Minutes of Authority meeting held on 18 May 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		
Agenda item	2		
Meeting date	19 July 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 18 May 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 18 May 2022 held at the HFEA Office, 2nd Floor 2 Redman Place, London E20 1JQ

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

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. The Chair stated that the meeting was audio recorded in line with previous meetings and for transparency reasons, and that the recording would be made available on our website to allow members of the public hear it.

1.2. Members were advised that Catharine Seddon was now on the board of Children and Family Court Advisory and Support Service (Cafcass).

1.3. Declarations of interest were made by:

- Tim Child (PR at a licensed clinic)
- Jason Kasraie (PR at a licensed clinic)
- Geeta Nargund (Clinician at a licensed clinic)
- Alison McTavish (Professional at a licensed clinic).

2. Minutes of the last meeting

2.1. Members agreed that the minutes of the meeting held on 23 March 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 the decision-making committees of the Authority. The Chair commented that she spoke at the British Infertility Counselling Association (BICA) conference last week giving an update on the HFEA's preparation for modernising the Act, including the establishment of the Legal Advisory Reform Group (LRAG). It was noted that the Chair of BICA had joined LRAG. The Chair further commented that even though we did not currently have a counsellor sitting as an Authority member, the involvement of BICA in the work of LRAG was very much valued.

3.2. Regarding filling vacancies to the Scientific and Clinical Advances Advisory Committee (SCAAC), members were advised that following an open process of selection and interviewing, two new members had been appointed.

3.3. The appraisals for longer standing Authority members took place in the last fortnight and the Chair's appraisal will take place next week. Following the Chair's appraisal, objective setting will occur with all Authority members.

3.4. The annual accountability meeting with the Department of Health and Social Care (DHSC) was scheduled for the week commencing 23 May and the Chief Executive had written a letter summarising our work during the past year to the department, which would form part of the discussion at the meeting. It was noted that the letter will be circulated to Authority members.

3.5. The Chair further commented on the induction session for new members that took place recently and that she had joined for part of it. She expressed her thanks to the Chief Executive and the Senior Management Team (SMT) for putting the programme together. Members commented that they felt it was a very good induction and thanked SMT for giving up their time to do this. Members also commented that the training with the Legal Advisor for Licence Committee and Statutory Approvals Committee members was very useful.

3.6. The Chair commented that some members were yet to complete their online cyber security training.

3.7. The Chief Executive provided an update on the key external activities that he has been involved in since the last Authority meeting.

3.8. In response to a question, it was noted that there were no enquiries or updates on the import or export of gametes or any news relating to surrogates from Ukraine.

3.9. In terms of the effects of inflation on staff recruitment, the Chief Executive commented that recruitment was holding up, but some roles were more difficult than others to fill as the labour market remained competitive. He further commented that the longer this current situation continued, the higher the risk of it having an adverse effect on the HFEA.

Standing orders

3.10. The Chief Executive presented the update to Standing Orders to enable the Scientific and Clinical Advances Advisory Committee (SCAAC) to have an additional Authority member to sit on the committee.

3.11. All members voted in favour of the change.

Decision

3.12. Members noted the Chair and Chief Executive reports and that the accountability letter to the department will be circulated to members.

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 on 5 May 2022 and welcomed the new members that had joined the committee.

4.3. The Statutory Approvals Committee (SAC) Chair (Jonathan Herring) commented that they had met three times since the last Authority meeting and that similar to the Licence Committee, there was now a change in membership, and welcomed all the new members.

4.4. The Chair commented that members on SAC operated from a pool and that as long as members could attend six to seven meetings a year the committee's monthly meetings would remain quorate.

Decision

4.5. Members noted the Committee Chairs' updates.

5. Performance report

5.1. The Chief Executive commented that by the next meeting, there will be an updated version of the key performance indicators report, following development work on several indicators.

5.2. Members were advised that performance in March was generally good but that there were four red indicators:

- HR1: Sickness
- HR2: Turnover
- C1: Efficiency of the end-to-end inspection and licensing process
- C3 PGT-M average processing.

5.3. It was noted that the staff sickness indicator had remained red over the last two months, partly as a result of two staff members being on long term sick leave.

5.4. During March, staff turnover remained high. It was noted that an all-staff event was held in May and a third of the staff members were new since the last such opportunity, before the Covid pandemic. The Chief Executive commented that such a level of turnover put a considerable strain on our work and that there was an expectation that this would continue to be a challenge.

5.5. An update was given on the status of PRISM. The Chief Executive stated that progress with PRISM was positive. Members were advised that clinics that were using PRISM directly had an average error rate of less than 1% but those clinics using third party solutions (API) had an average error rate of between 6 to 8%. We therefore needed to work with the latter group to get every clinic up to the same level of performance on error rates. There were six clinics left to deploy and this should happen over the next few weeks.

