

Minutes of Authority meeting 13 September 2017

Strategic delivery: Setting standards Increasing and informing choice Demonstrating efficiency economy and value

Details:

Meeting Authority

Agenda item 2

Paper number HFEA (15/11/17) 854

Meeting date 13 September 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 13 September 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 Dr Andy Greenfield
-----------------	--	--

Apologies	Ruth Wilde
-----------	------------

Observers	Steve Pugh (Department of Health)
-----------	-----------------------------------

Staff in attendance	Peter Thompson Nick Jones Juliet Tizzard Richard Sydee	Siobhain Kelly Sharon Fensome-Rimmer Paula Robinson Catherine Drennan
---------------------	---	--

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 fifth 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 Ruth Wilde.
- 1.3.** Declarations of interest were made by:
- Anthony Rutherford (Person Responsible at a licensed centre)
 - 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 28 June 2017

- 2.1.** Members agreed the minutes of the meeting held on 28 June, 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 28 June 2017.
- On 29 June, the Chair, the Director of Strategy and Corporate Affairs and the Head of Regulatory Policy visited Birmingham Women's Clinic. This visit was not part of the formal inspection cycle but is more to understand what the clinic does well and where they can improve. The Chair thanked the clinic for hosting the visit.
 - On 27 July, the Chair and the Chair of the Audit and Governance Committee (AGC) interviewed for two new members of AGC. The Chair is pleased to announce that two successful candidates, Geoffrey Podger and Mark McLaughlin, will start their respective terms of office on 1 October 2017.
 - On 5 July, the Chair and the Director of Strategy and Corporate Affairs met Veronica English and John Chisholm of the British Medical Association.

4. Chief Executive's report

- 4.1.** The Chief Executive informed members that there had been an staff away day on 10 July. This was held to review progress against commitments made at the last away day in December and to look ahead in the context of the new strategy, the completion of the Information for Quality programme (IfQ) and the organisational restructure. Feedback was positive generally, but there is still progress to be made around staff morale following the restructure.
- 4.2.** The members heard that the Chief Executive met with the CEOs of the Human Tissue Authority (HTA) and the Health Research Authority (HRA) on 11 July. These quarterly meetings are a useful opportunity to discuss the wider impact of system changes on smaller organisations.
- 4.3.** Members heard that on 13 July, the Chief Executive attended the Health and Care Leaders senior talent board meeting chaired by the Chief Executive of Public Health England. These meetings are focused on how to develop and keep talent within the healthcare system.
- 4.4.** On 14 July, the Chief Executive met the new chair of the Association Clinical Embryologists (ACE), Jason Kasraie, at his NHS clinic in Shrewsbury. The Chief Executive thanked both Mr Kasraie and the Trust Clinical Director for hosting the visit.

Press coverage

- 4.5.** The Chief Executive informed members that it had been a quiet period in terms of media interest in the fertility sector, due to the election and other significant world events.
- 4.6.** Recently, media interest had picked up on sperm donation, in particular unregulated donation. As a consequence, the Head of Regulatory Policy spoke to the Economist about HFEA rules around donation and the impact on donation levels.
- 4.7.** Members raised concerns about patients' sourcing sperm themselves and the implication for safety and parental responsibilities of going outside the regulated system and that the pitfalls should be highlighted to those who might consider this option.

- 4.8.** The Chief Executive confirmed that the HFEA only has jurisdiction over sperm donation and IVF treatment that takes place in a licensed clinic in the UK, and assured members that there is information about this issue on the website.

General Data Protection Regulation

- 4.9.** The Chief Executive informed members that the General Data Protection Regulation (GDPR) will come into force 25 May 2018. The Authority, like other public bodies, is already subject to a range of statutory rules around data protection and this is a substantial update on those rules. Members heard that the Authority will need to be more proactive in this area, with larger fines for non-compliance and greater requirements to notify breaches than there is at present.
- 4.10.** Members queried whether the regulations would apply to the HFEA Register, and whether an individual would have the option to have their name removed from the Register. The Chief Executive confirmed that collecting IVF data for the Register is a statutory duty for the HFEA and that the submission of patient's data to the HFEA is part of having IVF treatment. The GDPR applies to personal information that is not part of the Register. Whilst confidentiality and protecting data is at the heart of the HFEA already, preparing for the GDPR is going to be a significant piece of work.

