

Minutes of Authority meeting 11 November 2015

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

Details:

Meeting	Authority
Agenda item	2
Paper number	HFEA (20/01/2016) 779
Meeting date	20 January 2016
Author	Charlotte Keen, Information Access and Policy 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	<input type="checkbox"/> Low <input type="checkbox"/> Medium <input type="checkbox"/> High

Annexes

Minutes of the Authority meeting on 11 November 2015 held at ETC Venues, Hatton Garden, 51-53 Hatton Garden, London, EC1N 8HN

Members present	Rebekah Dundas (Chair of the meeting) Dr Susan Price Bishop Lee Rayfield Anthony Rutherford	Dr Alan Thornhill Kate Brian Yacoub Khalaf Margaret Gilmore Anita Bharucha
Apologies	Sally Cheshire (Chair) Professor David Archard Dr Andy Greenfield	
Observers	Kim Hayes (Department of Health)	Steve Pugh (Department of Health)
Staff in attendance	Peter Thompson Nick Jones Juliet Tizzard Sue Gallone Hannah Verdin	Catherine Drennan Paula Robinson Joanne McAlpine Charlotte Keen

Members

There were 9 members at the meeting, 6 lay members and 3 professional members

1. Welcome, apologies and declarations of interest

- 1.1.** The Chair of the meeting opened by welcoming Authority members and members of the public to the final meeting of 2015. As with previous meetings, it was being audio-recorded and the recording would be made available on the HFEA website to enable interested members of the public who were not able to attend the meeting to listen to the HFEA's deliberations. This was part of the HFEA's drive to increase transparency about how the Authority goes about its business.
- 1.2.** Apologies were received from Sally Cheshire (Chair), Professor David Archard and Dr Andy Greenfield.
- 1.3.** Declarations of interest were made by:
- Anthony Rutherford (Consultant in Reproductive Medicine and Gynaecological Surgery 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 16 September 2015

- 2.1.** Members agreed the minutes of the meeting held on 16 September as a true record, for signature by the Chair of the meeting.

3. Chair's report

- 3.1.** The Chair of the meeting advised members that two new Authority members, Ruth Wilde – a senior fertility counsellor - and Dr Anne Lampe – a clinical geneticist who had previously provided expert advice to the Statutory Approvals Committee (SAC) - had been appointed. Ruth Wilde's appointment would commence on 1 January 2016 and Dr Anne Lampe's on 1 February 2016.
- 3.2.** The Chair of the meeting informed members that this meeting was Dr Alan Thornhill's last board meeting for the HFEA as his term of office would come to an end on 31 December 2015. The Chair of the meeting thanked Dr Thornhill on behalf of all the Authority members for his invaluable contribution to the work of the HFEA and wished him well for the future.
- 3.3.** The Chair of the meeting also expressed her thanks to Sam Hartley, Head of Governance and Licensing, who was leaving the HFEA to return to the Parliamentary Boundary Commission. On behalf of the Chair of the Authority and Authority members, the Chair of the meeting wished Mr Hartley all the best for the future and thanked him for his support in servicing all the HFEA's committees and the Authority during his time at the HFEA.
- 3.4.** The Chair of the meeting provided members with a summary of events that the Chair of the Authority had attended with organisations in the IVF sector and the wider health and care system since the last Authority meeting.
- 3.5.** On 23 September, she chaired the Multiple Births Stakeholder Group and on 29 September, together with the Chief Executive and other members of the Authority, attended the Department of Health's arm's length bodies (ALBs) summer conference.
- 3.6.** On 14 October, the HFEA Appointments Committee met to consider the renewal of three of the members of the Representations Committee and agreed to renew them all for a second term of office.

4. Chief Executive's report

- 4.1.** The Chief Executive began by paying tribute to the HFEA's former Chair, Professor Lisa Jardine, who died on 25 October after a long battle with cancer. The HFEA issued a statement on its website the day afterwards, with tributes from Sally Cheshire, the current Chair, and Jane Ellison, the Public Health Minister. However the Chief Executive wanted to pay formal tribute at this meeting which was the first since Lisa's passing.
- 4.2.** Lisa was an extraordinary woman. An academic of world renown, she authored 20 significant books and won numerous awards and received several honours. She was a regular broadcaster for the BBC and was, in the truest sense of the word, a public intellectual. If anyone bridged the famous divide between the 'two cultures' of the arts and the sciences, it was surely Lisa.
- 4.3.** All of this was well known to anyone who had read the obituaries of Lisa in the major national newspapers or heard the coverage on the BBC. It was striking how many of Lisa's ex-colleagues had written very warm and detailed obituaries. Lisa's passing was also marked on social media.

