Kafetz Maria Nyberg (Department of Health and Social Care - DHSC) Amy Parsons (DHSC)	
Staff in attendance	Peter Thompson Richard Sydee Clare Ettinghausen Rachel Cutting Catherine Drennan Sonia Macleod	Paula Robinson Debbie Okutubo Shabbir Qureshi

Members

There were 9 members at the meeting – six lay and three professional members.

1. Welcome and declarations of interest

- 1.1. The Chair opened the meeting by welcoming Authority members, observers and staff.
- 1.2. The Chair informed everyone present that the Secretary of State had announced the appointment of seven new Authority members and was pleased to welcome five of the seven members to the meeting as observers.
- 1.3. The Chair stated that the meeting would be audio recorded in line with previous meetings and the recording would be made available on our website to allow members of the public who wanted to listen to our deliberations to hear it afterwards.
- 1.4. Declarations of interest were made by:
 - Tim Child (PR at a licensed clinic) and
 - 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 9 February 2022 were a true record of the meeting 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 and advisory committees of the Authority. She commented that we had recently advertised for new members of the Scientific and Clinical Advances Advisory Committee (SCAAC) and that interviews will take place with her in the chair, supported by Tim Child (SCAAC Chair) and Andy Greenfield (previous Authority member and current SCAAC external adviser).
- 3.2.** Members were also advised that Authority meetings will now be held in person. Committee meetings will mainly be held online as this would enable members to participate fully in their respective committees to fit in with their other commitments.
- 3.3.** On the work the Authority had set up to consider how the Act should be modernised, members were advised that the aim was for proposals to go to the Department of Health and Social Care (DHSC) by the end of the year. To inform the Authority's work an Advisory Panel had been set up with a range of stakeholders representing different interests in the sector.
- 3.4.** Members were informed that all papers from the Advisory Panel will be shared on our website. Members welcomed the work that had started on this.
- 3.5.** Members also welcomed the progression of the Government proposal to extend the storage limits for gametes and embryos, which was part of the Health and Care Bill due to go through the final parliamentary stages later in March.
- 3.6.** The Chief Executive provided an update on the key activities that he was involved in since the last Authority meeting. He reflected on a meeting on the Women's Health Agenda: redressing the balance, and commented that meetings like these gave the HFEA the opportunity to look at fertility treatment in the context of women's health generally.
- 3.7.** On the business plan for 2022/23, members had previously commented on equality and diversity and how we need to ensure that it was embedded in everything we do. Members were assured that work was underway and that there was now a wider government agenda committed to tackling health inequalities, some of which had been identified in HFEA reports. A member commented that she had heard of an apprenticeship scheme aimed at encouraging diversity on boards which was worth pursuing.
- 3.8.** Members asked how the war in Ukraine was affecting UK patients who imported and or exported gametes from and to the country. The Chief Executive commented that some British patients do go to Ukraine particularly for surrogacy. Change in visa requirements now mean that surrogates from Ukraine are now eligible to come to the UK. Although there had been some importing of gametes and embryos from Ukraine, this was a very small percentage of overall use of donated gametes and embryos and would not impact on fertility treatment in the UK.

- 3.9.** Members commented that in terms of cyber-attacks we need to be mindful that as a small organisation we could be targeted as a gateway to cause embarrassment to the government.
- 3.10.** The Chief Executive responded that we now have heightened internet security and that we were contacted recently by NHS England and have met all their requirements. This does not mean that we are complacent, but we feel well placed as our cyber security currently stands. It was noted that cyber security penetration testing was also carried out on a regular basis.
- 3.11.** The Chair commented that members have been asked to do the civil service learning module on information security and data protection online training and that it was mandatory.

Decision

- 3.12.** 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 reports.
- 4.2.** The Licence Committee Chair (Alison Marsden) gave an update on the meeting held in March 2022. She thanked Ermal Kirby and Ruth Wilde who had now stepped down from the committee as they were both finishing their terms of office as Authority members.
- 4.3.** The Statutory Approvals Committee (SAC) Chair (Jonathan Herring) reported that in addition to items approved, there were some complex issues that were discussed in detail at the meeting. He thanked Margaret Gilmore for her dedication and professionalism whilst she was chair of the committee.
- 4.4.** Margaret paid tribute to all the staff who administered the SAC meetings. She extended her thanks to member colleagues and in particular to Anne Lampe and Ruth Wilde for their invaluable contribution to making her tenure on the committee a successful one.
- 4.5.** The AGC Chair (Catharine Seddon) gave an update on items discussed at the meeting and thanked Margaret for her time on the committee, for many years as the deputy chair. The AGC Chair also extended her gratitude to Ermal Kirby, Gudrun Moore and Anne Lampe who joined the National Audit Office session on cyber risk.
- 4.6.** The Scientific and Clinical Advances Advisory Committee (SCAAC) Chair (Tim Child) informed members that the terms of office of some members on the committee was coming to an end which meant that there were four vacancies. Interviews were scheduled to be held in March 2022 with the positions being advertised widely.
- 4.7.** The Authority Chair thanked everyone who had contributed thus far on all committees and to new members who would also be sitting on committees in due course.

