

Minutes of Authority meeting held on 14 September 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	16 November 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 14 September 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 14 September 2022 held via teleconference

Members present	Julia Chain Catharine Seddon Jason Kasraie Tim Child Frances Flinter Zeynep Gurtin Alison Marsden	Gudrun Moore Frances Ashcroft Graham James Geeta Nargund Alison McTavish Jonathan Herring
Apologies	Alex Kafetz	
Observers	Steve Pugh (Department of Health and Social Care – DHSC) Amy Parsons DHSC	
Staff in attendance	Peter Thompson Richard Sydee Clare Ettinghausen Rachel Cutting	Debbie Okutubo Anna Wilkinson Ana Hallgarten Paula Robinson

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 welcoming Authority members and staff present. The Chair stated that during this time of national mourning following the death of Her Majesty Queen Elizabeth II, we had decided that our meeting should not be held in public nor audio recorded but the minutes will be published on our website.
- 1.2. On behalf the HFEA, the Chair passed on condolences to the Royal family.
- 1.3. Declarations of interest were made by:
 - Tim Child (PR at a licensed clinic)
 - Jason Kasraie (PR at a licensed clinic) and
 - Geeta Nargund (Clinician at a licensed clinic).

2. Minutes of the last meeting

- 2.1. Members agreed that the minutes of the meeting held on 19 July 2022 were a true record and could be signed by the Chair subject to the following changes:
 - 4.7. To read:

“...The AGC Chair continued that there would be refresher training on the analysis of financial statements for AGC members and that this would be opened up to Authority members who would like to participate”.

6.1. To read:

“The Scientific Policy Manager presented this item. Members were reminded that Treatment add-ons had been discussed at three Authority meetings since September 2021”

2.2. The status of all matters arising was noted.

3. Chair and Chief Executive’s report

- 3.1.** Members noted updates on activities from the Chair and the Chief Executive. Some speaking engagements were postponed because of the mourning period.
- 3.2.** The Authority were informed that there is a new Secretary of State for Health and Social Care who is also the Deputy Prime Minister. Members were also advised that following the mourning period we will be advised of ministerial portfolios at the DHSC and which minister will be responsible for our area.

Decision

3.3. Members noted the Chair and Chief Executive’s report.

4. Committee Chairs’ reports

- 4.1.** The Chair invited Committee Chairs to comment on the presented reports.
- 4.2.** The Licence Committee Chair (Alison Marsden) commented that the Committee considered some particularly serious cases of non-compliance which underline the limitations of our current regulatory powers.
- 4.3.** The Statutory Approvals Committee Chair (Jonathan Herring) commented that they had been meeting monthly and an example of the kind of issues being discussed included where PGT-M could be allowed in relation to deafness where a range of ethical considerations need to be looked at. The licence was allowed as the committee had to consider the worst-case scenario and, in addition, just because something is licensed, does not mean patients *have* to test for the condition.
- 4.4.** The Chair suggested that it would be proper for Authority members to be made aware of exceptional licensing issues following any regulatory decision. Authority members agreed that there should be space at Authority meetings to discuss such issues where they raised wider concerns about the state of the sector, policy issues or the regulatory options open to us.
- 4.5.** The Chief Executive commented that we would get back to the Chair on how to take this forward.

Decision

4.6. Members noted the Committee Chairs’ updates.

5. Performance report

- 5.1.** The Chief Executive commented that the review of the key performance indicators (KPIs) had led to a number of changes. In particular, some KPIs had been expanded, notably the efficiency of the end-to-end inspection and licensing process, which should provide greater transparency of any arising issues.

