Minutes of Authority meeting 28 June 2017

Strategic delivery:	☐ Setting standards	☐ Increasing and informing choice	☐ Demonstrating efficiency economy and value
Details:			
Meeting	Authority		
Agenda item	2		
Paper number	HFEA (13/09/17) 847		
Meeting date	28 June 2017		
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 28 June 2017 held at 10 Spring Gardens, London SW1A 2BU

Members present	Sally Cheshire (Chair) Kate Brian Dr Anne Lampe Dr Andy Greenfield	Yacoub Khalaf Margaret Gilmore Anita Bharucha Bobbie Farsides
Apologies	Ruth Wilde Anthony Rutherford Bishop Lee Rayfield	
Observers	Steve Pugh (Department of Health)	
Staff in attendance	Peter Thompson Nick Jones Juliet Tizzard Paula Robinson Richard Sydee	Rosetta Wotton Jessica Watkin Anjeli Kara Siobhain Kelly

Members

There were 8 members at the meeting, 6 lay members and 2 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 2017. As with previous meetings, it was audio-recorded and the recording was 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 Ruth Wilde, Bishop Lee Rayfield and Anthony Rutherford.

1.3. Declarations of interest were made by:

- Kate Brian (Regional organiser for London and the South East for Infertility Network UK)
- Yacoub Khalaf (Person Responsible at a licensed centre)

2. Minutes of Authority meeting held on 10 May 2017

2.1. Members agreed the minutes of the meeting held on 10 May, for signature by the Chair.

3. Chair's report

3.1. The Chair summarised a range of activities she had undertaken since the Authority meeting on 10 May 2017.

- On 24 May, the Chair and Chief Executive attended the annual accountability meeting with the Department of Health (DH), where it was recognised that the business plan had been delivered alongside ground-breaking work on gene editing, mitochondrial donation and significant progress on the Information for Quality (IfQ) programme and the new website.
- The Chair reported that all member appraisals are complete and have been submitted to the DH. The Chair thanked members for being available so the deadline was met.
- The Chair chaired a lively and positive Multiple Births Stakeholder group on 7 June.
- On 28 June, she chaired the Remuneration Committee at which the committee discussed the annual pay award and performance of the Senior Management Team (SMT).
- Continuing the programme of clinic visits, the Chair will be visiting Birmingham Women's Clinic with the Director of Strategy and Corporate Affairs and the Head of Regulatory Policy.
- Finally, the Chair informed the Authority that following the general election, there is a new Minister of State for Health, Philip Dunne MP. No meeting has been arranged yet, but the Chair is looking forward to meeting him in the future.

4. Chief Executive's report

4.1. The Chief Executive reported that he also attended the annual accountability meeting on 24 May and the Multiple Births Stakeholder group meeting on 7 June.

4.2. On 7 June, the Chief Executive attended the Audit and Governance Committee (AGC) meeting.

4.3. On 16 June, Juan Alberto, the Director of Bioethics and Law Observatory of the Universidad del Desarrollo, Chile, visited the Chief Executive to discuss options for the introduction of a legal framework for assisted reproduction in Chile. The Chief Executive has agreed to provide further advice and meet again in the future if required.

4.4. The Chief Executive pre-recorded a keynote speech which will be delivered on 29 June at an international seminar in Mexico on mitochondrial donation. Members were reminded that the first baby born using this technique involved a team of US doctors who went to Mexico to evade US regulations. The event is a collaboration involving the national Bioethics Commission of Mexico, the Institute of Legal Research of the National Autonomous University of Mexico and the British Embassy in Mexico and the Mexican Embassy in Britain.

4.5. The Chief Executive stated that the organisational change programme had made further progress notably that the Planning and Governance team is now in place. A Chief Information Officer has been appointed and is starting in September and an offer has been made and accepted for the new Head of Intelligence, the start date for which is likely to be October.

4.6. The Chief Executive informed members that the changes will enable us to make better use of our information and to inform how we regulate and engage with the sector and wider public about the issues that matter.

5. Committee Chairs' updates

5.1. The Chair of the Statutory Approvals Committee (SAC) reported that the committee met on 25 May and considered and approved seven preimplantation genetic diagnosis (PGD) applications.

5.2. The Chair of SAC noted the increasing complexity of the PGD conditions and added that agendas are lengthening, there are more grey areas and special directions are becoming more common.

5.3. The Chair of the Executive Licensing Panel (ELP) reported that the panel met three times; on 19 May, 2 June and 16 June. The panel approved four renewal licences and deferred one; it considered three interim inspection reports, approved three licence variations and granted two new licences. Members heard that there was also a variation approved by the Licensing Officer.

