Minutes of Authority meeting 15 November 2017

Strategic delivery:	☐ Setting standards	☐ Increasing and informing choice	☐ Demonstrating efficiency economy and value
Details:			
Meeting	Authority		
Agenda item	2		
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Meeting date	24 January 2018		
Author	Siobhain Kelly, 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 15 November 2017 held at 10 Spring Gardens, London SW1A 2BU

Members present	Sally Cheshire (Chair) Kate Brian Dr Anne Lampe Anthony Rutherford Bishop Lee Rayfield	Yacoub Khalaf Margaret Gilmore Anita Bharucha Bobbie Farsides Ruth Wilde
Apologies	Dr Andy Greenfield	
Observers		
Staff in attendance	Peter Thompson Nick Jones Juliet Tizzard Richard Sydee Caylin Joski-Jethi	Siobhain Kelly Helen Crutcher Paula Robinson Anna Quinn Catherine Drennan

Members

There were 10 members at the meeting, 6 lay members and 4 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 last meeting of 2017. As with previous meetings, it is audio-recorded and the recording is 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 Dr Andy Greenfield.

1.3. Declarations of interest were made by:

- Anthony Rutherford (Person Responsible at a licensed centre)
- Yacoub Khalaf (Person Responsible at a licensed centre)

2. Minutes of Authority meeting held on 13 September 2017

2.1. Members agreed the minutes of the meeting held on 13 September, for signature by the Chair of the meeting.

3. Chair's report

3.1. The Chair summarised the events that she has attended since the last Authority meeting on 13 September 2017.

3.2. On 21 September, the Chair attended the formal launch of the Elizabeth Bryan Multiple Births Centre at Birmingham City University. Jane Denton, a former member, has played a key role in the establishment of this centre and has been one of the most prominent advocates of our work on reducing multiple births.

3.3. On 22 September, the Chair spoke to participants on the Health and Care Leadership, Aspiring Directors programme in Ashridge. The aim was to encourage programme participants to reflect what they have learned about the health and care system with senior panel members of NHS Chairs and NEDs.

3.4. On 5 October, Peter Thompson and the Chair met Phillip Dunne (Minister of State for Health). This was a useful and positive introductory meeting where a wide range of topics was discussed, including:

- Patient safety
- NHS commissioning and fairer access
- Research and innovation in the life sciences.

3.5. On 24 October, the Chair attended the PGD policy workshop organised by the policy team. The Chair thanked the Policy Manager who organised the session. The Chair was particularly pleased to see Authority members and staff, clinicians, embryologists and other stakeholders at the workshop and the feedback was very positive. It is hoped one of the outcomes will be an improved process from the 20 PGD clinics currently making applications for authorisation to the Statutory Approvals Committee (SAC).

3.6. On 16 October, the Chair attended the Scientific and Clinical Advances Advisory Committee (SCAAC) meeting.

3.7. Lastly, the Chair informed the members that the Authority's independent Appeal Committee met 16 - 19 October to hear an appeal brought by three licensed clinics. The Hearing did not reach a decision, since the matter was settled by agreement. The Authority will be working with the clinics involved to progress the agreement.

4. Chief Executive's report

4.1. The Chief Executive informed members that on 19 September, he and Nick Jones met representatives from Healthcare UK, an arm's length body set up to promote UK healthcare abroad, to discuss the promotion of UK fertility services overseas.

4.2. On 22 September, the senior management team (SMT) had the quarterly accountability meeting with the sponsor team at the Department of Health (DH).

4.3. On 3 October, the Chief Executive attended the Audit and Governance committee (AGC) meeting.

4.4. On 4 October, the Chief Executive attended the Health and Care Leaders Senior Talent Board which was set up to identify and develop talented individuals within the health sector.

4.5. On 9 October, the Chief Executive took part in a debate at the Royal Institution on genome editing, as part of Biology Week. A range of views were expressed but there is broad support for the Authority's regulatory regime, and agreement that it is flexible to allow innovation while providing assurance to the wider public.

