

Minutes of Authority meeting 9 February 2022

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	23 March 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 9 February 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 9 February 2022 held via teleconference

Members present	Julia Chain Margaret Gilmore Anne Lampe Catharine Seddon Jason Kasraie Tim Child	Jonathan Herring Gudrun Moore Ruth Wilde Ermal Kirby Alison Marsden
Apologies	None	
Observers	Steve Pugh (Department of Health and Social Care - DHSC)	
Staff in attendance	Peter Thompson Richard Sydee Clare Ettinghausen Rachel Cutting Catherine Drennan Nora Cooke O'Dowd	Paula Robinson Debbie Okutubo Shabbir Qureshi Joanne Anton

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, the public and staff present online. The Chair apologised for the meeting not being face to face on this occasion, due to the proximity of the latest government announcements on Covid to the meeting. The March meeting would be face to face in the new office in Stratford.
- 1.2. 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.
- 1.3. Declarations of interest were made by:
 - Tim Child (PR at a licensed clinic)
 - Ruth Wilde (counsellor at licensed clinics)
 - 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 24 November 2021 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 the decision-making committees of the Authority. The Chair spoke at the Progress Educational Trust (PET) conference in December 2021 and at the Fertility 2022 conference in January 2022, where she outlined our plans to bring forward proposals to modernise the HFE Act. A small advisory group will be formed, made up of stakeholders, who will review and advise on our proposed changes to the Act. Detailed proposals will be shared with our sponsors at the Department of Health and Social Care (DHSC) later in the year.
- 3.2.** The Chief Executive provided an update on the key activities that he was involved in since the last Authority meeting. Work was ongoing with the treatment add-ons working group that he chaired.
- 3.3.** The Chief Executive gave a status update on PRISM. Since PRISM went live in September 2021 over 50,000 units of activity has been submitted through PRISM from over 60 clinics. 37 clinics are currently using PRISM directly, while the remainder use third party suppliers to provide an API. The Chief Executive commented that clinics using PRISM directly were showing excellent data quality with error rates of less than 1%. The target for clinics to complete deployment is 31 March 2022.
- 3.4.** There were four system supplier API solutions supporting 60 clinics and three of them had started deployment. There was an API error rate average of 6-8% and the Register Team were working with them to ensure validation errors were addressed and that they achieve the same quality levels that clinics directly inputting into PRISM are achieving.
- 3.5.** Members were advised that a PRISM lessons learned meeting was held with the Audit and Governance Committee (AGC) in December 2021 and the key learning points were shared with the Board:
- Managerial communication and planning – Appointing a technically skilled programme manager who has the ability to act as an interface between technicians and management.
 - Governance – Using managerial key performance indicators to better support good governance and be prepared to review the programme once progress slips significantly.
 - Design complexity – Ensure the organisation is clear about what is being built and is asking the question 'why' of technical staff and eliciting the technical intelligence needed to inform decision-making.
 - Alternatives to PRISM - The future replacement of PRISM would be unlikely to be wholly outsourced given the complexity of the fertility data involved, so we need to maximise the longevity of PRISM and ensure there are always staff in the HFEA that understand the detailed operation of the system.
 - Avoiding reliance on single individuals for important pieces of work - So that there is more resilience.
 - IT resources required for modern regulation – Understanding the capacity and capabilities needed to support core systems.
 - Support from the DHSC – Ask the department how small ALBs can be supported on large IT programmes.

- 3.6.** Members welcomed the fact that PRISM was now being delivered, since it had been a very long journey to this point. Regarding the current error rates, members sought assurance that patients' data would remain secure and that there will be wider sharing of the lessons learned.
- 3.7.** The Chief Executive responded that the security of register data was 100% assured through our cybersecurity measures and secure infrastructure, and that the error rates referred to data sets being submitted from clinics. It was also confirmed that there will be wider sharing of the lessons learned with our sponsors at the DHSC, our external auditors at the National Audit Office (NAO) and with other similar sized ALBs.

Decision

- 3.8.** Members noted the Chair and Chief Executive reports.
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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 meetings held in November 2021 and January 2022. Members were advised that cases discussed were complex and she thanked the committee staff for their hard work.
- 4.3.** The Statutory Approvals Committee (SAC) Chair (Jonathan Herring) reported that in addition to items approved, there were some tricky ethical and medical issues that were discussed in detail at the meeting.
- 4.4.** The AGC Chair (Catharine Seddon) gave an update on items discussed at the meeting and welcomed the new Risk and Business Manager, Shabbir Qureshi as the December meeting was his first meeting. Authority members were reminded that the NAO led cyber security training invite was open to all members. Also, at the December meeting the committee had the opportunity to say thank you and a fond farewell to Anita Bharucha who was the Chair of the committee for a number of years.
- 4.5.** The Scientific and Clinical Advances Advisory Committee (SCAAC) Chair (Tim Child) gave an update on items discussed at the meeting held on 31 January 2022. Members were informed 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.

