Minutes of Authority meeting 23 September 2021

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	24 November 2021		
Author	Debbie Okutubo, Governance Manager		
Output:			
For information or decision?	For decision		
Recommendation	Members are asked to confirm the minutes of the Authority meeting held on 23 September 2021		
Resource implications			
Implementation date			
Communication(s)			
Organisational risk	☒ Low	☐ Medium	☐ High
Annexes			

Minutes of the Authority meeting on 23 September 2021 held at ETC.venues, Chancery Lane WC2A 1HL and via teleconference

	In person	Via teleconference
Members present	Julia Chain, Chair Margaret Gilmore Gudrun Moore Alison Marsden Tim Child Catharine Seddon Ermal Kirby Yacoub Khalaf	Anita Bharucha Jonathan Herring Emma Cave Ruth Wilde Jason Kasraie Anne Lampe
Apologies	None	
Observers	Csenge Gal (Department of Health and Social Care - DHSC)	Steve Pugh- DHSC Amy Parsons - DHSC
Staff in attendance	Peter Thompson Clare Ettinghausen Rachel Cutting Paula Robinson Debbie Okutubo	Richard Sydee Amanda Evans

Members

There were 14 members at the meeting – ten lay members and four professional members.

1. Welcome and declarations of interest

1.1. The Chair opened the meeting by welcoming Authority members, observers and staff present both in person and online.

1.2. The Chair stated that the meeting was being 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)
- 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 7 July 2021 were an accurate record and could be signed by the Chair.

3. Chair and Chief Executive's report

3.1. The Chair had continued to engage with the decision-making functions of the Authority and with key external stakeholders, as covid restrictions allowed.

3.2. The Chair stated that she would be carrying out more informal visits to licensed centres across the UK.

3.3. The Chair noted that Lord Bethell had moved on as our minister and we were waiting to find out who would have the HFEA portfolio within the new ministerial team.

3.4. The Chair also commented on the government's plans to extend the time that frozen eggs, sperm and embryos could be stored to 55 years, which would bring the law in line with advances in science, changes to modern society and individual reproductive choices. The HFEA were supportive of these changes.

3.5. The Chief Executive commented that he continued to support the Chair and took part in a number of external facing activities.

3.6. The Chief Executive provided an update on our new data submission system PRISM. It was noted that as agreed with Audit and Governance Committee (AGC), the old data submission system EDI was switched off on Friday 27 August. A detailed cutover exercise was undertaken and was tested both internally and with selected clinics.

3.7. PRISM was launched on 14 September. As at 22 September, 29 clinics had logged into PRISM and conducted 2,184 units of activity, including adding new registrations, cycles, movements and amending legacy data.

3.8. Initial clinic feedback has been generally good and we were responding to clinic queries quickly.

3.9. Members were advised that PRISM was currently only available to those clinics that submitted data directly to the HFEA through EDI.

3.10. The next stage of the rollout was to ensure that the majority of licenced clinics that used a third party electronic patient record system (EPRS) could link automatically to PRISM. There are four current EPRS suppliers who needed to migrate to PRISM.

3.11. It was noted that Mellowood (IDEAS system) were the largest supplier with 40 clinics and that the expectation was for them to start deployment in October and complete by November.

3.12. Members were informed that the expectation was for all EPRS suppliers to have completed deployment by 10 December 2021 - 3 months after go-live.

3.13. The General Direction that sets out the rules governing data submission had been relaxed until that date.

3.14. The Chair thanked the AGC, the Chief Executive and the teams both past and present that had worked so hard to achieve the launch of PRISM.

3.15. Members commended the launch of PRISM and asked how long it would take before the system was working perfectly. The Chief Executive responded that a plan was being put in place but the expectation was that the links between the new Register and PRISM and most other HFEA systems should be in place by the end of this business year.

Decision

3.16. Members noted the Chair and Chief Executive's report.

4. Committee reports

Statutory Approvals Committee (SAC)

4.1. The SAC Chair (Margaret Gilmore) presented this item to the Authority. It was noted that a number of PGT-M applications and Mitochondrial donation applications were granted in July and August when the Committee met.

