

# Minutes of Authority meeting 27 January 2021

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## Details:

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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	24 March 2021
Author	Debbie Okutubo, Governance Manager

## Output:

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For information or decision?	For decision
Recommendation	Members are asked to confirm the minutes of the Authority meeting held on 27 January 2021 as a true record of the meeting

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Resource implications

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Implementation date

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Communication(s)

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Organisational risk       Low                       Medium                       High

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Annexes

## Minutes of the Authority meeting on 27 January 2021 held via teleconference

Members present	Sally Cheshire Margaret Gilmore Anita Bharucha Anne Lampe Jason Kasraie Catharine Seddon	Jonathan Herring Gudrun Moore Ruth Wilde Yacoub Khalaf Ermal Kirby Kate Brian Tim Child
Apologies	Emma Cave	
Observers	Alison Marsden Marina Pappa (Department of Health and Social Care - DHSC)	
Staff in attendance	Peter Thompson Clare Ettinghausen Richard Sydee Rachel Cutting Catherine Drennan	Paula Robinson Debbie Okutubo Nora Cooke-O'Dowd Dan Howard

### Members

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

## 1. Welcome and declarations of interest

- 1.1. The Chair opened the meeting by wishing everyone a happy new year and welcoming Authority members, observers and staff present online. She welcomed the new Authority members Jason Kasraie, Tim Child, Catharine Seddon and Alison Marsden and informed all present that Alison's appointment starts on 1 April 2021 but she would be observing the meeting today.
- 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:
  - 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 11 November 2020 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 18 December, the Chair met online with Lord Bethell; the Chief Executive (CE) and the Director of Strategy and Corporate Affairs were also present. The discussion focused on our plans to celebrate the 30th anniversary of the HFEA in 2021.
- 3.2. The Chair commented that the HFEA was one of the longest serving public bodies in the health sector, supporting patients over the last 30 years. The impact of Covid-19 on clinics and patients could not be underestimated, and as a regulatory body we will continue to support clinics and see that our inspection regime and the way we ensure safety for patients is carried out in an effective and efficient way.

#### Decision

- 3.3. Members noted the Chair's report.
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### 4. Chief Executive's report

- 4.1. The Chief Executive (CE) reported back on some of the engagements he had with the sector. He explained that due to the Covid-19 restrictions, the 2021 joint professional societies' fertility conference was held online and he was part of a wider panel discussion reflecting on the impact of Covid-19 on the sector.
- 4.2. The CE updated the Authority on the impact of Covid-19 on the organisation. Staff had been working at home since March 2020 and staff, systems and IT were all working well. The organisation continues to support staff who find it difficult to work from home. The CE commented that the added impact of this third lockdown was now having a negative effect on some staff who had coped well during the first lockdown.
- 4.3. It was noted that some staff were eligible for key worker status which has helped some who have children of school age. Covid-19 continues to impact on the welfare of staff and we continue to look at ways to support wellbeing.
- 4.4. The CE informed the Authority that with the agreement of the sector we will be delaying the launch of PRISM, our new information submission system for clinics, as it was felt that launching an IT system in the middle of a pandemic would not be beneficial to clinics who would have other priorities. It was noted that this item was on the agenda for this meeting and will be discussed further then.
- 4.5. The EU exit transition period ended on 31 December 2020. We issued all relevant changes to clinics including new general directions in advance of this date. We also passed on all communications from the Department of Health and Social Care (DHSC) to licensed clinics.
- 4.6. It is too early to determine the full impact of EU exit on clinics but we are monitoring the situation and we communicate regularly with the DHSC. There are some issues relating to VAT on imported sperm that have been brought to our attention and we have raised this with the DHSC who are liaising with the HMRC. As soon as we get any definitive answers we will pass them to clinics. We are at the beginning of this new process and will keep Authority members abreast of developments.

- 4.7.** Lastly, the CE updated on the appointment of a new Chair. He commented that the process was run by the DHSC and members would be kept informed of the outcome. The CE stated that we do not expect to be without a Chair at any point in time and DHSC will put in place any interim arrangements if needed.

#### Decision

- 4.8.** Members noted the CE's report.
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## **5. Performance report**

- 5.1.** The CE introduced the performance report covering the period up to November 2020. It was noted that performance was generally good and that there were no red indicators. Despite the pressures from the impact of Covid-19 on staff, turnover was at manageable levels and the sickness absence rate was also very low. Some staff had contracted Covid-19 and all but one recovered fairly quickly.