Staffing

- 4.11.** Members were informed that staff turnover is still higher than the desirable range for a number of reasons, notably public sector pay restraint and the organisational change programme redundancies. Recruitment is happening and a number of high calibre appointments have taken place. Pressure arising from turnover is being actively managed.
- 4.12.** Finally, the Chief Executive informed members that over the summer, twice the amount of licensing activity (including PGD) has taken place. The Chief Executive thanked all the staff involved in this significant bulge of work and the members who sit on the licensing committees.

5. Committee Chairs' updates

- 5.1.** The Chair of the Statutory Approvals Committee (SAC) reported that the committee met on 29 June, 27 July and 31 August. At the June meeting, it considered seven preimplantation genetic diagnosis (PGD) applications and one request for Special Directions. Four of the conditions were approved, two adjourned for more information and one was refused. At the July meeting, three PGD applications were approved and one was approved for a specific family. The special directions application at the July meeting was refused. The minutes from the August meeting have not yet been published.
- 5.2.** The Chair of the Licence Committee advised members that the committee met twice, on 13 July and 7 September. At the July meeting one initial research application was approved, two research renewals were approved, one interim research licence was continued and a variation to a licence was approved. The committee also added a condition to a licence following an investigation report, considered an Executive update and continued a licence following an interim report and grade 'A' incident. The minutes from the September meeting have not yet been published.

- 5.3.** The Director of Strategy and Corporate Affairs advised members that the Executive Licensing Panel (ELP) met six times since the Authority last met; on 30 June, 14 and 28 July, 11 and 25 August and 8 September. The panel considered 42 items across these meetings including one new centre application, nine renewals, twelve interim inspection reports, six variations and several licence variations. The Licensing Officer approved three licence variations.
- 5.4.** The Chair thanked all the staff who support these committees and prepare the papers as well as the members who sit on these committees.

6. Performance report

Strategy and Corporate Affairs

- 6.1.** The Director of Strategy and Corporate Affairs informed members that the dashboard at the front of the Performance Report is designed to be a snapshot of performance at a high level. Members noted that measurement of delivery against the strategy used to be demonstrated by a 'totaliser' which did not work in practice as effectively as the Executive hoped. As an alternative, from now on the Executive will report back on packages of work (this meeting being leadership and culture) that the members had asked for the Executive to deliver.
- 6.2.** Members agreed that this will enable the Authority to assess effectiveness as well as milestones met and welcomed this change in approach. Members noted that sometimes this will be a progress report and a particular work package may not be complete as this is a three-year strategy, however, this arrangement will mean that members will have better oversight on progress.
- 6.3.** One of the four indicators on the dashboard relates to Opening the Register requests (OTR) being processed within 20 working days. Members heard that this KPI, because of its obvious impact on the donor conceived, is always met, so it is not necessarily a meaningful indicator to have on the dashboard. It will of course continue to be a priority and be measured, but the Executive propose replacing this indicator with one that measures website traffic.
- 6.4.** Members heard that the website launched successfully in July due to the hard work and dedication of the Communications team. Early analysis shows that website sessions and pages visited are lower than this time last year. This is to be expected as it takes time for the search engines to index the website.
- 6.5.** Members heard evidence that demonstrates better engagement with the content on the new website compared with the old one. The average length of a page visit is now is three and a half minutes, as opposed to just under two minutes on the old website, and the number of pages visited per session is more than double what it used to be.
- 6.6.** Members also heard that 76% of visitors come from the UK as opposed to 50% on the old site and that phones and tablets are being used to access the site. Choose a Fertility Clinic and information on fertility treatments, as expected, are the most popular pages and most visitors come through search engines.
- 6.7.** So far we have received 252 patient ratings of clinics and posters and leaflets for clinics are proving to be popular and should drive up the number of ratings.