5.6. Members asked about the PGT-M average processing time and where the bottlenecks were. The Chief Executive responded that there was some variability in the factors causing delays from month to month. Part of the issue was the unpredictability of when applications would be made, and in what numbers; and securing a peer reviewer who could perform their part of the process in time for an application to progress to a monthly meeting meant that some items would take longer to reach the committee. On the part of members, it was felt that attending SAC meetings once a month was all we could ask members to accommodate. Lastly, it was difficult to predict how complicated an application will be until we received it.

5.7. Members commented that we needed to become more pragmatic about peer reviewers, and that from the patient's point of view the wait was probably twice as long, and therefore turnaround time needed to be improved where possible.

5.8. The SAC Chair also agreed that it was difficult to predict the number and end to end length of applications since all agendas were application led. The committee often considered similar conditions alongside the condition applied for, and it was suggested that one possibility might be to consider whether this was always the right course of action.

5.9. Regarding the key performance indicator scorecard, the Chief Executive commented that the new report format would address some of the concerns that members might have and provide better insight into the data.

5.10. Members asked what was being done about the PRISM outliers. The Chief Executive responded that clinics that had PRISM could see their input errors immediately, since it was visible to them on their systems. With API clinics, the errors were not so apparent to users, however, it is possible for API users to log on to PRISM to see errors.

5.11. The Chief Executive commented that we were trying to build a culture among clinics of getting it right first time and that training would continue to be rolled out for PRISM and API users so they can deliver the best care for patients and make accurate data returns to the HFEA.

5.12. Members asked if the Authority could work with third party suppliers (APIs) to eliminate errors. The Chief Executive responded that these were commercial companies that we do not regulate. We engaged with them on developing their API solution for PRISM but they were now responsible for ensuring their customer clinics was able to provide accurate data to the register.

5.13. On staff turnover, members asked what were the common themes from exit interviews, so that lessons learned could be implemented to retain staff. The Chief Executive responded that the general theme was that in a small organisation like the HFEA there were few opportunities for promotion and that in some roles, public sector salaries were not competitive compared to the private sector. The Chief Executive commented that unfortunately there was little or nothing the HFEA could do about either.

Strategy and Corporate Affairs

5.14. The Director of Strategy and Corporate Affairs presented this item. She informed members that the Fertility Show took place in London as a face-to-face event for patients to meet with clinics and this year the HFEA took the decision not to have a stand. However, various staff and Authority members had taken part in sessions on specific topics for patients.

5.15. It was noted that the Director of Strategy and Corporate Affairs was in conversation with the British Fertility Society about further follow-on actions from the ethnic diversity in fertility treatment report. A second clinic workshop following the actions in this report would be held in June.

5.16. The report on the HFEA patient survey has been published in April and was covered in the media and social media. Our report on Covid-19 and fertility treatment in 2020 had been published in May and also received widespread coverage.

5.17. The Planning and Governance team were working on an updated set of Key Performance Indicators for the report to be presented at the July Authority.

5.18. SCAAC's next meeting would be in June and they will be looking at whether the evidence base used to review treatment add-ons should be expanded. A patient and clinic staff survey on the HFEA add-ons information was currently being undertaken and we had received a very good response. The results of the survey on what information we presented on the HFEA website on add-ons, as well as the SCAAC recommendation on the evidence base would be brought back to Authority for decision in due course.

Compliance and Information

5.19. The Director of Compliance and Information presented to the Authority. There was good progress being made against the backlog on the Opening the Register (OTR) service. The team closed 147 cases in March and received 70. In April, 67 cases were closed and 58 were received, the lower number processed was due to staff annual leave and other project work. In May, to date they had closed 62 cases with another 72 ready for second checking and 97 were being worked on. In this calendar year the team had responded to 403 requests for information.

5.20. Members were advised that they had received positive feedback from service users and the Director thanked the OTR team.

5.21. Members were advised that in April, four planned and one additional inspections were carried out. In May there are eight planned and four additional inspections. There are 70 planned inspections scheduled for the remaining months of this year.

5.22. The new Head of IT is now in post with a handover period with the current Head of IT who is retiring at the end of May. Members were advised that much focus was on cyber security in response to the increased global threat. A penetration test has been carried out on PRISM and the Register and a further test is planned for IT infrastructure in July. Other control measures have been put in place and we will continue to monitor our systems.

5.23. The Chair commented that she was pleased to see that the OTR backlog was being cleared as this would put us in good stead for 2023.

Finance and Resources

5.24. The Director of Finance and Resources presented this item. Members were advised that the figures were not actuals as the billing of clinics was based upon assumptions from the 2019/2020 figures. It was noted that until a full reconciliation was done, we would not know the actual income. It was further noted that the clinics that were not yet on PRISM would continue to have estimates which would be reconciled once they were fully reporting through PRISM.