Decision

- 4.8.** Members noted Committee Chairs' updates.

5. Effective governance

- 5.1.** The Governance Manager presented this item. It was noted that on an annual basis all committees reviewed their own effectiveness using a standard framework. The summary of positives and areas to note and for improvement was presented to the Authority.
- 5.2.** Members were assured that areas for improvement highlighted would be put into an action plan and committee officers would work with the committee chairs to see how these can be implemented.
- 5.3.** Members also noted that some aspects of the standing orders had been revised and as stated in the notice of motion circulated to members, a formal vote will be required to pass the amendments.

Appointments committee

- 5.4.** Members were advised that the appointments process for external members was now formalised, with the full involvement of the Chair and Deputy Chair at interview and selection stages. This meant that two of the three members were already involved from the beginning of the recruitment process. As a consequence when Appointments Committee meetings were convened, they were only to ratify what had already been agreed by a majority of those who sit on the committee since it is made up of three members.
- 5.5.** It was therefore recommended that the current Section 5 in Standing Orders (the terms of reference for an Appointments Committee) be deleted and the Chair formally signed off all external member appointments as part of her delegated powers from the Authority, following a formal recruitment process.
- 5.6.** Members were advised that the main required change (other than the deletion of the terms of reference) was shown in 3.3.1(i) under particular responsibilities of the Chair of the Authority, but in addition several other paragraphs are also required to be edited, as follows:
 - 3.3.1(i) The appointment of external members and advisers to committees or working groups, and the oversight of associated selection processes.
 - 7.2.3 The Chair of the HFEA shall only appoint persons who are not Authority members to a committee or working group where it has been agreed during the recruitment and interview process that such persons are suitable for appointment.
 - 7.3.3 (c) where appropriate, sign the minutes of any previous meetings with any agreed amendments that may be necessary; except in the case of the Remuneration Committee, whose minutes should be signed off by the Chair as soon as they have been agreed by members following the most recent meeting.

Statutory Approvals Committee (SAC)

- 5.7.** The SAC currently operates from a pool of up to seven members with no more than five members attending each meeting. Members were advised that the proposed change was in section 3.4:
 - The Statutory Approvals Committee shall operate from a pool of up to 10 members, with no more than five members attending each meeting.
- 5.8.** In the section immediately below that to read ‘the membership shall include’:
 - c) up to eight other Authority members.

- 5.9.** A further minor change was proposed to the list of persons who would usually attend the meetings 3.11(c), to include the correct up to date job title of the Licensing Manager (formerly called the Senior Governance Manager).
- 5.10.** A member commented that over the last seven years there had never been an instance where the committee was not quorate and for continuity reasons it was best if members remained as consistent as possible, as this was helpful on the rare occasions that items were adjourned.
- 5.11.** The SAC Chair commented that this was a new way of working and would be subject to review.

Remuneration Committee

- 5.12.** It was recommended that in the event that the Deputy Chair of the Authority and the Chair of the AGC are one and the same person, the Authority Chair should appoint another Authority member to take the third place on the committee.
- 5.13.** This required the addition of a new section 4.5:
- In the event that the Deputy Chair of the Authority and the Chair of the Audit and Governance Committee are the same person, the Chair of the Authority shall appoint another Authority member to the third place on the Committee.

Scientific and Clinical Advances Advisory committee

- 5.14.** Members were advised that to ensure a good skill mix it was proposed that expert advisers of SCAAC be appointed for a maximum of two terms, with a term lasting for one, two or three years.

Licence Committee

- 5.15.** The current terms of reference of the Licence Committee, set out in Annex D of Standing Orders, prevented most staff from observing a Licence Committee meeting.
- 5.16.** It was proposed that paragraph 5.3 of annex D be eased slightly to allow new inspectors and those with other relevant roles to observe a meeting of the committee as part of their induction into the organisation.