5.4. The Chair of the Audit and Governance Committee (AGC) informed members that the committee met on 13 June and thanked members and staff for their contribution. Aside from the usual standing items AGC considered:

- Implementation of audit recommendations and contracts and procurement, from the Head of Finance.
- Cyber security, Business continuity, Information assurance and Security and IfQ, from the Director of Compliance and Information.
- HR update on reorganisation and post staff survey, from the Chief Executive.
- Whistle blowing and annual report and accounts, from the Director of Finance and Resources.
- ALB risk interdependencies and strategic risks 2017/18, from the Head of Planning and Governance.

5.5. The Chair of the Scientific Clinical Advances and Advisory Committee (SCAAC) informed the Authority that the committee met on 19 June and the following items were discussed:

- An analysis of intra-cytoplasmic sperm injection including risks and the fact there is no benefit to using the technique if there is no male factor infertility.
- A literature review (2015 onwards) of health outcomes in children born following ART and the suggestion of including birthweight in patient information.
- A literature review of developments in research on embryo culture media and the decision to write to the Medicine and Healthcare products Regulatory Agency (MHRA) to seek clarity on their role and responsibilities in relation to regulating embryo culture media.
- Developments in embryo research including granting a licence to carry out genome editing on human embryos and growing human embryos in culture up to 13 days.
- The committee also considered issues which might be important for the Authority to consider in the future.

5.6. The Chair asked that the executive consider how to share issues discussed at SCAAC more widely for the benefit of members who do not attend the meetings.

5.7. The Chair informed members that the Remuneration Committee met on 28 June, as it does annually, to agree the pay award under current public sector pay constraints. Following Treasury approval, staff will be informed and thanked for their hard work in the last year.

6. Performance report

Strategy and Corporate Affairs

6.1. The Director of Strategy and Corporate Affairs introduced the new version of the performance report which now focuses on key indicators about people, performance, information, licensing and financial data. She said that when the new website goes live, we will add communications performance data to the report. Progress against the strategy will be reflected in separate reports to the Authority.

6.2. The Authority heard that the new website has passed the Government Digital Service (GDS) assessment, which ensures compliance with accessibility and other standards, and is now almost ready to go live.

6.3. The Director of Strategy and Corporate Affairs gave a demonstration of the website, showing how it is designed to give patients quick routes into information – either through the treatment type, the person's situation (same sex couple etc.) or through common tasks. Written information is complemented by key facts, quotes and charts, as well as animation. In future, there will be short films about different treatments.

6.4. Members were shown the new Choose a Fertility Clinic service which combines the Authority's vision with what patients have told us they find most useful. An animation will tell patients that an excellent service means transparent pricing, good emotional support, a good birth rate and a low multiple birth rate. Importantly, the animation educates about birth rates and how it can be unhelpful to dwell on small percentage points when choosing a clinic. Clear birth rates are accompanied by the inspection rating (how well the clinic meets our standards) and a patient rating (what it feels like to be treated there) which is collected directly via the website.

6.5. Members congratulated everyone involved in developing the new website. Staff had worked very hard to get the website ready, it is simple to use and clean to look at and is a high quality service for patients, donors and donor-conceived people.

6.6. Members stressed that it is important that the HFEA website is the 'go to' place for fertility information as it is independent, advertisement free and patient focused. Co-ordinated communications will promote the new website via clinics, partner organisations and social media.

Compliance and Information

6.7. The Director of Compliance and Information gave an update on the performance indicators in his Directorate. Of the 26 indicators that have a target assigned, almost all are green. Only three are red. Errors in data submissions went above the target threshold in the reporting period. Getting reports to clinics within 20 days has usually been achieved, but 2 reports went over the target for reasons of complexity. The overall licensing performance (from inspection to offer of licence) indicator is at 63 days, well within the target of 70 days.

6.8. Members heard that the third red indicator related to the annualised rolling target for preimplantation genetic diagnosis application processing which is still affected by delays in processing applications earlier in the year; current performance is good. Members agreed that PGD complexity has increased and made some suggestions for managing workload to be discussed with the Executive.

6.9. The Director of Compliance and Information reminded members about the allegations made by a newspaper about practices in a number of clinics. The five clinics have been visited by inspectors and the reports will be considered in July and August. The committee or panel that considers these reports will decide on any further action as they do with normal business. The Chair added that she understood more clinics had been investigated but their practices were not of further regulatory interest.

Finance and Resources

6.10. The Director of Finance and Resources informed members that there is a small surplus and an underspend on staff budget. There has been a small fall in income and a 5% drop in activity which is bigger than the projected 3%. Members noted there would have to be a 10% drop in activity for the organisation to be concerned about income.

