

# Minutes of Authority meeting 27 June 2018

## Strategic delivery:

Safe, ethical  
effective  
treatment

Consistent  
outcomes and  
support

Improving standards  
through intelligence

## Details:

Meeting Authority

Agenda item 2

Paper number HFEA (12/09/18) 888

Meeting date 12 September 2018

Author Catherine Burwood, Senior Governance Manager

## Output:

For information or  
decision? For decision

Recommendation Members are asked to confirm the minutes as a true and accurate record of the meeting.

Resource implications

Implementation date

Communication(s)

Organisational risk  Low  Medium  High

Annexes

## Minutes of the Authority meeting on 27 June 2018 held at Church House, 27 Great Smith Street, London SW1P 3NZ

Members present	Sally Cheshire Kate Brian Andy Greenfield Anthony Rutherford Bishop Lee Rayfield	Yacoub Khalaf Margaret Gilmore Bobbie Farsides Ruth Wilde Anita Bharucha
Apologies	Anne Lampe	
Observers	Steve Pugh, Department of Health and Social Care	
Staff in attendance	Peter Thompson Nick Jones Richard Sydee Clare Ettinghausen Catherine Drennan Erin Barton	Dan Howard Sumrah Chohan

### Members

There were 10 members at the meeting, 7 lay members and 3 professional members.

## 1. Welcome, apologies and declarations of interest

- 1.1.** The Chair opened the meeting by welcoming Authority members and members of the public to the fourth meeting of 2018. As with previous meetings, it was audio-recorded and the recording would be made available on our website to enable interested members of the public who could not attend the meeting to listen to our deliberations.
- 1.2.** Apologies were received from Anne Lampe.
- 1.3.** Declarations of interest were made by:
  - Anthony Rutherford (Clinician at a licensed centre)
  - Yacoub Khalaf (Clinician at a licensed centre)

## 2. Minutes of Authority meeting held on 09 May 2018

- 2.1.** Members agreed the minutes of the meeting held on 09 May 2018 for signature by the Chair.

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### 3. Chair's report

- 3.1.** The Chair attended Fertility Fest on 11 May. This event centred on the 40<sup>th</sup> anniversary of IVF. The Chair took part in a panel which discussed the triumphs and challenges of IVF.
- 3.2.** Also on 11 May, the Chair spoke at the British Infertility Counselling Association's (BICA) 30th anniversary conference, on improving clinic leadership, the importance of emotional support for patients and counselling.
- 3.3.** On 30 May 2018 the Chair, Authority member Kate Brian, and the Director of Strategy and Corporate Affairs, met Professor Lesley Regan, President of the Royal College of Obstetricians and Gynaecologists (RCOG). This was a follow up to a previous event at the RCOG in March that the Chair and Professor Regan participated in. The HFEA and RCOG committed to working together more closely on a range of issues related to fertility treatment.
- 3.4.** Also on 30 May, the Chair and Chief Executive had the HFEA annual accountability meeting with the Department of Health and Social Care (DHSC). The DHSC agreed that the HFEA has had a very successful year and delivered all its objectives in the 2017/18 business plan. The Chair thanked Authority members and HFEA staff for the role that everyone played in this achievement.
- 3.5.** On 6 June, the Chair and the Senior Management Team (SMT) met Jane Stewart and Raj Mathur from the British Fertility Society (BFS) to discuss how we can develop a more strategic relationship. Key issues discussed included such as NHS commissioning, treatment add-ons, ovarian hyperstimulation syndrome (OHSS) and clinic leadership.
- 3.6.** On 18 June the Chair met Nicola Blackwood, the new Chair of the Human Tissue Authority (HTA). Both Chairs committed to work together on issues of shared interest.
- 3.7.** The Chair also attended the Scientific and Clinical Advances Advisory Committee (SCAAC) on 18 June.