Equality and diversity

- 5.17.** A member commented that in addition to the above that in Standing Orders where equality and diversity was mentioned that the word 'inclusion' should be added. This was agreed.

Board effectiveness

- 5.18.** The Chair commented that in around a year's time a full board effectiveness review should be considered as new members would have been in their roles for a few months by then and that it was good practice.

Decision

- 5.19.** Members noted the feedback from the annual reviews of committee effectiveness and the action points for each committee.
- 5.20.** Members unanimously approved the revised Standing Orders which would come into effect from 1 April 2022.

6. Performance report

- 6.1.** The Chief Executive commented that a new 'Working from Home' policy had been launched and it offered permanent work from home contracts to all staff. Staff would also have the option of a new more flexible office-based contract.
- 6.2.** Members were informed that it was an offer to staff subject to the agreement of the line manager and that both of these contracts were planned to be in place from the start of the new financial year.
- 6.3.** Members asked if this would extend to the opening the register (OTR) team, because at the start of the pandemic when everyone was working from home, the team suspended operations for register security reasons.
- 6.4.** The Chief Executive responded that the OTR service was suspended because clinics were closed. In deciding whether HFEA staff could work from home we needed to be satisfied that they have an appropriate place to work and that information can be stored securely. It is an offer of working from home, not a guarantee, but as long as staff met the security standards their request would in most cases be granted.
- 6.5.** Members asked if there was a tipping point for staff working from home. The Director of Finance and Resources responded that desk to officer ratio was 1:3 and that from a policy perspective the new contract better enables us to recruit from outside of London and means we are in line with the government's wider agenda of levelling up. There were staff who would be more likely to opt to work from home due to the distance to the office.
- 6.6.** The Chief Executive commented that in line with the new business plan we would review the key performance indicators to ensure we measured the things that were the most meaningful and useful in terms of understanding our performance.
- 6.7.** On C1: Efficiency of the end-to-end inspection and licensing process, members commented that it had remained red for a very long time and that this should be one of the key performance indicators that are revisited. It was confirmed that this measure is under review.

Strategy and Corporate Affairs

- 6.8.** The Director of Strategy and Corporate Affairs presented this item. She briefly outlined some of the major pieces of work happening in her directorate which included:
 - The national fertility patient survey, the report on which would soon be published in April
 - Analysis of fertility treatment numbers in 2020 to be published in May
 - Many HFEA staff were working to ensure changes to the law on gamete and embryo storage would be implemented smoothly and particular thanks was given to Catherine Drennan, Rachel Cutting, Joanne Anton and other members of the compliance and policy teams.
 - A working group of clinic staff had met to discuss aspects of the Ethnic Diversity in fertility treatment report. This was chaired by Jason Kasraie and had usefully discussed issues relating to donor use and recruitment and multiple births.
- 6.9.** The Chair commented that as part of the work on equality, diversity and inclusion, some patients had raised the issue of requiring translation and it was noted that in some conversations with patients, translation was being given by a partner or another person and, on some occasions, there was uncertainty as to whether risks relating to treatment, such as those from multiple births, were being fully discussed.

Compliance and Information

- 6.10.** The Director of Compliance and Information provided an update on the number of inspections. It was noted that by the end of March, 120 inspections would have taken place in the 2021/22 business year.
- 6.11.** Members were reminded that during the Covid pandemic we stopped unannounced interim inspections to clinics but that the Inspectorate wanted to re-start interim inspections on this basis for those clinics having their SAQ released from April 2022
- 6.12.** Members were informed that the OTR service had turned a positive corner with respect to the number of OTR applications being closed. In February 72 were closed and in March, 105 responses have been sent out so far with 57 ready for second checking.
- 6.13.** The Director of Compliance and Information outlined the challenges of 2023 when the first donor conceived people reach 18 following the change in legislation whereby donors became identifiable from 2005 onwards. Members were advised that the demand for the service had increased over the last two years and that there had also been a rise in the complexity of applications. The Legal and Policy teams were building a framework to deal with these complexities and a project is underway to improve the service in terms of processing and efficiency.
- 6.14.** In response to a question, it was noted that it takes some months to train up staff in the OTR team but we were now building resilience in the Register team to provide cover for the OTR team should the need arise.
- 6.15.** Members asked about the counselling service for donors conceived individuals. The Director of Compliance and Information responded that the current contract with The Hewitt is being extended for a 4th year under terms of the contract. This will give more time to work on projecting future demand and undertaking a review of the service. An options paper would be brought to the Authority in the autumn.
- 6.16.** The Chief Executive commented that counselling was part of the service we currently provide but we need to evaluate the service to determine what the future demands and associated costs may be.
- 6.17.** Members commented that the current fees structure could disadvantage non-traditional families who relied on donors, for instance same sex families. The Chief Executive responded that we would have to reflect on the cost of regulation when conducting our forthcoming fee structure review. The board was clear that the information we send out needs to be accurate and being the information provider has an attached cost which we needed to recover.
- 6.18.** The Chair commented that the issues around counselling would need to be revisited.
- 6.19.** The Chair acknowledged the amount of work that was being done on storage of gametes, particularly work done by the Head of Legal and Director of Compliance and Information.

