Minutes of Authority meeting 11 November 2020

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	27 January 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 11 November 2020 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 11 November 2020 held via teleconference

Members present	Sally Cheshire Margaret Gilmore Anita Bharucha Anthony Rutherford Emma Cave Anne Lampe	Jonathan Herring Gudrun Moore Ruth Wilde Yacoub Khalaf Ermal Kirby Kate Brian
Apologies		
Observers	Marina Pappa Steve Pugh (Department of Health and Social Care - DHSC)	
Staff in attendance	Peter Thompson Richard Sydee Rachel Cutting Catherine Drennan Dan Howard Andrew Leonard	Paula Robinson Debbie Okutubo Dina Halai Helen Crutcher Emily Tiemann

Members

There were 12 members at the meeting – eight lay and four professional members.

1. Welcome, apologies and declarations of interest

1.1. The Chair opened the meeting by welcoming Authority members, the public and staff present online. She stated that the meeting was audio recorded in line with previous meetings and the recording would be made available on our website to allow members of the public who were not able to listen in during our deliberations to hear it afterwards.

1.2. There was one staff apology for absence from Clare Ettinghausen, Director of Strategy and Corporate Affairs.

1.3. Declarations of interest were made by:

- Yacoub Khalaf (PR at a licensed clinic)
- Anthony Rutherford (clinician at a licensed clinic)
- Ruth Wilde (counsellor at licensed clinics)
- Kate Brian (working at Fertility Network UK).

2. Minutes of the last meeting

2.1. Members agreed that the minutes of the meeting held on 16 September 2020 were a true record of the meeting and could be signed by the Chair.

3. Performance report and strategic risk register

3.1. The performance report, covering data up to September 2020 was presented to the Authority. It was noted that there were three indicators classed as red, F1 - debt collection; F3 - prompt payment; and R1 - register errors.

3.2. The Chief Executive (CE) commented that overall performance was good. Sickness absence was very low with only eight days in total. The majority of staff had adapted well to working from home, but staff wellbeing remained a concern and will continue to be kept under review.

3.3. In response to a question, it was noted that staff were encouraged to take annual leave to avoid burn out, even though it was appreciated that people were unable to travel anywhere due to the current lockdown and the pandemic. It was noted that this information was cascaded to staff through a number of avenues including the all-staff meetings, team meetings and during one to ones.

3.4. The Chair commented that HFEA staff were doing incredible work even though we were not regarded as frontline staff. At the persons responsible (PR) virtual event held recently, it was noted how stressful clinic staff were finding working during this pandemic and the effect it was having on morale and efficiency.

3.5. The CE elaborated on this and explained that we hosted the annual PR event with identical morning and afternoon sessions. They were very well attended and the agenda was varied. The Chair opened the meeting at both sessions and among other topics, the challenges posed by Covd-19 were discussed.

3.6. Today, in the absence of the Director of Strategy and Corporate Affairs, the CE informed members that the Competition and Markets Authority (CMA) had launched their draft guidance for the fertility sector about clinics' consumer law obligations. The guidance has been issued for consultation and would be finalised next March. After a period of 'bedding in', enforcement action could be taken by the CMA if they found that UK consumer protection law was not being adhered to by clinics. The HFEA have been closely involved in developing this work and are fully supportive of it. It will be very helpful for patients to ensure costs and terms of treatment are fully transparent and more easily comparable between clinics.

3.7. The week commencing 2 November 2020 was National Fertility Awareness week and the HFEA had supported it through online activity and a video message from the Chair. Staff were thanked for all their work on this.

3.8. The State of the Sector report, our annual review of compliance, would be published later in the month. As we now published quarterly non-compliance reports via Clinic Focus, this would be a shorter report than in previous years.

3.9. It was reported that progress had been made on the patient forum to ensure a regular flow of feedback between the HFEA and patients. This would be via virtual and online activity and more information would be given at the next Authority meeting.

3.10. The Chair commented that she spoke at a Wellbeing of Women webinar on egg freezing where the HFEA website was being signposted as an excellent source of independent information and advice.

3.11. The Director of Compliance and Information presented to the Authority. Members were advised that the paused opening the register (OTR) service was re-opened on 20 October. The OTR team had processed the earlier backlog of applications. Due to the service being closed for six months there has now been a significant influx of new applications which would take longer to process.