Decision

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

- 5.1.** The Chief Executive commented that due to the timing of this meeting we were presenting three months' worth of data. The good news was that HR1 - sickness levels had decreased, and the previous high sickness rate was not a trend.
- 5.2.** HR2 – turnover remained high at 18%. We continue to recruit successfully to vacancies although some roles had been advertised more than once. However, from discussions with fellow Chief

Executives this was not peculiar to the HFEA as the labour market conditions were also making recruitment very difficult across the board.

- 5.3.** In response to a question, the Chief Executive commented that further retention measures that might be possible now that we share office space with other ALBs were not yet possible due to the present situation. The gradual transition back to more office-based working may provide an opportunity to develop those links.
- 5.4.** Also, civil service pay had been frozen for a long time and we still do not know what the pay increase might be in 2022. Should there be an increase in pay, ideally it should be fully funded by the Treasury rather than individual organisations needing to make other budget cuts to plug the pay gap themselves.

Strategy and Corporate Affairs

- 5.5.** The Director of Strategy and Corporate Affairs presented this item. The multiple births report was recently published and thanks to the collaborative work both from the HFEA, licensed clinics and our stakeholders, the multiple birth rate was down to an average of 6% and there was an increase in success rates from fertility treatment over this time.
- 5.6.** The Director thanked the Intelligence team for their work on using the data we hold for public use to inform policy makers, clinics, patients and researchers. She also thanked the Communications team for positively changing how the information looked on our website and social media infographics to accompany the report.
- 5.7.** As with previous meetings, an update was given on the actions following the publication in March 2021 of the Ethnic Diversity in Fertility Treatment report. We are reviewing the patient survey results and follow-up actions would be planned where relevant with others, including our patient engagement forum. Members were advised that there were two clinic workshops coming up, one in March looking at donor availability and multiple births and in June on success rates and access to treatment. We would also be exploring whether there might be opportunities linked to the Government's forthcoming Women's Health Strategy.
- 5.8.** The National Institute for Health and Care Excellence (NICE) are reviewing their guidelines on fertility treatment and one of the resources they will refer to is our Ethnic Diversity in Fertility Treatment report.
- 5.9.** The work on treatment add-ons continues, which will be coming back to the Authority later in the year with proposals for evolving the presentation of the rating system and we will be discussing the evidence base with SCAAC during this year.

Compliance and Information

- 5.10.** The Director of Compliance and Information presented to the Authority. Members were informed that the inspection team were busy with desk-based assessments in preparation for inspections. In terms of numbers, eight inspections were carried out in January, 12 are scheduled for February and 11 for March.
- 5.11.** Members were informed that pre Covid approximately 100 inspections occurred per year. By April 2022, approximately 122 inspections will have been undertaken.
- 5.12.** Regarding IT, members were advised that we are working to improve our security protection from ransomware and other attacks. A number of changes have already been implemented such as

further use of multi factor authentication, preventing the use of non HFEA laptops and changes to how emails can be accessed from personal devices.

- 5.13.** It was noted that access to websites that present a technical threat to the HFEA would be blocked and that this was to prevent malware being downloaded onto HFEA laptops. Going forward, it would only be possible to access the HFEA's IT systems from within the UK. Temporary exceptions could be requested from the Information Governance Manager.
- 5.14.** Members were advised that changes were being made to how Authority members could exchange and receive emails with the HFEA. These changes had been agreed with the Authority Chair.
- 5.15.** On training, a session on information governance was arranged for staff in January 2022 and there was a high turnout from staff.
- 5.16.** For the OTR service, there are currently 682 applicants waiting for information and we are currently averaging 52 new applications per month. Over the past few months, the team has been fully staffed, and we were now responding to more applications than we were receiving.
- 5.17.** The number of OTR responses to be sent out in the next few months will increase when the Senior Donor Information Officer starts to close OTRs. Due to the amount of experience needed to be responsible for releasing Register information, there is a long lead-in period for this aspect of the role. At present the Team manager is the only one who can do the final check.
- 5.18.** The manager is also heavily involved in the 2023 OTR service development project which is progressing.
- 5.19.** Members will recollect that extra staff were taken on to support the OTR service as a temporary measure. The permanent posts have now been advertised and we will have four permanent members in the team very shortly.
- 5.20.** The Chair commented that the increasing volumes of OTR had put a huge burden on the Executive but they were rising to the challenge. The Deputy Chair (Catherine Seddon) had agreed to be the lead board member providing support and assurance on this matter to the Authority.

