Minutes of Authority meeting 15 March 2017

Strategic delivery:	☐ Safe, ethical effective treatment	☐ Consistent outcomes and support	☐ Improving standards through intelligence

Details:	
Meeting	Authority
Agenda item	2
Paper number	HFEA (10/05/17) 834
Meeting date	10 May 2017
Author	Erin Barton, 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 March 2017 held at Church House, 27 Great Smith Street, London SW1P 3NZ

Members present	Sally Cheshire (Chair) Dr Andy Greenfield Kate Brian Dr Anne Lampe Anthony Rutherford Bishop Lee Rayfield	Yacoub Khalaf Margaret Gilmore Anita Bharucha Bobbie Farsides
Apologies	Ruth Wilde	
Observers	Steve Pugh (Department of Health)	
Staff in attendance	Peter Thompson Nick Jones Juliet Tizzard Paula Robinson Richard Sydee Catherine Drennan	Chris Hall Joanne Anton Helen Crutcher Joanne McAlpine Erin Barton

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 second 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.

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 18 January 2017

2.1. Members agreed the minutes of the meeting held on 18 January, for signature by the Chair of the meeting.

3. Chair's report

3.1. The Chair gave an update on the events that she attended since the Authority meeting on 18 January 2017.

- On 18 January, the Chair and the Chief Executive had an introductory meeting with Clara Swinson, our new senior sponsor at the Department of Health
- On 7 February, the Chair attended the ALB Chairs & NED's Compassionate Leadership Seminar at the Department of Health
- On 8 March, she chaired an interview panel to select a new Chair for our Independent Appeals Committee and appointed Peter Freeman.

3.2. The Chair also talked about the HFEA Annual Conference the following day, at which we planned to launch our new strategy for 2017-20 and set out some new expectations of the cultural and ethical leadership needed to improve services.

4. Chief Executive's report

4.1. The Chief Executive advised members that on 3 February he attended our quarterly accountability meeting with Department of Health colleagues and on 6 February he attended our Scientific and Clinical Advances Advisory Committee.

4.2. On 21 February, the Chief Executive, along with the Director of Compliance and Information, met with a legal officer from the West Indies University who is providing advice to the Jamaican government on the regulation of IVF.

4.3. On the 24 February, the Chief Executive attended the Healthcare Leaders scheme graduation and engagement event.

Organisational change

4.4. At the meeting on 18 January, the Chief Executive set out our proposals for organisational change in the light of the Authority agreeing its new strategy for 2017-20 and the near completion of the Information for Quality programme (IfQ). The Chief Executive informed members that a draft proposal was sent to staff at the end of January for consideration, closing in late February. The responses were analysed and a revised organisational structure was published. All staff that were directly affected received a letter setting out how the changes will impact on their role. That letter was supported by a 1:1 meeting with the relevant Director.

4.5. The new organisational structure will be phased in between April and September. Members were reassured that staff will be supported through this uncertain time and any redundancies will be approved by the Remuneration Committee.

Press coverage

4.6. The Chief Executive informed members that it had been a quiet couple of months in the press office, with relatively few mentions of the HFEA in the press. However, he highlighted two developments relevant to research and responsible innovation.

4.7. There had been a series of stories around genome editing, beginning with the relatively positive assessment in the report from the US National Academies, the outcome of the patent dispute over who owns the Crispr-Cas9 technology, and the work being done by the House of Commons Science and Technology Select Committee into genomics and genome editing. It is too early to tell whether the use of gene editing in treatment will become a serious public policy possibility, but the picture is changing rapidly.

4.8. A new study was published by researchers from the University of Cambridge, which involved the creation of an artificial mouse embryo using stem cells. The researchers were reported to have claimed an intention to try and repeat the procedure with human cells. We were contacted by a few members of the press for our views on whether this would be legal and declined to comment as we had not had the chance to study the paper in detail. Again, this is likely to require consideration in the future.

5. Committee Chairs' updates

5.1. The Chair of the Statutory Approvals Committee (SAC) reported that the committee met on 23 January and 23 February. It considered four preimplantation genetic diagnosis (PGD) applications in January and three requests for Special Directions, all of which were approved. At the February meeting, three PGD applications were considered, all of which were approved.

5.2. The Chair of the Licence Committee advised members that the committee met on 9 March to consider one new research licence application, one research licence renewal, and one application to vary a centre's licence to permit mitochondrial donation. The minutes have not yet been published.

