Minutes of Authority meeting 12 May 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	7 July 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 12 May 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 12 May 2021 held via teleconference

Members present	Julia Chain, Chair Margaret Gilmore Anita Bharucha Jason Kasraie Catharine Seddon Emma Cave	Jonathan Herring Gudrun Moore Ruth Wilde Yacoub Khalaf Ermal Kirby Alison Marsden Tim Child
Apologies	Anne Lampe	
Observers	Marina Pappa (Department of Health and Social Care - DHSC) Steve Pugh, DHSC Csenge Gal, DHSC	
Staff in attendance	Peter Thompson Clare Ettinghausen Richard Sydee Rachel Cutting Catherine Drennan	Joanne Triggs Paula Robinson Debbie Okutubo Helen Crutcher

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, observers and staff present online. She commented on it being her own, and Alison Marsden's, first Authority meeting as Chair and an Authority member respectively.

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. The Deputy Chair (Margaret Gilmore) extended a warm welcome to the new Chair on behalf of the Authority. She praised the staff and Authority members for inspirational work over the years as the HFEA became a leader among regulators in recognising where scientific and technological advances could benefit patients. She commented that the new Chair would enable the HFEA to continue to flourish in this vein and offered her support and the best wishes of the members in her new role. The Chair thanked Margaret for her comments.

1.4. 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 24 March 2021 were an accurate record and could be signed by the Deputy Chair (Margaret Gilmore) since the Chair was not in post at the last meeting.

3. Chair and Chief Executive's report

3.1. The Chair summarised the numerous meetings she had had over the last six weeks since she became Chair, including visiting two licenced centres and speaking to the persons responsible (PRs). Her impression was that the sector held the HFEA in high regard. The Chair also paid tribute to the previous Chair, Sally Cheshire, for ensuring the Authority was viewed in such a positive light.

3.2. The Chair said that she and the Chief Executive had begun to look at the expertise required on the board as there were up to six members with terms of office coming to an end this year. She outlined that it was a risk to the Authority with so many experienced members stepping down and that starting the recruitment process to replace them was being looked at as a matter of urgency. The Chair also noted that 3 members were up for reappointment and that the DHSC had been asked to confirm these reappointments.

3.3. The Chair set out her priorities:

- Modernising the Act. The Chair stated that she believed that this was a key strategic aim. While parts of the Act had held up very well over time, some aspects were now out of date.
- The use of data. There would be opportunities in the future to use our data more effectively, building on the launch of PRISM this summer. It was important that we used our data to help patients, clinics and to facilitate research.
- Inequalities. While this had been particularly highlighted in the recent report on ethnic diversity in fertility treatment, the Chair was keen to look further at these and other inequalities in particular inequality in access to treatment.

3.4. The Chair commented that the themes and priorities that she had listed would be discussed with Lord Bethell at their introductory meeting taking place later in the month.

Chief Executive

3.5. The Chief Executive and Directors had the quarterly accountability meeting with the Department of Health and Social Care and reported that the meeting went well. It was noted that despite the pandemic we were meeting our commitments in the business plan and that we continued to recognise challenges ahead.

3.6. The Chief Executive had spoken at a roundtable discussion on the contribution of Mary Warnock to fertility regulation.

3.7. Members were advised that the Chief Executive would be attending a Regulatory Horizons Council meeting to speak about the role of the HFEA in encouraging innovation.

Decision

3.8. Members noted the Chair and Chief Executive report.

4. Committee Chairs report

Audit and governance committee (AGC)

4.1. The AGC Deputy Chair (Margaret Gilmore) reported back to the Board. At the 28 April meeting, the committee received a paper and reviewed options for a revised PRISM go live date, slightly delayed due to Covid-19 pressures. They were pleased with the progress made on PRISM in the last few weeks.

4.2. The three criteria the committee would consider before authorising the go-live of PRISM in mid-June, were: patient security, clinic usability, and HFEA business processes.

4.3. At the last meeting the Committee received assurances that PRISM cut-over was on target, data quality issues were resolved and simulations showed a high level of accuracy.

4.4. The team were frequently in-touch with clinics and the majority were on track for launch, with an appropriate communications strategy in place.

4.5. RITA, the internal reporting system for HFEA staff was also ready for launch.

4.6. The AGC Deputy Chair reported that an internal audit was carried out on PRISM and a lessons learned report which the committee had requested was being compiled. This would be shared with the AGC and the Authority Chair once finalised.