4.2. An additional meeting was held in August to manage additional applications for Special Directions that would otherwise have been delayed. There was currently a higher number of Special Direction applications, possibly because of Covid-19 travel restrictions.

4.3. The SAC Chair noted that this was Emma Cave's last meeting and thanked her for her work and her inspiring contribution to the Committee to date.

Licence Committee (LC)

4.4. The LC Chair (Jonathan Herring) commented that two meetings had been held and both had to deal with complex issues.

Decision

4.5. Members noted the Committee Chairs' reports.

5. Performance report

5.1. The Chief Executive commented that there were three red indicators on the performance scorecard presented. Staff turnover was at 16% (just outside tolerance) but this was expected as Covid-19 restrictions were lifted and the public sector jobs market reopened.

5.2. It was also noted that we were getting fewer applicants to advertised positions compared to previous 12 months. It was not clear why this was the case but one likely factor was the civil service pay freeze. This would be kept on the agenda of the Senior Management Team (SMT).

5.3. The return to the new office meant that there have been discussions with staff about how we plan to use the office going forward.

5.4. Members asked if there was any scope to think creatively when it comes to salary increases, for instance flexibility around additional annual leave or training incentives. The Chief Executive responded that there was limited flexibility, but that we would continue to explore what was possible within the rules.

5.5. In response to a question about staff finding it worthwhile returning to the office, the Chief Executive commented that there was a discussion at the Corporate Management Group (CMG) about how often some meetings should be held in person, for instance team meetings. Guidance was being drawn up and we wanted to ensure that there was consistency across teams. This would remain an ongoing discussion in CMG.

Strategy and corporate affairs

5.6. The Director of Strategy and Corporate Affairs gave a summary of her area of work.

5.7. Members were advised that a new national patient survey would take place later this year. This would follow up on the first patient survey that the HFEA had undertaken in 2018. The follow up survey would enable some benchmarking against the earlier survey and importantly, help us to explore some of the issues that resulted from the Ethnic Diversity in Fertility treatment report from earlier in 2021.

5.8. The Patient Engagement Forum was launched with a soft target of 100 patients to enable greater patient involvement in our work. There had been over 160 applications, but we may need to do further work to ensure underrepresented groups were involved.

5.9. A formal in-person event for the 30th anniversary of the HFEA would not be held during 2021 because of the impact of Covid, but we would continue with our guest blogs on potential changes to legislation and the Chair would have two opportunities to set out the case for reform of the HFE Act later this year.

5.10. Members were advised that we would work with the DHSC as and when legislation to change the storage limits for eggs, sperm and embryos was introduced. This was likely to impact on other planned work as we will need to prioritise work of storage to ensure we give timely and effective guidance to clinics and patients.

5.11. In reporting back on the actions in the Ethnic Diversity in Fertility Treatment report, it was noted that progress was being made in a number of areas, for example, in understanding more about patient experience through the patient survey and follow up work with the new patient engagement forum; in working with some volunteers from clinics to look at the issues from the clinic perspective. We presented the findings of the report to the Royal College of Obstetrics and Gynaecology (RCOG) Race Equality Taskforce together with `Dr Raj Mathur, Chair of the British Fertility Society; the Chief Executive also spoke at the Primary Care Women's Health Forum annual conference to highlight our findings.

5.12. Following the launch of PRISM and some staff changes, a decision had been made to pause new applications to the Register Research Panel until we were able to access the data in the new Register. We would continue to support researchers interested in applying in future and would work to provide data to projects that had already been approved. The anonymised register had recently been updated on our website which would also be useful to researchers until we are able to provide data sets again next year.

5.13. In response to a question about the patient survey it was noted that we would not be using an external company and that the survey would be done in-house as we have the required tools. The survey would be publicised through social media and existing stakeholders.

5.14. The Chair commented that it was good to see patients wanting to engage with us through the patient engagement forum.