Finance and Resources

- 6.20.** The Director of Finance and Resources informed members that as at the end of January we were migrating our data into PRISM, leading to some uncertainty about income while bills had to be estimated. Invoicing was estimated according to historic data with income projections based on previous activities of clinics.

- 6.21.** It was also noted that a number of clinics might not have submitted their data by the end of this financial year, and therefore until we reconciled with the real data we would not know the actual costs and income which could mean that final figures vary significantly.

Decision

- 6.22.** Members noted the performance report.

7. 2022/23 Budget proposal

- 7.1.** The Director of Finance and Resources presented this item. Members were advised that at the November meeting the Authority agreed the proposal to increase the clinic fee for IVF cycles from £80 to £85 and that the increase will take effect from 1 April 2022. We now had HMT approval for that increase.
- 7.2.** It was noted that the increased licence fee would allow the HFEA to increase its headcount to accommodate a growth in workload and invest further to support our use of data.
- 7.3.** The expenditure budgets contained a number of assumptions around inflationary and demand pressures, as well as providing for some difficult to predict areas of spend.
- 7.4.** A detailed breakdown of the income and expenditure budgets was discussed with the Authority.
- 7.5.** It was noted that data relating to the 2020/21 and 2021/22 business years varied significantly from historic activity data in both volume and distribution. As such our budget for 2022/23 was based on activity from the 2019/20 business year. Members were advised that a 1% variance against this estimate would result in a change to our income forecast of £55,000.
- 7.6.** Members asked about grant in aid. The Director of Finance and Resources responded that it had remained the same amount for a long period now which give inflation was a reduction in real terms. However, this payment was for work carried out on behalf of the government, which is not covered by the licence fee or treatment fees.
- 7.7.** The Chair commented that recruiting IT capacity for PRISM and to other pertinent business areas was essential, since the extra resources were required.

Decision

- 7.8.** Members:
- Noted the approval and announcement of the HFEA licence fee increase for 2022/23
 - Approved the HFEA operating budget proposed by the Executive for 2022/23
 - Noted the assumptions that underpinned the 2022/23 budget, and that further work would be undertaken with the AGC to review the HFEA's financial performance for 2021/22 at its meeting in June 2022.

8. Next steps in relation to HFEA response to Covid-19

- 8.1.** The Director of Compliance and Information presented this item. Members were reminded that in March 2020 the Authority made the decision to suspend all licensed fertility treatment in the UK,

in response to the Covid-19 pandemic, professional body guidance and government restrictions. Treatment was halted from 15th April by means of General Direction 0014.

- 8.2.** The framework governing the resumption of treatment was set out in the revised General Direction 0014 v2 which was issued on 11 May 2020 and remains in place. It was noted that it was introduced to ensure the safe resumption of treatment.
- 8.3.** It was noted that the British Fertility Society (BFS)/Association of Reproductive and Clinical Scientists (ARCS) issued updated guidance on 28 February 2022.
- 8.4.** Members were advised that it was good regulatory practice to remove unnecessary rules and if the pandemic developed a serious further wave in future that required new restrictions, we could always reintroduce the measure in the same form or an amended form to suit the new circumstances.
- 8.5.** A discussion ensued and majority of members felt that it was too soon to revoke GD 0014v2 as there are some restrictions which still remain a legal requirement across some of the four nations.