4.7. The committee heard that there was still a risk that a lot of knowledge and technical knowhow lay with contracted staff, but to mitigate this, there was a handover programme in place to transfer the knowledge to permanent HFEA staff.

4.8. Training for clinics and support continued and the committee was assured that the programme spend remained in line with the reviewed forecast.

Statutory Approvals Committee (SAC)

4.9. The Chair of SAC (Margaret Gilmore) addressed the Authority. The committee continued to meet monthly and had considered a large number of PGD applications since the last Authority meeting. The committee had also regularly considered Special Direction applications. Many of these were Covid-19 related and concerned people unable to travel to or from a country where they intended to have treatment, due to travel restrictions. They therefore requested permission for gametes to be imported or exported in cases where this could not necessarily be compliant with UK general directions (GD).

4.10. The SAC Chair reported that cases coming before the committee were increasingly complex and challenging and she expressed her thanks to committee members for the depth of their discussions and to staff for supporting the committee. She pointed out the decisions reached would be life changing for the patients involved.

Decision

4.11. Members noted the Chairs' updates.

5. Performance report

5.1. The Chair invited the Chief Executive to introduce the report. It was noted that there are currently three red indicators, which were set out in the report. The indicators on staff turnover and sickness were currently classed as green. The mental health and wellbeing of staff remained paramount and there were a number of initiatives in place to support staff.

5.2. Members were advised that the earliest staff would be formally returning to the office was 21 June – dependent on the lifting of wider Covid related restrictions - and that conversations would be held with staff about return to an office setting.

5.3. The Chair commented that a framework should be developed to ensure arrangements provide direction from the SMT on office attendance and flexibility, rather than simply having a series of ad hoc individual working arrangements for each member of staff.

Strategy and Corporate Affairs

5.4. The Director of Strategy and Corporate Affairs gave a brief overview on ongoing work in the directorate.

5.5. It was noted that since the Authority last met, a number of actions relating to treatment add-ons had progressed including publishing for the first-time information on holistic and alternative therapies. The patient questions on what to ask about add-ons, which we worked on with Fertility Network, had also been published. The work on EU exit continued and the team was compiling the annual fertility trends report to be published later in May.

5.6. As noted at the last meeting, following the publication of our report on ethnic diversity in fertility treatment in March, we will be updating Authority on progress against the actions in the report. The report received a great deal of media and social media coverage. Since publication we have also discussed with some of our stakeholder groups and presented the findings to the NHS Health Race Equality Observatory Maternal Health group. We are now planning further work on the actions in the report and will continue to update Authority on this.

5.7. A member commented that there were concerns that counsellors in clinics could become marginalised and suggested that the HFEA should engage in dialogue with licensed centres to ensure that post Covid-19, counsellors were not a casualty of cost-cutting exercises. Members were advised that the British Infertility Counselling Association (BICA) had raised concerns about this. Members were informed that some these issues were staffing concerns for individual clinics. However, where there were wider issues, we would work with BICA to see if there were any further actions we could take.

5.8. A member updated the Authority that a few arms-length bodies (ALBs) in the health sector had recently come together to discuss diversity and inclusion and the conclusion from the meeting was that more needed to be done on inclusion.

Compliance and Information

5.9. The Director of Compliance and Information gave an overview. The inspection schedule was busy and we continue to inspect via a risk based approach with desk-based analysis (DBA) / virtual technology (as restrictions have eased site visits are resuming). An unannounced inspection was undertaken with a clinic where we had concerns. We have sent a survey monkey questionnaire to centres who have gone through the DBA/virtual inspection to gather feedback. So far feedback

has been very positive from PRs but, there is the challenge of extra paperwork for inspectors to assess, but this is under review. The PR and inspector feedback will help to inform how inspections will be conducted once all restrictions have been lifted.

5.10. Members were reminded that during the pandemic the decision to close the opening the register (OTR) service led to an increased backlog. There had also been a rise in applications since the service resumed. To mitigate this, an additional member of staff has been appointed. A wider review of the service is also planned.

5.11. Members asked if there were plans to train other existing staff members as a way of reducing the backlog as the waiting times listed were not acceptable. It was noted that this would be difficult to achieve due to the expert nature of the role and length of time to train, but more resources were being sought.

5.12. Members asked if the red indicator on regulatory efficiency was still appropriate. The Director of Compliance and Information responded that it related to inspectors having backlogs owing to workload pressures, but that we would continue to work on this.