5.3. The Director of Strategy and Corporate Affairs advised members that the Executive Licensing Panel (ELP) met three times; on 27 January, and 10 and 24 February. The panel considered three treatment and storage renewal applications, two of which were approved and one of which was adjourned; three interim inspection reports, including two where the licence was continued and one which was adjourned; one additional inspection report where the licence was continued; and one voluntary licence revocation which was approved. The Licensing Officer considered two applications to change the Licence Holder which were both approved.

5.4. The Chair of Scientific and Clinical Advances Advisory Committee (SCAAC) advised members that the committee met on 6 February, and considered the following items:

- Developing a traffic light system for treatment add-ons which will be published when the new website launches in Spring 2017, and will be reviewed annually as part of the horizon scanning process
- New technologies in embryo testing
- Prioritisation of issues identified through the horizon scanning process
- The implementation of audit recommendations. The following issues were considered as high priority for the coming year:
  - Use of ICSI
  - Mitochondrial donation
  - Genome editing

- Fertility preservation
- Embryo culture media
- Health outcomes in children conceived by ART
- Alternative methods to derive embryonic and embryonic-like stem cells
- New technologies in embryo testing
- Treatment add ons.

6. Strategic performance report

6.1. The Chair introduced this item, advising that the strategic performance report was a general summary of our performance measures, the progress towards implementation of the strategy, our programmes and their status, and generally the wider performance of the Authority.

6.2. The Director of Finance and Resources gave an overview of our income and expenditure for 2016/17 and introduced the draft budget for 2017/18. He apologised to members that some of the figures in the strategic performance report they had received were incorrect and not consistent between different pages and tables. The figures contained within the PowerPoint presentation were accurate.

6.3. Members heard that our budgeted income for 2016/17 assumed that there would be around 55,000 IVF treatment cycles. The number of cycles had already surpassed this figure, and was predicted to reach 62,000 cycles by the end of the financial year. An underspend of just under £620k at year-end was forecast, primarily due to the additional income we received from activity. Legal costs were above our original budget but this included a conservative reserve against costs relating to a judicial review, and these costs will fall significantly should we receive a favourable judgment. There may also be some provision for the organisational restructure in this financial year.

6.4. The draft budget for 2017/18 was similar to that of the previous year. As the IfQ programme finishes and we recognise the asset from an accounting perspective, we will begin to depreciate it which will increase our costs. We are also taking on the running of the donor conceived register from the Department of Health (DH) which will increase costs.

6.5. The Director of Finance and Resources informed members that a new piece of work is planned to study any correlation between the demand for treatment and demographics, as well as other socio-economic factors, in order to predict our future income more accurately and to gain a better understanding of the treatment market more generally. The following areas will be explored to understand how changes within them might impact on activity:

- NHS Commissioning
- Providers
- Patient behaviour
- Economic outlook
- Scientific advances.

6.6. The Director of Strategy and Corporate Affairs reminded members that our annual conference was taking place the following day. The focus was the new Strategy for 2017-2020 but other themes included: good care for transgender patients; facilitating research; medicines management; reducing multiple births; emotionally safe treatment; and responsible innovation.

6.7. The Director of Strategy and Corporate Affairs informed members that we are working with NHS England and a number of partners including the BFS, to develop a benchmark IVF price and commissioning guidance, to help commissioners to make fair and cost effective decisions about fertility services for their local population. Guidance and a benchmark price is expected by the next financial year. Members will be kept up to date with our progress.

6.8. Following discussion, members noted the latest strategic performance report.

7. Information for Quality: update

7.1. The Director of Compliance and Information reminded members that the IfQ programme is a comprehensive review of the information that we hold, the systems that govern the submission of data, the uses to which it is put and the ways in which the information is published. It includes:

- The redesign of our website and Choose a Fertility Clinic (CaFC) function
- The redesign of the 'clinic portal' used for interacting with clinics
- Combining data submission functionality
- A revised dataset and data dictionary which will be accredited
- A revised Register of treatments, which will include the migration of historical data contained within the existing Register
- The redesign of our main internal systems that comprise the Authority's Register and supporting IT processes.

7.2. The Director of Compliance and Information advised members that the new Clinic Portal was launched on 19 January. The launch went well but there were queries from some clinics, most of which were dealt with quickly and effectively. The focus was now on embedding business-as-usual practices.

7.3. Since the launch of the Clinic Portal, the priority has been completing the website and preparing for the Government Digital Service (GDS) gateway assessment, which took place on 8 March 2017. The assessment identified a few issues which needed to be addressed before going live, including testing the speed and ensuring we have the resources and structure in place to maintain a secure service after the website has gone live.