Decision

- 8.6.** It was agreed to retain GD 0014v2 until the next Authority meeting in May.
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9. Strategic risk register 2020-2024

- 9.1.** The Head of Planning and Governance presented this item. Members were advised that the planned risk policy review was overdue and that an internal audit of our operational risk system was currently underway, which would further inform the policy review. It was noted that at a future meeting there would be a discussion with the Authority about risk appetite.
- 9.2.** Members noted that the new Choose a Fertility Clinic (CaFC) data would not be published until after November 2022, once the data had been validated.
- 9.3.** The Authority noted the update on all risks, controls and scores and made the following points in discussion:
 - C2: Leadership capability - members commented that the inherent and residual risk were quite high considering the calibre of the senior management team and the Authority Chair, and the recent appointments of new Authority members.
 - CS1: cyber security – Members confirmed that this should be considered a high risk at present, considering current world events.
 - I1: Information provision - members commented that they agreed with the rating but that the risk needed to be reviewed once the findings of the patient survey were known and that this should also feed into the new communication strategy.
- 9.4.** The Chair commented that the risk register would be brought back to the board one more time this year.

Decision

- 9.5.** Members noted the strategic risk register.

- 9.6.** Members agreed that CV1: Coronavirus should be discontinued from June 2022 onwards and any residual elements should be integrated into C1: Capability.

10. Add-ons rating system and survey options

- 10.1.** The Chair explained the treatment add-ons rating system and commented that we were currently working with SCAAC members and other relevant stakeholders on further improving the rating system. The Chair invited the Scientific Policy Manager to present this item.
- 10.2.** Members were reminded that at the September 2021 Authority meeting it was agreed that more work would be done to make the presentation of the treatment add-ons rating as useful as possible for patients and ensure that patients remained the primary audience for any future system.
- 10.3.** Members made a number of comments including:
- For people who were colour blind, some of the colours looked too similar
 - For option 2 with the additional grey rating, members felt that the two meanings of no evidence, 'We cannot rate the effectiveness of this add-on as so few studies have been done' and 'This add-on has no impact on the chance of having a baby' should not be conflated. It would be clinically incorrect for an add-on to be used if there was no evidence for its efficacy, and so this should be red rated.
 - The concept of financial harm was raised where some members felt patients were being encouraged to spend money on add-ons where there was no evidence that it would help them have a baby.
- 10.4.** Members asked if grey could become amber in time when enough RCTs had been done.
- 10.5.** Members commented on whether aromatherapy should be classified as an add-on. It was noted that holistic therapies were not rated in the HFEA system and a previous Authority discussion had agreed that there should be information on the HFEA website on alternative and holistic therapies but not given a 'traffic light' rating.
- 10.6.** Members commented that the different outcomes remained important but the main add-on ratings need to be based on live birth rates. Also, that where there was no evidence of benefit to live births, the add-on should be rated red under the current system.
- 10.7.** Clarification was sought on what 'on balance' meant. Members were informed that it meant patients needed to interpret the rating with some caution, since there was not absolute certainty.
- 10.8.** It was suggested that the National Institute for Health and Care Excellence (NICE) were using a system of having broad statements which were layered with information when clicked on and suggested that staff could look into this approach of laying out the information.
- 10.9.** The Chair commented that we should not go out to consultation with any option that was not viewed as clinically correct. Staff should liaise with the professionals on the Authority to agree wording before it goes out to consultation.

Decision

- 10.10.** Members agreed that the wording on options one and three would be reviewed by professionals on the Authority prior to consultation.
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11. Any other business

- 11.1.** The Chair commented that there were a number of members standing down and this meeting would serve as their last Authority meeting.
- 11.2.** The Chair thanked Ermal Kirby in his absence for his contribution and support whilst on the Authority. It was noted that he first joined the Authority in 2009 and left in 2012 and then returned in 2019.
- 11.3.** Ruth Wilde joined the Authority in 2016. In her absence, Ruth had sent in a message that the Chair read to the meeting. Ruth was thanked for her commitment and dedication as a member of the Authority.
- 11.4.** Anne Lampe first worked with the HFEA as a peer reviewer before becoming a member in 2016. The Chair thanked Anne and commented that she hoped that Anne would be willing to offer training in clinical genetics to new members.
- 11.5.** Margaret Gilmore was thanked for her contribution and dedication during her tenure on the Board. She became a member in 2015, and had served as the Chair of SAC, the Deputy Chair of the Authority and from 2018 the Deputy Chair of the AGC.
- 11.6.** Anne and Margaret thanked everyone who had contributed to their time at the HFEA including the HFEA Chair, Chief Executive, Senior Management Team, staff and other Authority members.
- 11.7.** Margaret thanked all member colleagues.
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Chair's signature

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

Signature



Chair: Julia Chain

Date: 18 May 2022