- 6.8.** Members were keen to ensure that user testing will continue on the website and that this should involve both qualitative and quantitative analysis. Members heard that there are plans for the next 12 months for ongoing monitoring to assess the 'reach' of the website, user engagement and how interesting users find the website.
- 6.9.** Finally, Members heard that the Policy team has started the project to deliver the ninth version of the Code of Practice.

Compliance and Information

- 6.10.** The Director of Compliance and Information informed members that the licensing process has been very busy over the summer. Whilst the end to end target from inspection to minutes being issued is still under the 70 day target, there have been some stresses and strains delivering the business. The components under pressure have notably been processing PGD applications and minute production and the red ratings relate to this.
- 6.11.** Additionally, members heard that clinics have had a few problems clearing errors and this can be attributed to HFEA staff being busy and not being available to assist the clinics in addressing these errors.
- 6.12.** Members raised concerns about staff pressures and wanted confirmation on the nature of the risks related to staff as missing KPIs can seem like failure or mistakes. Members probed whether these issues related to overload, capacity or lack of experience. Members praised the hard work and dedication of staff during this peak in activity.
- 6.13.** The Director of Compliance and Information informed members that there are a number of factors. PGD will continue to be busy and complex, but the other inspection/licensing activity is more likely to be a bulge that is going to level off. New staff are joining the HFEA and being trained and the workload of existing staff will continue to be monitored and managed.
- 6.14.** Members were encouraged that despite these issues and a lengthy, complex process, PGD applicants are not being kept waiting for a decision.

Finance and Resources

- 6.15.** The Director of Finance and Resources introduced the financial information in the performance report. Members were asked to note there is an underspend of £250,000 which is related to higher than expected vacancies and an underspend on legal costs. Forecasts will not be adjusted at this stage.
- 6.16.** Members heard that income is volatile and is difficult to predict and is lower than last year. The members who work in the sector agreed that income is difficult to predict for clinics too. The market has changed with NHS funding being withdrawn and patient's choices changing.
- 6.17.** Members heard that it was important to try to balance fee income with the operating costs the HFEA needs, though it is very difficult to pitch this at the right amount. This will as always, stay under review, as fees paid by patients should be justified.
- 6.18.** Members noted:
- The Performance Report and approved the addition of the website metric to the dashboard of the Performance Report

7. Data Submission Project

- 7.1.** The Director of Compliance and Information reminded members this project is the package of work left over from the IfQ programme aimed at moving the Register data to a new structure and improving the data entry experience for clinics. The team have already been working on this as the programme was not run in a sequential way.
- 7.2.** Members were shown an example of the new patient led system which will be rolled out to clinics. There was agreement that this will not only be easier for clinics to send us treatment data, but will ensure there are fewer errors.
- 7.3.** Members heard that the IfQ lessons learned report will go to AGC and expressed agreement that doing this quickly is good practice following the closure of a big programme. The biggest lesson that has been learned is balancing business as usual with a huge change programme and the impact of drawing from the same pool of staff.
- 7.4.** Members heard that the migration of Register data is making slower than expected progress and there are still challenges balancing delivery of this work and business as usual. Members expressed the hope that staff working towards delivering the data migration would be able to concentrate on doing so without interruptions. Members heard that the two new Head appointments should be a positive contribution in this regard.
- 7.5.** The Director of Compliance and Information advised members that user testing with six clinics will be critical to the success of the new data entry system. Members were also advised that an extra £350k has been authorised however, there continues to be staff challenges.
- 7.6.** The Chair thanked the staff involved in the data migration for the work they have done so far.
- 7.7.** Members noted:
- Good progress on the new data submission system
 - Slower than expected progress with data migration
 - The budget update and spending to date which is in line with plans
 - Key risks and issues

8. Draft business plan 2018/19

- 8.1.** The Head of Planning and Governance introduced the cycle of business planning for 2018/19. A CMG discussion has informed this paper. This business plan will be delivered under the strategy in place until 2020.
- 8.2.** Members were given the opportunity to give an early steer on the business plan. The objectives are brigaded under the strategy areas of;
- Safe, ethical, effective treatment
 - Consistent outcomes and support for patients and donors
 - Improving standards through intelligence