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### 4. Chief Executive's report

- 4.1.** On 24 May the Chief Executive attended an event at the Institute for Government to mark the publication of a report examining the first five years of NHS England.
- 4.2.** On 30 May, as the Chair mentioned, the Chief Executive also attended the HFEA annual accountability meeting. The Chief Executive also thanked staff and Authority members for their hard work.
- 4.3.** On the 6 June, again as the Chair also mentioned, the Chief Executive met Jane Stewart and Raj Mathur of the BFS.
- 4.4.** On 12 June the Chief Executive attended the HFEA's Audit and Governance Committee meeting.
- 4.5.** On the 18 June, the Chief Executive attended the SCAAC meeting.

- 4.6.** Lastly, on 26 June the Chief Executive attended an event at the House of Lords to mark the launch of a new report from the Institute for Government and the Health Foundation, on the future funding of health and social care. The report looks at previous attempts to depoliticise controversial public policy issues and the HFEA was cited as one successful case study of that. The Chief Executive reminded members that they had been sent a link to the report.

## Press Coverage

### LaingBuisson report

- 4.7.** Recently, a report on the financial state of the private fertility sector was published by a well-known healthcare research company, LaingBuisson, in which reference was made to the HFEA and which made use of HFEA data.

### Guardian interview and comment for You and Yours

- 4.8.** The Chief Executive gave an interview to the Guardian two weeks ago, on the theme of treatment add-ons. He explained the work we have been doing to ensure the introduction of add-ons is responsibly done and clearly explained to patients, highlighting the traffic light system introduced last year. The article was published last week.
- 4.9.** We also provided a comment on treatment add-ons and overseas treatment to Radio 4's You and Yours programme.
- 4.10.** The Chief Executive explained that on each occasion the HFEA emphasised the value, not just of the traffic light system, but of our website overall, using this coverage as a chance to raise awareness of topics such as responsible innovation.

### Comment for i newspaper

- 4.11.** Last week we provided a comment for the i newspaper on the development of IVF within the context of the 70th anniversary of the NHS.
- 4.12.** The Chief Executive noted that we can look forward to more coverage related to the 70th anniversary over the coming weeks, especially as IVF was specifically referenced by the Secretary of State in Parliament recently, as an example of the NHS's excellence and innovation.

### Data requests

- 4.13.** The Chief Executive reported that our Register continued to be a considerable press resource, and this month we provided data on (among other areas):
- Male infertility (to the BBC Victoria Derbyshire show)
  - Treatment numbers (to the Sunday Express)
  - Egg freezing (to BBC Capital)
  - Patient ethnicity (to BBC Impact)
  - Patients aged over 50 (to the Mail on Sunday)

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## 5. Committee Chairs' reports

### Licence Committee

- 5.1.** The Chair of the Licence Committee advised members that the Committee met on 3 May to consider an executive update regarding one clinic. The Committee noted the update.

### Statutory Approvals Committee

- 5.2.** The Chair of the Statutory Approvals Committee (SAC) advised members that the Committee met on 26 April and 24 May. All applications considered in April were approved: five pre-implantation genetic diagnosis (PGD) applications and two special direction applications. In May one mitochondrial donation application; four PGD applications; and one special direction application was considered. All applications were approved.

### Executive Licensing Panel

- 5.3.** The Chair of the Executive Licensing Panel (ELP) advised members that the Panel had met four times since the last Authority meeting, on 10 May, 25 May, 8 June and 22 June. 17 items were considered in total: one initial licence application; three renewal applications; five interim inspection reports; seven variation of licence applications; and one executive update. All were approved.
- 5.4.** The Licensing Officer considered four applications, which were all approved: two change of licence holder and two EU import certificate applications.

### Audit and Governance Committee

- 5.1.** The Chair of the Audit and Governance Committee (AGC) advised members that the Committee had met on 12 June. Aside from the usual standing items and updates from internal and external audit, the committee received reports on: annual accounts; HR, people planning and processes; a digital programme update; resilience, business continuity management and cyber security; the strategic risk register; whistle blowing and fraud; and contracts and procurement.
- 5.2.** The Chair of AGC thanked the Director of Finance and Resources and the Head of Finance for the work they had contributed towards the creation of the Report of the Audit and Governance Committee activity 2017/18.