3.12. Members asked what the timeliness risk was in turning around the backlog in OTR requests. The Director of Compliance and Information responded that the previous backlog had already been cleared, and that it was the increased influx of requests since the service had re-opened which were the issue. The OTR team are working through them and applicants are being told that there may be a delay but the team will do their very best to expedite requests as soon as possible. The new Register Information Team Application (RITA) was being developed and it would support the register. It was noted that the website states that requests would be responded to as soon as possible.

3.13. It was noted that the Choose a Fertility Clinic (CaFC) verification exercise in preparation for the forthcoming update was progressing well.

3.14. The Director of Finance presented on HFEA finances and reiterated that debt collection was in the red. He commented that this indicator had been affected by Covid-19 impacting the sector, but we had started to see improvements in recent weeks and we expect the collection rate to continue to improve over time.

3.15. Members were advised that we were forecasting an underspend in expenditure against the budget.

3.16. Regarding the office move to Redman Place, Stratford E20, the premises would be ready by 18 November and we will change our address officially on 1 December 2020. Staff will potentially be able to go into an office setting subject to government guidance from January 2021.

Strategic risk register

3.17. The strategic risk register was noted. The Chair commented on board appointments and hoped that it should be resolved shortly via our sponsor team at the DHSC. Also, although the rating of this risk had been reduced earlier due to progress made on recruitment, as time passed we may wish to raise this higher than a medium (amber) rating as we still do not have clarity on when new members will be appointed.

Decision

3.18. Members noted the performance report and the strategic risk register.

4. Covid-19 updates

4.1. The Director of Compliance and Information presented the Covid-19 updates, and it was noted that regular catch-ups were held with NHS England alongside the two progress meetings held directly with the Secretary of State for Health and NHSE to assess progress in reopening the fertility sector to patients.

4.2. The CE issued a position statement following the announcement of the second lockdown which was well received by clinic staff and patients. In the statement, it was acknowledged that clinics had robust procedures in place to be Covid-19 secure; and that there was an expectation for

clinics to promptly review their policies and procedures and to demonstrate how their service would be safely maintained.

4.3. The statement went on to inform clinics that we would closely monitor the situation and requested that referrals for necessary urgent or emergency treatment made by licensed clinics to an NHS facility other than their own clinic be reported through the HFEA incident reporting system. Lastly it was not envisaged that a further national closure of clinics would be necessary.

4.4. Members were reminded that they had approved inspections to recommence in November and currently government restrictions during this second lockdown were not as severe as the lockdown which happened in March 2020 since travelling for work purposes was currently allowed. Clinics remained open and inspections would be undertaken wherever possible.

4.5. Members were informed that virtual inspections would be conducted if a centre has had a visit within the last 2 years. Risk assessments were conducted on centres and inspectors had been provided with PPE by the DHSC.

4.6. In response to a question, it was noted that, although there has not been a further national closure of clinics, local circumstances such as staff being redeployed may mean that individual clinics will have to close or restrict appointments. It was also noted that some patients had reported that they had found the period of closure very hard and some clinics had not communicated well with patients during the pandemic.

4.7. Members advised that clinics need to keep reporting on the good work they have been doing and translating this back to patients, whilst updating their Patient Support policies.

4.8. The Chair commented that at the PR event some clinics said they were short staffed, some due to ill health or self-isolation. At the PR event they agreed that there should be another event in three months' time to specifically discuss best practice and share experiences with respect to the pandemic.

4.9. Members commented that the current national situation was having a huge impact on patients in terms of what it meant for their treatment and mental health, which could not be ignored. Best practice needed to be shared.

4.10. The Chair thanked the inspection team for responding to the sector in an agile manner.

Decision

4.11. The Covid-19 update was noted.

5. PRISM update

5.1. The Chief Information Officer (CIO) presented the PRISM update to the Authority. Members were advised of the progress made and the remaining steps of the launch process.

5.2. It was noted that the PRISM release candidate was launched on 13 October. Clinic engagement sessions and a refresh of the data in choose a fertility clinic (CaFC) had also started. The reprofiling of the PRISM launch and the CaFC verification exercise was allowing clinics to spend more time ensuring their 2020 data was as accurate as possible. The legacy EDI system migration was also completed in early November.

5.3. Members were advised that the steps to the PRISM launch process that were still outstanding included:

- Data quality improvement work and essential PRISM functionality for staff in December 2020
- Launch of live release candidate, integrated testing and cutover and system suppliers' updates in January 2021.

5.4. The CIO stated that PRISM was planned to go live on 25 January 2021 and would be embedded by 31 March 2021.

5.5. Members asked what would happen to patients' data during the cutover period, and the CIO responded that the EDI system would be switched off so no data would then be transferred until PRISM went live.