- 8.3.** Members noted the access to donor gametes item, under consistent outcomes and support, and expressed the view that safety should be part of this aim.
- 8.4.** Members raised a concern about the impact that staff retention might have on the delivery of this business plan and were informed that a lot of thinking about this had already occurred and informed a people strategy, which is still in draft at present. The people strategy, which will be launched shortly, will include developing and supporting staff to ensure that the HFEA can deliver its strategic aims.
- 8.5.** Members were informed that a detailed business plan will be provided in November.
- 8.6.** Members approved the outline objectives for 2018/19 as the basis for drafting the next business plan.

9. Fertility sector report 2016/17

- 9.1.** The Chief Executive introduced a draft report, due to be published in the next few weeks, which provides an overview of the performance of the sector in 2016/17.
- 9.2.** Members heard that every September, the Authority receives a summary of compliance activities and a report on incidents. This new report, in a change of emphasis, recognises the largely compliant nature of the fertility sector and tries to provide a better balance between where the sector is doing well and where it needs to improve.
- 9.3.** This will be one of two annual reports and will sit alongside the Fertility Trends report. The report covers a summary of the sector, leadership and staffing, regulatory compliance, safety and patient experience.
- 9.4.** There had been consolidation in the sector and a third of treatments are now being carried out by just ten clinics with 45% of treatments taking place in clinics in London. In contrast to other areas of medicine in the UK two thirds of treatments are self-funded.
- 9.5.** Members were informed that there is a lot of positive news about the sector's performance that is presented in this report. Multiple births have come down from 1 in 4 to 1 in 10 and the pregnancy rate in 2016/17 stands at 32% as compared to 24% in 2008.
- 9.6.** Incident numbers are consistent with the volume of treatments with a fall in grade B incidents and only one grade A incident reported.
- 9.7.** In the report there is a summary of regulatory compliance arising from the 81 inspections carried out, with information about what the clinics are doing well, areas that have improved and critical/major non-compliances. Of the 299 non-compliances all but 10 are now closed demonstrating the effectiveness of the regulatory activity.
- 9.8.** Members agreed that the sector will welcome this report. One member noted that some in the sector have expressed frustrations over the continuity of assessments over time: one inspection report can be good and then the next inspection find many non-compliances. Of the 299 non-compliances, members probed whether these were new issues or issues that had been raised with clinics before.

- 9.9.** Members heard that detailed analysis had not been carried out on whether non-compliances found were new or persistent, and noted that work had gone in to ensuring Inspection teams are consistent. The inspection is a snapshot in time and other inspection tools indicate there can be a drop off in performance between inspections. Members were assured that if inspectors find a non-compliance that has been identified before, it will be graded as a more serious non-compliance in the subsequent inspection report.
- 9.10.** Members noted that as inspectors become more experienced and established they are likely to find more non-compliances. In addition, the inspector's portfolio of centres only changes every few years, so it's likely the inspection is being carried out by the same lead Inspector.
- 9.11.** Members suggested that other positive sector information could be included in this report through vignettes, for example around the world class research carried out in the UK. Members also wondered whether the research sector should be included in this report.
- 9.12.** The Chief Executive agreed to discuss further whether research should be covered in this report, or whether there should be a separate report on embryo research.
- 9.13.** Members agreed that case studies are a good way of sharing learning, with the Grade A incident mentioned in this report, being a good example. Members welcomed this report as a method of achieving this.
- 9.14.** Members felt that this report has the potential to be a 'go to' document for people writing about the sector more broadly and hoped that social media would be deployed to promote the publication of the report.
- 9.15.** Members suggested that the decision by commissioning groups, not to follow NICE guidelines on the provision of IVF, could also be touched on in this report as this will be a factor in the reporting of how many cycles are self-funded.
- 9.16.** Members agreed that the tone of the report centred around information and learning is the right one and that the language used should be clear to a wide audience, in particular, the information around multiple births and success rates. Further, members agreed that it is appropriate to highlight what clinics are doing well and how some of them are going beyond good compliance.
- 9.17.** Members further agreed that a stronger narrative might be provided to point out that there are six clinics which are outliers in multiple births and explain why patients should actively not choose these clinics.
- 9.18.** Members also agreed that where non-compliances are identified and action taken this is a positive story for the sector. Members noted that the executive summary, which as yet is unwritten, could bring together the positive comments about the sector, highlights and trends.
- 9.19.** The Chief Executive thanked members for their comments and informed them that some of their suggestions will be fleshed out in the other scheduled report, Fertility Trends. In addition, he stated that the Executive will read across both reports for consistency and balance.
- 9.20.** Members heard that further comment would be welcome in the coming weeks and a decision will be made as to how best to let members have sight of the final draft before publication.
- 9.21.** Members:
- Endorsed the decision to move away from a focus on clinic non-compliances