5.13. A member asked about whether the internal incidents red indicator was patient safety related. The Director of Compliance and Information confirmed that this was not and that it related to incidents within the HFEA, not clinics. More work had been done to increase reporting and learning from such occurrences.

5.14. The Chair commented that the additional resource for the Register team formed part of a larger conversation on succession planning that she was having with the Chief Executive and with the DoH.

Finance and Resources

5.15. The Director of Finance and Resources presented to the Authority. It was noted that one of the red indicators related to debt collection but commented that he had every confidence that the debt would be collected. It was noted that a large part of the underspend was from the Legal budget as it was not fully used in the last financial year.

5.16. Members asked about the project cost for EU transition and if there were increased known risks. The Director of Finance and Resources responded that there were no financial risks incurred. The Director of Strategy and Corporate Affairs commented that operational risks had been mitigated as no work had been delayed by the HFEA, since we continued to follow the government timelines.

5.17. It was noted that the financial data presented were unaudited and the audit work would be starting at the end of May 2021.

Decision

5.18. Members noted the performance report.

6. Covid-19 update

6.1. The Director of Compliance and Information presented to the Authority. It was noted that privately funded cycles saw an increase in 2021 compared to 2019.

6.2. In terms of clinic activity, private clinics are working at higher activity levels compared to NHS clinics.

6.3. The Director of Compliance and Information commented that concerns had been raised about delays in patients accessing primary care and that there were difficulties in recruiting donors and sourcing products. There were also concerns that NHS patient cycles were being capped.

6.4. Professional members on the board commented that they had also experienced delays in patient referrals both from primary and secondary care. NHS funded IVF patients could also be seeing delays because there were more patients seeking fertility treatment in the UK while travelling abroad was restricted.

6.5. The Chair commented that we needed to keep an eye on this especially if there was evidence that NHS patient intake and cycles were being capped.

Decision

6.6. Members noted the Covid-19 update.

7. Strategic risk register

7.1. The Chair invited the Risk and Business Planning Manager to present this item. Members were advised that the risk register was revised last year to reflect our current strategy. The AGC continued to provide assurance to the Authority that the executive was managing risk effectively as they reviewed the register at every AGC meeting.

7.2. Members were advised that we had one above tolerance risk, C2, which related to our board and senior management team (SMT) capability. This followed a reassessment and reframing of the risk in April following a discussion with AGC at their March meeting.

7.3. Members were advised that the executive intended to review the wider risk management approach, including the risk policy and strategic risk register in the coming months.

7.4. The AGC deputy chair commented that legacy planning was important at SMT level.

7.5. The Chair responded that as a small organisation it would always carry some element of risk in relation to this, and that Authority members and leadership team turnover required good succession planning to be in place to the extent possible.

7.6. There was a suggestion from members that under risk I1, information provision, we needed to capture a new risk cause that the HFEA could be perceived as less consumer-focused or out of step with other regulators in terms of the transparency of information about regulatory action.

7.7. Members asked if there was robust evidence that patients knew about us and what we do as a regulator and if there was a way of gathering evidence of what was known about us.

7.8. Professional members on the Authority commented that some patients knew about the HFEA, but more could still be done as only a few would have interacted with the HFEA or be aware of our remit.

7.9. The Chair commented that the relative lack of enforcement powers was an issue, we therefore needed to rethink how we let patients know about what we do.

7.10. The Chief Executive commented that some of the work that we had to reschedule for later at the start of the pandemic would have raised awareness - an example was how we link in with GP practices which would have given patients more early information about the HFEA.

7.11. The Director of Strategy and Corporate Affairs responded that staff would revisit risk I1 and have a further discussion internally.

7.12. Members asked about P1 – positioning and influencing, and whether we were influencing optimally. Also, if there was scope for developing a role whereby we became a sector leadership convenor on certain matters. Further interdependencies could perhaps also be reflected over time.

7.13. Under C1 – capability, it was hoped that we could act swiftly to facilitate mentoring and other such arrangements, jointly with the other ALBs we will be sharing space with at our new premises.

7.14. Members commented that going forward good messages and good impacts could be built on further. We could use PRISM to promote and raise the transparency of some aspects of our work and also use our data to educate as required. Research carried out could be tagged on the website.

7.15. The Chair concluded the discussion by stating that prioritising was key and that the Executive would take the comments away, revisit and report back at a future Authority meeting.