Finance and Resources

- 5.21.** The Director of Finance and Resources informed members that the budget was showing a significant underspend but that a lot of this resulted from non-cash costs. At present, our income position was an estimate because of the impact of the PRISM roll-out on clinics ability to submit data; once the reconciliation was done we would see the actual costs.
- 5.22.** Members were reminded that when they approved the increasing fee to clinics it was subject to DHSC and HM Treasury approval. Both had now agreed in principle to the increase from 1 April 2022 and that a letter will be going out to licensed clinics to that effect.
- 5.23.** The Chair thanked the Finance team for all their hard work.

Returning to the office

- 5.24.** The Chief Executive commented that we had adopted a policy to allow office-based staff to work in the office for a minimum of one day a week. The Corporate Management Group (CMG) were

currently working on a new home working policy which the Senior Management Team would review and cascade to staff shortly. Members will be kept informed of further developments.

- 5.25.** The Chair thanked the Chief Executive for the update and commented that there were social and cultural benefits to being in the office.

Decision

- 5.26.** Members noted the performance report.
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6. Covid-19 update

- 6.1.** The Director of Compliance and Information presented the update.
- 6.2.** Members were advised that just before Christmas we became aware that there was a temporary deferral of fertility treatments for unvaccinated patients in Scotland and that we were not so far aware that this policy had changed.
- 6.3.** When centres reopened in May 2020, after the temporary suspension of licensed treatments, we asked all PRs to report any hospital admissions and all OHSS cases as an incident to the HFEA. This was because at the time it was critical that any treatment offered did not result in referrals to NHS emergency care. It was therefore important for this to be monitored.
- 6.4.** We were also monitoring closely the impact of Covid-19 on fertility treatment rates and therefore also asked PRs to report positive Covid-19 cases.
- 6.5.** As restrictions have eased and hospital admissions have fallen, and as treatment numbers are now at good levels, with centres managing staff absences at a local level, we felt this extra reporting burden on clinic staff was no longer required. We therefore emailed during the week commencing 7 February to tell PRs that they no longer need to do this.

Decision

- 6.6.** Members noted the Covid-19 update.
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7. Gamete and embryo storage

- 7.1.** The Head of Policy presented this item. It was noted that the HFE Act currently sets out the storage limit as a maximum of 10 years. In 2009 the limit was extended to a maximum of 55 years, but only where a patient was or was likely to become prematurely infertile in the written opinion of a medical practitioner.
- 7.2.** Members were advised that changes to the storage and consent regime were being considered by Parliament via amendments to the Health and Care Bill.
- 7.3.** It was noted that over the next six months this piece of work will be a priority for a number of teams.
- 7.4.** Members commented that they were glad that this was now on the political agenda and sought confirmation that the gametes and embryos included sperm and not just eggs.
- 7.5.** In response to a question, members were informed that the Executive were developing guidance that will map out various storage scenarios and what steps clinics will need to take and when. However this document cannot be finalised as the amendments are still subject to the

parliamentary process. This document will be provided to clinics and would also be useful for the inspection team. We have also engaged an embryologist and an external lawyer who have both been seconded to work with us on this project and will be looking at the different consent forms.

- 7.6.** In response to a question, the Head of Legal commented that imported gametes would also benefit from the 55-year statutory storage period, provided gamete providers had consented to that period of time and in certain circumstances Special Directions would be needed for such imports. She also noted that whilst it appears to be a relatively straightforward shift to storage for up to 55 years, the practical implementation was more complex.
- 7.7.** Members asked what onus would be on clinics in terms of ethical considerations for longer storage. The Head of Legal responded that already the law required licensed clinics to provide relevant information to patients and the offer of counselling, prior to giving consent and that the information already needs to be tailored to the patients' needs. Our new guidance to clinics on what information needs to be provided to patients in these circumstances will need to be clear. The new provisions will require clinics to provide relevant information and the offer of counselling to patients before every renewal of consent to storage.
- 7.8.** Members asked if clinics are likely to charge patients more for longer periods of storage and were concerned that this would increase disparity between people who could afford to pay and those who could not. Professional members commented that private clinics are likely to charge extra for longer storage, and patients who receive NHS funding for storage generally only had two or three years storage covered. Members noted that decisions around storage fees and NHS funding for storage was outside of the HFEA's remit.
- 7.9.** It was agreed that the Executive would provide regular updates to the Authority on the progress of this work.
- 7.10.** The Director of Strategy and Corporate Affairs commented that a collective effort had progressed the work to this stage and thanked the DHSC sponsor team colleagues for their work. PET and the Fertility Network were also thanked for their input into this campaign.

