

# Minutes of Authority meeting 29 January 2020

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## Details about this paper

Area(s) of strategy this paper relates to:	Safe, ethical effective treatment/Consistent outcomes and support/Improving standards through intelligence
Meeting:	Authority
Agenda item:	2
Meeting date:	18 March 2020
Author:	Debbie Okutubo, Governance Manager
Annexes	

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## Output from this paper

For information or decision?	For decision
Recommendation:	
Resource implications:	
Implementation date:	
Communication(s):	
Organisational risk:	Low

## Minutes of the Authority meeting on 29 January 2020 held at ETC.venues Victoria, 1 Drummond Gate SW1V 2QQ

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Members present	Sally Cheshire Margaret Gilmore Anita Bharucha Ermal Kirby Emma Cave	Jonathan Herring Gudrun Moore Ruth Wilde Yacoub Khalaf Kate Brian
Apologies	Anne Lampe Anthony Rutherford	
Observers	Steve Pugh Dafni Moschidou	Department of Health and Social Care (DHSC)
Staff in attendance	Peter Thompson Clare Ettinghausen Richard Sydee Rachel Cutting Catherine Drennan	Amanda Evans Joanne Triggs Paula Robinson Nora Cooke-O'Dowd Debbie Okutubo

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### Members

There were 10 members at the meeting – eight lay members and two professional members.

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## 1. Welcome and declarations of interest

- 1.1.** The Chair opened the meeting by welcoming Authority members, the public and staff present. 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 at the meeting to listen to deliberations.
- 1.2.** Declarations of interest were made by
- Yacoub Khalaf (PR at a licensed clinic)
  - Ruth Wilde (Counsellor at a licensed clinic).

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## 2. Minutes of Authority meeting held 13 November 2019

- 2.1.** Members agreed that the minutes of the meeting held on 13 November 2019 were a true record and be signed by the Chair.

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## 3. Chair's report

- 3.1.** On 19 November the Chair gave a talk at the University of Bristol entitled 'Shaping Fertility Treatment in the 21st century: the best care and the right information within the law'.
- 3.2.** On 27-30 November the Chair and Yacoub Khalaf, Authority member, spoke at the annual Egyptian Fertility Society Conference on 'Shaping fertility treatment in the 21st century: the UK

model of patient safety & quality improvement'. It was noted that Yacoub received an award of honour at the Conference for his work in the fertility field internationally.

- 3.3.** On 4 December the Chair spoke at a session at the Progress Educational Trust conference on 'regulating for the best patient treatment'.
- 3.4.** On 9 December the Chair attended the all staff awayday.

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## **4. Chief Executive's report**

- 4.1.** On 14 November the Chief Executive (CE) gave a talk on 'Add-on treatments' to the London Women's Clinic Symposium.
- 4.2.** On 15 November the CE gave evidence on the regulatory challenges posed by gene editing to the International Human Germline Genome Editing Commission. This was a public event held at the Royal Society.
- 4.3.** On 21 November the CE provided advice to the Australian National Health and Medical Research Council (NHMRC) who wanted to understand our experience of regulating mitochondrial donation in treatment. The NHMRC are advising the Australian Government on this issue.
- 4.4.** On 27 November the CE attended the Huxley summit at the Royal Institution and took part in a seminar on the communication of risk.
- 4.5.** On 17 December the CE attended an EU exit delivery partners meeting involving the DHSC and other Arms-Length Bodies (ALBs).
- 4.6.** On 11 January the CE spoke at the Fertility 2020 conference in Edinburgh on the subject of regulating innovation in a changing world, where he focused particularly on add-ons.
- 4.7.** On 15 January the CE and the Senior Management Team (SMT) attended the quarterly DHSC/HFEA accountability meeting.
- 4.8.** On 16 January the CE attended the health and care leaders' talent board.
- 4.9.** On 28 January the CE spoke at Cambridge University on 'regulating innovation: policy-making in reproductive technologies'.
- 4.10.** The CE gave an update on EU exit. He stated that the UK would leave the EU at the end of January. The transition period would last until the end of December 2020. During this period nothing would change. He continued that looking ahead, much will depend on the agreement that the UK reaches with the EU and stated that the Authority and clinics would be updated as soon as there was more detail.

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## **5. Committee Chairs report**

### **Licence Committee**

- 5.1.** The Chair of the Licence Committee reported that the committee met on 7 November 2019 and considered five items: two renewals for treatment and storage licences which were granted, one interim treatment and storage licence which was approved to continue, and two executive updates on treatment and storage centres which were noted.

- 5.2.** They also met on 9 January 2020 and considered two items: one renewal for a treatment and storage licence and one interim inspection report for a treatment and storage licence. The minutes were still in draft.