Compliance and information

5.15. The Director of Compliance and Information presented her area of work. She stated that one of the red indicators on the performance scorecard related to an increase in register errors. In the lead up to PRISM go live there was an increase in the submission of forms in preparation for EDI being switched off. In this period seven clinics had increased errors in the way they were registering patients. The Head of Information investigated this further and staffing issues seem to be a contributing factor to the increase in errors in the individual clinics. The Head of Information has worked with the individual clinics to correct the errors and ensure future errors are reduced. It was noted that PRISM flags errors up immediately on the users' home screen making it easier for centres to deal with errors immediately.

5.16. Regarding recruitments, the Chief Technical Officer position had not attracted suitable applicants. The interim plan therefore was for our Systems Manager to become the interim Head of IT. The vacant systems manager post is currently being advertised. This interim solution allows time to determine the IT needs of the organisation and put in place a workable structure in the future.

5.17. As previously reported, following suspension of the Opening the Register (OTR) service due to the Covid-19 pandemic there had been an increase in the number of applications, which led to substantial waiting times for applicants to receive information. To help reduce waiting times, two new staff members had been recruited on fixed term contracts until March 2022. Training is ongoing and from next month we should start seeing a decrease in the waiting list. Longer term, we intend to look at the service as a whole in preparation for 2023, which would include the application process and IT system.

5.18. The Chair remarked that the challenge in 2023 would be considerable and asked that the OTR service be a regular feature in reports to the Authority, especially in light of the backlog.

5.19. A Member commented that the OTR service was important and so was turnover of staff, but the end-to-end inspection and licensing process also had a red indicator and reasons for the delay needed to be explored.

5.20. The Chief Executive responded that we would be looking at the key performance indicators (KPIs) generally and we would bear this in mind.

Finance and Resources

5.21. The Director of Finance and Resources informed members that there was an underspend in some areas of the business. This was however still an interim position as we were yet to reach the full year forecast.

5.22. Members were advised that there was higher than planned activity and should the current trend in treatment activity continue, we could expect to exceed our income forecast by around 4%.

Decision

5.23. Members noted the performance reports.

6. Covid update

6.1. The Director of Compliance and Information presented this item to the Authority.

6.2. It was noted that there were no reported treatment delays relating to Covid-19 restrictions in licensed centres. However, in the referral pathways there were reported delays possibly due to delays in patients accessing surgery in secondary care prior to referral for fertility treatment.

6.3. Regarding the shortage of blood tubes, guidance has been issued by NHS England which states that diagnostic blood tests for fertility patients in primary care should be delayed in patients under the age of 35 where there is no known cause of infertility. There have been no issues reported from licenced centres.

6.4. To ease any potential blood tube shortages we have issued a communication to the sector that with regard to viral screening bloods, centres are allowed to risk assess individual patients if the initial treatment commenced after the 3 month window for screening. This would prevent repeat blood tests having to be taken.

6.5. Members asked about the shortage of carbon dioxide (CO2) and the possible impact on clinics and patient care. The Director of Compliance and Information responded that a major supplier had, in correspondence to the Chief Inspector, stated that CO2 was being prioritised for health care purposes. We presume that this is not an issue for the fertility sector as we have not received any communications from the sector on this; however, we would continue to keep this on our radar.

Decision

6.6. Members noted the Covid-19 update.

7. Developing the new approach to Inspection

7.1. The Director of Compliance and Information presented this item. Members were reminded that in response to the Covid-19 pandemic, inspections were suspended between March and November 2020. During that time the inspections methodology was updated and introduced post November 2020.

7.2. To assess the robustness of the process, the new inspection methodology was audited by our internal auditors, the Government Internal Audit Agency (GIAA). They gave our updated approach to inspections a 'substantial' rating (the highest available) and recommended that we should conduct a retrospective evaluation exercise with both internal and external users and conduct in time an assessment of cost savings.