- Agreed the scope and coverage of the report
- Agreed the final report should be published in the autumn.

10. Investigation into fertility clinics

- 10.1.** Members received a presentation from the Chief Inspector regarding the follow-up to the allegations made by the Daily Mail regarding five clinics. This paper explores, following normal regulatory investigation, if there are any wider policy implications.
- 10.2.** Members heard the allegations include:
- Financial inducement for egg donation/egg sharing
 - Exaggeration of frozen egg success rate
 - Loans for treatment
 - Overcharging for drugs
- 10.3.** Members were informed that in addition, it was alleged that there is widespread under-reporting of ovarian hyper stimulation syndrome (OHSS).
- 10.4.** Members heard that verbal information on egg donation/sharing was not reflected in the written information given to patients in the clinic investigated. However, there is evidence that counselling is always offered.
- 10.5.** A Member noted that egg sharing often only happens if treatment for a patient is unaffordable, though agreed that all clinics egg sharing/donation programmes should be fit for purpose, with good information being central to this. Members noted the good practice on independent counselling that is taking place in clinics which is a significant step forward for the sector.
- 10.6.** Compliance will monitor information on websites around this area and ensure that patient feedback is scrutinised where these types of treatment have been accessed.
- 10.7.** Members also heard that in the clinics investigated the success rates of frozen egg treatment were usually based on their own data which runs the risk of not being statistically robust owing to the small numbers involved. Again, it was found that written information could be clearer, enabling patients to decide themselves.
- 10.8.** Members agreed that egg freezing is no longer an experimental treatment but the numbers are still low. It is not unreasonable for clinics to present their own data but it should be within an ethical framework with no bias either way.
- 10.9.** Members noted that Compliance will be looking at the presentation of success rates on clinic websites, as part of the review of guidance on information for patients.
- 10.10.** Members heard that loans in the case investigated are being offered for treatment without regulatory oversight. The Financial Conduct Authority (FCA) responded very quickly to this, as did the loan company involved, and there is a plan for the HFEA and the FCA to work together in future. Members agreed that there are other clinics offering financial packages, within a framework backed by the FCA, and these can work for patients.