6.11. Members speculated as to whether NHS commissioning is having an impact on activity, pushing patients to go abroad or not seeking treatment at all. Members agreed that evidence on this would be helpful for forecasting.

6.12. Members heard that staff turnover is currently higher than normal for the HFEA, though only just above tolerance. Pay constraint and lack of promotion opportunities have an impact on this, though some level of turnover can be a good thing, bringing in fresh skills and thinking.

7. Information for Quality: update

7.1. The Director of Compliance and Information reminded members that the IfQ programme budget had expended at the end of April and the programme is drawing to a close with the launch of the website, meaning this is the last IfQ update to the Authority. Outstanding digital products will still come to the Authority and AGC. AGC will also have oversight of benefits realisation.

7.2. The Register migration project and the development of the new data submission system are ongoing. The residual work will be delivered within the 2017/18 business plan, with an additional £350k budget. Testing the data submission element with clinics will begin in September 2017.

7.3. Members agreed that this was a successful and important programme where an enormous amount has been achieved and the Authority is grateful for all the efforts of the staff in bringing this work to its conclusion.

7.4. Members stated that the lessons learned exercise, always conducted after projects, should assess how useful the GDS process was as an external source of assurance. The Director of Compliance and Information confirmed that this would be part of the lessons learned process and that staffing priorities would be closely managed until final delivery.

7.5. The Authority noted:

- The HFEA website GDS assessment and arrangements for launch.
- Progress on the new data submission system.
- The progress with data migration and assurance.
- Budget update and spending to date.

- Key risks and issues.

8. Donor information requests

8.1. The Donor Information Manager gave the Authority the annual update on donor information requests (or Opening the Register, OTR, requests). The requests are for information about donors and for donors themselves to remove their anonymity. This is an extremely important service that has a real, personal impact on the users.

8.2. The Authority noted that the number of OTR requests received per year has increased by more than 100% between 2010 and 2016. A total of 165 donors have removed their anonymity to date, and 137 donor-conceived people have joined Donor Sibling Link (DSL) since it was launched.

8.3. In a recent survey respondents rated the service highly. Members noted the positive feedback on the OTR service and some of the informal comments from service users.

8.4. Members heard that the three-year pilot for the counselling support service is now in its second year. Demand is low so far but feedback has been positive so there are no concerns about the service being delivered. Further, post pilot there will be a full evaluation of the service offered, where feedback can be obtained from a larger group of users.

8.5. Members commented that there could be a surge in requests in 2023 when donor conceived people born from 2005 onwards would start to turn 18, and this should be carefully planned for.

8.6. Members thanked the Donor Information Manager for her dedication to delivering this excellent service and wished her well in her new role in a different organisation.

8.7. Members noted:

- The update on OTR performance and figures
- The timely and supportive way in which these requests are handled
- The second-year evaluation of the pilot support service and the informal positive feedback received from service users
- The need to decide on the future of the support service at an Authority meeting in 2018.

9. Improving embryo research

9.1. The Policy Manager overseeing this project introduced a paper explaining that improving embryo research is a key element of the new strategy. She highlighted that, although many patients would be willing to donate their embryos to research, only a small proportion of them actually do so. Following research, stakeholder engagement and a survey of patients, the Policy Manager had identified a number of actions that could improve this:

- improved literature and website pages to inform patients and increase awareness
- increasing collaboration between clinics and research projects - only one in five clinics are involved in a research project
- a review of the consent process to make it simpler and increase donation rates.

9.2. The Policy Manager informed members that a survey of patients (188 responses) showed that 83% did or would consider donating embryos, so the appetite for this piece of work was reflected in patents' attitudes.

9.3. Members heard that it was recommended that better patient information and improving co-ordination between clinic and research centres should be pursued in the first instance, to see if that approach alone improved the numbers of embryos being donated. Following that, this should be evaluated to decide whether a change to the consent regime should be considered.

9.4. Members welcomed this proactive approach to match up clinics and researchers. Because around 60% of IVF takes place in the independent sector, there will be a resource implication in establishing collaborations in these clinics. However, members hoped that private clinics could receive kudos from being involved with important research.

9.5. Members agreed that these are individual decisions that are challenging and complex for patients. Indeed, for some, the difficulty in making a decision about allowing their embryos to be disposed of shows that some patients are unable to make a decision they are morally comfortable with. Good support for patients in enabling them to make these difficult decisions is crucial.

9.6. It was mentioned that research teams could help improve understanding of their research by describing their projects in a clearer way when applying to the Authority for a licence. Members heard that new guidance was being developed to encourage research centres to describe their projects in a much more 'lay' way so that patients could look at this information on our website, and understand the benefits that can arise from these projects.