7.3. Members congratulated the team on the 'substantial' rating and asked if the recommendations from the GIAA report could be adapted as a lessons learned tool across other business areas. The Chief Executive agreed to look into this.

7.4. Members also asked if Inspectors had shown any reluctance in attending onsite visits and whether all centres would now be visited within the 2 year legal requirement period.

7.5. The Director of Compliance and Information responded that we currently have the ability to extend licences by a year and have taken a risk-based approach. The majority of clinics would have an inspection within two years. In terms of workload, it was noted that it was being shared evenly and we had two new inspectors who were doing well with their training. We could also now use external inspectors should the need arise.

7.6. In response to a question, it was noted that unannounced inspections would be reintroduced when we were on the other side of the pandemic. At present, we are using the new methodology for the renewal inspections and would consider how this could be incorporated into interim inspections in time.

7.7. Members asked if persons responsible (PRs) were engaging in a timely manner. The Director of Compliance and Information responded that majority of PRs were, and that there was a system in place to chase twice and then a full inspection takes place if we still did not get a response.

7.8. Regarding patient feedback, Members asked how patient feedback could be gained by inspectors. The Director of Compliance and Information responded that we continue to encourage more feedback from patients and the compliance and communications team were working on this.

Decision

7.9. Members endorsed the recommendations and noted that there was continued use of the desk based analysis (DBA) and further refined inspection methodology. Also, that the GIAA actions had been completed.

8. Licence fee proposals 2022/23

8.1. The Director of Finance and Resources presented this item to the Authority. Members were advised that we had not increased our licence fees since 2016 and that we had been able to meet our statutory duties through internal savings and the growth in the number of IVF cycles undertaken each year. It was reiterated that the HFEA did not charge fees to patients.

8.2. Members were, however, advised that we were facing a number of additional demands this financial year which would require additional resources and that those demands were likely to continue.

8.3. The proposal was to increase the licence fee for an IVF cycle by £5. It was noted that the argument for any fee increase was complicated because presently there was higher treatment activity in clinics which should this become the trend, would generate additional funds similar to what could be realised through the proposed £5 fee increase.

8.4. Members were reminded that the HFEA continued to hold significant cash reserves and that government accounting rules prevented us from accessing these reserves without the approval of the DHSC.

8.5. Members asked how the current rate of £80 per IVF cycle treatment was arrived at.

8.6. The Director of Finance and Resources commented that like other regulators we were required by HM Treasury to recover the cost of regulation from the people we regulate. Under the current fee regime, the more treatments carried out by clinics the higher the fees income we receive. This reflected the increased cost of regulation.

8.7. Members commented that some clinics may choose to pass on any increase in fees to patients and asked what benefits could patients expect in return. Also, should it be the case that the increased revenue led to extra cash reserves which we would not be able to spend without permission, then it might not be worth raising fees.

8.8. The Director of Finance and Resources responded that the rules that govern public sector finance mean that we can only spend what is in our budget and that the licence fee meant that we were duty bound to spend it on patients.

8.9. The Chief Executive commented that in the longer term we would need to make a structural change to the fee regime.

8.10. Members commented that they agreed that we need more resources, however some thought that the rationale presented in the annex for the £5 increase needed more detailed work in light of the volatility of the operating income.

8.11. Members commented that the SMT should ask the DHSC for permission to gain access to our reserves and if the response remained no, we could then say to patients that we tried our best to avoid a fee increase but government rules did not allow for this.

8.12. Members suggested that there should be a breakdown on how the money was used.

8.13. Some members also commented that an increase of £5 seemed to be reasonable and appropriate and that we should therefore opt for a dual approach asking the DHSC and HM Treasury either to increase our revenue to cover our increasing costs, or to gain access to the reserves for the same purpose.

8.14. Members asked if we could spread the increase gradually over a three-year period rather than the increase of £5 all at once.

8.15. The Director of Finance and Resources commented that we would go back and ask to gain access to the reserves but in the past when we had asked, the answer had always been no.