5.6. The Chair of the Audit and Governance Committee (AGC) congratulated the team both past and present on the launch of the release candidate and the progress made, and advised members that AGC continued to have monthly meetings to ensure oversight of PRISM.

5.7. It was noted that AGC would continue to have oversight on staff maintaining the timetable, cost and the integrity of data.

5.8. The Deputy Chair of AGC commented that the risk remained of the reliance on a small number of key staff and asked the CIO if there was a difference between private and NHS clinics' take up of PRISM. The CIO responded that they had not seen a major difference.

5.9. A member commented that clinics needed to be given time to allow them to transfer from the legacy EDI system to PRISM as this would be in addition to clinics' business as usual activity and extra work associated with being Covid-19 compliant.

5.10. Clinics were thanked for their engagement with PRISM.

Decision

5.11. Members noted the PRISM progress to date, timetable to launch and go live date.

6. Business planning 2021/22

6.1. The Risk and Business Planning Manager presented the business plan for 2021/22 to the Authority. Members were advised that the DHSC had recently signed off the six-month business plan for the remainder of 2020/21, approved at the last Authority meeting, so this would now be published on our website.

6.2. Members were reminded that the three-year plan which was presented in November 2019 had been refined in the light of the impact of Covid-19 and following earlier Authority discussions about priorities.

6.3. The business plan for 2021/22 would cover the first full year of delivery of our 2020 - 2024 strategy.

6.4. The Chair asked if members felt that the right things had been focused on and if they were achievable.

6.5. Members responded that it felt like a good business plan and thanked everyone who had worked on it.

6.6. Members asked whether the HFEA would need to undertake tasks relating to surrogacy and the linkages between surrogacy and some of our processes.

6.7. The Chief Executive (CE) responded that there is a Law Commission review on surrogacy that has not yet been completed and it would therefore be advisable to wait for the outcome of this work before making a decision on what HFEA actions may be needed.

6.8. In response to a question, it was noted that work was ongoing to analyse areas of our Act in anticipation of a future review of legislation, and that we continued meanwhile to do other beneficial strategic work on aspects of treatment not directly covered by the Act, for instance on treatment add-ons and leadership.

6.9. Members cautioned about staff resources and suggested that this looked like an ambitious plan. It was therefore imperative to know that there were sufficient resources to implement it, bearing in mind the small size of the organisation.

6.10. Members commented that the right things were contained within the plan as these had emerged out of conversations about the strategy over recent months. In addition, it would be worth considering how further partnership working could be helpful in some areas of work.

6.11. The Risk and Business Planning Manager responded that work was underway on more detailed planning and consideration of resources, as service delivery planning and resource allocation was discussed in teams. These would be aligned with the business plan and considered together in upcoming management conversations. Members' comments will be taken on board.

6.12. The CE advised that he would feed back to the Authority once the business plan and service delivery plans have been reviewed at CMG.

6.13. The Chair asked that communication plans for different stakeholder groups be included in our planning, so as to share our plans and engage with relevant groups, such as researchers.

6.14. The Chair thanked all involved.

Decision

6.15. The next steps were explained and agreed.

6.16. The business plan would be re-presented at a future meeting.

7. Treatment add-ons progress report 2020

7.1. The Scientific Policy Manager presented to the Authority and commented that our work on add-ons is a key feature of our new strategy and that as far as we knew, we were the first regulatory body to attempt to tackle issues around unevidenced fertility treatment add-ons.

7.2. Treatment add-ons were described as 'extra' to routine fertility treatment and often claimed to improve patients' chances of having a baby. We have provided a traffic light assessment of the state of the evidence base for a number of the most widely available treatment add-ons on the HFEA website.

7.3. The Authority were asked to consider our approach to providing information about the use of holistic/alternative therapies during fertility treatment. It was noted that some fertility patients choose to use holistic/alternative therapies, but they are not a licensable activity and are often not offered in a licensed fertility clinic. However, occasionally patients do come to us for advice and

there is therefore an argument that it would be appropriate for us to publish information about them on our website.

7.4. The Authority agreed that holistic/alternative therapies should be featured as additional treatments that were sometimes offered during fertility treatment, especially in light of the new CMA guidance which mentions complementary therapies.

7.5. The Authority were then asked to consider the best approach to providing information about green rated add-ons. It was explained that a green add-on would be where there was more than one good quality randomised controlled trial (RCT) which showed that the procedure was effective at improving live birth rates and was shown to be safe for patients to use. Currently, none of the add-ons reviewed by the HFEA were rated green. And it could be argued that if an add-on was green for all patient types, it should be part of standard treatment, and not an optional add-on.

