Minutes of Authority meeting 7 July 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	23 September 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 7 July 2021 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 7 July 2021 held at ETC.venues, One Drummond Gate, SW1V 2QQ and via teleconference

	In person	Via teleconference
Members present	Julia Chain, Chair Margaret Gilmore Gudrun Moore Alison Marsden Tim Child Jason Kasraie Catharine Seddon	Anita Bharucha Jonathan Herring Ruth Wilde Yacoub Khalaf Ermal Kirby Emma Cave
Apologies	Anne Lampe	
Observers by teleconference	Marina Pappa (Department of Health and Social Care - DHSC) Steve Pugh, DHSC Csenge Gal, DHSC	
	In person	
Staff in attendance	Peter Thompson Clare Ettinghausen Richard Sydee Catherine Drennan	Paula Robinson Debbie Okutubo Nora Cooke-O'Dowd Emily Tiemann Joanne Anton

Members

There were 13 members at the meeting – nine lay members and four professional members.

1. Welcome

1.1. The Chair opened the meeting by welcoming Authority members, observers and staff present both in person and online. She commented that this was the first in-person Authority meeting in 18 months due to the covid restrictions.

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 12 May 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 external stakeholders, as covid restrictions allowed.

3.2. The Chair commented that the HFEA was a UK wide organisation and she aimed to ensure she could visit licensed centres across the UK, including those within the devolved nations.

3.3. The Chief Executive commented on the annual accountability meeting with the Department of Health and Social Care (DHSC) sponsors. He noted that the HFEA was on target to meet the objectives within the business plan and had started to look at challenges ahead.

Decision

3.4. Members noted the Chair and Chief Executive report.

4. Committee Chairs' report

Audit and governance committee (AGC)

4.1. The AGC Chair (Anita Bharucha) presented this item to the Authority. The last formal meeting was on 22 June and the annual report and accounts were presented at the meeting.

4.2. The AGC Chair commented on the delay to the launch of PRISM which was because one of the major third-party API suppliers had asked for a significant delay to complete their work. It was noted that AGC will continue to meet monthly until the launch of PRISM.

4.3. The Authority Chair commented that it was frustrating that PRISM had been delayed.

Statutory Approvals Committee (SAC)

4.4. The SAC Chair (Margaret Gilmore) welcomed Jason Kasraie and Tim Child as new committee members and commented on the use of new PGD terminology (PGT-M) that was presented at the June meeting.

4.5. It was noted that there had been an increase in special direction applications.

4.6. The SAC Chair thanked committee staff for their support.

Scientific and Clinical Advances Advisory Committee (SCAAC)

4.7. The SCAAC Chair (Yacoub Khalaf) summarised the meeting held in June.

4.8. It was noted that an application had been considered to add Endometrial Receptivity Analysis (ERA) to the HFEA list of add-ons and SCAAC will give the add-on a RAG rating recommendation at the October meeting.

4.9. The Authority Chair thanked all Committee Chairs, members and staff and commented that the Licence Committee had not met in the relevant period. In terms of future committee meetings, it was noted that conversations were ongoing as some committees would keep meeting online while some would start to meet in person.

Decision

4.10. Members noted the Committee Chairs' reports.

5. Performance report

5.1. The Chief Executive commented on the recent internal audit of our performance scorecard and KPIs (key performance indicators), and that the auditor had identified a number of reporting errors from teams but that these were not material. Recommendations from the audit were being taken forward.

5.2. It was noted that on human resource issues, sickness levels were rising but were still within the target set. It was further noted that there was one staff member on sick leave who was suffering from long covid.

5.3. Staff turnover was also rising. It was believed that as the economy was improving and there were more job opportunities, some staff would be looking for promotion opportunities elsewhere. This could prove to be problematic, but we were keeping it under review.

5.4. In response to a question on reasons for the resignations, it was noted that there was no evidence from exit interviews that there was any single cause for people leaving.

5.5. Members asked if there was more that could be done to reduce staff turnover and if moving to Stratford was a factor. The Chief Executive responded that conversations were already happening with the other ALBs there in terms of mentoring staff. Also, that we have not been in Stratford long enough for us to measure the effect of moving there. Lastly, that the flexible home and work policy which we have would, we believe, be beneficial to staff.

5.6. In response to a question, it was noted that we have periodic reviews of the KPIs and that the regulatory efficiency indicator measured the performance of the organisation in relation to the end-to-end processing of items beginning with an inspection. This was an administrative measure of HFEA performance, rather than one that captured any sense of continuous improvements in the sector. Defining such a measure of sector improvement would need a wider discussion and consideration alongside our compliance and enforcement approach.

5.7. Regarding the PGT-M data, it was noted that the data presented was purely administrative. The Chief Executive commented that we had been outside the target for a while and we would be revisiting this to understand the reasons for the delay. In response to a question, it was noted that 75 working days was the current target and that it would be kept under review.