8.16. The Chair commented that we needed more resources and that we were a good regulator and wanted the flexibility that the extra funds would give us. Therefore, if we did not get permission to use our reserves, a modest increase to our fees would be proportionate, so a dual approach was our best way forward.

Decision

8.17. Members agreed that a dual approach should be explored with the DHSC and HM Treasury.

8.18. The Director of Finance and Resource confirmed that the proposals would be worked up and brought back to the November Authority meeting.

9. Multiple births

9.1. The Director of Strategy and Corporate Affairs and the Research Manager presented this item.

9.2. Members were advised that the combined efforts of the HFEA and the sector had led to a significant reduction in the multiple birth rate in the UK. This had been achieved through the successful implementation of the multiple birth rate policy, beginning with the 'One at a Time' campaign to change the practice of multiple embryo transfer to a single embryo transfer where possible.

9.3. Most clinics had reached the 10% multiple birth rate target whilst maintaining or increasing their live birth rate.

9.4. Members were reminded that multiple births remained a health risk for patients and babies and the reduction in multiple births from IVF should be viewed a public policy success not only in limiting the risk to patients and babies, but also in potential savings to the NHS.

9.5. The current target of 10% had been in place since 2012 and was achieved for the first time in 2017. Since then, the national average had fallen further, to just 6% in 2019.

9.6. Members were informed that the continued decline in the multiple birth rate had not had a negative effect on the birth rate which continued to increase.

9.7. Looking below the national average, it was noted that in 2019 the 38-42 years age group had the highest proportion of multiple births. Between 2014-18, black patients experienced higher than average multiple births as they had the highest rate of multiple embryo transfer (46% of cycles) over that period.

9.8. One of the professional members commented that in the general population, naturally conceived multiple births (1%) had a higher chance of being non-identical, whereas IVF multiple births tended

to be identical. Only 0.3-0.4% of all naturally conceived births were identical, which is a larger differential.

9.9. A member suggested that younger private patients were unlikely to have had a number of previous NHS funded cycles and this might be why they would be more likely to have more than one embryo transferred. Though not presented, this data had also been considered and had a similar pattern.

9.10. Members were informed that HFEA inspectors actively engaged with clinics who had non-compliances with multiple births, but we were limited in our powers to force compliance. In 2011, the HFEA introduced a licence condition on multiple births, which was later withdrawn following legal challenge.

9.11. Nonetheless, it remained a requirement for clinics to have a multiple births minimisation strategy through General Direction 0003 and guidance in our Code of Practice (December 2019). We would therefore continue to target clinics that were not adhering to their own minimisation strategy.

9.12. It was suggested that as there was geographical diversity in funding for fertility treatment, we ought to look at areas where there is little to no NHS funding and whether higher rates of multiple embryo transfers were occurring in those areas.

9.13. Members commented that no one size fitted all, and that we needed to avoid being too prescriptive. Clinics that were outliers would need to be looked at.

9.14. Following further discussion on the reported four clinics that were outliers, members suggested that they be asked why this was the case.

9.15. In terms of international comparisons, it was noted that countries like Japan had a lower multiple birth rate. Some members commented that while we needed to be mindful of what was happening in the world, we also should remember that the culture in each country was different.

9.16. Some members felt that continuing with the 10% target was reasonable in order not to risk patients' success rates.

9.17. The Chair commented that the discussion should be opened with stakeholders and clinics regarding the 10% target and that this be kept under review. Also, to ensure that we do not become complacent, work should be done with looking at the outcomes of fresh and frozen embryo transfers as we still do not know the tipping point.

9.18. This also meant that the General Directions and Code of Practice guidance and consideration of other regulatory levels would continue to be looked at and kept under review.

9.19. Some members suggested that the discussion regarding the review of the 10% target with stakeholders and clinics should be time limited and further suggested that we should publish a version of the data we hold to focus that discussion.

9.20. The Chair stated that this item should be brought back to a future Authority meeting.

9.21. Members commented that the disparity especially in black patients could be because they tended to start fertility treatment later which might explain why they tend to have multiple embryo transfers. This therefore needed to be borne in mind during discussions.