#### Strategy and Corporate Affairs

- 5.2.** The Director of Strategy and Corporate Affairs gave a brief overview on ongoing work in the directorate.
- 5.3.** We are looking forward to marking the 30<sup>th</sup> anniversary of the HFEA and looking to the future of us as a regulator and the fertility sector. Lord Bethell had said in the meeting in December that he was supportive of us looking into possible legislative change in the years ahead.
- 5.4.** The Competition and Markets Authority guidance in relation to the fertility sector is in the final days of their public consultation. They have consulted widely with professionals, patient groups and individuals and we look forward to the launch of their final guidance later in the year.
- 5.5.** The Advertising Standards Authority (ASA) would also be issuing guidance to ensure clinics are aware of their obligations under the ASA Code.
- 5.6.** Members will be aware that we publish an annual report, Fertility Trends, which is our annual statistical report on our register data. In March 2021, we will publish a supplementary report looking at our register data relating to black and minority ethnic patients.
- 5.7.** We are working on some small updates to the Code of Practice to incorporate, for example, any legislative changes and further guidance, for example, on medicines management, where there have been high levels of non-compliance in recent years. The draft text for the Code of Practice would be brought back to the Authority later in the year.
- 5.8.** We are making further progress on our work on treatment add-ons following the discussions at the Authority meeting in November 2020, for example on changing the website text in response to patient feedback and adding text on holistic therapies. There will be an update on this at the March Authority meeting.
- 5.9.** The next Scientific and Clinical Advances Advisory Committee (SCAAC) meeting would take place in February.

#### Compliance and Information

- 5.10.** The Director of Compliance and Information gave an overview of the work in her directorate. Starting with the compliance side, she reminded the Authority that inspections resumed in

November 2020 and that the methodology had been developed to minimise time on site. A risk-based desk-based assessment alongside virtual technology is now undertaken. This allows inspectors to have a virtual 'walk around', discuss issues with staff and minimise time on-site. If concerns remain after the assessment process, on-site visits are carried out. The feedback from inspectors and clinics was positive, although the document review process for inspectors is proving work intensive.

- 5.11.** Both interim inspections and renewals have been scheduled to take place in the next few months using the new approach. In a few instances, licences of clinics with no concerns have been extended from 4 to 5 years to enable the workload to be spread out. The Director of Compliance and Information commented that we will continue to learn from this process and it will inform how inspections can be conducted after the pandemic.
- 5.12.** Members were reminded that the Opening the Register (OTR) service reopened in October and there has been a substantial increase in requests received. Individuals who made a request have been emailed and advised of an increased waiting time due to the increase in requests. There is a recruitment in progress for a 12-month contract for an additional staff member to support the service. The demand will continue to be monitored.
- 5.13.** Members asked about the increased number of people coming forward for information and if this was the start of a trend ahead of people preparing for 2023, which is 18 years after donor anonymity was removed. The Director of Compliance and Information responded that there was no evidence that it was a trend. It was believed that it was the backlog from when the service was closed at the start of the pandemic which meant that people were unable to ask for the information they required.
- 5.14.** Members commented that the website cited an 8 to 10 month delay in processing applications for OTR and requested that this be looked at, including the possibility of re-deploying internal resources to reduce the waiting time. The Director replied that the waiting time will be reviewed once the new member of staff is in post and working through requests. It is anticipated that this will significantly reduce waiting times.
- 5.15.** The Register team have completed the data verification process ahead of Choose a Fertility Clinic data (CaFC) being published in February. The data is now frozen and the team have resolved a significant number of data quality issues. There remain six clinics that are yet to sign off their data and we will continue to work with them.

### Finance and Resources

- 5.16.** The Director of Finance and Resources presented to the Authority. It was noted that in line with the performance data in the report, the HFEA was expecting a small shortfall against budget, but it now appeared to be smaller than anticipated.
- 5.17.** The ongoing PRISM work had increased our expenditure, but savings had been realised from fewer activities including travelling to on-site inspections and face to face meeting costs.
- 5.18.** For the office move, this is now complete and we are formally operating from the new office. However, staff are not yet able to attend the office due to the present lockdown.
- 5.19.** The Chair thanked all staff for the hard work during this difficult period and asked, on the income side, how many treatments were anticipated in clinics.