### Scientific and Clinical Advances Advisory Committee

- 5.3.** The Chair of the Scientific and Clinical Advances Advisory Committee (SCAAC) advised members that the Committee considered four items during their 18 June 2018 meeting.
- 5.4.** The four items covered: selecting sperm for intracytoplasmic sperm injection; treatment add-ons; supporting research; and the potential regulation of so-called embryo-like entities.

### Remuneration Committee

- 5.5.** The Chair advised members that the Remuneration Committee had met that morning.

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## 6. Report of the Audit and Governance Committee activity 2017/18

- 6.1.** The Chair of the Audit and Governance Committee (AGC) presented a report summarising the Committee's activity during the year and giving its opinion on the HFEA's risk management and internal control arrangements. The report supports the Accounting Officer's Annual Governance Statement.
- 6.2.** During this period AGC scrutinised regular reports on the progress of the remainder of the IfQ programme (covering data submission and the migration of the Register to a new database), the HFEA response to IT and cyber incidents as well as overall data and cyber security.
- 6.3.** The Chair of AGC explained that the Committee had provided scrutiny and challenge to the remainder of the IfQ work in order to receive assurance that risks were being effectively managed. Approval had been given to go ahead with the final work needed for this.
- 6.4.** The Chair of the AGC thanked staff for the high quality support provided to the Committee.

### Decision

- 6.5.** The Chair noted that one financial control (assurance that the HFEA had adequate and effective systems of control, governance and risk management in place) had been rated as 'moderate' during the internal audit carried out by the Government Internal Audit Agency. She enquired if there were any specific improvements that had been suggested and it was confirmed that the recommendations had been implemented.

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## 7. Performance report

- 7.1.** Members were presented with a paper summarising performance up to the end of April 2018, with financial data covering both April and May.
- 7.2.** The Director of Strategy and Corporate Affairs outlined activity in what was a busy period. This included changes being developed for the Statutory Approvals Committee (SAC) to assist with increasingly heavy agendas; work towards the 40<sup>th</sup> anniversary of IVF, including the development of a social media campaign; the preparation of a report on egg freezing in the summer and one on the state of the sector for the autumn; developing the qualitative work on the pilot national patient survey with YouGov; and the Code of Practice update.
- 7.3.** The Chair noted the Science Museum exhibition about would open on 5 July 2018 and members had received invitations to the launch.
- 7.4.** Members thanked the Director of Strategy and Corporate Affairs for the new 'Authority Update' newsletter which was now circulated to them.
- 7.5.** The Chair of SAC highlighted that there was a lot of background work going on regarding this Committee, in particular with respect to mitochondrial donation applications.

- 7.6.** The Director of Compliance then reported on overall performance and the IfQ programme.
- 7.7.** Overall performance was good. The organisation experienced technical issues with its IT systems from 19 April to early May, which affected a number of processes and therefore key performance indicators (KPIs).
- 7.8.** Three KPIs were classified as red (outstanding errors; average number of working days from day of inspection to the day the draft report is sent to the PR; and Opening the Register requests responded to within 20 working days) and one as amber ('unplanned' leavers).
- 7.9.** The Director of Compliance reported that the HFEA was on track with the IfQ programme and provided an overview of milestones and decision points. A beta version of PRISM was live with feedback being taken from clinics. Positive progress was being made in data migration, but this still remained the biggest risk to delivery.
- 7.10.** The Chair asked if we were confident there would be no further IT issues. The Director of Compliance confirmed that although this could not be guaranteed, all the appropriate and available steps had been taken. The Chief Executive clarified that there had not been any data at risk during the issues experienced in April and May.
- 7.11.** The Authority members who work in fertility clinics were asked if they felt positive about the proposed data submission changes; they confirmed they were.
- 7.12.** The Authority members had a discussion around clinics updating their Choose a Fertility Clinic page on the HFEA website and the lack of up to date information regarding egg and sperm donor availability. It was confirmed that the executive looked into this at inspections, but did not have the resources to interrogate data thoroughly for every clinic in between inspections. It was agreed that the messaging about this, including during inspection, should be looked into.
- 7.13.** The Director of Finance reported that annual accounts had been signed by the Chief Executive today and would now be provided to the National Audit Office. It was reported that we were still awaiting approval from the DHSC for additional capital expenditure on IfQ work.

