

Minutes of Authority meeting 13 November 2019

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:	29 January 2020
Author:	Debbie Okutubo, Governance Manager
Annexes	

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 13 November 2019 held at ETC.venues Victoria, 1 Drummond Gate SW1V 2QQ

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

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 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. Bobbie Farsides sent her apologies. The Chair commented that today would have been Bobbie's last Authority meeting as her term of office would come to an end on 21 November. She thanked Bobbie for her contribution to the work of the Authority over the last three years. The Chair further commented that Bobbie had a national and international reputation as a leading medical ethicist and that her judgement and wisdom would be missed. The Chair stated that she had written to Bobbie on behalf of the board to express her appreciation.
- 1.3. Declarations of interest were made by
 - Yacoub Khalaf (PR at a licensed clinic)
 - Anthony Rutherford (Clinician at a licensed clinic)
 - Anne Lampe (Clinician)
 - Ruth Wilde (Counsellor at licensed clinic).

2. Minutes of Authority meeting held 11 September 2019

- 2.1.** Members agreed that the minutes of the meeting held on 11 September 2019 be signed by the Chair.
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3. Chair's report

- 3.1.** The Chair welcomed Rachel Cutting to her first meeting as the Director of Compliance and Information. With two Authority member positions vacant, the Chair commented that member appointments were a matter for the Secretary of State, and that therefore advertisements for the vacant positions would not be able to go out until after the general election to be held on 12 December 2019.
- 3.2.** On 18 September the Chair and Chief Executive (CE) had an introductory meeting with the Health Minister, Caroline Dinenage. From the meeting it was clear that the Minister was committed to our agenda and just before Parliament rose, the Minister wrote to Chairs of Clinical Commissioning Groups (CCGs) that currently offered no local fertility services to ask what their plans were.
- 3.3.** On 19 September the Chair attended the HFEA patient support event in Manchester and thanked Ruth Wilde and staff for leading the event.
- 3.4.** On 25 September the Chair and CE attended the Royal College of Obstetricians and Gynaecologists (RCOG) Steptoe and Edwards lecture.
- 3.5.** On 2 October the Chair attended our second event for PRs in London and noted that this was a worthwhile event to be run annually.
- 3.6.** On 14 October the Chair and CE attended the Scientific Clinical Advances and Advisory Committee (SCAAC) meeting.
- 3.7.** On 28 October the Chair appeared on the Victoria Derbyshire programme and Sky News to talk about the 10-year limit on egg storage.
- 3.8.** On 8 November the Chair chaired the Remuneration Committee meeting to consider the pay award for Senior Management Team (SMT) members.
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4. Chief Executive's report

- 4.1.** The CE reported back on key meetings since the last Authority meeting.
- 4.2.** On 30 September he and other HFEA colleagues had a meeting with the Law Commission to discuss their review of surrogacy.
- 4.3.** On 2 October the CE attended the PR Leadership event in London.
- 4.4.** On 7 October the CE and SMT colleagues attended the DHSC/HFEA quarterly accountability meeting.
- 4.5.** On 9 October the CE attended the Medicines and Healthcare products Regulatory Agency (MHRA) annual lecture given by Sir John Bell.
- 4.6.** On 16 October he attended the Health care leaders scheme meeting.

- 4.7.** On 22 October he represented the HFEA at the memorial service for Mary Warnock at St Margaret's, Westminster. Ermal Kirby and Gudrun Moore were also in attendance alongside several previous Authority members.
- 4.8.** The CE announced the passing of former MP Frank Dobson. He was Secretary of State for Health 1997 – 1999 and played a pivotal role in relation to HFEA.
- 4.9.** Authority members were polled by email prior to the meeting, in relation to changes required for the Code of Practice following a court ruling. In compliance with standing orders, a vote on the written resolution was passed in accordance with Standing Orders, as follows:
- 11 voted yes
 - 0 abstentions
 - 0 declines.
- 4.10.** The resulting changes to the Code of Practice were signed off by the Secretary of State just before Parliament rose.
- 4.11.** In relation to EU exit the CE discussed the current position for the Authority. He stated that in terms of readiness, this had already been assessed and we remained well placed to manage required changes come 31 January 2020, in the event of either a deal or no deal EU exit.

5. Committee Chairs report

Licence Committee

- 5.1.** The Chair of the Licence Committee reported that the committee met on 5 September 2019 and considered four items: one renewal for treatment and storage which was granted, two interim treatment and storage which were approved and one executive update on research which was noted.
- 5.2.** They also met on 7 November and considered five items: two renewals for treatment and storage, one interim treatment and storage and two executive updates on treatment and storage. The minutes were still in draft.