**5.20.** The Director of Finance and Resources responded that it was too early to put a figure on this but that we monitored the situation carefully and the Director of Compliance and Information discussed treatment numbers regularly with the DHSC and NHS England including any concerns we have about referrals into the IVF pathway from primary and secondary care.

#### Other issues

**5.21.** The Chair invited professional members to reflect on the situation in relation to the pandemic.

**5.22.** Some members working in the sector commented that the present situation was not as bad as in March 2020 when the pandemic started but redeployment of targeted medical staff was still expected and happening already in some cases. Lessons learnt from 2020 were being implemented and patients were now more familiar with what to expect.

**5.23.** It was discussed that whilst the number of patients being treated has been near normal levels in many licenced centres, we are seeing an issue with a drop in referrals into the start of the IVF pathway due to delays in referrals from primary care, whether from GPs to specialist fertility clinics or from GPs to hospital trusts for general gynaecological tests and procedures.

**5.24.** The availability of the vaccine for patient facing staff in private centres had been raised and we had worked to ensure they were included in the correct group of priority staff for vaccinations. Concerns had been raised from patients about the effect of the vaccine on fertility or in pregnancy. We had updated our FAQ on this following a change in advice from the JCVI and further statements from professional bodies.

**5.25.** It was also raised that the two-year extension to storage limits that had been introduced last year by the DHSC, was still causing concern for clinics and patients, who wanted the storage period to be longer.

**5.26.** Communication from clinics to patients had much improved during the pandemic, although there was still some variability. It was noted that NHS funding for those who had gone over the age limit due to Covid-19 was a concern for patients in light of the extended waiting times.

**5.27.** A member raised whether partners were being allowed to attend appointments at clinics with patients. This varies by clinic, depending on their wider policies about attendance for in clinic appointments. Clinics should be encouraged to offer support and counselling to patients at this difficult time.

**5.28.** The Director of Compliance and Information commented that part of the inspection process was to ask about the counselling that was made available to patients.

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

#### In conclusion

**5.30.** The CE commented that most of these subjects were covered in the Covid-19 FAQs for patients and professionals that were on the HFEA website and updated frequently.

**5.31.** Members asked if there were any developments with the Government consultation on storage limits for Gametes and Embryos. The Director of Strategy and Corporate Affairs commented that the DHSC had consulted on this issue and were working through the responses. This was confirmed by the DHSC representative attending the meeting.

## Decision

**5.32.** Members noted the performance report.

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## 6. Covid-19 update

- 6.1.** The Director of Compliance and Information presented to the Authority. Members were advised that following the start of the January lockdown, the CE issued a letter informing all centres through their persons responsible (PR) that treatments could continue in a safe manner for both patients and staff in accordance with our general direction 0014 (GD0014 v.2). The importance of minimising referrals into NHS emergency care was stressed in the statement.
- 6.2.** It was noted that inspections would continue with a different methodology utilising a risk-based approach. As noted earlier, a thorough desk-based assessment of requested centre information is undertaken and virtual technology is used to explore concerns and discuss issues with staff members. Visits will be arranged on a risk-based approach if concerns remain. The rationale of not having onsite visits is being documented for all clinics.
- 6.3.** The data to December 2020 on all cycles taking place in NHS and private centres in England was shared with the Authority. It was noted that cycle numbers were now similar to those seen in 2019.
- 6.4.** Members were advised that nine centres had either suspended or reduced treatment services and this will continue to be monitored. It was acknowledged that we were aware of delays in referral pathways and have brought it to the attention of NHS England and the DHSC.
- 6.5.** The Director of Strategy and Corporate Affairs informed the Authority that there were high levels of patient anxiety but patient feedback had indicated that they were appreciative of HFEA updates during this Covid-19 period, especially the recent announcement that a national closure of clinics was not expected.
- 6.6.** The frequently asked questions (FAQs) section on the website will continue to be updated as soon as any professional or government guidance changes are issued.
- 6.7.** Some patients who were also healthcare staff and in an early priority group to receive the vaccine had been in touch with concerns. It was noted that the UK advice is that those who are trying to become pregnant do not need to avoid pregnancy after vaccination.
- 6.8.** It was noted that the British Fertility Society (BFS) and Association of Reproductive Scientists (ARCS) had updated their guidance on this.
- 6.9.** In response to a question, the Director of Finance and Resources commented that it was too early to be certain about the implications for income.