7.4. As outlined to the Authority at the previous meeting, we were expecting the judgment on the judicial review relating to proposals for publishing performance measures within CaFC, by the end of January 2017. To date, this had not been received, and the impact of this on plans to launch the website is unclear.

7.5. In December 2016, we asked clinics to undertake a verification exercise relating to their performance data in respect of CaFC. This differed from previous years' exercises due to the new focus on cumulative birth rates, but was necessary to enable us to start the new CaFC with a high

quality dataset. We extended the deadline a month to the end of March 2017, to ease the burden on clinics.

7.6. Members heard that data migration was planned to take place over five stages, which will become progressively easier, and that the team has made good progress. Data cleansing has taken place for all errors with the potential to prevent migration. We commissioned an external specialist to audit our process and ensure that our approach conforms with our data migration strategy. Feedback from their preliminary audit in January 2017 was very positive. Further audits were scheduled for May 2017, one as we move to the third stage, and one final audit prior to migration.

7.7. The Director of Compliance and Information informed members of the intention to close the formal aspects of the Programme on 31 March and scope the outstanding work as a project of activity within our business plan commitments for 2017-18.

7.8. Members noted:

- the Clinic Portal is now live
- the intention to launch the HFEA website and choose a fertility clinic as live, in April 2017
- the intention to close the programme at the end of March 2017
- the arrangements for securing completion of the programme components in 2017/18.

7.9. Members agreed that the programme should not close after a set date, but after the amendments to the website and CaFC. Members also requested that the Audit and Governance Committee continue to receive regular updates on progress. The Chair thanked all staff and stakeholders who have contributed to the programme.

8. Draft information policy

8.1. The Head of Information advised members that, with the IfQ programme drawing to a close, we need to revisit the rules and expectations which are currently set out in a mixture of policy, directions and guidance in the Code of Practice, in order to agree a new information 'bargain' between ourselves and the bodies we regulate. In doing so, we aim to:

- ensure that clinics hold treatment information safely and securely, and submit high quality information to us on time
- drive better performance
- facilitate conversations between our inspectors and clinics about performance
- enable patients and donors to make more informed choices about their options.

8.2. The Head of Information summarised the specific areas under review which included:

- The foundations of the Register
- Register data submission: quality and timeliness
- Publishing data on Choose a Fertility Clinic
- Clinics' websites and marketing
- Information security
- Accessing anonymised and identifying HFEA register data for research and understanding

- Opening the Register.

8.3. Members heard the proposal for a 'mixed-model' approach to consultation, using a range of approaches to gather views, including:

- gathering feedback from users on the new data dictionary and submission system further to user testing
- seeking the views of stakeholder using our existing framework of licensed centres' panel, professional stakeholder organisation group and so on
- focused pieces in Clinic Focus, including links to e-survey tools
- engagement through the new Clinic Portal – which now provides the mechanism for gathering views more quickly
- face-to-face events, for example workshops.

8.4. Members thanked the Head of Information for his very comprehensive paper outlining the draft information policy. Some members stressed the importance of incentivising the timely submission of data, and others were interested in exploring the regulatory levers that could be used to sanction the minority of centres who do not comply with our policy, especially regarding their own websites and marketing. After some discussion, the Authority noted:

- The areas of focus for consultation regarding the HFEA policy on information
- That following consultation a revised Information Policy together with General Directions and revisions to the Code of Practice will be presented to the Authority for approval.

9. Governance and transparency

9.1. The Director of Strategy and Corporate Affairs gave an overview of the committees' annual reviews. All committees are working well with good quoracy and effective chairing, although technical issues involving telephone systems had disrupted some meetings. The use of external members, expert advisors and peer reviewers is working well, and the additional patient perspective provided to the Statutory Approvals Committee is greatly appreciated when considering applications for preimplantation genetic diagnosis.

9.2. Following discussion, members noted the committees' annual reviews and agreed that the Standing Orders remain unchanged.

10. Facilitating research and responsible innovation

10.1. The Head of Regulatory Policy gave an overview of our planned work on embryo, data and clinical research, and sought a wider discussion about our role on emerging issues within the context of our new Strategy.

Embryo research

10.2. Members heard that a wide-ranging project on embryo research had commenced, focussing on giving patients greater opportunity to donate embryos to research if they so wish, and improving access to donated embryos for research projects. Early feedback from the sector presented a complex picture with different issues affecting different types of clinics.

10.3. Further work is planned for the coming months to explore potential barriers to embryo research and develop ways to overcome these barriers. This includes gathering feedback through clinic and patient surveys on consent and ways to encourage more collaboration between clinics and researchers. A paper will be presented to Authority in June to incorporate changes into the Code of Practice for October 2017.