### Decision

- 7.14.** Following discussion, the members noted the latest performance report.

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## 8. Code of practice

- 8.1.** This item was introduced by the Chief Executive who confirmed that the updated Code of Practice had been subject to consultation and that detailed responses had been received from over 100 respondents, with many from professional organisations. The Chief Executive thanked all contributors for their comments.
- 8.2.** The Policy Manager explained that of the 33 guidance notes in the Code of Practice, 23 had been updated. Changes were reported to members in groups and the feedback received during the consultation was highlighted.

### Least substantive changes

**8.3.** These related to areas where no feedback, or positive feedback, had been received:

- Egg sharing
- Screening
- Data protection
- Import and export of gametes and embryos
- Single European Code
- Data submission
- Corrections and minor clarifications

### Decision

**8.4.** Following discussion of the evidence base regarding reducing the quarantine period for screening, and confirmation that the impact on patients will be monitored on an ongoing basis, all of the changes to the Code of Practice, regarding the areas listed above, were approved.

### Ovarian hyperstimulation syndrome (OHSS), Consent, Surrogacy and Storage

**8.5.** The Policy Manager presented information on planned changes to these areas of the Code of Practice, in addition to changes made following the consultation.

### Decision

**8.6.** Members approved the changes regarding OHSS, noting that the changes were sensible and pragmatic.

**8.7.** There was a discussion around consent, with members highlighting uncertainties over the process of receiving and taking consent electronically and whether a particular process being used in a clinic at present was sufficient. The Head of Legal reassured members that the process highlighted was sufficient under the new guidance.

**8.8.** Suggestions for new wording to this section of the Code of Practice were made and it was agreed to discuss this further outside of the meeting. Otherwise, the Members approved the changes regarding consent.

**8.9.** Members approved the changes regarding extension of storage. They noted that, although it is for Parliament to change the law, there is increased concern from clinicians about the 10 year storage period and the impact on some patients.

**8.10.** Subject to clarifying in the Code of Practice that determining suitability for surrogacy should be a clinic level decision, the Members approved the changes regarding surrogacy.

### Substantive changes

**8.11.** The following areas of guidance were covered in this group:

- Leadership
- Patient support
- Information provision to patients
- Counselling
- Discussion of implications



## Decision

- 8.12.** Members approved the changes regarding leadership, noting that examples of good leadership and support for PRs would be further developed by a specific project on leadership taking place later this year.
- 8.13.** Members approved the changes regarding patient support, noting that patient support was strengthened via the amendments.
- 8.14.** Members approved the changes regarding information provision.
- 8.15.** Members approved the changes regarding counselling.
- 8.16.** Members discussed the importance of ensuring that there is a distinction between counselling and a discussion of implications and whether the Code of Practice was clear about who should undertake the discussion of implications. It was agreed that work on a final proposal for the discussion of implications section of the Code would be continued outside of the meeting and considered by relevant Members prior to approval.