9.7. Members felt that improving collaboration between clinics and researchers should take place first before increasing patients' awareness so expectations can be managed and patients' generosity can therefore be maximised.

9.8. Members felt our goal should be to give patients more opportunity to donate to research, rather than to have high donation rates. The whole process should not be rushed and patients should have the freedom to decide not to take part in research.

9.9. On reviewing the consent process, members heard that patients were broadly in favour of generic consent rather than having to consent to specific projects. One member observed that 33% of the survey respondents had donated embryos, which is a much higher proportion than all patients, and therefore the views about generic consent are not necessarily representative. If a change to generic consent is to be considered in the future, there should be a bigger sample surveyed to confirm this.

Decision

9.10. Members agreed:

- To improve the information and support available to patients when making decisions about what to do with their embryos.
- To encourage better collaboration between treatment clinics and research centres using the new clinic portal facility and via annual workshops.
- To leave the consent policy unchanged at the moment.

10. Guidance on treating transgender patients

10.1. The Policy Manager leading this work informed Members that transgender issues are growing in prominence and the workshop at the HFEA annual conference confirmed that although the number of patients is small, clinics have a real desire to treat patients sensitively, whilst complying with the law. Although our Code of Practice refers to gender reassignment, and we remind clinics of their obligation not to discriminate, the HFEA does not yet have adequate information, guidance for the sector, or a way for a trans patient to record their consent. An internal working group had begun to consider how to address this.

10.2. Members received a paper setting out proposed changes to the Code of Practice to add guidance for clinics, building on the gender-neutral consent forms released in April 2017.

10.3. The members thanked the Policy Manager for the very detailed paper, which set out clearly the issues and the legislation that surrounded the treatment of transgender patients. They agreed that clinics really want to care and support these patients well, so it is important for the Authority to assist them to do this. The Chair suggested another workshop at the next conference, or indeed a separate one, to inform and enable clinics on approaching the emotional support they want to offer these patients.

10.4. Members raised concern over disclosing highly personal information about the donor around transitioning, which could be inferred by a female name given for a sperm donor, for example. Members heard that clinics will be encouraging trans patients via the counselling process to disclose this information in their pen portrait. In addition, donor conceived people will only be given a name, with no commentary from the HFEA, to ensure that there is no breach of confidentiality.

10.5. Members heard that part of the criteria to obtain a Gender Recognition Certificate (GRC) is demonstrating an intention to be legally considered their acquired gender until death. This effectively means gender can be changed and legally recognised once, as this is how it is set out in the Gender Recognition Act 2004. This rules out the concept of gender fluidity, but members appreciated that this was how the law was drafted, even if some might now view this as out of date.

10.6. One Member raised a question about how we can ensure that donor-conceived people have access to up-to-date information about their donor, including whether he or she had changed gender. Members noted that when there is a request for information about a donor, the HFEA does not contact the donor but the information held in the Register is supplied. This system relies upon the clinic and the donor keeping the information up to date.

10.7. Members heard that should a donor not decide to inform the clinic where the donation was made, the original information in the Register will be disclosed. This means there is always a chance the Register will be at variance with the current situation.

10.8. Members agreed that whilst this is unavoidable, the counselling process in the clinic touches on the importance of issues like keeping in contact and information held for the donor conceived. Further, when we receive a request for identifying donor information, the OTR team lets the donor know that such a request has been made, hopefully triggering them to report any significant change to their situation if they had not reported it before. If a change is reported, the donor-conceived person can be warned that there is a change to the non-identifying information they

were given. This has typically occurred when a donor conceived person has requested information on their anonymous donor, who has later made the decision to be identifiable.

Decision

10.9. Members agreed to all the proposed amendments to the Code of Practice as set out in the paper and these changes will be effective from October 2017.

11. Updates to the Code of Practice 2017

11.1. Members considered a paper with detailed changes, clarifications and updates for the update to the Code of Practice in October 2017. In addition to the new guidance on treating trans patients and donors, the proposals included new guidance on embryo research ethics approval, and other minor amendments and corrections relating to mitochondrial donation and medicines management.

Decision

11.2. Members considered and agreed all the changes to the Code of Practice as set out in the paper, for implementation on 2 October 2017.

12. Any other business

12.1. The Chief Executive announced to members that in the Queen's birthday honours, Sally Cheshire was awarded a CBE for her services to the NHS and infertility patients. Members congratulated Sally on the award.

12.2. The Chair stated that nothing is more important than services to patients and she is delighted that work is being recognised. She also added the CBE reflects well on the HFEA as an organisation, the staff working within it and the sector as a whole.

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

Signature

Chair: Sally Cheshire