Statutory Approvals Committee

- 5.3.** The Chair noted that at the 29 August 2019 meeting one mitochondrial donation application and two new PGD conditions were approved and one special direction granted.
- 5.4.** At the 26 September 2019 meeting one mitochondrial donation application and five new PGD conditions were approved and one special direction was adjourned.
- 5.5.** The Committee also met on 31 October 2019 and considered five items: one mitochondrial donation application and four new PGD conditions. The minutes from the meeting were still in draft.

Executive Licensing Panel

- 5.6.** The Chair of the Executive Licensing Panel (ELP) advised members that the panel had met five times since the last Authority meeting on 17 September, 3 October, 15 October, 29 October and 12 November. The panel considered 17 items in total: three renewals, four interims, eight variations, one executive update and one application for HLA testing. All items were approved.

- 5.7.** In addition there were 22 Licence Officer approvals: 14 EU import certificates, five changes of Licence Holders, two change of centre name and one voluntary revocation of a licence.

Audit and Governance Committee

- 5.8.** The Chair of AGC reported back to the Authority. It was noted that in addition to the standard items, there was a substantive report on capability risks which would be discussed during the item on the Strategic risk register. The Chair also noted that the external auditors attended the meeting.
- 5.9.** She continued that the annual SIRO (Senior Information Risk Officer) report was presented and they reviewed the Reserves policy and received an Estates update. She stated that updates would be received by the committee until the office move happened.
- 5.10.** Also at the meeting, she commented that the Digital programme was discussed at length and the committee will be looking at it again at their December meeting.
- 5.11.** Cyber security was discussed and they had recommended that all Authority members do their annual information security training on Civil Service Learning. It was noted that staff would send out instructions on how to log on to the site before the end of the year.
- 5.12.** Lastly, they looked at the gift and hospitality register and the counter fraud strategy.

Scientific Clinical Advances and Advisory Committee

- 5.13.** The Chair of SCAAC reported back to the Board. The committee met on 14 October 2019 and advised that they looked at treatment add-ons and their traffic light ratings.
- 5.14.** It was noted that one treatment add-on, pre-implantation genetic screening (day 5) was suggested to be demoted from an amber to a red traffic light rating. The remaining 10 treatment add-ons had no suggested change to their traffic light ratings.
- 5.15.** The committee suggested that retrospective studies of large data could not replace, but could support, randomised controlled trials (RCTs), for example identifying subgroup populations and evaluating long term patient safety outcomes.
- 5.16.** The committee also discussed consulting with the stroke national database to see what resources were required to maintain a large database that could be used to identify co-morbidities.

Remuneration Committee

- 5.17.** The Committee met on 8 November 2019 to consider the pay award for SMT members.

Decision

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

6. Performance report

- 6.1.** A report summarising performance data up to the end of September 2019 was presented to the Authority.
- 6.2.** It was noted that there were five red key performance indicators (KPIs) shown in the overall status. The five areas were, (1) establishment leavers per year, (2) outstanding errors in the register 12 months running total, (3) average number of working days from day of inspection to the day the draft report is sent to the PR, (4) average number of working days taken for the whole process, from the day of inspection to the decision being signed by Chair, (5) average number of working days between Licence Committee date and minutes being signed by the Chair.
- 6.3.** Despite these red KPIs, overall performance was considered to be good. For the first time since June 2018 it was noted that our performance in processing PGD applications had returned to 100% for the rolling three-month period to September 2019.
- 6.4.** The CE commented that it was better that we set stretching and meaningful targets rather than non-challenging ones which could result in us regulating badly. He further thanked staff and contractors for all the work put into resolving some of the issues identified.
- 6.5.** The Director of Strategy and Corporate Affairs reported back on a range of initiatives and events that were in progress including the launch of a role description for PRs, collaborating with other regulators and responding to the Law Commission review on surrogacy.
- 6.6.** She further commented that we had a stand at the recent Fertility Show and it was very busy with people raising a range of issues. We were also in the process of planning for the next professional and patient stakeholder group meetings.
- 6.7.** Members commented that feedback about the Fertility Show indicated that the number of overseas clinics represented there outweighed UK based ones. Work therefore needed to be done to encourage UK based clinics to attend and exhibit at such events and we should consider whether our attendance was an effective use of HFEA resources.
- 6.8.** The Director of Finance and Resources reported that we were forecasting break-even against budget as the profiling of the budget currently was not fully reflective of expenditure activity. It was noted that this was being closely monitored to ensure we delivered the forecast at year end.
- 6.9.** The Director of Compliance and Information commented that she was now picking up the reins in her new role, and in the new year she would report back to the Authority on her emerging priorities.

Decision

- 6.10.** Authority members noted the performance report.