4.6. On 16 October, the Chief Executive attended SCAAC and on 24 October, he attended the PGD workshop with the Chair.

4.7. Following interviews in October, an interim Head of HR was appointed for three months. Interviews for a permanent Head are imminent.

4.8. On 1 November, The Chief Executive took part in a panel discussion on NHS commissioning. This was organised by the Fertility Network UK as part of National Fertility Awareness Week.

Press coverage

4.9. The Chief Executive informed members that there was an upturn in press coverage on fertility over the last couple of months, culminating in extensive coverage during the recent National Fertility Awareness Week.

National Fertility Awareness Week

4.10. The Chief Executive reminded members that a press release with some new data in support of the initiative was released, which attracted some coverage. The lead piece of information was the 300,000 IVF baby statistic, and that a third of IVF babies were born in the last six years. This shows a real acceleration in treatment numbers. Other information released included a breakdown of treatments by region to attract the attention of local and regional press, with some success.

40th anniversary of IVF

4.11. Members were informed that one of the themes of Fertility Awareness Week was the 40th Anniversary of IVF. The Chair gave an interview to the Daily Mail discussing the impact of IVF.

4.12. Members noted more generally, that a new and improved monthly Communications report on all activity will be circulated to members. This will include, but not be limited to, all the latest media stories. This will be developed further and discussion will take place around how this will be complemented by reporting at Board meetings.

5. Committee Chairs' updates

5.1. The Chair of the Statutory Approvals Committee (SAC) reported that the committee met on 28 September and 26 October. In September the Committee considered two PGD items, one of which was approved. In October the Committee considered one mitochondrial donation application and six applications for new PGD conditions. The minutes of that meeting were not yet finalised.

5.2. The Chair of the Licence Committee advised members that the committee met on 9 November and the minutes were yet to be signed off by the Chair.

5.3. The Chair of AGC informed the Authority that they met on 3 October and welcomed two new external members, Geoffrey Podger and Mark McLaughlin. In addition to the usual standing items, the committee discussed progress against strategic delivery by the Strategy and Corporate Affairs Directorate, received updates on the Data Submissions Project, business continuity, resilience and cyber security and reviewed the risk register.

5.4. The Director of Strategy and Corporate Affairs advised members that the Executive Licensing Panel (ELP) met four times since the Authority last met; on 22 September, 6 October, 20 October and 3 November, and considered 28 items. There were six renewal inspection reports, 17 interim inspection reports, four licence variation applications and one whistle blower report, which found no evidence of the problems raised by the whistle blower. In addition, five variations and one voluntary revocation were approved by the Licensing Officer.

5.5. SCAAC met on 16 October and discussed genome editing research, informed by a speaker from the Francis Crick Institute research group, new patient information on treatment add ons, and the work of the Register Research Panel, with some proposals for improving access to data for researchers.

6. Performance report

Compliance and Information

6.1. The Director of Compliance and Information reminded members that the Data Submission project is still underway, with launch scheduled for April 2018. AGC is providing ongoing scrutiny.

6.2. Members noted that most clinics have a third-party system which stores treatment data. As a consequence, the HFEA has to work closely with these suppliers to ensure that the HFEA data submission integrates effectively. These suppliers have received details of the new system this week and will have six months to work on integration.

6.3. On data migration, our risk management is focused on moving the Register into the new environment. There is a robust plan in place and risks are being mitigated. The migration will not occur until we are ready. AGC will receive an update in December.

6.4. The Chair of AGC stated that assurance had been provided that key staff will be concentrating on this work without distraction.

6.5. On the red indicators in the report, members noted that complexity and volume of committee items are still affecting compliance with key performance indicator (KPIs) targets. Members heard that staff continue to aim to meet KPIs on PGD applications because they know there is a patient awaiting each decision. Alongside this, elements of the administrative process continue to be reviewed, to ensure any issues are identified and resolved.