5.8. In response to a question, the Chief Executive said pressure on PGT-M was likely to grow as the HFEA licenses new conditions and that testing was getting faster, cheaper and more accurate. All of which suggested an increase in applications and since decisions are made by members, that in itself was limiting as there is only so much of members' time that can be allocated for SAC meetings.

5.9. The Chair of SAC responded that her committee had monthly meetings and asked why PGT-M targets were missed this month. The Chief Executive responded that we would look at the PGT-M KPI again.

5.10. The Authority Chair commented that PGT-M applications would increase as we go forward so modelling will need to be done to ensure that there is no adverse effect on patients.

Strategy and corporate affairs

5.11. The Director of Strategy and Corporate Affairs gave a summary of her area of work. It was noted that we were continuing to make progress against actions in the ethnic diversity in fertility treatment report including: The HFEA Research Manager presented the data to the European Society of Human Reproduction and Embryology (ESHRE) pre-conference which was received with great interest; and we were looking into further work with patients, with Fertility Network, and also through our own means.

5.12. The Patient Engagement Forum (PEF) would be launched very soon and this would be in addition to the existing Professional and Patient Stakeholder groups. It was noted that the purpose of the PEF was to encourage greater participation of, and feedback from, patients in our work.

5.13. It was noted that the Fertility Trends report was launched in May with good engagement and was of particular interest as it covered 30 years of data.

5.14. The Advertising Standards Authority (ASA) and Competition and Markets Authority (CMA) guidance was launched in June and would be discussed later in the meeting.

5.15. The final transition resulting from EU exit occurred at the end of June. All guidance was now up to date, the re-licensing exercise had been completed, and we were happy to report that no problems were encountered. Staff had worked hard for a long period of time on implementing the changes from EU exit and thanks were given to them, as well as those who had overseen a full re-licensing exercise of all HFEA licensed clinics resulting from changes to legislation relating to EU exit.

5.16. The Scottish Government had recently launched a campaign to recruit egg and sperm donors and it would be interesting to see how it develops.

5.17. In response to a question, it was noted that we would try and recruit as large a number as possible to the PEF (up to 100 people plus) as we want particular underrepresented groups to become more involved. There would therefore be targeted recruitment if needed.

Compliance and Information

5.18. The Director of Strategy and Corporate Affairs presented on behalf of the Director of Compliance and Information.

5.19. Members were advised that we were continuing with the risk-based approach for inspections which was combined with a desk-based assessment, but inspectors were also now conducting onsite inspections when needed.

5.20. It was noted that on average 12 inspections per month were carried out. A revised methodology was being worked on as the desk-based approach was very labour intensive and increased workload, which was in addition to onsite inspections. Members were informed that further information would be presented to the Authority in September.

5.21. The Chief Information Officer would be leaving the HFEA later this month and the Senior Management Team had decided to split the role into two – a Chief Technology Officer and a Head of Information, as it was felt that this would better meet the organisation's needs.

5.22. Dan Howard, Chief Information Officer was thanked for his work at the HFEA.

5.23. It was noted that two further temporary staff members had been recruited to the Open the Register Service (OTR) and would be starting at the end of July. There are over 500 applications outstanding and we were receiving 57 applications a month on average. The performance of the team was being monitored as we continue to train new staff members. Members were informed that work was underway on a plan to develop the service operationally so that it is able to meet demand, including how to process applications from 2023. Progress in the team is good and for the first-time last month more applications were processed than received.

5.24. The Authority Chair commented that she had received feedback that the hybrid model of carrying out inspections was working well and that the clinics she had visited had commented that they found it useful and felt that they had a better inspection.

5.25. The splitting of the role of the Chief Information Officer was also welcomed. When recruitment of new Authority members commences, to replace those whose terms of office come to an end in December 2021 or shortly thereafter, we would be looking for a member with experience in big data and information management.

5.26. The Chair commented that 2023 was not far away, and we therefore could not allow the backlog on OTR to get any longer.

5.27. The Chief Executive commented that we were on course to reduce the backlog on OTR and we would report back to the Authority in the Autumn on progress.

Finance and Resources

5.28. The Director of Finance and Resources informed Members that a discussion was held with the DHSC about the HFEA fee regime and the conclusion from it was that an increase in fees was within the remit of the Authority as long as the increase was within reason and the fee regime itself remained unchanged. We would therefore be working up the options for the Authority in the Autumn.

5.29. Regarding the new office, in line with government guidance, the office is open but retains social distancing and covid restrictions. Staff who had attended the new office had given positive feedback and we were looking to hold all our meetings in the new office when it was practical to do so.