7. Strategic risk register

- 7.1.** The Risk and Business Planning Manager presented an overview of the strategic risk register. This was last reviewed by both AGC and SMT at their October meetings.
- 7.2.** This register was last brought to the Authority in May as it is presented bi-annually.
- 7.3.** The regulatory effectiveness risk was currently the only above tolerance risk. This is about our ability to take advantage of enhanced data due to ongoing delays to data migration and the launch of PRISM.

- 7.4.** The Authority heard that the wider impact of the delay meant that we were unable to commit certain resources to other work for as long as the delay continued. This would continue to be reported to AGC, with their next meeting occurring in December 2019.
- 7.5.** All other risks were within their tolerances.
- 7.6.** It was noted that there was an emerging risk around the renewal of Authority members and we were liaising with the Department to ensure that the board and its committees were able to continue to function effectively. The executive committed to discussing this at the next AGC meeting.
- 7.7.** The new estates risk captured risks relating to the office move scheduled for late 2020 and its potential to disrupt operations and strategic delivery. It was noted that there were particular capability risks arising from the office move.

Decision

- 7.8.** The Authority noted the latest edition of the risk register.

8. HFEA strategy 2020-2023

- 8.1.** The full draft of the new HFEA strategy for 2020-2023 was presented to the Authority following earlier Authority discussions and a period of consultation.
- 8.2.** The main consultation points that had been addressed in the new draft strategy were:
- Greater emphasis on the word effective, in relation to treatment. Members welcomed the emphasis on effective treatment.
 - Recognition of donors, donor-conceived people, surrogates and professionals (as relevant), in addition to patients.
 - Clearer delineation between the two parts of the 'right information' aim.
 - Clearer drafting in the 'shaping the future' section to recognise that there may be other legislative changes within the next three years, for example in relation to storage duration; and to broaden the wording of the section about our future operating environment.
 - Other minor edits to improve wording, flow and clarity in response to queries and observations about our intended approach.
- 8.3.** Members welcomed these changes and agreed that further editorial changes would be discussed with the committee chairs outside the meeting. The final version would be brought to the January 2020 Authority meeting for approval.
- 8.4.** It was suggested that more collaboration between clinics be included into the strategy.
- 8.5.** Members noted that the proposed new vision statement for 2020-2023 was:
- Regulating for excellence: the best fertility care, support and information.**
- 8.6.** Members observed that as good as the vision was, it could be made better by being more ambitious in terms of the Authority's role in bringing future developments into current practice. As a regulator we needed to educate people to enable a better understanding of this complex area.
- 8.7.** A revised vision statement was suggested, for further discussion after the meeting:

Evidence, support and information: regulating for excellence.

- 8.8.** It was further suggested that pre-treatment information could usefully include links to advice about lifestyle choices which could prevent or reduce infertility problems.

Decision

- 8.9.** It was agreed that committee chairs will be involved in the final editing on behalf of the board, taking into account all comments made during the discussion.

- 8.10.** The final version to be brought back to the January 2020 Authority meeting for approval.
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9. Opening the Register annual report

- 9.1.** The HFE Act requires the Authority to keep a register of information about donors and treatments involving the use of donor gametes and embryos in the UK.
- 9.2.** Improvements have been made to the Opening the Register (OTR) service during 2019, and a paper providing an overview of the changes and their impact was presented to Authority. Members noted the very high satisfaction levels of the users of the OTR service.
- 9.3.** Members were advised that the introduction of DocuSign software meant that people no longer needed to send in their original documents (by post) which could be a reason for the rise in activity in this area.
- 9.4.** In response to a question about emotional care for HFEA staff dealing with OTR enquiries from donor-conceived people, it was confirmed that there was support from line management and access to external counselling support, should it be required.
- 9.5.** Members commented that there was likely to be an increase in applications from 2021 onwards, when donor-conceived people born after the law on donor anonymity was changed (in 2005) turned 16. Staff confirmed that the workload would be monitored, and that work on the anticipated growth in OTR requests would form part of the delivery of the new strategy.

Decision

- 9.6.** Members noted:
- the update on OTR activity and performance
 - the supportive way in which OTRs are handled by the team
 - the level of applications in 2018 and the early indications of further increases received during 2019
 - the planning underway to cope with future increase in applications following donor anonymity changes in 2005.
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10. Donor Conceived Register

- 10.1.** In April 2017, at the request of the Department of Health and Social Care (DHSC), responsibility for the Donor Conceived Register (DCR), which related to treatments before the HFEA came into being, transferred from the DHSC to the HFEA. At that time the DCR was serviced by the National Gamete Donation Trust under a rolling 12-month contract. That contract ended on 31 March 2019.

- 10.2.** The DCR service comprises three main parts a) administration b) DNA testing and matching and c) counselling.
- 10.3.** Since the last Authority update in March 2018, we have successfully awarded the contract to the Hewitt Fertility Centre and we will continue to work with them.
- 10.4.** We will regularly monitor service performance and customer satisfaction to ensure the new service delivers the service standards we are seeking and meets its vision of a stable, long term and high-quality service.
- 10.5.** In response to a question, it was noted that there was ongoing engagement with the registrants panel.