- 5.2.** The Chief Executive commented that the red indicator on staff turnover remained from previous months. Part of the explanation was pay, where we had received approval from the DHSC and Treasury to award a pay settlement of 2% to all staff under the level of the Senior Management Team (SMT). It was noted that the pay settlement in the Civil Service was less than that awarded to the NHS, and this differential could impact on turnover as many HFEA staff have the skills and experience to work in organisations on the NHS pay scale. In a small organisation like the HFEA, the lack of progression in the civil service pay scale meant that promotion elsewhere was the main way staff could increase their pay.
- 5.3.** The Chief Executive expressed his gratitude to staff who have to carry the workload when other staff members leave the HFEA. Members were advised that the previous staff survey had indicated that majority of staff liked working for the HFEA but pay rates remained a problem.
- 5.4.** On PRISM, it was noted that all but three clinics are now submitting their data through PRISM.
- 5.5.** We were also building our expertise in-house to support PRISM long term. We now need to ensure that the legacy data that was brought over to PRISM undergoes a validation exercise.
- 5.6.** The Chair commented that the Authority recognised the issues of pay and its effect on staff turnover.

Strategy and Corporate Affairs

- 5.7.** The Director of Strategy and Corporate Affairs presented this item. She commented that the publications planned for later this year were firstly, the annual State of the sector report, that looked at the sector from a compliance angle, noting trends in compliance, incidents and complaints. Later in the year, a report on donation would be published to provide information on who is having donor treatment, numbers of children born through donation and other relevant data in advance of opening the register (OTR) in 2023.
- 5.8.** It was noted that the next persons responsible (PR) event will be held in-person in our Stratford office on 31 October 2022 and will focus on the recent change to the law on the storage of gametes and embryos as well as preparing for 2023.
- 5.9.** The National Institute for Health and Care Excellence (NICE) were consulting on their review of fertility guidelines and we will respond. Members requested that the HFEA response be shared with them.

Compliance and Information

- 5.10.** The Director of Compliance and Information presented to the Authority.
- 5.11.** On Compliance, it was noted that we have a busy inspection schedule with a mix of renewals and interims alongside extra visits where there are concerns.
- 5.12.** On IT, the current focus was on infrastructure security improvements. An Infrastructure penetration test was scheduled for week commencing 12 September 2022.
- 5.13.** On the data security and protection toolkit (DSPT), Members were advised that we had started preparing for next year's submission. However, NHS Digital have raised the bar this year and moved Arms-length bodies (ALBs) to category 1, which is the same level as NHS Trusts. This meant that there are now 113 mandatory items (out of 133), a 28% increase from 2021/22 (where there were 88 mandatory items). The Director of Compliance and Information commented that this was putting further pressure on the team and our resources.

- 5.14.** On OTR, the waiting list did not change in terms of absolute numbers as more applications were received than were closed over the last two months. This was due to staff turnover in the team but we were now recruiting to the vacant positions. On a more positive note, only 7% of applications received in 2021 remained open.
- 5.15.** The Chief Executive commented on the significant increase in the number, scope and requirements of what is now required to meet the DSPT. The Chief Executive also noted that there was an increase in the audit demands that were coming from the central government (rather than the DHSC as our sponsor department), and that this was placing additional pressure on resources.
- 5.16.** As a small organisation we have to prioritise our limited resources on ‘frontline’ activities. The additional requirements to the DSPT and other corporate reporting standards meant that we were in danger of spending more time on such exercises at the expense of carrying out our statutory role as a regulator.
- 5.17.** Members asked if the case of proportionality could be made to the government department responsible for Arms-length bodies (ALBs) and with the sponsor team.
- 5.18.** The Chief Executive responded that we will be taking this forward with our sponsor.
- 5.19.** The Chair stated that this will be kept under review.

Finance and Resources

- 5.20.** The Director of Finance and Resources presented this item. It was reported that the estimated billing of clinics using data from 2020/21 continued whilst we were awaiting all clinics to catch up with their data inputs. This raised the risk of over/under estimation of our income which in turn impacted on expenditure for the remainder of the year.
- 5.21.** It was noted that the auditors were now content and our accounts would be laid before Parliament as soon as possible in October 2022.

Decision

- 5.22.** Members noted the performance report.