5.25. For the underspend, that will be reconciled once the proper data has been inputted.

5.26. Members were advised that the budget for this financial year had been delegated and that the Chief Executive had signed it off.

5.27. Members asked about our policy on reserves. The Director of Finance and Resources responded that we could only spend money that we had generated in that financial year.

Decision

5.28. Members noted the performance report.

6. Covid-19 update

6.1. The Director of Strategy and Corporate Affairs commented that the decision regarding whether to revoke GD0014 v2 was deferred from the last meeting. Members were advised that to help understand the impact of Covid-19 on fertility treatment, a report was published on 17 May 2022. The Authority noted the hard work from clinic staff to ensure safe services could resume during the pandemic.

6.2. Members were advised that from March 2020 until April 2022 information for patients and clinic staff related to Covid-19 was prioritised on our website. Going forward these pages will no longer be updated but the information will be retained on the website for reference and will be revised if the pandemic situation changes in the future.

6.3. At the March 2022 Authority meeting, members considered whether it was the right time to revoke GD0014v2 as legal restrictions had now eased across the UK and it was good regulatory practice to remove unnecessary rules.

6.4. In response to a question the Director of Compliance and Information reassured members that there was flexibility to quickly reintroduce GD0014 v2 should a significant wave occur in the future.

6.5. The Chair commented that there was anecdotal evidence that many patients suffered delays in accessing tests or procedures before having fertility treatment due to the effect of the pandemic and asked the professional members what their experiences were.

6.6. Members commented that delays were seen in services (both in women's and men's services) and this adversely affected patients, in particular older women. Some members commented that in terms of diagnostics, they were no longer seeing any delays in semen analysis although in some areas such as general gynaecology there were still delays.

6.7. Members asked how staff planned on using and learning from the report, especially in the primary care setting and in communities where they already were experiencing delays in accessing services.

6.8. The Director of Strategy and Corporate Affairs commented that GPs could be both an enabler and a blocker to accessing treatment and that there was anecdotal evidence that some patients from Black and Minority Ethnic communities sometimes delayed accessing GP services. It was noted that there were originally plans for working with GPs to be part of the business plan but owing to pressures on primary care due to Covid it had been necessary to delay this work.

6.9. In response to a question, it was noted that if there was a regional lockdown, it may not be necessary to reintroduce GD0014 v2 since clinics had developed their protocols for the first wave which they could reintroduce.

6.10. Members commented that the vaccination programme in the UK had helped us in terms of Covid and therefore, while caution was appropriate, we did not need to be overcautious as we were not in the same place as some other countries. It was also noted that in the National Health Service (NHS) they planned six months ahead and that learning had occurred through working and living with Covid.

6.11. A member asked if the Authority received feedback from patients about their experience of announcements from the HFEA and agreed to discuss with the Director of Strategy and Corporate Affairs outside of the meeting and share the feedback that they had received in their organisation.

6.12. Some members commented that they were comfortable with the way the Authority navigated the Covid-19 situation and asked about the psychological impact and the live birth rate as there was some evidence that this had fallen globally over the last two years.

6.13. The Director of Compliance and Information responded that there was no data that we could use to verify this, because not all clinics have caught up with data submission following PRISM launch. At the moment there was therefore no way of measuring the effects of the pandemic on live births. This would be updated in the future fertility trends data report in 2023.

6.14. Members commented that there was huge demand for translation services in some clinics and asked if the HFEA experienced the same. The Director of Strategy and Corporate Affairs responded that we had very few, if any, direct requests to translate our information.

6.15. The Chair commented that we would continue to keep an eye on this situation and that once PRISM was fully implemented across all the clinics, we should analyse the data we held.

Decision

6.16. Members agreed to revoke GD 0014v2 since almost all legal restrictions had been lifted by the Westminster and devolved governments.

6.17. Members noted the Covid-19 and fertility treatment report published in May 2022.

6.18. Members noted that patient and professional information relating to Covid-19 would no longer be updated on our website unless the situation with the pandemic changed again.

6.19. Members noted the preparation that had taken place as required for the Covid-19 Public Inquiry.

7. Gamete and embryo storage

7.1. The Head of Policy presented this item. The current legal regime was outlined and members were advised that following a consultation on gamete and embryo storage, the Government introduced changes to the HFE Act 1990 in the Health and Care Act 2022.

7.2. The key storage changes were discussed. Members were told that:

- patients wishing to store gametes or embryos for their own treatment would be able to store for up to a maximum of 55 years, provided that they renewed their consent every 10 years
- Donors would be able to store for up to 55 years and did not need to renew their consent
- Transitional provisions would enable patients who already had gametes or embryos in storage to benefit from the extended storage period provided certain steps were taken within prescribed timeframes

- The 2009 regulations were being revoked. All patients would need to move to the new regime. Patients using extended storage for premature infertility would need to be contacted by their clinic.
- Patients could consent to the use and storage of their gametes or embryos in the event of their death for 10 years from their date of death, or 10 years from when they were certified as having lost capacity.