### **Statutory Approvals Committee**

- 5.3.** The Chair of the Committee reported that the Committee met on 31 October 2019 and considered five items: one mitochondrial donation application and four new PGD conditions, all of which were approved.
- 5.4.** At the 28 November 2019 meeting they received a briefing on gamete donation trends and approved four PGD conditions. It was noted that one of the PGD conditions was approved for one family specifically. One special direction that had been adjourned was also approved.
- 5.5.** The Committee met on 12 December 2019 and considered four items. Three new PGD conditions and one special direction were approved.
- 5.6.** Authority member Anthony Rutherford also presented a paper on ovarian reserve testing and fertility treatment for information. Lastly, they conducted their annual committee review.

### **Executive Licensing Panel**

- 5.7.** The Chair of ELP advised members that the panel had met four times since the last Authority meeting, on 26 November 2019, 10 December 2019, 14 January 2020 and 28 January 2020. The panel considered 19 items in total: one initial licence application, two licence renewals, 12 interim reports, and four licence variations. 18 items were approved, with one interim report was deferred.
- 5.8.** In addition, there were 19 Licence Officer approvals: 11 import tissue establishment certificates, five changes of Licence Holder, one change of centre name and two voluntary revocations of licences.

### **Audit and Governance Committee**

- 5.9.** The Chair of the Audit and Governance Committee informed the Authority that they had met twice since the last Authority meeting, on 3 December 2019 and 21 January 2020.
- 5.10.** At the 3 December 2019 meeting in addition to the standard items, there was a substantive report on the recent internal audit of our corporate governance. This was scored as substantial (the highest rating) with no audit recommendations. She noted that this was a testament to the Board and all officers involved in maintaining our high standards of governance.
- 5.11.** The reserves policy was approved. The committee also looked at the gift and hospitality register and the counter fraud strategy.
- 5.12.** At the meeting the digital programme was discussed at length and the committee agreed to have monthly meetings to review this item.
- 5.13.** The Committee met on 21 January 2020 to review the progress of the digital programme and will meet again in February.

### **Decision**

- 5.14.** Members noted the Committee chairs' reports and the licensing activity report.

- 5.15.** They further noted that the licensing activity report and its frequency would be reviewed by the executive now that sufficient data had been accumulated.

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## **6. Performance report**

- 6.1.** A report summarising performance data up to the end of November 2019 was presented to the Authority.

### **Compliance and Information**

- 6.2.** The Director of Compliance and Information reported back on her area of responsibility. It was noted that the new person responsible entry programme (PREP) was now operational and PRs could use it as a training tool for staff.
- 6.3.** There had been a slight increase in patient complaints about centres and this was being monitored for trends and themes by officers.
- 6.4.** Members were reminded that complaints were reported annually in our State of the Sector report.
- 6.5.** The inspection schedule for 2020 was on track. Members were also advised that the clinic level performance data on our 'choose a fertility clinic' function on the website had been updated.
- 6.6.** Due to the publicity about donor anonymity there was a lot of ongoing work with the 'Opening the Register' team as they were receiving a higher number of enquiries than usual.

### **Strategy and Corporate Affairs**

- 6.7.** The Director of Strategy and Corporate Affairs advised the Authority of ongoing work in her area and several pieces of which were on the agenda for the meeting - the new strategy and business plan, the communication strategy and the two presentations on multiple births and success rates.
- 6.8.** Work was ongoing in relation to the research engagement day scheduled for 18 May 2020. The Person Responsible leadership event was also being planned for the Autumn.
- 6.9.** Reviews of effectiveness for all committees had been carried out and would be reported at the next Authority meeting.
- 6.10.** Lastly, she reported that the report on 'family formations' would be published in March. And preparations were in hand on the annual fertility trends report, work was ongoing in relation to the Code of Practice and other key areas of activity.

### **Finance and Resources**

- 6.11.** The Director of Finance and Resources reported back to the Authority. He stated that we had reduced our income forecast since the publication of the performance report but we were still on target to balance our books for the current financial year.
- 6.12.** He commented that the office move programme was on track and that we had a deadline to move out of our current premises by December 2020.
- 6.13.** It was noted that our readiness to move our IT to the new premises was also on track and that the impact on staff was being monitored.

- 6.14.** In response to a question about specific planning for staff who would be impacted negatively by the move, officers responded that in line with other ALBs, excess fares would be reimbursed. Also that home working arrangements would be reviewed and if there were specific requests, they would be dealt with on a case by case basis as we did not want to lose talented staff.