- 4.4.** The HFEA's Lisa was, of course, the Lisa who chaired the Authority, which she did so ably from 2008 until 2014. For much of that time, the future of the organisation was in doubt, yet Lisa rarely let it show. She was relentlessly enthusiastic and positive. During her time, Lisa led the HFEA on several high profile initiatives, including the donation review in 2009 and the very long-standing piece of work on mitochondrial donation which, of course, led to Parliament passing Regulations to allow such treatment from October this year – a world first, about which Lisa would have been delighted and very proud.
- 4.5.** HFEA staff all had their good memories of Lisa and most had experienced her great wisdom, together with her exuberant character. The Chief Executive said he, together with many members of the organisation, would miss Lisa greatly: as a friend, a colleague and as a mentor. Our thoughts and deepest sympathy continued to be with Lisa's family and friends at this difficult time.
- 4.6.** The HFEA had opened a book of condolence for Authority members, staff and sector colleagues and anyone who wished to leave a message could do so, by contacting the Executive Assistant to the Chair and Chief Executive.
- 4.7.** The Chief Executive advised members that, on 25 September, he was interviewed by Dr Neil Stephens from the Cardiff Centre for the Ethical and Social Aspects of Genomics and Epigenetics, who was conducting an Economic and Social Research Council (ESRC) funded project at Cardiff University looking at the debates around mitochondrial donation from a social science perspective.
- 4.8.** On 2 October, the Chief Executive attended a meeting at the Department of Health, with colleagues from the Human Tissue Authority (HTA), in relation to a number of regulatory initiatives from the Department for Business, Innovation and Skills (BIS). The details were still being finalised and members would be provided with a fuller outline of these initiatives at a future Authority meeting. However, the context was the Government's concern around economic growth more generally, and BIS was tasked with seeing how the regulatory environment as a whole could best foster growth.
- 4.9.** The Chief Executive advised members that there was a range of initiatives falling within the scope of this work, including the establishment of a Small Business Appeals Champion, where there was an ongoing discussion about an exemption for the HFEA, given that the organisation already had a very well established statutory independent appeals process. There was also an initiative relating to an economic growth duty, although there was recognition in Parliament that it may be inappropriate in a health context.
- 4.10.** Other initiatives included a business impact target, with legislation forthcoming, which aimed to quantify and reduce the cost of regulation to private sector businesses.
- 4.11.** The Chief Executive advised members that this was an area of public policy which was moving quickly and the HFEA's ability as a small specialist regulator to influence the overall outcome would be limited. In view of this the Chief Executive advised members that, if they were content, he, together with the Director of Compliance and Information, would develop the HFEA's response in close collaboration with the Chair of the Authority.
- 4.12.** On 21 October, the Chief Executive attended the second Department of Health led project board meeting of the HFEA's triennial review. The Chief Executive reminded members that it had long since been Government policy that all public bodies should be subject to a periodic

review. The review would look at the functions of the organisation and whether those functions were carried out in the most efficient way possible. The work on the triennial review was progressing well, although was slightly behind schedule.