## Decision

**6.10.** Members noted the Covid-19 update.

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## 7. PRISM update

**7.1.** The Chief Information Officer (CIO) presented the PRISM update to the Authority.

- 7.2.** As the CE noted earlier, clinics had advised that they were likely to encounter challenges in being able to go live with PRISM during the lockdown. As staff are currently working from home this is causing difficulties and delays as the live data can only be tested within a licenced centre.
- 7.3.** The audit and governance committee (AGC) met on 11 January and supported the position that we should not launch in January given the pressure in the sector. It was concluded that we should commence go live at the earliest by 31 March but ideally not beyond end of May 2021. However, the situation within clinics should be monitored so launch could proceed if the situation with regard to the pandemic improves and pressures decrease.
- 7.4.** Members were informed of the programme elements that were being brought forward including the clinic engagements, bulk API testing, PRISM familiarisation, training for the Register and OTR teams. It was noted that they had originally been scheduled for after PRISM go live.
- 7.5.** Handover had commenced to ensure that staff are able to provide a good level of support for PRISM as this is a key priority.
- 7.6.** The AGC Chair commented that the programme was on track and that the team remained flexible about go live.
- 7.7.** In response to a question, members were advised that all IT systems were now on cloud-based servers. Members asked about the affordability of the extra work that PRISM was incurring. Staff responded that we planned to meet additional programme costs through underspends in other areas.
- 7.8.** Staff commented that the Covid-19 situation will continue to be monitored and launch options will remain flexible.

## **Decision**

- 7.9.** Members noted the PRISM progress to date.

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## **8. The register research panel (RRP) annual report**

- 8.1.** The Head of Research and Intelligence addressed the Authority. Members were advised that we hold the largest Register of data on assisted reproduction treatments in the world.
- 8.2.** We are also governed by legislation that enables us to provide information requested for research purposes. In 2020, two projects were approved and the team were in contact with 11 new researchers. A researcher engagement day was planned to take place in May 2020, but it had to be cancelled due to the Covid-19 pandemic and we will review how to carry out that engagement in alternative ways in 2021.
- 8.3.** Members asked for clarification on the criteria on grounds for refusal of research projects. The Head of Research and Intelligence responded that this was clearly set out in the Regulations and it could be that the research question needed more work done and cited instances where the researchers had asked for data, but the panel felt that the data requested would not be adequate to answer the research question so the request had been turned down. In cases like that staff would work with the researchers to improve their proposal.
- 8.4.** Members also asked if applications were encouraged from around the world. Staff responded that the Regulations were prescriptive on this issue but that anonymised data could be requested from anywhere in the world. However, identifiable data could only be requested by a UK based



research establishment. Where collaboration between a UK based and non-UK based institution or organisation had requested the data then a discussion would be held.

- 8.5.** In response to a question it was noted that there is a maximum charge of £5000 per approved application.
- 8.6.** Members commented that the availability of this data may not be known by researchers especially non-UK based researchers. In light of the HFEA's appetite to promote research, including international use of anonymised data, it should be advertised more broadly.
- 8.7.** Members were informed that the anonymised data was already published on our website and was due to be updated in the Spring.
- 8.8.** The Director of Strategy and Corporate Affairs commented that in terms of resources we had limited staff capacity. She also pointed out that the annual report lists only the formal requests that have come through and that on a daily basis, Register data was published through enquiries, freedom of information requests, and our reports.
- 8.9.** Members suggested that in due course we should consider having a wider research panel to support the HFEA with screening and advising on decisions.
- 8.10.** Members suggested that the make-up of the panel could include people with clinical and ethical expertise as one of our aims was to be a global leader in facilitating scientific research. A way to bring this to the awareness of the research community could be via the 30th anniversary communication tools.
- 8.11.** The CE thanked Authority members for the endorsement and noted that some of these activities may need to take place in due course when this work has been further developed.
- 8.12.** The Chair thanked staff, and members for their contribution.

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## **9. Any other business**

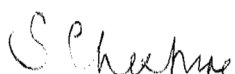
- 9.1.** There was no other business.

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## **Chair's signature**

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

Signature



**Chair:** Sally Cheshire

**Date:** 24 March 2021