5.30. The programme board involving all the arm's-length bodies (ALBs) at the new office would be meeting next week to decide what the next steps would be for staff if the government lifts all restrictions on 19 July.

5.31. Office based staff were being encouraged to attend the new office at least once between now and September 2021 and from September 2021 to attend the office at least one day a week.

5.32. We are also hoping to host the next Authority meeting in our Stratford office.

5.33. In response to a question, it was noted that we do not want to become a virtual organisation and we also needed to avoid isolating staff by continuing to work from home, and so we would continue to explore all possibilities.

5.34. The Director of Finance and Resources confirmed that in terms of commuting costs, the agreement was that we would pay for additional costs for three years to December 2023 for all staff, apart from inspectors who were home-based.

5.35. The Chair commented that it was important that as staff started to attend the office, there was sufficient support from senior staff members.

Decision

5.36. Members noted the performance report.

6. Covid update

6.1. The Director of Strategy and Corporate Affairs presented this item on behalf of The Director of Compliance and Information.

6.2. The summary of all cycles taking place by month in England from January to May in 2021 compared to 2019 was presented. Activity in both the private and NHS sector was good with the private sector being above activity levels compared to 2019 and NHS nearing previous activity levels.

6.3. In terms of NHS funded cycles in 2021 as a proportion of 2019 by nation, it was noted that Northern Ireland went through a downturn but since April 2021 it had started to rise but had not yet caught up with the other nations.

6.4. A revised General Direction 0014 (GD0014) was issued to allow licenced centres to recommence treatments from 11 May 2020. It was noted that the GD specified centres should have a strategy to set out how they would comply with specified guidance to ensure safe and effective treatment could be provided.

6.5. As government restrictions relating to covid change, GD0014 can be left in place as it would have different degrees of relevance for clinics.

6.6. In light of the recent announcement to remove covid restrictions in England from 19 July, we would review and update the information we provide to both patients and clinic staff through our frequently asked questions (FAQs).

Decision

6.7. Members noted the covid update.

7. Code of Practice update

7.1. The Head of Policy and Policy Manager presented this item.

7.2. Members were reminded that we had a statutory duty to produce a Code of Practice and ensure that it was fit for purpose and working effectively. It was noted that members had received drafts of the update in May 2021 and had provided useful comments.

7.3. The timeline of the next few months leading up to the publication of the new guidance was outlined.

7.4. It was noted that proposed changes had been grouped into legislative, least substantive and most substantive changes.

7.5. The legislative changes incorporated the changes in the law since the Code of Practice was last updated in 2019 and these had been communicated to the sector through Chair's letters.

7.6. The least substantive changes were smaller additions to our Code of Practice, mostly incorporating guidance previously communicated through our Clinic Focus newsletter.

7.7. The most substantive changes were amendments to guidance which would be added to the Code in order to build upon and clarify areas of existing guidance.

7.8. The Policy Manager explained that the Authority had adopted a policy which stated that donor gametes should not be used to create more than 10 families (or any lower limit specified by the donor). To respond to questions and for clarity, guidance had been added to guidance note 11 and guidance note 20.

7.9. In September 2019 a Clinic Focus article on e-consenting was issued which has further developed and put into guidance note 5. This included guidance on what we expect from clinics to ensure the e-consenting platforms they use were secure.

7.10. On legal parenthood, guidance note 6 was updated to include the various scenarios that could occur when patients returned to clinics as a single person or with a new partner and how clinics must record patients' status.

7.11. It was noted that guidance 18 had been amended which related to witnessing requiring three identifiers.

7.12. Medicines management was an area in which a high number of non-compliances on inspections are found. Additional guidance in guidance note 25 on the duty of clinics to comply with the relevant regulations and best practice was also updated.

7.13. Members commented that in terms of PGS and PGD and the recent change of terminology to PGT-A and PGT-M, there was a third type not mentioned, although it was recognised that the HFEA was not involved in its licensing. This was PGT-SR.

7.14. A member sought clarity on annex 8 – section 17 – storage of gametes and embryos and asked about the non-mandatory nature of the guidance.

7.15. The Head of Legal commented that a discussion would be held about whether it would be appropriate to change the terminology of parts of the Code from 'should' to 'must', to make it mandatory. Regardless of the wording, in practice clinics recognise the seriousness of cases in which legal action is a realistic prospect or is being threatened and in all cases that the Head of Legal had dealt with, the PR or clinic staff would either contact their inspector who would raise the matter with the Head of Legal, Director of Compliance and Information or the Chief Executive. Very often the clinic's lawyers or lawyers for the patient are involved and would approach the Head of Legal directly.

7.16. Members thanked staff for the very comprehensive piece of work. For legal parenthood there was a suggestion that paragraph 6.38 in the Code be made more prominent due to its complexity and importance.