9.22. It was noted that we it may not be appropriate to have different multiple birth strategies for different ethnic groups but clinics should be mindful of the data we have presented on a higher multiple birth rate in Black patients when reviewing their multiple birth strategies.

9.23. The Chair thanked everyone involved in the Intelligence team in analysing and presenting the data.

Decision

9.24. Members agreed

- to maintain the 10% multiple births target for now and continue to monitor on inspection;
- to encourage clinics to be mindful of their multiple birth minimisation strategy in relation to patients from ethnic groups;
- a report should be published outlining the data presented to the Authority to stimulate further discussion and following that;
- discussions should be opened over time with key stakeholders, patients and clinics, with the aim of considering a future review of the 10%.
- that the four clinics that were outliers, should be asked why this was the case.

10. Treatment add-ons next steps

10.1. The Director of Strategy and Corporate Affairs presented this item. It was explained that we currently employed a traffic light rating system consisting of red, amber and green that indicated whether the evidence showed that a treatment add-on was effective at improving the chances of having a baby for most fertility patients. Members were informed that patients had access to clear information on the HFEA website, enabling them to better understand the evidence and risks and potential benefits for each treatment add-on. Also, that information on each treatment add-on was framed with a reminder that for most patients, routine IVF remained an effective treatment.

10.2. The evidence that informs these traffic light ratings is reviewed on an annual basis by the Scientific and Clinical Advances Advisory Committee (SCAAC).

10.3. Members were informed that it was now proposed to carry out further policy work and consultation with experts, the sector and patients/public on how best to evolve the rating system for our treatment add-ons information. Members commented that the review of the rating system would be welcome if it makes information clearer for patients.

10.4. A member noted their view that we should not have any green treatment add-ons on our list as they should form part of routine treatment.

10.5. The Authority were also asked to agree to consider broadening the range of data that the HFEA consider when assigning ratings to treatment add-ons. There were a variety of views expressed. Some members raised concerns about broadening the range of data beyond randomised controlled trials (RCTs) as this was the ‘gold standard’ of evidence of effectiveness and it could discourage the sector from carrying out RCTs. Other members noted that patients were willing to take risks and wanted to be informed and make their own judgments and therefore a wider evidence base may help patients make informed choices.

10.6. Some members felt that the ratings for treatment add-ons needed to evolve and that there should be more differentiation than: red, amber, green. Members were asked if there could, for example, be degrees of amber rated add-ons.

10.7. In response to a comment, it was noted that although treatment add-ons with a red rating may not cause physical harm, they could still cause financial harm.

10.8. It was noted that the HFEA's website information on treatment add-ons may not be helpful when clinics offer patients a 'cocktail' of treatment add-ons as a package.

10.9. It was noted that in only using RCTs and the evidence of impact on live births, may not reflect the full range of decisions some patients face.

10.10. The Chair summarised the discussion: Members agreed that the rating system should be reviewed to see if it should be altered in any way, ensuring that patients remained the primary audience for any future system; Members also agreed that SCAAC should review the evidence base it considered as part of their add-ons review.

Decision

10.11. Members agreed the proposal to evolve the presentation of the rating system for treatment add-ons and to consider broadening the range of data that the HFEA consider when assigning ratings to treatment add-ons.

10.12. Members agreed for these issues to be brought back to a future Authority meeting.

11. Any other business

11.1. The Chief Executive advised members that the business plan was in draft and would go through various iterations before it was brought to an Authority's future meeting.

11.2. A member suggested that actions with dates should form an action tracker for the Authority meeting and should be reviewed at each meeting.

11.3. The Chair commented that this was Emma Cave's last meeting and thanked her for time, contribution and for being such a splendid Authority member. Other members and staff echoed this.

11.4. Professor Emma Cave thanked everyone for their kind words and the privilege of working as a member of the HFEA Authority.

Chair's signature

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

Signature

Chair: Julia Chain

Date: 24 November 2021