- 4.13.** Also on 21 October, the Chief Executive attended part of the Scientific and Clinical Advances Advisory Committee (SCAAC). On 4 November, the Chief Executive gave a speech at an event at the Swedish Parliament on genome editing, organised by the Swedish National Council on Medical Ethics. The talk related to the mitochondrial donation debate in the UK and what lessons it might have for debates about genome editing. The Chief Executive reminded members that genome editing including the CRISPR¹ technique had been legal in a research context in the UK since 2009, although use of such techniques in treatment remained illegal.
- 4.14.** Press Coverage: the Chief Executive summarised press coverage since the last Authority meeting, details of which had been circulated to members.
- 4.15.** Adverse Incidents Report: the Chief Executive reminded members that, at the last Authority meeting, they had considered adverse incidents and the Executive's latest report, which had been published shortly afterwards. Coverage had been sporadic, with only limited national coverage and had tended to focus on the A Grade incidents at the expense of the message the Executive was trying to communicate about the sector actively working to reduce the largely administrative C Grade errors. It was the third such annual report and was beginning to be an important part of the HFEA's regular publications schedule.
- 4.16.** Genome Editing: the Chief Executive advised members that the Executive had received enquiries from two national newspapers about whether the HFEA had received a research application to use the genome editing technique Crispr-Cas9. The Executive had simply confirmed that such an application had been received although it had not yet been put before the Licence Committee, and as such no further comment would be made. There had, nonetheless, been some coverage in the press, which highlighted the continued interest in this area.
- 4.17.** Egg freezing: the Chief Executive advised members that egg freezing continued to be one of the most popular topics in the press throughout 2015. There had been coverage in the Observer, which prompted a letter from the Chief Executive that had tried to address some of the misconceptions within that coverage. The Chief Executive advised members that, given the interest, the Executive would be carrying out some work on egg freezing for publication in 2016. The new website, which would also be launched in 2016, would also contain some more information on the subject.

5. Committee chairs' updates

- 5.1.** A member of the Statutory Approvals Committee (SAC) reported that the committee had met on 24 September and 29 October. There had been six preimplantation genetic diagnosis (PGD) applications in September, all of which were approved. At the October meeting (the minutes of which had not yet been published), five PGD applications had been considered.

¹ CRISPR is a scientific acronym, and stands for 'clustered regularly interspaced short palindromic repeats'.

- 5.2.** The Deputy Chair of the Licence Committee advised members that the committee had met on 5 November. The minutes had not yet been published. The committee had considered three research renewal applications, an interim licence application and a licence variation to allow embryo testing.
- 5.3.** The Chair of the Audit and Governance Committee advised members that the committee had met on 7 October and, had received reports on:
- Stakeholder relations, risks involving Parliamentary Questions and Freedom of Information requests, and communication risks relating to the redesign and relaunch of the HFEA website as part of the Information for Quality (IfQ) programme, from the Director of Strategy and Corporate Affairs
 - A regulatory update on legal parenthood cases and an IfQ update, from the Director of Compliance and Information
 - A cyber security briefing from the Head of Information Technology
 - The strategic risk register, from the Head of Business Planning
 - Updates from Internal and External Audit
 - The reserves policy, from the Director of Finance and Resources.
- 5.4.** The Chair of SCAAC advised members that the committee had met on 21 October and she expressed her thanks to the Scientific and Clinical Policy Manager, who had since left the HFEA, for her invaluable contribution to the committee. Aside from looking at the work of the committee for the next six months, committee members received an update on embryo culture medium and a presentation on time-lapse imaging from Professor Roy Homburg, a specialist in reproductive medicine and assisted conception, Andy Vail, Professor of Clinical Biostatistics at the University of Manchester, and Dr Sarah Armstrong from the University of Glasgow. The committee also received a round-up of articles relating to health outcomes in children conceived using assisted reproductive technologies, and considered the annual committee review.
- 5.5.** The Director of Strategy and Corporate Affairs advised members that the Executive Licensing Panel (ELP) had met four times since the last Authority meeting. At the first three meetings, the panel had considered five treatment and storage renewal applications, all of which were approved; five variations, all of which were approved; one voluntary revocation, which was granted; and two interim inspection reports, where the licences had been continued. At the meeting on 30 October, the minutes of which had not yet been published, the panel had considered two interim inspections, one variation, one unannounced inspection report and one application to carry out PGD using human leukocyte antigen (HLA) typing.

6. Strategic performance report

- 6.1.** The Chair of the meeting introduced this item, advising that the strategic performance report was a general summary of both the HFEA's performance measures, the progress towards implementation of the strategy, the HFEA's programmes and their status, and generally the wider performance of the Authority.