Decision

- 10.6.** The Authority noted:
- the update on progress to establish a new improved Donor Conceived Register service
 - the outcome of the tender process and commencement of the new service
 - the arrangements for monitoring the new service.

11. Update on storage consent

- 11.1.** The Head of Legal set out the approach taken to address cases and steps taken to equip the sector with a better understanding of the law. The aim is to ensure that the necessary steps are taken at the appropriate time to enable patients to continue storing their gametes and embryos legally.
- 11.2.** Members were advised that where situations arise with consent, this could lead to tensions between patients' wishes and the requirements of the law and we have a statutory responsibility to uphold and promote compliance of the law.
- 11.3.** It was noted that there had been a number of cases where the Act has been breached. When HFEA inspectors became aware of such cases clinics were required to explain what actions they had taken and that this would continue to be the approach going forward.
- 11.4.** In such situations Inspectors check that clinics understand the law, that they are able to apply it correctly and that measures are in place to ensure that gaps in consent do not re-occur.
- 11.5.** Members were advised that clinics are required to ensure that there is effective consent at all times with no gaps in consent.
- 11.6.** We have sought to balance the interests of the patient with the obligations we have as the regulator.
- 11.7.** The HFEA's patient-centred stance on these issues has not been tested by a court. However, given the lengths the Courts went to in the legal parenthood cases to find a way to make the declarations that were sought, the view is that it is likely that a similar approach would be taken with storage consent cases.
- 11.8.** It was noted that going forward there will be more workshops and engagements to embed clinics' understanding of the law. The introduction of the new Person Responsible Entry Programme

(PREP) would also assist and may be a tool that clinics can use for their training for staff who deal with storage consent.

11.9. Members commented that we needed to be mindful not to stretch the law but ensure that we remained human rights compliant.

Decision

11.10. The Authority endorsed:

- the approach to storage consent as set out in the report
- the multi-pronged approach to raising awareness of the issue and improving understanding of a complex area of law.

11.11. The Authority noted that:

- the new PREP learning tool would be launched early in 2020
- the proposed new Code of Practice guidance on storage consent would be included in the next iteration of the Code which would be presented to the Authority for sign-off.

12. Register Research Panel annual report

12.1. The Head of Research and Intelligence presented the report to the Authority. The last annual report on the Register Research Panel (RRP) to the Authority was on 30 January 2019.

12.2. The Authority noted that between 2010 and 2018, 16 projects were approved in total with a maximum of two projects approved each year. In 2018 there was an increase in interest, and seven projects were approved in a single year.

12.3. In 2019 there have been 26 expressions of interest from separate research projects although none of these have yet translated into formal applications to the Register Research Panel.

12.4. The Head of Research and Intelligence commented that the larger volume of activity meant we needed to adapt our processes to meet demand. This would be done by:

- working with other public bodies on information governance
- creating a single internal log of project approvals and amendments
- seeking legal advice on contract issues around data linkages
- RRP meetings to be scheduled every other month (an increase in frequency)
- Information Governance and Records Manager to provide advice to the panel
- basing our application form on those used by the office for Data Release at Public Health England
- continuing to strengthen our processes to ensure they were transparent and well documented.

12.5. It was noted that as we expect to see further increases in interest in register data there was a proposal that we start charging fees in line with other similar organisations who ran a cost recovery model. In law, the relevant Regulations allowed for a fee to be charged.

- 12.6.** From conversations with researchers, it had emerged that researchers expected to be charged to access data and built provision for this into their funding proposals. Anonymised data and underlying data tables would still be available free of charge on our website.
- 12.7.** Members commented that it was legitimate and reasonable to charge.
- 12.8.** In response to a question, it was noted that a maximum charge of £5000 was defined in the Regulations.
- 12.9.** Members requested that the list of published research papers that had resulted from researchers' approved data requests should be published on our website.
- 12.10.** Members also noted that the HFEA would be hosting a Research Engagement day on 18 May 2020 as part of our continued efforts to encourage and support more research.

Decision

- 12.11.** Members agreed that the maximum of £5000 be charged and advised strongly that there be no exceptions.
- 12.12.** The Authority approved the introduction of the RRP fee effective from 1 April 2020.

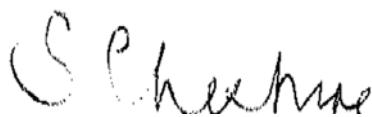
13. Any other business

- 13.1.** There was no other business.
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14. Chair's signature

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

Signature



Chair: Sally Cheshire

Date: 29 January 2020