Decision

7.16. Members noted the strategic risk register.

8. Licence fee review project – timing and next steps

8.1. The Director of Finance and Resources presented this item to the Authority. The Authority last received a paper on the fees review work at its meeting in June 2020. The Director of Finance and Resources commented that it was important to note that as a regulator we did not charge patients.

8.2. Following the June 2020 meeting further work was undertaken on modelling the potential impact of the agreed options. It also became apparent that it would be difficult to continue this work to a successful conclusion with the full engagement of the sector given the pressures of operating through the ongoing Covid-19 pandemic.

8.3. Members were advised that subject to the agreement of the DHSC, we were looking to delay this work to 2022 with the intent of introducing any new fees from the start of the 2023/24 financial year.

8.4. Members were invited to comment, and stated that in reality, increases to fees would be passed on to patients by clinics but if it were a small increase, it might be absorbed by centres and asked if the Director of Finance and Resources had considered charging for the storage of frozen embryos.

8.5. There was the suggestion of having the option of a flat fee and making it clear to clinics that it was not for a specific treatment, but it was a flat fee linked to the size and activities of clinics.

8.6. Members commented that the current charging structure needed to be reviewed as it was out of date compared to current treatment trends, but we must not lose sight of anything that would make people on a low income lose out on affordability grounds.

8.7. Members cautioned that the data available in this financial year was for the last six months since clinics reopened and that its accuracy could be questioned especially if was to be used to model future charges. Members suggested that strategic risks needed to be carefully evaluated. They

commented that going from an underspend this financial year to an increase in fees could appear to be out of step and requested that the executive think carefully about this.

8.8. The Director of Compliance and Information reminded members that the charge was to cover the cost of regulation and reiterated that as a regulator we did not charge patients.

8.9. The Chair commented that looking at the challenges ahead, we would need more resources. Some of the good ideas put forward included charging for some treatment types that we did not currently charge for or adding a small increase to the current charge given the fact that the existing fee had not been uprated for inflation for several years. Any option proposed would require us to be able to demonstrate to the DHSC and the Treasury that this was a fair assessment of our actual regulatory costs. Also, once agreed, we would need to implement any new charges speedily.

8.10. The Chief Executive commented that Authority members had shown that they had an appetite for further discussion. We would therefore work on the suggestions put forward, approach the DHSC and in time the Treasury, and keep Authority members informed.

8.11. The Chair stated that the Executive would do some re-modelling and bring it back to the Authority.

Decision

8.12. Members noted the licence fee review project and that further information would be provided to the Authority in due course.

9. Transparency and Regulation

9.1. The Director of Strategy and Corporate Affairs presented this item. Members were advised that this was an initial discussion to frame future work about the transparency of our regulatory information.

9.2. Members were reminded that inspection reports and licensing committee minutes were published for every clinic on Choose a Fertility Clinic (CaFC) but that these could be hard to find and were written primarily for the purposes of making a licensing decision.

9.3. Members were also reminded that the work we were doing with the Competition and Markets Authority (CMA) and the Advertising Standards Authority (ASA) had shown that both regulators routinely published enforcement actions on their websites and in future, if enforcement action by the CMA or ASA was taken against an HFEA licensed clinic, we should consider whether to publish this information too, for patients to find easily.

9.4. It was noted that some other regulators published enforcement actions in different ways and clearer visibility was given to non-compliances, and so the HFEA should consider whether our approach was now out of step with other modern regulators. Regardless of the outcome of this discussion, we should continue to ensure consistency with the Compliance and Enforcement Policy.

9.5. Members commented that increasing transparency around our compliance work was in the best interests of patients and was therefore very welcome. Raising transparency goes to the heart of our duty to provide information to patients. Patients being able to access information readily was very important.

9.6. Members also commented that while collaborative work with the sector was important that should not prevent the HFEA drawing attention to non-compliances. Also, the CMA and the ASA publishing enforcement actions gave us a good case also to make more visible our own enforcement actions.

9.7. Members commented that we already published information but since it was contained within each clinic's CAFC page, it was not easy to find. This needed to be worked on.

9.8. Comments were made on the merits of the publication of 'league tables'. While this recognised 'good' or 'poor' clinic performance, there was the potential for patients to be excluded from some clinics to drive up success rates which could have a wider negative effect on patient care.

9.9. Some members cautioned that inspection reports needed to be seen in context as the narrative within them needed to be told in full. We also should note that whatever we publish must be within the legal powers of the HFEA.

9.10. The Chair noted that there was a will to progress some of these matters further and more detailed options would be brought back to the Authority for discussion and decision in due course.

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: 7 July 2021