7.3. The risks associated with these changes were also explained to members, which included:

- The complexity of the new rules
- Provisions on posthumous use would negatively impact some patients
- Significant changes required clinic staff to understand them, which would take time
- There was a short time frame for implementation.

7.4. Members were advised that the starting date for the new law was 1 July 2022 and the transitional period would start on that date and end on 30 June 2024.

7.5. The Head of Policy went on to explain the HFEA's next steps which were:

- To publish the new Clinic guide, along with new and revised consent forms, (including renewal of consent forms) and the revised General Directions on the Clinic Portal by the end of May/early June.
- The new standard licence conditions and General Directions which would come into force on 1 July 2022 would be signed off by the Chair who had delegated authority from the Board.
- There would be a strikethrough of out-of-date Code of Practice guidance on storage and clinics would be directed to the Clinic Portal storage information, with an update to the Code of Practice to follow in due course.
- To use the transitional period to continue to work with clinics to develop further guidance and training material, including hosting a number of training events and webinars to help clinics understand and implement the new changes.

7.6. In response to a question from members, it was noted that the Chair of the Association of Reproductive and Clinical Scientists (ARCS) was engaged on the storage changes. Members further commented that ARCS should have a role to play in providing best practice guidelines on contacting patients for renewal of consent.

7.7. Regarding the website, members requested that the website should be updated and that there should be explanations on cost.

7.8. On the 10-year renewal of consent, members asked who had the responsibility for keeping patient contact details up to date – the clinic or the patient. Staff explained that there was no legal duty on either and so there would therefore need to be co-operation between both parties.

7.9. Also, the guidance to clinics on the renewal of the consent process would include an explanation of the actions they needed to take. The Head of Legal explained that pro-forma notices were being developed to reduce the burden on clinics. Members commented that templates will be very useful as the language used in the regulations says 'reasonable steps' should be taken, which could have a number of definitions.

7.10. The Director of Compliance and Information commented that short videos or other tools would be put together as part of the training for clinic staff.

7.11. Members commented that GPs usually had up to date addresses for patients, therefore clinics should be encouraged to work with GP surgeries to contact patients who might inadvertently not update their addresses.

7.12. In response to a question, the Chief Executive clarified that our role as the regulator was to provide all the necessary advice and guidance to clinics to support them in managing the changes, but that ultimately it is the clinics' responsibility to ensure that they comply with the new storage rules and that they obtain the necessary consents from their patients.

7.13. Members commented that careful communication with patient groups and patients should also be considered.

7.14. The Director of Strategy and Corporate Affairs stated that there was an agenda item on the stakeholder group meetings later this month and in June to discuss the storage changes.

7.15. The Chair thanked the team for all the work they were doing.

Decision

7.16. Members noted the gamete and embryo storage changes and the next steps for the HFEA.

8. Modernising Fertility Regulation - update

8.1. The Director of Strategy and Corporate Affairs presented this item. Members were reminded that the aim of this work was to deliver an outline proposal on the modernisation of the HFE Act to the DHSC at around the end of the year.

8.2. Members were advised that a group had been established to advise the Authority on some of the issues. The Legislative Reform Advisory Group would be meeting periodically and the papers would be circulated to members and posted on the HFEA website.

8.3. It was noted that all suggestions that came out of the group would be shared with the Authority.

8.4. Members commented that it was interesting to see views on the power to levy financial penalties and commented that they were in support of that area being pursued.

8.5. A question was raised about whether the roles and responsibilities of Persons Responsible (PRs) and Licence Holders should be reviewed, with a view to incorporating wider board responsibility for the way clinics function. In response, Members commented that PRs set the culture in clinics and there may be an issue if more than one person held this responsibility, since it might render the role less effective. It was noted that the idea of having a nominated deputy for a PR could perhaps be explored further but in terms of the governance structure and ensuring compliance, licence holders and PRs should be the ones taking on that responsibility.

8.6. The Director of Strategy and Corporate Affairs commented that some of the points raised by members were brought up during the deliberations at the last LRAG meeting and that the responses from LRAG will be shared with the Authority.

8.7. It was noted that in proposing ways of modernising the Act, we were hoping to have powers which would give us greater flexibility to improve patient protection.

8.8. The Chair commented that papers would come to the Authority in early autumn and members would have the opportunity to get together and have a detailed discussion at that stage.

Decision

8.9. Members noted the issues raised and the next steps in relation to modernising the Act.

8.10. Members were advised that LRAG minutes will be sent to them.

9. Any other business

9.1. There was no other business.

Chair's signature

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

Signature

Chair: Julia Chain

Date: 19 July 2022