- 6.2.** The Director of Finance and Resources provided an overview of financial performance and referred to the graph on page three of the report, which showed the overall position compared to what was anticipated. The Director of Finance and Resources explained that, whilst a small deficit had been expected, a small surplus has arisen and this was anticipated to continue for the remainder of the year. The graphs on page six of the report showed the situation for income and expenditure respectively. Both income and expenditure were a little less than expected and that trend was likely to continue.
- 6.3.** The Director of Finance and Resources provided a summary of the financial position. At the end of September, there was a surplus of £249k which was expected to continue. The surplus was partly due to a lower spend on salaries and legal costs. It was anticipated that all of the revenue grant-in aid from the Department of Health would be spent and about 18% of the capital grant-in-aid would carry over to the next financial year for spend on the Information for Quality programme.
- 6.4.** The Director of Finance and Resources provided a summary of cash reserves. The graph on page 13 of the report showed the HFEA's cash balance. It was important to note that the cash reserve was slightly different in that it took account of accruals and was not impacted by the timing of payments. In terms of cash reserves, there was £2.5m at the beginning of 2015/16. This was likely to drop significantly to £1.6m by year end due to planned spend on the IfQ programme, and by a further £200k in 2016/17. This would come very close to the minimum level of reserves of £1.38m, needed in order to cover general cash flow or any unforeseen difficulty.
- 6.5.** Turning to the 2016/17 financial year, the Director of Finance and Resources advised members that the work carried out for setting fees had determined that £938k of grant-in-aid would be required, which was less than the current financial year. However, funding may also be required for the HFEA's office move. Discussions had taken place with the Department of Health finance team, in the context of the impending spending review. The Director of Finance and Resources advised members that the HFEA's indicative budget should be confirmed in December and that all other financial performance was on course, including prompt payments, recovery of debts and the production of the HFEA's accounts.
- 6.6.** In relation to the HFEA's office move, the Director of Finance and Resources explained to members that the lease on the current building would come to an end in May 2016 and the Executive was unable to renew it. It had been initially anticipated that the HFEA would move to Buckingham Palace Road where a number of other ALBs were situated. However, this offer of accommodation had been withdrawn at fairly short notice and it had now been agreed that the HFEA would be sharing office space elsewhere in central London with another ALB, enabling the organisation to be kept as an integrated unit, albeit in a smaller office. This would mean developing more flexible ways of working for staff and a 'ways of working' group had been set up which would play a key part in making sure that staff concerns were addressed.
- 6.7.** The Director of Compliance and Information advised members that, since the judgement by the President of the Family court on legal parenthood, he had attended the AGC meeting in October to provide the committee with a full update on progress, which included a message in Clinic Focus from the Chief Executive and Chair, setting out the HFEA's course of action. At the next meeting of the Authority, the Director of Compliance and Information would be in a position to provide a more complete and comprehensive summary.

- 6.8.** The Director of Compliance and Information explained that the clinics involved, as a result of an audit of practice, had identified between 75 and 80 cases where there was some level of doubt about the quality of the parenthood based on a review of the records and discussions with the couples. The Executive had recently completed an extensive exercise where HFEA staff had conducted a review, on a clinic by clinic basis, to understand more about the particularities of each specific case. The Executive would draw up some actions that clinics would be expected to take following consideration of the outcome of that review.
- 6.9.** The Director of Strategy and Corporate Affairs provided members with a summary of activities within her Directorate, including participation in the National Fertility Awareness Week which took place from 2 November. This included a programme of activities, led by Infertility Network UK, leading up to the Fertility Show at Olympia on 7 and 8 November. There had been a lot of press coverage of fertility issues, and the week involved some very successful collaboration between the HFEA and professional and patient organisations. The Director of Strategy and Corporate Affairs had spoken at a debate on 3 November organised by the Progress Educational Trust (PET). The debate had focused on how the donation field had fared since the removal of donor anonymity ten years ago.
- 6.10.** The Director of Strategy and Corporate Affairs advised members that she had given a presentation at the Fertility Show on how to understand pregnancy and live birth rates, which had been well received. Other members of the Authority had also given seminars at the show and the HFEA had a stand, and had handed out 600 copies of the 'Getting Started' guide, together with a significant number of 'One at a time' and 'Lifecycle' leaflets. There had been over 3,500 visitors to the show and the Director of Strategy and Corporate Affairs expressed her thanks to HFEA staff who had attended the event.
- 6.11.** A member noted that it was evident there was a need for such an event given the increasing numbers of patients attending. However, it was apparent from feedback from those who had attended, that it was incredibly confusing for patients and there was an awful lot of 'myth' information, advertising and treatments that would not necessarily be recommended by clinics or the HFEA.
- 6.12.** It was noted that the collaboration of the HFEA, professional and patient groups all working together at the Fertility Show should continue because it was an opportunity to build on, and improve the objectivity of, the information that patients were getting. The Chair reminded members that it was important to consider, as a UK wide regulator, how to access all patients and parents throughout the UK, not just those in London. The Director of Strategy and Corporate Affairs advised members that there were other shows in existence and the Executive had already visited some regional events.
- 6.13.** The Director of Strategy and Corporate Affairs reminded members that the Mitochondrial Donation Regulations came into force on 29 October and there had been a significant amount of work in the organisation in order to design and prepare a regulatory framework within which the HFEA could implement the law. The Regulations had been the result of extensive work over the last four years, carried out by researchers, campaigners, policy makers and stakeholders alike and was a significant milestone.
- 6.14.** Following the discussion, members noted the presentation and the latest strategic performance report.