Decision

7.17. Members approved the changes subject to the inclusion of the suggestions.

8. Fertility Trends

8.1. The Head of Research and Intelligence presented this item. It was noted that there was evidence of a significant increase in fertility treatments over the last 30 years. Birth rates in 2019 were three times higher than in 1991.

8.2. Frozen embryo transfer had increased over time and the use of donor eggs and sperm had increased significantly over the last 30 years.

8.3. There was substantial variation in IVF funding across the UK and we had started to see a decrease in NHS funded cycles among the younger age groups.

8.4. The multiple birth rate in 2019 was at 6%. However, multiple birth rates for patients of black ethnicities remained high.

8.5. Members discussed issues relating to the data and what they would like to understand further in relation to multiple births.

8.6. Members asked how the 10% multiple birth rate target was arrived at. The Chief Executive commented that the target was both realistic and aspirational and had been reduced over time to its present 10%. Progress in reducing multiple births was a combination of good engagement from clinics and the development of protocols from the professional bodies, which were updated and shared with clinics. Over the years, this had led to low multiple birth rates but higher success rates.

8.7. The professional members, when asked to comment on this, suggested that we needed to consider what the tipping point was between multiple birth rate and success rates and ensure that patients were not disadvantaged.

8.8. Also, that the changes still needed to be reviewed regularly. Clinics that were above the 10% target set should be targeted and asked for their minimisation embryo transfer policy to be reviewed as we need to understand why some centres are still not achieving rates of 10% and below.

8.9. We also need to pay close attention to patients that have more than one embryo transferred. We should consolidate around the 10% target and get those clinics who were still above the target to improve their practices.

8.10. Some members asked how the target can be maintained. Members were reminded that all licensed centres must have a multiple births minimisation strategy in place and GD 0003 sets out some basic requirements which need to be adhered to.

8.11. Some members commented that conversations with Black patients in particular would be helpful to understand why multiple births were predominantly in that group.

8.12. The Director of Strategy and Corporate Affairs suggested that a more detailed discussion would be held in the Autumn.

8.13. The Chair suggested that we do not need to alter the target, instead more analysis should be done using what we already know. There may be more work to do with those above the 10% target.

8.14. During the discussion in the Autumn, the paper to be presented should identify the risks of reducing and not reducing multiple birth rates, the weighting of risks in multiple births and in particular risks to any child born.

8.15. Members commented that it might be helpful to analyse data relating to unsuccessful treatments in particular relating to social and economic influences on fertility treatment. However, it was noted that we do not have access to this type of socio-economic data of patients in the Register.

Decision

8.16. To report back to the Authority in the Autumn with the details requested for further discussion.

9. Update on work with the Competition and Markets Authority (CMA) and the Advertising Standards Authority (ASA)

9.1. The Director of Strategy and Corporate Affairs presented this item. It was explained that the Competition and Markets Authority (CMA) set out to provide guidance to enable compliance by clinics and others with existing Consumer Law and the Advertising Standards Authority (ASA) set out to provide guidance to be used by those advertising services. The work had taken place over nearly two years and the HFEA had been closely involved in it. We welcome the work since, given the limitations of our powers in particular the absence of powers of enforcement, by working with other specialist regulators we can deliver benefits to patients.

9.2. It was explained that both the CMA and the ASA would allow time for clinics to review their information after June 2021 and make changes if needed.

9.3. After about six months, they will carry out reviews to see if clinics are compliant and if they found cases of non-compliance then they may take enforcement action.

9.4. In terms of the next steps for the HFEA, it was explained that the CMA and ASA would provide training for our inspectors in relation to the guidance. Even though HFEA inspectors would not review compliance with CMA or ASA rules or legislation, they need to be aware of any issues and know what to do if they spot something, or if a complaint is raised with them.

9.5. Memoranda of Understanding (MOU) and protocols with CMA and ASA would be developed.

9.6. We would also develop proposals on transparency as last discussed with the Authority in May 2021, relating to how others publish information, and we would return to the Authority later this year for further discussion.

9.7. In response to a question, it was noted that conversations were ongoing about the HFEA's role in the CMA and ASA guidance and that we would continue to bring this to the attention of patients.

9.8. In terms of how the guidance had been received by clinics, it was noted that there was initially a concern about how the guidance would be used and the effect of the enforcement powers by the either the CMA or the ASA. Broadly speaking, clinics were waiting to see how this developed.

9.9. Members commented that it was good that there was time for both sets of guidance to be embedded.

9.10. It was noted that the HFEA should continue to publicise the guidance enabling patients to understand that they have consumer rights and that the guidance could lead to a better working relationship between patients and clinics.

9.11. Members suggested that social media campaigns should be kept up by giving patients examples of practices that are not fair.

Decision

9.12. Members noted the CMA and ASA update.

10. Any other business

10.1. 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: 23 September 2021