7.6. Members commented that RCTs remained the only evidence which was sufficient to change a red or amber traffic light rating to green.

7.7. In discussion, Members commented that this was a complex issue, where it was important that patients were presented with information on whether a proposed add-on was optional with no proven benefit or strongly recommended with some proven benefit of increasing the chance of a live birth. It was noted that some patients found it difficult to opt out of any additional treatments offered, for fear that it might reduce their chances of having a child.

7.8. The Chair commented that add-ons needed to be put in a wider context of 'routine' treatment. She suggested that we should:

- clarify what a 'routine IVF treatment' cycle involved for most patients
- clarify which add-ons could be green for some types of patients (while perhaps being amber or red for other patients)
- clarify which treatment add-ons have limited evidence and therefore would fall into the amber or red categories.

7.9. Members stated that the information we publish on our website should make it clear for patients that it is their own choice to opt for a treatment add-on which is over and above the routine IVF cycle, and that they should bear in mind that it would cost extra, and there may be no robust evidence base to suggest that it would have any benefit.

7.10. The Chair of the Scientific and Clinical Advances Advisory Committee (SCAAC) commented that the work of the committee to review the evidence base for add-ons will continue. It was their role to look at evidence impartially and independently and information relating to holistic/alternative treatments needed to be communicated well to patients.

Decision

7.11. Members agreed that information on holistic/alternative therapies should be featured on our website as a separate item to the treatment add-ons list and that it need not be traffic light rated.

7.12. Members agreed that we should publish information about what a routine IVF cycle involves, and which add-ons may be appropriately offered to some patients.

7.13. This information should make it clear that treatment add-ons and holistic/alternative therapies were in addition to IVF cycles and could be expensive.

7.14. The CE commented that a broader framework would be worked on and brought back to a future Authority meeting.

7.15. The Chair concluded that we had made huge progress in this area and thanked everyone involved.

8. Compliance & enforcement policy pre-consultation

8.1. The Director of Compliance and Information presented the revised draft compliance and enforcement policy to the Authority.

8.2. It was noted that the current policy was approved in 2016. The new policy incorporates several improvements to

- ensure the escalation of concerns is undertaken through a process which is managed consistently, fairly, and transparently
- define the process inspectors follow when deciding what recommendations to make to Licence Committee
- mitigate the risk of centres feeling they have been treated unfairly or disproportionately
- provide a robust framework when we are faced with legal challenge, setting out when and how regulatory action will be taken.

8.3. Members commented that the updated policy would help avoid potential inconsistencies.

8.4. The CE responded that what has been set out is a framework which leaves room for individual clinic circumstances and balanced judgements to avoid it becoming a tick box exercise. The policy includes examples of mitigating and aggravating factors but it is not an exhaustive list.

8.5. In response to a question it was noted that this policy would not affect the licensing representations and appeals processes.

Decision

8.6. Members approved the revised draft version of the Compliance and Enforcement Policy to go out for consultation for a four-week period in January 2021.

9. HFEA preparations for the end of the EU exit transition period

9.1. The Chief Executive presented this item and thanked staff directly involved in the development of this piece of work.

9.2. The 2020 Regulations provided for a six-month transition period.

9.3. After the transition period the HFEA will remain the Competent Authority for Northern Ireland (CA-NI) and we will continue to regulate licensed clinics and embryo research in NI, in line with the requirements of the HFE Act 1990 (as amended) and to reflect the provisions of the NI protocol.

Decision

9.4. Members noted the arrangements relating to the Authority's preparedness for the end of the transition period.

9.5. Members agreed to delegate to the Chair the power to make any decisions necessary to give effect to the 2020 Regulations and the application thereof.

10. Any other business

10.1. The Chair commented that this was going to be the last meeting for Anthony Rutherford who had been an Authority member since 2014. Members thanked him for his hard work and expertise on the board and valuable contribution during his time on the Authority and the committees that he sat on.

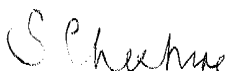
10.2. Mr Rutherford thanked everyone for their kind words and the privilege of working on the HFEA's board.

10.3. The Chair commented that Mr Rutherford had agreed to advise the HFEA in the future as an external expert when required, particularly if professional expertise was needed before the appointment of the HFEA's new Board members is approved by Ministers.

Chair's signature

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

Signature



Chair: Sally Cheshire

Date: 27 January 2021