## **Decision**

- 6.15.** Authority members noted the performance report.
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## **7. 2020/21 fees and budget**

- 7.1.** The Director of Finance and Resources presented to the Authority. He stated that forecasting future activity from trends in fertility treatment since 2009/10 indicated that there could now be a real decrease in billable treatment cycles which would impact on fees.
- 7.2.** Members were reminded that we raise most (c.80%) of our operating funds through charging fees to licensed establishments to recover the cost of regulation. It was noted that the charge was to licensed establishments and not patients.
- 7.3.** Overall licence fee activity which had increased year on year for some years had this year remained stagnant and recently started to decline, in particular for the NHS funded clinics. This was no longer offset by increased activity in the private sector. In particular, it was noted that the proportion of cycles that were billable had reduced and that as a general principle the cost of all regulated activity should be recouped.
- 7.4.** It was noted that licence fee income would fall if these emerging trends continued.
- 7.5.** There was an option to increase fees but officers were conscious that increases in fees would inevitably be passed to patients by clinics.
- 7.6.** Members were advised that an increase to the current charges of £5 per IVF cycle and £2.50 per donor insemination (DI) cycle would raise approximately £325k more in fees than the current charge. It was noted that this would be sufficient to cover the income shortfall identified for 2020/21. Members were clear that this was not an option they could support at this stage.
- 7.7.** In response to a question about the decrease in NHS funded treatment, it was also noted that the HFEA's grant in aid from the Department had halved over recent years. Also, some non-billable activities were essentially deferred payments, since the activity could then lead to a billable activity. However, by the time any such cycle occurred and became billable it could be too far in the future. An example was given of there being a social trend towards egg freezing - these cycles were not billable until, and unless, the eggs and sperm were used in treatment, which would be billable.
- 7.8.** Members asked, if they agreed on introducing a revised fee regime, how long it would take before this could be implemented. Staff responded that they would need to work with the DHSC and possibly the Treasury to gain approval for any changes, and so this could take up to 12 months.
- 7.9.** Members commented that they needed more information before they could take a decision, as there was not yet enough information to know if it was a definite trend.

**7.10.** It was noted that any proposal to change the fee structure would require a plan to be in place before the end of this financial year. It was also noted that the HFEA's fees had not changed since 2016.

### **Decision**

**7.11.** Following deliberations, members approved the 2020/21 budget assumptions.

**7.12.** They agreed that the Executive should continue to explore options for managing the financial risk for 2020/21.

**7.13.** They agreed that further work should be undertaken to consider whether the existing licence fee structure remained the appropriate mechanism for recovering the cost of regulation and to identify an alternative proposal that could replace the existing model.

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## **8. Strategy and planning**

**8.1.** The Head of Planning and Governance presented the final draft of the new strategy for 2020-2023 alongside the business plan for 2020-2021.

**8.2.** It was noted that the Committee Chairs had kindly assisted with finalising the draft strategy.

**8.3.** The Authority was also advised that the vision had been slightly revised to read:

**Regulating for excellence: shaping the future of fertility care and treatment**

**8.4.** Members were advised that background operational planning was in progress and would be discussed at the next Corporate Management Group (CMG) meeting.

**8.5.** Members welcomed the strategy.

**8.6.** Comments on delivery included:

- In the work on partners, it was important to remember our initial particular focus was specifically on male partners and male infertility, since male partners were felt to have been particularly overlooked in the past.
- On donor conception, it was noted that the world was changing and we therefore had an opportunity to address this area through our work to prepare for higher numbers of OTR enquiries. The quality of donor information was also very important. It was noted that a conversation about the 10-year rule about storage, in terms of shaping the future, would be required if proposals for change were introduced.

**8.7.** Members commented on the wording of the final aim, that whilst it was important to embrace changes in the law we also needed to engage well and work with the law. Lastly, we needed to be as proactive as possible in our shaping the future work.

### **Decision**

**8.8.** The Authority approved the strategy for 2020-2023 and the draft business plan for 2020/21 subject to considering the wording of the final aim in the strategy, to include engaging with, as well as embracing, future developments.

**8.9.** Members approved the activities section of the business plan and agreed that the more developed version could be circulated to Authority members via email, rather than coming back to a meeting.

