

Minutes of Authority meeting 1 June 2020

Details:

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| Area(s) of strategy this paper relates to: | Safe, ethical effective treatment/Consistent outcomes and support/Improving standards through intelligence |
| Agenda item | 2 |
| Meeting date | 2 July 2020 |
| Author | Debbie Okutubo, Governance Manager |

Output:

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|------------------------------|---|
| For information or decision? | For decision |
| Recommendation | Members are asked to confirm the minutes of the Authority meeting held on 1 June 2020 as a true record of the meeting |
| Resource implications | |
| Implementation date | |
| Communication(s) | |
| Organisational risk | <input checked="" type="checkbox"/> Low <input type="checkbox"/> Medium <input type="checkbox"/> High |

Annexes

Minutes of the Authority meeting on 1 June 2020 held via teleconference

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|---------------------|---|--|
| 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 | None | |
| Observers | Steve Pugh (Department of Health and Social Care - DHSC) | |
| Staff in attendance | Peter Thompson Clare Ettinghausen Richard Sydee Rachel Cutting | Paula Robinson Debbie Okutubo Joanne Triggs Catherine Drennan |

Members

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

1. Welcome, apologies and declarations of interest

- 1.1.** The Chair welcomed everyone present to the Authority meeting and stated that this meeting marked the beginning of a return to a more balanced agenda, combining both Covid-19 and business as usual items after a series of extraordinary meetings focussing on managing the Covid-19 pandemic and its effect on the sector.
- 1.2.** To ensure that we continued to be a transparent public body she advised members that the meeting was audio recorded and the recording would be made available on our website to allow members of the public to listen to deliberations and the minutes would be issued in draft shortly after the meeting.
- 1.3.** There were no apologies for absence.
- 1.4.** 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).

2. Minutes of the meeting held on 7 May 2020

- 2.1.** Members agreed that the minutes of the meeting held on 7 May 2020 be signed by the Chair.

3. General update

3.1. The Chief Executive (CE) introduced this item and focussed on two areas.

Staff survey

3.2. Members were informed that the staff survey was now open and will be closing by mid-June. Prior to this, there was a pulse survey and responses from staff were informative. It was felt that a staff survey will also be useful.

3.3. It was noted that the survey would be an opportunity to further gauge how staff felt as some questions in the survey included how we will move back to an office setting and our future ways of working which could be described as the new normal. Members were advised that they would be kept abreast of the outcomes.

PRISM

3.4. The CE reminded members that regular oversight on PRISM was provided by the Audit and Governance Committee (AGC) and that progress remained on-track and we would be in a position to launch in late summer. However, following the earlier cessation of treatment at licensed centres and the gradual staggered re-opening under General Directions 0014 (relating to Covid-19), the launch strategy to introduce and train PRs would be discussed at the next AGC meeting scheduled for 5 June 2020.

Strategy and Corporate Affairs

3.5. The Director of Strategy and Corporate Affairs addressed members and it was noted that the Licence Committee, Statutory Approvals Committee (SAC) and Executive Licensing Panel (ELP) had all been busy over these last few months.

3.6. She reported on a range of issues including Fertility Trends, our annual publication, and that it would be released later on in the month.

3.7. The work on add-ons was ongoing as a key aspect of our strategy. We were also continuing our work with the Competition and Markets Authority (CMA).

3.8. In response to a question on horizon scanning, which usually happens at the European Society of Human Reproduction and Embryology (ESHRE) conference each year, staff commented that this would go ahead on 9 July 2020. This would be the day after ESHRE conference, which will be held online. The next SCAAC meeting is scheduled for 8 June.

3.9. Members were informed that the work being done to facilitate the UK's transition process following EU exit would be brought back to a future meeting. This would include information about the impact of the Northern Ireland Protocol.

3.10. It was noted that the new regulations relating to the change in storage period for gametes and embryos as a result of the Covid-19 pandemic was expected soon. Members were also thanked for supporting the HFEA's response to the Department of Health and Social Care (DHSC) public consultation on the 10-year limit and this was now available to read on our website..

3.11. In response to a question it was noted that there was no automatic extension for Special Directions for import and export relating to the two-year extension of the storage period.

Finance and Resources

- 3.12.** The Director of Finance and Resources reported on the office move to Stratford later in the year. It was noted that increased activity on site had brought the project back on track and the new premises should be ready for occupation from November 2020. However this would be subject to adherence to government guidance relating to social distancing and Covid-19 compliance.
- 3.13.** Regarding our finances, it was noted that the auditors were currently auditing our 2019/2020 accounts and the interim report was suggesting that we were bordering on a small overspend but at this stage it did not appear to be material. For the 2020/21 financial year we continue to await confirmation of our grant in aid.