Decision

- 7.11.** The Executive agreed to consult with Authority members to seek advice, review documents and provide input where necessary, between February and May 2022.
- 7.12.** Approval and sign-off of key documents was delegated to the Chair for any new or revised General Direction(s), Licence conditions, guidance, and other material necessary for the implementation of the proposed amendments.
- 7.13.** Regular updates would be shared with the Authority on the progress of this work.

8. Business planning 2022/23

- 8.1.** The Head of Planning and Governance presented this item. Members were advised that the Corporate Management Group (CMG) met in January 2022 to consider how best we could deliver key elements of our strategy in the coming year, bearing in mind current and new pressures on our capacity.

8.2. During the discussion top priorities were identified, and also work that could be delayed or scaled down in order to ensure that the activities with the most practical and strategic benefit could be done successfully.

8.3. Members were advised that the majority of our resource would always be expended on core statutory work including:

- Inspection and licensing regime
- Opening the Register requests
- Maintaining the Register
- Information for researchers
- Annual horizon scanning and maintenance of the Code of Practice
- Information provision (including CAFC update)
- Information requests
- Fulfilling wider DHSC or healthcare system requests
- Meeting external legal requirements, for example responding to statutory information requests.

8.4. In addition to the statutory work, activities which had the highest strategic priority were also identified:

Best care

- Completing the review of the treatment add-ons traffic lights and evidence base.
- Engagement with NICE on their fertility guidelines review.

Right information

- Work following the launch, in 2021, of PRISM and our new register of treatments. This work is necessary to ensure that PRISM is fully operational for clinics, and that various internal systems that were linked to the old register, are now linked to the new register to restore full functionality.
- Linked to this, working towards a fresh publication of our CaFC data in 2022.
- Clearing the backlog of OTR requests that built up as a result of clinic closures during the first Covid lockdown, combined with increased volumes of requests.
- Reviewing our communication activities to ensure we are getting the most impact with the tools and resources we have

Shaping the future work

- Our Donor Information Service Development Project, which will help us to prepare for future, higher, levels of demand.
- Continued preparatory work to present our ideas for modernisation of the HFE Act.
- Other work relating to more imminent legislative developments, such as changes to gamete and embryo storage limits.
- A review of our fee regime (agreed previously with the DHSC and HM Treasury).

8.5. Work that had been deprioritised or scaled down included:

- The project on reducing clinic variation (although we have retained some of the intended components of that project, such as work on transparency in regulation, and work on our intelligence dashboards).
- A review of guidance on the ten-family limit – we intend to resume scoping of this work in 2023.
- Active review of donor egg availability (beyond encouraging clinics to present up to date information on the Portal).
- Large-scale work with GPs on information provision to patients – however we will do targeted work, where we are able, to improve GPs’ access to information.
- Further work on our guidance for clinics on conditional donation.
- Further work on encouraging responsible innovation and ensuring clinics assess innovative treatments (apart from some already planned work on authorising new processes, which has been scheduled for the second half of the coming business year).
- Guidance and information particularly focused on partners – this had been reduced in scope to a review of our website information and social media activity. Further work in this area may however arise from the Government’s Women’s Health Strategy, when it is published.

8.6. In terms of the deprioritised areas, members asked about donor egg availability, particularly for ethnic minority patients and if there was any scope in reviewing the Scottish government’s recent campaign. The Director of Strategy and Corporate Affairs commented that the Scottish campaign had started in the summer and we had not heard since then, but this will be followed up.

8.7. In response to a comment on the OTR service, members were advised that the counselling service was separate from the OTR service. The counselling service had a three-year contract and now that the contract was nearing its end it was being reviewed. A proposal would be brought to the Authority for consideration in the future, and meanwhile it was possible to extend the current contract pending resolution.

8.8. In terms of right information, members asked if the review of the communications activity was looking at the most effective ways of raising awareness about our work. This would also apply to the planned targeted work with GPs on access to fertility information for patients.

8.9. Members felt that it was essential that diversity and inclusion are built into our corporate DNA and our ways of working. The Chief Executive responded that when patients from black and minority ethnic groups have had inadequate experiences these could be seen as ‘lead indicators’ that provide insight into the wider experience of all patients.