## 9. Communication Strategy

- 9.1.** The Head of Communications presented to the Authority. It was noted that the objective of the new communication strategy included:
- Improving partnership working
  - getting information to primary care professionals
  - increasing our reach
  - being proactive with the media
  - using clinic communication to share messages and learning.
- 9.2.** Members were advised that there was now more access to metrics and feedback which enabled us to identify necessary changes to be more effective.
- 9.3.** What would be done to improve our communication across the board was also laid out in the strategy and included maximising opportunities identified, building on our strengths, addressing our weaknesses and being aware of potential threats.
- 9.4.** It was noted that there were new accessibility rules for digital channels which we were adhering to and work was continuing in this area.
- 9.5.** Members commented that it was a detailed strategy and expanding the new patient forum would be very important. Also, that bolder messaging fitted well into our strategy for the future.
- 9.6.** Members also commented that we need to reach a position where the HFEA came up first in digital searches for fertility treatment. Also, that the website could be improved further by including more rich media including videos and pictures.
- 9.7.** Members noted that there was now a separate event for clinic leaders.
- 9.8.** Regarding more pictures on our website, staff responded that there was some animation on our website but that this might be hard to find, so this would be looked into and comments taken onboard.
- 9.9.** Also that some professional websites had an HFEA link on their website which remained a positive way forward.
- 9.10.** Lastly, members commented that due to the limited resources, we needed to focus our work as we could not do everything at once.

### Decision

- 9.11.** Members noted the communications strategy.
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## 10. Multiple births

- 10.1.** The Head of Research and Intelligence and the Research Manager presented to the Authority.
- 10.2.** It was noted that the proportion of single, double and triple embryo transfers had changed over the last 20 years. Also, that multiple birth rates were decreasing across the sector and the average 10% target reached, but some outliers remained high.



- 10.3.** Members were advised that clinics with fewer than 150 cycles were excluded because the small number made analysis complicated.
- 10.4.** Members commented that outlier clinics needed to be investigated further as it was not clear if outliers over the years were the same clinics.
- 10.5.** It was noted that patients going abroad for treatment meant that in some areas of the UK there had been an increase in multiple births, which was outside of the HFEA's area of responsibility.
- 10.6.** Some members wanted to know how the 'one at a time campaign' had been so successful. Staff responded that the joint efforts with the sector and the public meant that there was an increase in awareness about the risks of transferring more than one embryo at a time..
- 10.7.** Other members commented that the 'one at a time' campaign had valuable support from professional bodies and it could be timely now to ask them to review their professional guidance.
- 10.8.** It was suggested that we would seek to work further with the sector, and, resources permitting, we would explore reducing the targets further.
- 10.9.** In response to a question it was noted that European Society of Human Reproduction and Embryology (ESHRE) produce a comparative data report on international birth rates.
- 10.10.** Members commented that in particular, among those aged 37-39 year the multiple birth rate had not decreased as far as possible and good practice from the 'one at a time' campaign could be used in this age group. However, it was suggested that some patients using IVF treatment actively sought a multiple birth.
- 10.11.** Members commented that the disparity could be due to funding as research showed that increasing government funding would also decrease the multiple birth rate. Also, it needed to be borne in mind that single embryo transfer in NHS clinics was non-negotiable, as that remained the policy.
- 10.12.** It was suggested that some privately funded patients were going into IVF with the view of having only one birth, which could be a multiple, so it was imperative to educate the public about the risks involved in multiple births.

## **Decision**

- 10.13.** Members noted the work that could be done with the public, sector and professional bodies to review the multiple birth rate target in due course.

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## **11. Birth rates**

- 11.1.** The Head of Research and Intelligence and the Research Manager presented to the Authority. It was noted that birth rates have increased across the sector in the last ten years and that Scotland had the lowest multiple birth rate and highest live birth rate of any UK nation.
- 11.2.** There was a suggestion that clinic-level data could be included in the next fertility trends statistical release. However, it was generally agreed that through 'choose a fertility clinic', patients could choose up to three clinics at a time.

- 11.3.** Members commented that we needed to find out what successful clinics were doing differently and what others could learn from them. From a regulatory perspective, clinics with low success rates could and should learn from those with high success rates.
- 11.4.** There was a comment that some clinics argued that their success rates were a direct result of their patient mix. Different practices occurred in different clinics which meant that some degree of variation would continue.
- 11.5.** It was noted that we needed to get the comparator right given the mix of patients in clinics to avoid a heightened disparity between clinics. The credibility and reliability of data was therefore important.
- 11.6.** Members asked if another organisation could conduct some analysis for us, in light of resource restrictions. There was also a comment that data we hold needed to be presented in context.

### **Decision**

- 11.7.** Staff to investigate what best practice ideas can be acquired from Scotland and what protocols they were planning to put in place.
- 11.8.** Members requested that staff do further work on identifying what a successful clinic should look like, and due to the complexity of the variables involved clinic-level data will not be published in Fertility Trends this year.

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## **12. Any other business**

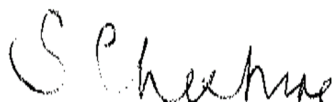
- 12.1.** The Chair thanked everyone who was present at the meeting.
- 12.2.** There was no other business.

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## **13. Chair's signature**

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

### **Signature**



**Chair: Sally Cheshire**