7. Draft business plan 2016/17

- 7.1.** The Head of Business Planning reminded members that they had agreed an outline of the new business plan at their September meeting. The business plan was designed to help the organisation deliver its overall strategy, year by year, and this would be the second full business plan since the strategy was published in August 2014.
- 7.2.** The Head of Business Planning provided members with an overview of the timetable for the implementation of the 2015/16 business plan and the development of the 2016/17 business plan. The business planning cycle commenced each year in August, with development of the draft plan occurring from September through to December. During October, when the delivery cycle had reached the end of quarter two of the financial year, a review took place to consider progress against the current business plan. This was an opportunity to either re-publish the current plan if any changes were required, or identify what would need to be continued through to the next financial year. The HFEA strategy was also considered, with a three year delivery outline having previously been agreed by the Authority in 2014.
- 7.3.** This part of the timetable had been completed and the Corporate Management Group (CMG) had also considered current and future aims, what activities these required and what resources would be needed to deliver them. The Head of Business Planning advised members that, in December, the Department of Health would need to receive a first draft of the business plan for 2016/17, and this was an opportunity for members to agree that draft. From January through to April 2016, there would be an iterative process, where discussions took place with the Department of Health about the draft plan, identifying anything that the sponsors or Ministers would like changed or incorporated. The aim was to finalise the plan and associated budget in order for it to be signed off in March and published in April 2016.
- 7.4.** The Head of Business Planning advised members that the draft followed the same basic template as the current 2015/16 business plan, which had been redesigned previously to align with the strategy. Members were provided with an overview of the main points and activities proposed for 2016/17, which were set out in more detail in the paper. The activities continued to focus squarely on achieving the HFEA's vision of 'high quality care for everyone affected by assisted reproduction'. All the HFEA's statutory work was included (regulation and information provision) and the IfQ programme would be a major part of the plan. The plan would reflect the HFEA's continued emphasis on being a high-value, high-quality public body.
- 7.5.** The Head of Business Planning also advised members that, if there should be any recommendations arising from the triennial review about the HFEA's regulatory processes, these would be included when known. For the first time, members noted that the processing of PGD and mitochondria applications had been highlighted as a specific area of work due, in part, to the ongoing rise in the number and complexity of PGD applications.
- 7.6.** Members noted that the following sections of the business plan would not be written until later in the business year:
- What the HFEA did in 2015/16
 - Measuring the HFEA's performance
 - The financial picture.

- 7.7.** Members also noted that the activities set out in the main section of the business plan, in relation to delivering the strategy, would still require some further refinement over the next few months, particularly with respect to timescales.

Decision

- 7.8.** Following a discussion, members:

- Approved the draft business plan at its current stage of development
- Noted that if major changes were made to the draft prior to submission to the Department of Health, a revised version would be circulated to members for comment
- Noted that a draft would be submitted to the Department of Health before the end of December
- Noted that CMG had reviewed the current business plan and that there was no need to publish an in-year revision.

8. Strategic risk register

- 8.1.** The Head of Business Planning presented this item to provide members with an overview of the risks, showing the relative risk tolerance positions and residual risk scores. Five of the twelve risks remained high and were deemed above tolerance:

- IfQ - improved information access: the residual risk of 12 was higher than tolerance (set at a medium level of 8) due to approval process delays at the first stage of the programme, and the risk to the quality of the final product that could be delivered if there were any further approval delays encountered.
- Data – incorrect data being released: although good controls were in place for dealing with PQs and other externally generated requests, volumes could not be controlled and the HFEA had received extremely high volumes in the first half of the year. The residual risk of 12 was therefore higher than the tolerance threshold of 8. It was not yet possible to tell if further high volumes would occur following the mitochondria project and in the course of the subsequent start-up of applications processing.
- Legal challenge: a relatively high risk tolerance of 12 was set for this particular risk due to the inevitability of some degree of resource diversion owing to the nature of the HFEA's work. The residual risk was currently higher than tolerance at 15.
- Financial viability – income and expenditure: the residual risk of 12 was above tolerance (set at 9), although 2014/15 overspend was able to be met from reserves.
- Capability – knowledge and capability: the residual risk of 9 was above the current tolerance level of 6. Staff turnover could lead to fluctuations in overall capability, although the period of highest turnover appeared to be ending.