Data research

10.4. Members heard that around 70% of patients give their consent to data research which, although an improvement on previous years, could be higher. Over the coming months further work is planned to increase patient awareness of data research, and to understand the potential reasons for the fluctuation of consent rates across the sector, including a clinic-led research workshop at the annual conference. Other possible actions include:

- Developing a patient leaflet on data research to provide patients with more information about the types and benefits of research.
- Exploring the advantages and disadvantages of setting a minimum target for consent to disclosure rates (similar to the way we introduced a minimum target for reducing multiple births) to help the inspectorate measure the effectiveness of the clinic.
- Making data research a key part of our information strategy which will be developed by the new Intelligence team. This will set out how we plan to work differently to carry out and facilitate data research to improve the quality of fertility services.

Responsible innovation for new treatments

10.5. In January, the Authority noted its concerns about the apparent proliferation of fertility treatment add ons that have not been rigorously tested in a clinical trial setting before being offered to patients. We want patients to have access to good quality treatments which maximise their chance of a pregnancy, but we must be careful not to stifle innovation in the fertility sector.

10.6. The following steps aim to encourage more robust clinical research:

- Our Scientific Clinical Advances Advisory Group have produced clear, honest information for patients about add ons; how safe they are, whether they work to increase pregnancy and birth rates, and how much they are likely to cost.
- We will encourage more clinics to participate in clinical trials by publishing on the new HFEA website information about which clinics are carrying out clinical trials and providing information to patients on how to get involved.
- We will use our new Intelligence Team to carry out a thorough analysis of our data and encourage clinics to carry out studies and publish their findings – all carried out through collaboration with scientific and clinical professional bodies, patient organisations and perhaps scientific publications.
- We will develop a consensus about responsible innovation in fertility treatment that we could agree with stakeholders and encourage clinics to sign up to. Our success with changing professional and patient attitudes towards single embryo transfer suggests ways that we could make progress, utilising the same style of collaborative working, coupled with an effective public education campaign.

10.7. Members heard that they will be presented with a plan for the above work later this year and were invited to discuss our role on emerging issues, in particular how we balance our regulatory

responsibilities with our strategic ambition to promote high-quality research and responsible innovation.

Our role on emerging issues

10.8. Some members felt that we should engage more with existing clinical trials and research projects. Randomised controlled trials are expensive and there is a general lack of funding in this area, worsened by problems with participation. Greater participation in current trials would increase interest and drive funding in future.

10.9. Members stressed that we should encourage evidence-based medicine consistently across all areas of practice, and not just in relation to novel techniques. Members were keen for us to play a greater role in highlighting where research is lacking or would be most beneficial, which could be questions relating to everyday practices. The IfQ programme provides the opportunity to share data trends and analysis more easily, in order to produce hypotheses. Some members also felt that we could do more in setting standards by ourselves collecting more outcome data, for example in relation to PGD, which could be used by researchers.

10.10. Members noted that patients may have differing views towards data research and embryo research, and therefore different views on consent. This requires us to take a different approach to consent for embryo and data research. Some members felt that a target rate for consent would be inappropriate because it implies that consent to research is desirable, when this should be a personal choice. Instead, members wanted to raise awareness amongst patients of the different types of research and their potential benefits which may, in turn, increase the rate of consent.

10.11. Members were keen to establish a dialogue with the sector about research through collaboration with professional stakeholders. Members noted the important role that we played in facilitating the debate around mitochondrial donation, and felt that we could similarly create a space for discussion of other topics. Members stressed that we can be engaged whilst still being impartial, and recognised that, as the regulator, our input can have a big impact.

10.12. Following discussion, members agreed that we should continue with the planned work and return to the Authority later in the year with an update.

11. Choose a Fertility Clinic – patient rating trial and evaluation

11.1. The Policy Manager reminded members that the decision to include patient feedback on our new website formed part of our strategy for 2014-17 and that the decisions agreed by Authority in 2015 included that:

- we will not include a system to authenticate patients, as user feedback and the stakeholder group told us this would discourage patients from taking part
- one questionnaire will be used for both patient ratings on CaFC and to gather patient feedback for inspection reports
- any ‘free text’ comments submitted will not be published on the website but will be available to clinics through their inspectors
- feedback should be from recent patients and donors (within a year) and should only count towards the ratings on CaFC for 12 months
- we will promote the tool to patients to maximise uptake.