8.10. The Chair commented specific work needed to be done around black and minority ethnic groups as it was important that we mainstream diversity and inclusion in everything we do and ensure it becomes part of our daily conversations.

8.11. Members echoed what was said and agreed that actions around diversity and inclusion should be made clear.

Decision

8.12. Members approved the draft business plan and agreed that senior staff and the Chair would reflect on the points made about diversity and inclusion.

9. Modernising fertility regulation: a plan for legislative change

- 9.1. The Director of Strategy and Corporate Affairs presented this item. The outline of what took place in 2021 and key plans for 2022 on how we intend to engage with key professionals, patient groups, licensed clinics in our proposals for legislative reform was discussed with the Authority.
- 9.2. It was noted that in 2021 we marked the 30th anniversary of the HFEA with a series of activities including events and blogs. The events were held online due to Covid-19 restrictions.
- 9.3. Members were also reminded that throughout 2021 we developed our thinking about elements of the Act that were in need of modernisation to keep pace with changes in the fertility market, science and society.
- 9.4. The then health minister, Lord Bethell, had agreed that modernisation was needed and the HFEA should work with the DHSC on an agreed way forward. The plan in 2022 is to bring some worked-up proposals back to the Authority later this year for discussion and approval. Following this, we will then present to the DHSC a set of proposals by the end of 2022.
- 9.5. Members were also advised that a small expert advisory group would be set up to gather views and discuss ideas. In addition, we would undertake a mix of engagement work which would include our standing stakeholder groups and getting feedback from licensed clinics and patients.
- 9.6. Members raised a concern on consent being described as overly complicated. Staff confirmed that this was not a comment on the central importance of consent, but rather about the administrative complexity entailed for clinics in obtaining the correct consents from patients.
- 9.7. Members commented further that Authority members should be part of the stakeholder group to be consulted and agreed that republishing blogs was a good idea to maximise awareness.
- 9.8. In terms of the patient protection section, members asked how detailed we wanted it to be and if we would also be offering solutions. Staff responded that we would.

Decision

- 9.9. Members noted the outline of activities that took place during 2021 and approved plans for developing proposals for reform of the HFE Act during 2022.

10. Annual report on the Register Research Panel (RRP)

- 10.1. The Head of Research and Intelligence presented this item. Members were reminded that the HFEA holds a statutory Register of all patients, partners, donors, treatments and children born as a result of fertility treatment. It is believed to be the largest database of assisted reproduction treatment in the world.
- 10.2. The Human Fertilisation and Embryology (Disclosure of Information for Research Purposes) Regulations 2010 state that the Authority may grant authorisation to a research establishment for the processing of disclosable protected information from the Register.
- 10.3. The launch of PRISM and the new Register means that there will be greater opportunities to do more with the data we hold in the longer term, with potential benefits for the efficacy of treatment and patient outcomes.

- 10.4.** However, this causes short-term issues and members were advised that as a result, the Register Research Panel was suspended in September 2021 and only one research project was approved. However work has continued and the team has engaged with 14 new researchers and continued to develop legal and administrative processes for the panel. The backlog of previously requested data extracts was also cleared.
- 10.5.** It was noted that the vast majority of people seeking to access the data in the register request anonymised data. This is released in our data publications and in response to parliamentary questions, Freedom of Information requests and public enquiries. An updated version of the anonymised register is now available on the HFEA website that researchers can access without applying for permission.
- 10.6.** Post-PRISM reporting and infrastructure work is being undertaken in 2022 and as a result Fertility Trends report cannot be published this year. A report of unvalidated treatment data will be published in 2022 looking at the Covid period.
- 10.7.** Members asked when to expect the next Fertility Trends, and the Head of Research and Intelligence responded that as soon as we had validated data, this would be possible again. It was anticipated that the next Fertility Trends will be published in the first half of 2023.
- 10.8.** In response to the question on pending research applications, the Head of Research and Intelligence responded that we remain in conversation with all applicants and continue to encourage researchers to stay in touch with us, as a lot of preparatory work is involved before the data can be made available to the research project.

Decision

- 10.9.** Members noted the Register Research Panel annual report.

11. Any other business

- 11.1.** The Chair requested that every effort be made (Covid-19 restrictions permitting) to hold the Authority meeting scheduled for 23 March Authority meeting in person at the new Stratford offices.

Chair's signature

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

Signature



Chair: Julia Chain

Date: 23 March 2022