Strategy and Corporate Affairs

6.6. The Director of Strategy and Corporate Affairs informed members that the new website is now attracting 30,000 visitors per month. Steps are also being taking to increase the presence of the website on search engines.

6.7. Members heard that National Fertility Awareness Week has raised the HFEA's profile and our impact is amplified when we work together with stakeholders.

6.8. Members noted that the HFEA now has over 4,000 followers on Twitter, which is a good channel for reaching professionals. The HFEA also now has a Facebook presence, launched in fertility awareness week, which helps us reach patients.

6.9. The Director of Strategy and Corporate Affairs reported that staff attended the Fertility Show in November. Members agreed it is very important for the HFEA to have that presence at the show to provide unbiased, free, reliable information to patients, and heard there was good take-up of printed materials. Members thanked staff for attending the show.

6.10. Members were informed that the HFEA's annual conference will be held on 15 March 2018, the day after the March Authority meeting.

6.11. Members noted that the 9th edition of the Code of Practice will be launched in October 2018 with the draft code being available in the Spring for consultation. The Authority will consider the revisions to be incorporated into the new Code at future meetings.

6.12. Members heard that an evaluation on the new patient ratings service will be presented to the Authority in March 2018, reporting on the pilot period. Clinics that are investing effort in encouraging this feedback are getting good results.

6.13. Members touched on the price of treatment. Although pricing is not within our regulatory remit, inspectors check that costed treatment plans are provided to patients. Members heard that patient feedback to date suggests that such costings may not always be accurate.

6.14. Members raised the issue of waiting times for egg donation and how time critical this is for patients, and that delays could push patients to consider going abroad for treatment. Members were assured that this would be put on the future development list for Choose a Fertility Clinic (CaFC).

6.15. Members discussed the presentation of clinics' own data on their websites and noted that this is something that is checked by the Inspection team. Going forward, the HFEA will be more robust with clinics if there is inaccurate or misleading data presented. This issue will also feature in the 9th edition of the Code.

6.16. Members discussed the verification process to ensure our data is accurate for CaFC, which in the past has been very time consuming for clinics. The impact of the Information for Quality (IfQ) programme will be felt here, in that the new system will allow less scope for incorrect data to be submitted in the first instance. How verification will take place in the future will be discussed at the January Authority meeting.

Finance and Resources

6.17. The Director of Finance and Resources introduced the financial information in the performance report. Members heard that in relation to staffing and capacity, opportunities to address resourcing pressures were being explored.

6.18. Members discussed the surplus and the practical difficulties in spending it or reducing it by reducing treatment fees. The HFEA was subject to Government rules about balanced budgets, which meant that the aim would always be to arrive at a net balance of zero at year end.

6.19. Members noted that 75-80% of the HFEA's income comes from treatment fees. That money is used directly in our work to support patients. The rest of our income comes from DH in the form of grant-in-aid. Like all public bodies, the HFEA aims to be as efficient as possible, spending wisely and accounting for what is spent appropriately.

6.20. Members noted the Performance Report.

7. Draft business plan 2018/19

7.1. The Head of Planning and Governance presented the draft business plan for 2018/19. This will be year two of the strategy, and the plan will remain a work in progress over the next four months, with further discussion taking place at the Corporate Management Group (CMG).

7.2. Members noted the main activities under our strategic aims for safe, ethical, effective treatment, consistent outcomes and support, and improving standards through intelligence.

7.3. Members heard that the Secretary of State's shared delivery plan highlights quality and safety for patients, and members agreed that the business plan should demonstrate that the HFEA's work is in step with a wider Department of Health approach.

7.4. Members agreed that the HFEA should be bold and be prepared to work at the limit of our legal boundaries. The way we do things is just as important as what we do.

7.5. The Head of Planning and Governance agreed to incorporate comments from members about values, providing more explicit linkage between the business plan and the strategy. In addition, members felt that since the IfQ developments will be available for use during the next business year, there should be emphasis in the plan on what elements will be new.

7.6. Members raised whether there is capacity and resilience to deliver this business plan and were assured that the plan had been drafted with resources in mind.