6. Implementation of the new gamete and embryo storage rules

- 6.1.** The Regulatory Policy Manager presented this item. Members were advised that the storage changes followed a successful campaign to extend the reproductive choices of patients who previously could only store for a maximum of 10 years unless they were prematurely infertile or at risk of becoming prematurely infertile.
- 6.2.** The key changes were explained including all patients being able to store their gametes or embryos for their own treatment for a maximum of 55 years. However, this could only be done if patients renewed their consent to storage at the first 10-year consent expiry period and at each successive 10-year period. It was explained that this meant there was no longer a requirement for patients to satisfy the premature infertility criterion.
- 6.3.** To enable us to accomplish this piece of work, other work was deprioritised to recognise the urgency and time-dependent nature of the introduction of the new storage regulations. This

impacted on the capacity of the organisation as a dedicated team was put together from across the HFEA with external support and advice was sought from sector and legal professionals.

- 6.4.** It was noted that members of the British Fertility Society (BFS) and the Association of Reproductive and Clinical Scientists (ARCS) provided advice and reviewed the new consent forms and guidance.
- 6.5.** Members were advised that a lot of material was ready before the deadline on 1 July 2022 including:
 - updated consent forms
 - new statutory notices for use when renewing consent and
 - a detailed clinic practical guide.
- 6.6.** To assist implementation the HFEA also drafted flowcharts for clinics with worked examples as a visual component to aid understanding of how the new legislation applied to new patients and those with gametes in storage pre-1 July 2022.
- 6.7.** It was noted that feedback from clinics often focussed on the limited time available to prepare given the legal implementation date. The HFEA also engaged in a number of ways with patients.
- 6.8.** Members were advised that there were a number of risks, including patients not knowing that they needed to re-consent as they might not be aware of the change in law. Weekly drop-in sessions for clinic staff were held throughout July and August which were well attended.
- 6.9.** Looking ahead, Members were informed that we would publish an updated frequently asked questions (FAQs) in the autumn of 2022 and update the Code of Practice in 2023 to reflect the storage changes.
- 6.10.** Members commented they were they were happy with the close engagement with clinics, and given the anxiety expressed by many clinics the outcomes were reassuring. Members also asked if the feedback included comments from patient groups.
- 6.11.** The Director of Strategy and Corporate Affairs responded that we were planning to do further work with patient groups particularly with patients who stored their gametes some years ago. Patient groups had re-purposed our information on their social media platforms, which was helpful.
- 6.12.** Members welcomed the proportionate approach adopted and commented that they were looking forward to further discussions at the persons responsible (PR) event.
- 6.13.** Some members wanted to know whose responsibility it was to remind patients about the need to renew consent every 10-years. The Director of Compliance and Information responded that the renewal period is now a defined legal process and clinics have a legal responsibility to get in touch with patients, which includes writing to the patients before the start of the renewal period and at consent expiry. Statutory notices also have to be issued to patients at defined time points in the renewal process.
- 6.14.** The DHSC representative thanked the HFEA for the hard work put in considering the very tight timeframe.
- 6.15.** Members asked about the lessons learned exercise and if it pointed to anything that could have been done differently. The Regulatory Policy Manager responded that a there were few areas we

could have been improved on and the use of external advice was very beneficial. There were staff joining at later times through the project which meant there was a slight overlap but on the whole the project worked well.

- 6.16.** The Director of Strategy and Corporate Affairs commented that because of the tight timeframe we dedicated a number of staff to the project including a Director, Head and other staff. The consequence of this however, was that other work these staff members were involved in had to be de-prioritised or dropped all together.
- 6.17.** A member commented that the resource issue was also felt in clinics and to ensure that it was fully embedded it was suggested that the support from the HFEA should continue.
- 6.18.** The Chair commented that the resource issue was an important one considering the work was not fully completed and thanked everyone for getting us to a good place.

Decision

- 6.19.** Members noted the implementation of the new gamete and embryo storage rules.