- 10.11.** Members agreed that whilst the HFEA has limited power on pricing, costed treatment plans can help, and the HFEA is working with NHS England on a benchmark price.
- 10.12.** Members noted that in the cases investigated, patients are not being informed that they can take their prescription elsewhere to get cheaper medication. Patient feedback in future will include a question about expected costs versus actual cost. Members agreed it is essential that clinics are transparent.
- 10.13.** Members were informed that OHSS only is reported to the HFEA when severe and critical, with between 60-80 cases being reported per year. When compared to hospital admissions ascribed to OHSS via data from NHS Digital, it suggests there is under reporting taking place.
- 10.14.** Members agreed though, that some patients admitted to hospital do not have OHSS and have been misdiagnosed. If this is the case, the recording of the diagnosis by the hospital would not necessarily be changed which may account for some of the discrepancy in the data.
- 10.15.** Members were informed that Compliance will work with NHS Digital to probe the data further to establish which of the 865 hospital admissions are severe and critical cases related to IVF treatment. Further, once the data is understood it will determine whether the discrepancy in reporting is because fewer of the patients had OHSS than data suggests or if there are serious cases slipping through the net.
- 10.16.** Members noted that the HFEA will work with the Royal College of Obstetricians and Gynaecologists (RCOG) and British Fertility Society (BFS) to improve definitions in guidance notes and consider a form for OHSS reporting.
- 10.17.** Members heard that the Code of Practice will be updated to ensure that clinics provide correct information to their patients on what they need to do in the event of an OHSS case, and what information the patient needs to provide the hospital they are attending. In addition, inspectors will ask questions about OHSS handling on inspection.
- 10.18.** Members wondered if it is possible to establish where a patient had been treated using the NHS Digital data (especially if that treatment had occurred abroad), but at present this data is not collected.
- 10.19.** Members asked for an update on the position with OHSS as soon as it is available.
- 10.20.** Members noted the range of recommendations of the different issues investigated on:
- Egg sharing and egg donation
 - Success rates from egg freezing
 - Promotion of loans to pay for treatment
 - Drug pricing
 - OHSS

11. Leadership in clinics

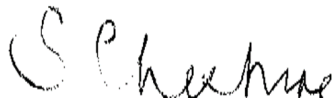
- 11.1.** The Director of Compliance and Information explained that this paper builds on the Chair's speech at the last HFEA annual conference, where she challenged the sector to reflect on what constitutes good leadership in their clinics.
- 11.2.** Although the responsibilities of the Person Responsible (PR) are well understood in clinic, there are now a growing set of complex ownership/partnership structures in place which can impact on leadership in clinics. In addition, there have been examples of poor leadership practice.
- 11.3.** In the past, the HFEA has taken a rather narrow assessment of leadership focused on qualifications and membership of professional bodies. Indeed, the Act only refers to the responsibilities of the PR and not to more generic leadership qualities.
- 11.4.** Members agreed that this could be an opportunity to drive up quality of care at source via clinic leadership. This direction of travel is also being pursued by the Care Quality Commission (CQC) and NHS Improvement who are turning their focus to what a well led service looks like.
- 11.5.** Members heard that Inspectors will need the tools, and as importantly the confidence, to step in to this area in order to make assessments about PRs.
- 11.6.** Members agreed that the sector on the whole is broadly compliant, with lots of very good practice and good patient care, but there are still pockets of poor leadership practice.
- 11.7.** Members agreed that this step will be a big ask of the sector as in the past PRs were appointed for reasons that are different to the holistic approach set out in the paper. Members hoped that the planned dialogue with the sector will help address this.
- 11.8.** Members felt Inspectors should also try to understand what the governance structure that supports the PR is; though they are legally responsible, they are usually part of a leadership team.
- 11.9.** Members expressed the importance of a PRs character and the challenge of assessing that for Licence Committee. It is very difficult to ascertain how that person affects the culture in a clinic and, some PRs may not actually be based at the site they are responsible for.
- 11.10.** Members agreed that in thinking about leadership there should be no distinction between NHS and private clinics. As the Act is 25 years old, the HFEA needs to get around any technical/legal constraints by influencing, incentivising and bringing people together, as many of the leadership qualities we want to see are not required by law. PRs embracing leadership in clinics will improve patient care, and that is the benefit the clinics will gain by engaging with this initiative.
- 11.11.** Members supported this piece of work and agreed that it is appropriate to be collaborative and sensitive when introducing this to the sector. In addition, they urged the Executive to identify metrics that might measure leadership.
- 11.12.** Members noted that there is new leadership at ACE and BFS (in the new year) and relatively new leadership at the RCOG, and these are the partners with which the HFEA will have to work to get this initiative off the ground.
- 11.13.** Members noted and agreed the proposed approach to leadership in the sector.

12. Any other business

12.1. There was no other business raised.

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

Signature

A handwritten signature in black ink, appearing to read 'S Cheshire', written in a cursive style.

Chair: Sally Cheshire