7.7. Members agreed that it was good to see a business plan with a focus on the patient's experience at the very heart of it and thanked the business planning team for this draft as presented.

7.8. Members:

- approved the draft Business Plan 2018/19
- noted the final version will return to the Authority in March 2018 for sign off.

8. Fertility sector report 2016/17

8.1. The Director of Compliance and Information introduced the report, reminding members that this version followed endorsement of the structure and format of the report at the September 2017 meeting of the Authority. Following comments at the meeting the report was revised to make it clearer how we regulate; to add context about the UK fertility sector; to emphasise the quality of service and compliance; to add good practice 'vignettes' identified by Inspectors; and to make the sections on minimising multiple births, learning from incidents and patient experience part of a new chapter on 'areas of focus'.

8.2. Members were invited to discuss the key messages that would be incorporated within the summary of the report. Suggestions included:

- A focus on clinic leadership, and how we can encourage clinics to improve performance from 'good to great'
- A strong message that many clinics have a five-star rating, and to highlight improvements to pregnancy outcomes
- Acknowledgement that whilst patient feedback levels are low (with an acceptance that the new website should address this over time) more explanation of this would be helpful
- Even more emphasis on the reduction of the multiple birth rate, whilst at the same time seeing no drop in success rates – together with a reminder of the importance of the policy.

8.3. It was agreed the final draft will be shared with a few members for final oversight prior to publication in early December 2017.

8.4. Members:

- approved the publication of this report
- agreed the report should be embargoed until publication.

9. Strategic risk register

9.1. Members received a presentation of the revised Strategic Risk Register for the first time, noting that AGC has already commented on this version. Members heard that the two new external AGC members were impressed with this risk register and commented that it is as good a format as they have seen in their other roles.

9.2. Members heard that two risks were above tolerance. One related to organisational change, which is drawing to an end as most of that change has been implemented. Members heard that the executive had reassessed the organisational change risk since the register was reviewed by AGC. The residual risk had been reduced slightly following successful recruitments and the near completion of all planned redundancies. This meant that the risk was at tolerance. This risk will be removed as a separate risk once all of the organisational changes have been completed, by the end of the business year. The remaining above tolerance risk was capability and capacity, for related reasons.

9.3. Members noted the Strategic Risk Register.

10. Scientific and Clinical Advances Committee annual report

10.1. Members received a presentation from the Policy Manager who supports the committee, which meets three times per year.

10.2. The key functions of SCAAC are to consider:

- Horizon scanning
- Updates on key areas of research
- Patient information
- Policy development
- Novel processes.

10.3. Horizon scanning occurs annually, and the relevance of any new issues is established by asking a standard set of five questions. In 2017, the international panel discussed the following:

- The use of ICSI
- How to define and register success in assisted reproduction
- Pre-implantation genetic screening for frozen embryos
- Embryo culture media.

10.4. Members heard that some clinics use ICSI in up to 90% of their treatment cycles. SCAAC discussed how research shows that ICSI does not improve treatment outcomes compared to IVF alone in the absence of male factor infertility.

10.5. Members heard that despite media interest, only one research group is using genome editing techniques on human embryos. It would be important for SCAAC and the Authority to stay abreast of these developments to ensure there is awareness of the wider debate.

10.6. New technologies in embryo testing, next generation sequencing, karyomapping and mosaic embryos were also discussed.

10.7. Members were informed that in the coming months, SCAAC will be looking at:

- Patient information for three new treatment add ons
- Revisiting previous novel processes applications
- Horizon scanning for 2018.

10.8. Members agreed that the SCAAC meetings address interesting and important topics, and asked that committee Chairs be invited whenever the subject matter was relevant.

10.9. Members agreed that the Policy Manager who supports the committee should contact members to see if they would like further information on any of SCAAC's recent activity.

10.10. Members noted the annual report from SCAAC.

11. Register Research Panel annual report

11.1. Members received a paper and presentation from the Head of Intelligence which was an annual update, reported to the Authority in its role as the oversight committee.