11.2. Members saw a preview of the new patient rating system on the beta version of our new website and were given an overview of the proposals to trial the feature, which will involve engaging patients, prospective patients and clinic staff in order to answer the following questions:

- Are the outputs from the rating system valuable to patients, inspectors and clinics?
- Will patients and donors use the tool to give their feedback and will potential patients use it to help make decisions about their treatment?
- Are HFEA procedures to manage the end to end feedback and ratings process effective?

11.3. Members suggested that information on whether prospective patients are using the feature could be gathered as part of the patient feedback system by including a question about whether they used the feature as part of their own decision-making prior to treatment.

11.4. Members were reassured that the trial plans to address the uncertainty around the lack of patient authentication, and agreed that this should be closely monitored and revisited in future, if necessary.

11.5. Following discussion, members agreed the plans for a trial of the patient feedback survey and ratings on CaFC.

12. Strategic risk register

12.1. The Head of Business Planning informed members that CMG reviewed the risk register at its meeting on 8 February. CMG reviewed all risks, controls and scores, and agreed to add a new risk relating to the forthcoming organisational change that is being planned. CMG also reviewed the two risks relating to donor conception and agreed to merge these into one single risk centred on running a good Opening the Register service. Both of these two new risks were currently at tolerance. We also updated the financial risk, since we were close to year end.

12.2. As the new strategy was about to be launched, the Head of Business Planning will be working with the Chief Executive and CMG to update the risk register – and also the performance report – to align them with the new strategy. The new version of the risk register will be ready for CMG in May, AGC in June and the Authority meeting in July.

12.3. The Head of Business Planning informed members that DH led an ALB Risk Network workshop recently, focused on identifying risk interdependencies between ALBs and with DH. They have put out new guidance to make sure we are all identifying and acting on any risks that we either share with another regulator, or experience as a result of another regulator's work, or potentially cause to another regulator through work we are doing. So, in the new version, each risk will have a separate section in which we can capture any risk interdependencies.

12.4. Four of the 12 risks were above tolerance. Two of these risks related to IfQ and the reasons for the earlier delays were recorded. Both these risk scores had gone up and down over the past few months, reflecting what was going on at the time. Delays to beta products meant that starting on release two had been very difficult, because it was the same small team delivering it. The focus was completing the first release of the clinic portal and the website, and passing our GDS service assessment, because these first releases, especially the portal, are the groundwork for a successful release two with a new data submission system.

12.5. On legal challenge, we set a high tolerance, since legal challenge will always be a risk, by virtue of the fact that we work in such an interesting policy area. It does at times, though, cause large peaks in workload for certain staff, and resource diversion. We have also had some delays in receiving judgments on some cases, which can worsen problems.

12.6. The final risk above tolerance related to data. We continue to receive an unpredictable flow of complex parliamentary questions and Freedom of Information requests and, because of some turnover in the policy team, we also lost a member of staff who was particularly expert in answering complex scientific parliamentary questions.

12.7. We also raised the general knowledge and capability risk at that time, because we were managing some turnover and internal churn, alongside some staff being fully occupied with IfQ. This situation was unlikely to go away during a period of organisational change.

12.8. Members noted the latest edition of the strategic risk register.

13. Business plan 2017/18

13.1. The Head of Business Planning reminded members of our three strategic aims for 2017-2020:

- Safe, ethical effective treatment
- Consistent outcomes and support
- Improving standards through intelligence.

13.2. To achieve these overall aims, we need to make sure that our next three business plans are carefully planned so that we deliver these aims. We also need to make sure that our risk register is capturing the risks to delivering these things, and that our strategic performance reporting helps us to keep track of delivery. Our teams need service delivery plans in place to deliver each business plan and staff need to have personal objectives in place which link to team plans, the business plan and to the overall strategy. Finally, we need to have the right organisational structure in place, which is in progress.

13.3. The Head of Business Planning gave members an overview of how we plan to meet our strategic ambitions and, following discussion, members thanked the Head of Business Planning for her excellent work and approved the near-final business plan for 2017/18. Members also noted that publication will follow, after the addition of year-end statistics and approval by DH of the budget and the business plan itself.

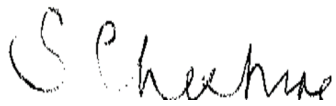
14. Any other business

14.1. The Chair of the meeting confirmed that the next meeting will be held on Wednesday 10 May at Church House, 27 Great Smith Street, London, SW1P 3NZ. Members were asked to confirm their attendance to the Executive Assistant to the Chair and Chief Executive as soon as possible.

15. Chair's signature

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

Signature



Chair: Sally Cheshire