- 8.2.** The Head of Business Planning also provided a brief overview of the remaining high level risks that were currently within or at tolerance. In particular, the regulatory model risk had recently decreased in its residual risk score and was well below tolerance, following the completion of recent recruitment and the implementation of a new, more resilient, staffing model.

- 8.3.** Following a discussion, members noted the latest version of the risk register.

9. Information for Quality update

- 9.1.** The Director of Compliance and Information explained that the IfQ programme was a comprehensive review of the information that the HFEA held, the systems that governed the submission of data, the uses to which it was put and the ways in which the information was published.

- 9.2.** The Director of Compliance and Information advised members that the purpose of this presentation was to update members on:

- The outcome of user research activity conducted during ‘Discovery+’
- Department of Health approval to proceed beyond Alpha phase
- Key progress made towards a proof-of-concept during the Alpha phase
- The agile methodology being applied to IfQ and ‘sprint’ progress
- Details of the Programme’s budget and timelines for delivery.

- 9.3.** User research outcomes of ‘Discovery+’: the Director of Compliance and Information advised members that the ‘Discovery+’ research conducted by Reading Room and the HFEA was now complete, having been conducted during July and August 2015. Its purpose was to expand on the knowledge and evidence from an earlier IfQ Discovery phase. Primary research had been conducted in the form of one to one interviews with a broad range of people using, or considering, fertility services. This included people considering fertility treatment as an option for the first time, through to people who had completed treatment, and also donors of eggs and sperm. Desk research and stakeholder interviews had also been undertaken.

- 9.4.** The Director of Compliance and Information advised members that the key insights from this work had been:

- The identification of a cognitive behavioural model that defined three categories of clinic user, which had been of crucial importance for designers of the HFEA website and CaFC
- A greater understanding of how people first approached the topic of fertility treatment and how the HFEA needed in the future to integrate with the NHS Choices online services, and the face-to-face provision from GPs, gynaecologists and fertility doctors
- An understanding of the importance of personal friendship groups and their role in decision making and emotional support around fertility issues, choice of clinics and treatment options
- Evidence of unmet user needs, especially around the ‘big picture’ of fertility treatment and the various patient pathways and decision points that people went through.

- 9.5.** Approval to proceed beyond ‘Alpha’ phase: the Director of Compliance and Information advised members that the programme could not proceed beyond the ‘Alpha’ (proof-of-concept) stage until approvals had been granted by the Department of Health in line with Government Digital Standards. Work to date had been closely focused on adhering to those standards and, upon the basis of close and ongoing discussions with colleagues at the

Department of Health, the Executive expected approval to be granted to proceed. The assessment was scheduled to occur on 12 November with approval granted soon after.

- 9.6.** Alpha phase progress: the Director of Compliance and Information provided members with an overview of Alpha phase progress. The overwhelming majority of the Alpha phase development of a proof-of-concept had now been completed, including the completion of front-end design samples of the Clinic Portal and website (including CaFC). The proof-of-concept work had been tailored to meet the needs of the HFEA's users, as established during the Discovery and Discovery+ phase research activity, and to comply with Government Digital Service Standards.
- 9.7.** The Director of Compliance and Information provided members with a sample of the front-end proof-of-concept work completed during Alpha phase, although he emphasised that this represented only a small portion of the work completed. The programme was progressing well, with each project well placed to progress beyond Alpha phase proof-of-concept, to building functionality during Beta phase.
- 9.8.** Agile methodology and 'sprint' progress: the Director of Compliance and Information reminded members that the programme management methodology for IfQ was scrum – an agile methodology. Incorporating an agile methodology ensured software was delivered effectively, in a user needs driven and iterative way that put software in the hands of users as quickly as possible. Within scrum, the programme's delivery timeline and development schedule had been broken down into two week 'sprints'. The Director of Compliance and Information provided members with an overview of how the programme was progressing through sprints, in relation to the overall delivery timeframes for the programme. The programme was in the final sprint before the commencement of Beta phase.
- 9.9.** Programme budget and delivery dates: the Director of Compliance and Information advised members that a detailed IfQ programme plan had been finalised and signed off by the IfQ Programme Board in October, in line with the overall £1.134m agreed by the Authority. Whilst applying a scrum based methodology to the programme meant that the exact outputs of each sprint remained subject to sprint planning, the anticipated programme budget and key milestones had been agreed and the programme was progressing in line with expectations.
- 9.10.** The IfQ programme budget remained consistent with the original business case and, as members had been advised earlier in the meeting, expenditure would extend to the next financial year and the budget had been recently adjusted to reflect this.
- 9.11.** Following a discussion, members noted the progress made on the IfQ programme.