4. Covid-19/sector/patient updates

- 4.1.** The Director of Compliance and Information provided an update on the number of clinics that had re-opened and treatment numbers undertaken. She stated that as of 29 May, 88 out of 106 licensed centres had applied to resume treatment services and these included both private and NHS centres.
- 4.2.** Members were advised that even though centres had applied and received the permission to reopen not all licensed centres will resume treatment due to various reasons including lack of PPE, Trust policy decisions and other locally based reasons, which meant that they were not actively treating patients.
- 4.3.** The Director of Compliance and Information commented that work with licensed centres was ongoing and that members would be sent updates on a weekly basis.
- 4.4.** Members provided insight and suggested that new referrals were delayed due to GP services not yet back to their full scale. Another reason was that to adhere to social distancing guidance, some Trusts had introduced a policy of operating at 30% delivery of fertility services which would be increased incrementally in a managed way. Patient appointments had also been scaled down in hospitals, and this included diagnostic and other investigations.
- 4.5.** It was noted that we had feedback from patients that some centres were over-charging patients for Covid-19 tests and for Personal Protective Equipment (PPE) usage at very high prices with no justification. Members commented that in terms of PPE some licensed centres were encouraging patients to bring their own as health services might have to ration supplies otherwise.
- 4.6.** Staff responded that Covid-19 and PPE charges were not directly within our remit but as the regulator we should comment on matters that appear to over-step the bounds of ethical treatment.
- 4.7.** The CE responded that he will be writing to all PRs later in the week about this.
- 4.8.** Members commented that Clinical Commissioning Groups (CCGs) had been advised that they could refer patients to other providers where their centres were not yet open. The DHSC representative commented that this was the intention and work was ongoing in this area.
- 4.9.** Members were concerned that the information passed on to patients from various clinics differed greatly in terms of content. Members advised that we should communicate with licensed centres about the benefits of giving detailed information to patients as this would ensure that no one was at a disadvantage due to incomplete information. The Chair commented that we might have to look

into passing the information to patients in other ways via our own website or HFEA communications.

- 4.10.** The Director of Strategy and Corporate Affairs gave an update and informed members that there was recently an Association of Fertility Patient Organisations (AFPO) meeting where attendees had commented that the information we had published on our website relating to the pandemic and the reopening of the sector was very useful.
- 4.11.** There had been over 200 individual Covid-19 related patient enquiries and the types of issues raised had changed over the last three months.
- 4.12.** Media interest had also reduced in relation to Covid-19 and fertility treatment and enquires were back to more general ones. In relation to social media, members commented that it was positive that the public could communicate directly with the regulator.
- 4.13.** Members were also informed that there had been lots of research/data enquiries and we were looking at how to manage this through the Register Research Panel (RRP) and SCAAC.
- 4.14.** Members asked how staff responding to enquiries were being supported. Members heard that training was provided annually, there were regular team meetings and regular one-to-ones with the relevant staff.
- 4.15.** The Chair also responded that the CE should pass on to staff the Authority's appreciation. The CE also commented that staff in the organisation were very well supported and there were mental health first aiders as part of that support package.

5. Revised licence fee model - development and consultation process

- 5.1.** The Director of Finance and Resources presented this item and commented that at this stage members are being asked to consider and agree the proposed options and how we will consult with the sector going forward.
- 5.2.** The suggested models below were presented
 - **Introduce new variable charges.** This would maintain a full activity-based charging regime but would consider increasing the number of chargeable activities under the licence, which could result in different charges for freeze all, fresh embryo transfer and frozen embryo transfer.
 - **Inspection fee +.** The cost of inspection would be recovered in the year of an inspection taking place and there would be a different charge for a renewal and interim inspection. The remainder of HFEA licence fees would be derived from activity levels at each clinic which was similar to current our approach.
 - **Semi fixed, some differentiation.** This would be a combination of fixed "minimum" annual fee plus an activity-based charge. Fixed charge bandings would be based on clinic size in terms of activity with a different fee based on number of IVF cycles for example 0 - 99, 100 - 249, 250 - 599, 600 - 999, 1000 - 1499, 1500 - 2249, 2500 +. A further direct activity-based charge would also apply per cycle.
 - **Fully fixed, some differentiation.** This would be a single fixed annual fee – with the annual licence fee being based on clinic size using historic activity levels and weighted against

agreed activity bands for example the number of IVF cycles - 0 - 99, 100 - 249, 250 - 599, 600 - 999, 1000 - 1499, 1500 - 2249, 2500 +.