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## 9. Voluntary contact register

- 9.1.** The Chief Information Officer presented a paper on ongoing work to develop a new vision and approach for the voluntary contact register, known as the Donor Conceived Register (DCR).
- 9.2.** The Chief Information Officer provided members with background about the DCR and how the service was run. In April 2017 responsibility for the DCR transferred from the DHSC to the HFEA. We sought to retender the service to ensure a high-quality service was provided, offering value for money. One bid was received from the National Gamete Donation Trust, the current provider. The bid failed to meet our quality and price criteria and the contract was not awarded.
- 9.3.** The Chief Information Officer outlined the options considered going forward, to ensure we were able to provide a stable, long term service. This included the preferred option, to develop a new service provided by industry and sector leading suppliers, with oversight from the HFEA.
- 9.4.** The Chief Information Officer outlined progress to date, including engagement with different stakeholders, and confirmed that a consultation on an outline service model would start in July. The plan was for the new service to go live in October or November 2018, with continual monitoring to ensure quality.
- 9.5.** The Authority was asked to note:
- The update on progress made to establish a new Voluntary Contact Register service
  - The update on consultation, engagement and dialogue with stakeholders, including DCR
  - The proposed timeline for the implementation of the new service
  - How performance of the new service will be reviewed and monitored.

- 9.6.** The Chair emphasised that this report reflected the general direction the HFEA would take to support patients. She asked the Executive to come back to Authority with the outcome of the consultation.

### Decision

- 9.7.** Members were pleased with the direction the work was taking. In discussion it was noted that it was important to raise the profile of the consultation amongst donor conceived people who have not yet expressed a view. Members also asked why it would not be preferable to provide the service in-house. It was accepted that the range of skills required were best sourced elsewhere. Members were happy for the consultation to proceed and that an update would be provided to Authority in September.

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## 10. Donor information requests

- 10.1.** The Donor Information Manager provided members with information about donor information requests (known as Opening the Register (OTR)) and associated counselling support.
- 10.2.** The Donor Information Manager outlined performance in relation to OTR requests, providing data about the number of applications received. Whilst application numbers were unpredictable, the number of donor-conceived applications has steadily risen since 2010, with 78 applications in 2017 compared with 45 in 2016.
- 10.3.** The Donor Information Manager also provided information about releasing identifying information. The first application for identifying information from an adult donor-conceived person, with an identifiable donor, was received in 2013. 11 such applications have been received in total to date. The first Donor Sibling Link (DSL) match was made in 2015, and there have been nine matches in total.
- 10.4.** The Donor Information Manager provided information about the quality of the OTR service. Responses from OTR applicants had been positive, with the majority of people rating specific areas of the process as good, very good or excellent. Survey responses from users of the support service, which began in 2014 and is run by PAC-UK, had all rated the service as good or excellent.
- 10.5.** The Donor Information Manager briefly spoke about DNA testing websites, and their potential impact on those affected by donor-conception. Such sites raised issues about anonymity which would be considered by the Executive and advice provided to the Authority in due course.
- 10.6.** The Donor Information Manager also spoke about future work, including considering the impact of DNA testing websites and preparations for 2023, when the first cohort of adult donor-conceived people turn 18. DSL will also be reviewed.
- 10.7.** The Authority was asked to note:
- the update on OTR activity and performance
  - the supportive way in which OTRs are handled
  - the positive feedback received about the support service, and the arrangements for its continuation

- potential impact of DNA testing ancestral websites
- the steps the Donor Information Team is taking to plan for the future of the OTR service

**10.8.** The Authority was also asked to agree:

- That we continue the counselling service on a rolling contract basis with PAC-UK.

### Decision

**10.9.** Members praised the OTR service and the work done by the Executive. The Chief Executive highlighted the need to prepare for 2023 and consider the potential challenges and resource implications.

**10.10.** It was agreed that further information would be presented to Authority in September, regarding DNA websites, to determine the scale of this work.

**10.11.** Members agreed to continue the counselling support service with PAC-UK.

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## 11. Egg freezing and infertility treatment – trends and figures

**11.1.** The Chair explained that this item was deferred and that it would be presented to Authority in September, when more information could be provided.

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## 12. Any other business

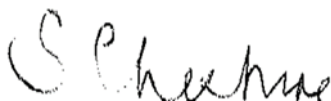
**12.1.** The Chair thanked Authority Member Bishop Lee Rayfield, for whom this was his last Authority meeting, for his service over the last six years.

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## 13. Chair's signature

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

Signature



Chair: Sally Cheshire

12 September 2018