7. Update on ethnic diversity in fertility treatment

- 7.1.** The Director of Strategy and Corporate Affairs presented this item. Members were reminded that in March 2021 we published the Ethnic Diversity in fertility treatment 2018 report, which highlighted disparities in access to, and outcomes of, fertility treatment by ethnic groups.
- 7.2.** The key findings from the report were discussed.
- 7.3.** It was noted that there was good engagement from clinic staff. The findings were also discussed with various groups and professional bodies including the Royal College of Obstetricians and Gynaecologists (RCOG), the BFS and Fertility Network.
- 7.4.** A working group of clinic staff met for two workshops to discuss specific topics raised in the report, which were chaired by Jason Kasraie and Tim Child.
- 7.5.** It was noted that this remained an area of huge concern for the Authority, clinics and patients and we needed to look at future work in this area when we considered of our draft 2022/23 business plan at our November Authority meeting.
- 7.6.** The Director of Strategy and Corporate Affairs thanked Anna Coundley, Policy Manager for facilitating the work on the clinic workshops.
- 7.7.** Members congratulated the HFEA for their work highlighting this area and commented that the data would need to be reviewed in future. It was important to ensure consistency on how clinics collect data, use it and ensure that it was in line with recognised ethnic categories.
- 7.8.** Members commented that delayed access to fertility treatment could be due to co-morbidities in women from ethnic backgrounds as those medical issues needed to be handled before these women were referred to fertility clinics. There might also be cultural issues for males to give sperm samples.
- 7.9.** Members commented that we needed to address the disparities working in partnership with other organisations, professional bodies and the DHSC.

- 7.10.** Members suggested that single embryo transfers should be promoted in older woman with co-morbidities and the translating service could be improved on.
- 7.11.** Members advised that ethnic diversity in fertility treatment should be discussed at the PR event in October and that it could also be escalated to the Equalities Minister, as well as working with Fertility Network. This also needs to be reflected in the new HFEA communication strategy.
- 7.12.** Members suggested that other avenues available to reach more black and ethnic groups could be through churches and places of worship. Community leaders could also help raise awareness on these issues.
- 7.13.** The Chair commented that prior to the Covid pandemic there were delays in black and minority ethnic women accessing fertility treatment and post pandemic those delays may have worsened.
- 7.14.** Members commented on the National Sperm Bank in Scotland; setting it up was costly and time consuming but what helped was a lot of support from the Scottish Government. The Director of Strategy and Corporate Affairs responded that we could only facilitate the discussion of a national sperm bank for England but it was not for the regulator to take this on.

Decision

- 7.15.** Members agreed the prioritisation for this work and noted the involvement of Authority members going forward.

8. Modernising Fertility Regulation - update

- 8.1.** The Director of Strategy and Corporate Affairs presented this item with the Public Policy Manager in attendance.
- 8.2.** It was noted that a key HFEA strategic priority was to develop proposals on modernising the law to ensure it remained relevant. Significant work is being conducted on the targeted consultation document that we plan to issue this autumn.
- 8.3.** The aim was to gather professional, key stakeholder patient groups and clinic staff views on our emerging proposals for legislative reform. It was noted that although this was a targeted public consultation it would also be publicly available for anyone to respond to.
- 8.4.** Members were reminded that we were going through several distinct stages and that the last stage would be a report to the DHSC around the turn of the year.
- 8.5.** Members were reminded that there were three key areas that we were focusing on to ensure that patients were at the heart of what we and clinics do. These areas are:
- Patient protection
 - Scientific developments and
 - Consent, data sharing & anonymity.
- 8.6.** The Director of Strategy and Corporate Affairs gave a brief overview of some of the issues in each of these areas that had been outlined in published Legislative Reform Advisory Group (LRAG) papers.
- 8.7.** Members were also reminded that future proofing the Act was important.

- 8.8.** The Chair commented that this discussion was the result of the work done by LRAG and the Board away day discussion. She reiterated that in the autumn we will release a targeted consultation.

Decision

- 8.9.** Members noted the work done to date on modernising fertility regulation.
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9. Any other business

- 9.1.** The Chair reminded members that the PR event was on 31 October 2022 and that it was an in-person event and that she hoped that all PRs will attend.
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Chair's signature

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

Signature

A handwritten signature in black ink that reads "Julia Chain". The signature is written in a cursive, flowing style.

Chair: Julia Chain

Date: 16 November 2022