- 5.3.** Following the presentation, members were invited to comment.
- 5.4.** Members asked what the chances of litigation were if we moved to a different modelling proposal. Staff responded that we could not rule out litigation completely but consultation with the sector would take place and the outcome would be communicated extensively to avoid misunderstandings.
- 5.5.** Members felt that detailing what the charges were based on would be a positive way forward and would be clearer to the sector. Charging an inspection fee once every 2 to 4 years might not be received positively, especially in the NHS clinics. Therefore, the semi-fixed third option above might be a solution to this. Some members felt that there should be an inspection fee as it was the norm in other sectors including the education sector. Therefore, having a less frequent inspection fee could be seen as a reward for compliance.
- 5.6.** Regarding consultation, members cautioned against limiting it to patient groups only and suggested that it should be extended to the wider audiences in the sector. Ensuring there was fairness in terms of size and volume of activity was a fairer way forward.
- 5.7.** The representative from the DHSC commented that timings needed to be factored in especially as other government departments would be involved in signing off the change to fees.
- 5.8.** Staff commented that the Treasury would be expecting the proposal to demonstrate fairness and that time for this had been built into the plan.

Decision

- 5.9.** Members considered and agreed the proposed modelling options for wider consultation.
- 5.10.** Members agreed the proposed timetable for approval of a new fees model in November 2020.

6. New strategic risk register

- 6.1.** The Risk and Business Planning Manager presented the new strategic risk register to the Authority.
- 6.2.** Members were advised that three new risks aligning to the new strategy for 2020-2024 had been drafted. They were
 - RF1 – Regulatory framework (the best care)
 - I1 – Information provision (the right information)
 - P1 – Positioning and influencing (shaping the future)
- 6.3.** Three risks which were all above tolerance had been identified and they were
 - Board capability
 - Financial viability
 - Relocation of HFEA offices in 2020.
- 6.4.** Coronavirus was a new high risk that has been added to the register, but it was at tolerance level.

- 6.5.** The Chair commented that it was a sensible risk register but there were concerns around the above tolerance risks. Regarding the board capability risk, the Chair commented that we continued to carry two vacancies and nine members would be coming to the end of their terms of office (be it first or second term) within the next few months. She stated that we were working with DHSC to try and stagger finishing dates for the purposes of continuity and invited other members to comment.
- 6.6.** Members asked if it was felt that the risk register adequately prepared us for our current position. Also, if the risk appetite for the board was appropriate for the current situation.
- 6.7.** Members suggested that some of the causes, sources and controls in the risk register be revisited so that they reflected strategic high-level points.
- 6.8.** Members felt that it was an excellent risk register. In particular, members welcomed the approach taken, responsiveness to information provision and how the register aligned with the strategy.
- 6.9.** Regarding Heads of service considering what work to prioritise, especially if income should fall below projected expenditure, members asked staff to ensure that the Authority was sighted on the proposals.
- 6.10.** In response to a question, it was noted that PRISM plans and the launch and roll-out to clinics remained under review and the PRISM report to AGC would include our underlying assumptions and management of risks.
- 6.11.** The Chair commented that there was pressure all around in doing business as usual and addressing the new normal due to the impact of Covid-19 but she felt that we were getting the balance right.

Decision

- 6.12.** Members noted and agreed the new strategic risks for the 2020 – 2024 strategy subject to the comments above.

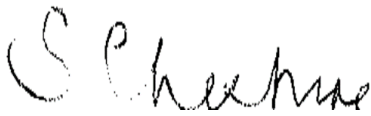
7. Any other business

- 7.1.** The Chair commented that she had nearly completed all member appraisals and would be sending them on to the DHSC when completed. It was noted that members whose terms of office were affected by the current discussions would be contacted directly by the Chair.
- 7.2.** The 30th anniversary of the HFEA and the Act was coming up and Lord Bethell, Parliamentary Under Secretary of State at the DHSC supported the idea of marking this key milestone.
- 7.3.** The Chair advised members that the date of the next meeting would be 2 July 2020.
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Chair's signature

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

Signature

A handwritten signature in black ink, appearing to read 'S Cheshire', written in a cursive style.

Chair: Sally Cheshire

Date: 2 July 2020