11.2. Members heard there had been two applications to the Register Research Panel since January 2016. One study is looking at the long-term effects of assisted reproduction technology on the health and well-being of women and their children. The other study is examining educational outcomes in children born from ART.

11.3. Members also received an overview of the progress of all authorised research studies since the law changed in 2009, and the results of studies conducted using the anonymised dataset.

11.4. In addition, the Authority heard how the new Intelligence team aims to increase impact by showing how Register research has a role in ensuring patients get safe and effective treatment. This will be achieved by using external, specialist expertise.

11.5. Members supported the development of an intelligence strategy and suggested further thinking on what the HFEA's role could be in signposting findings of studies to the patients who might benefit from that information. Members also felt that linking Register research with the work of SCAAC is an excellent new approach.

11.6. Members noted that better information for clinics and better information for patients would lead to safer, better care.

11.7. Members agreed that it is positive that the HFEA is making such connections and welcomed the direction of travel proposed by this new team.

11.8. Members:

- noted the report of Register Research Panel activities since 2016
- approved the suggested ways for extracting greater value from the data held.

12. NHS commissioning of IVF services

12.1. Members were given a summary of NHS treatment commissioning for each of the four nations of the UK. Although IVF is regulated on a UK-wide basis, commissioning is devolved to national level and, in England, to the local level.

12.2. Members heard that in England, the clinical guideline published by NICE is not implemented consistently, and access and pricing are variable. The Director of Strategy and Corporate Affairs demonstrated the worsening picture in England with respect to Clinical Commissioning Groups (CCGs) following the NICE guideline. In 2013, 76% of CCGs did not follow the guideline. In 2017, the figure had risen to 88%.

12.3. Members were surprised to note that 49% of CCGs use their own definition of an IVF cycle, not the NICE definition. The definitions used by CCGs often meant fewer frozen transfers, reducing success rates and potentially exposing patients to more ovarian stimulation and egg collections than are required, which is an undesirable outcome for patients. Many CCGs also have their own individual social eligibility criteria.

12.4. On pricing, since there is no national tariff members heard that CCGs negotiate locally with providers. There are examples of private providers undercutting NHS ones.

12.5. In 2016, NHS England commenced a project involving the HFEA, NHS Improvement, commissioning body representatives and fertility sector stakeholders which aimed to deliver three planned outputs:

- Guidance for CCGs on commissioning an IVF service, including standardised social eligibility criteria
- A benchmark price for IVF
- A national tariff including a performance incentive.

12.6. Members heard that progress has been made with these issues and reaffirmed the Authority's determination to ensure this works on the ground to improve commissioning, and therefore services for patients.

12.7. Members were informed that NHS England is unable to mandate CCGs to follow the NICE guidelines but they do have influence. The HFEA is committing to working closely with the sector and NHS England to use all opportunities for influence.

12.8. Members noted that IVF treatment accounts for less than one tenth of 1% of the NHS budget. Members agreed that there is no economic argument against providing IVF since there are now over 300,000 IVF babies who will contribute to our economy throughout their lives.

12.9. Members agreed that examples of best practice could be shared where effective treatment saves costs, demonstrated by singleton pregnancies and people not going abroad for treatment and subsequently returning with multiple births. This could also be evidenced by highlighting how funding is wasted on unnecessary tests.

12.10. Members also agreed that inefficiencies should be pointed out publicly, since the public debate is dominated by IVF being in competition for funding with lifesaving treatments. In addition, members suggested that, once the work on English commissioning is complete, we should look to address commissioning in Wales and Northern Ireland too. The position in Scotland is much better, with central commissioning and criteria, and a public commitment to provide three full cycles.

13. Any other business

13.1. Members thanked two members of staff who were leaving the HFEA for their years of dedicated service. Juliet Tizzard, Director of Strategy and Communications, and Siobhain Kelly, Senior Governance Manager would both leave prior to the next Authority meeting.

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

Signature

Chair

Date: 24 January 2018