10. Choose a fertility clinic update

- 10.1.** The Director of Strategy and Corporate Affairs reminded members of the discussion at the July Authority meeting in relation to Choose a Fertility Clinic (CaFC), specifically on the presentation of outcome statistics and patient ratings. Members had stressed the need to achieve a good balance between patient ratings, inspection findings and outcome statistics. This paper updated them on progress on patient ratings and presenting statistics since July, although the discussion would focus on patient ratings.

- 10.2.** The Director of Strategy and Corporate Affairs advised members that, since July, the Executive had refined the wording of the patient ratings questions, set out at Annex A of the paper, and had given thought to how they integrated with the patient questionnaire which informed inspections. Given that the questions in the patient ratings feature and inspection questionnaire had so many areas of overlap, the Executive had decided to combine them.
- 10.3.** The Director of Strategy and Corporate Affairs advised members that the questions were drafted in such a way that people were given the opportunity to give a range in their answers from one to five. Members were asked to consider, in relation to the presentation of the patient ratings results, whether:
- The Executive should only present an average rating for a clinic once it had received a certain minimum number of reviews, and if so, how many?
 - The overall rating should be based just on the 'Friends and Family' test question (question one, Annex A), or all of the questions. The Executive's current view was that it should be based on the 'Friends and Family' test as this was an overall impression, in itself
 - The average ratings should be limited to a particular time period, for example the past year. If yes, what period would be appropriate? This would perhaps be perceived as fairer for clinics which had responded to feedback and improved their service, but it would limit the sample size, thereby reducing reliability.

Decision

- 10.4.** Members felt that all reviews should be presented on receipt rather than waiting until a certain number of reviews had been received. If there were a minimum threshold, some clinics would wait for a very long time to have enough reviews to publish. Members felt that users of the service were accustomed to reading online ratings on other websites, and so would understand not to draw strong conclusions if a clinic had only a handful of ratings.
- 10.5.** Some members felt that the overall rating should be based on all of the questions, rather than just the 'Friends and Family' test question, whilst some felt the 'Friends and Family' test was the most important, although with the option of accessing ratings on other questions if desired.
- 10.6.** Members, however, agreed that the average ratings should be limited to a particular time period and that a rolling period of a year would be the most appropriate timeframe. It was also important to make it absolutely clear that it was patient generated information.
- 10.7.** Members flagged up some concerns for the Executive to consider, including the question relating to the level of involvement in decisions about treatment, as this could potentially penalise clinics with a harder multiple birth strategy than others, and the system could possibly disadvantage NHS clinics.
- 10.8.** The Executive agreed to take members' comments into account when continuing with the user testing and would provide an update on progress at a future meeting.

11. HFEA fees 2016/17

- 11.1.** The Director of Finance and Resources provided members with an explanation of the process the HFEA had engaged in to produce the proposals on fees, and the thinking behind them.

The Director of Finance and Resources explained that the HFEA was funded from a combination of fees from the sector it regulated and grant-in-aid (GIA) from the Department of Health. Fees were expected to cover the cost of regulation and GIA covered the cost of wider public policy purposes. The Director of Finance and Resources emphasised that the current fees structure had been in place since 2001 and fees had not been increased since 2006. Following a review, fees had been decreased in 2012 from £104.50 to £75, and the elective single embryo transfer discount (eSET) had been introduced. There had been no further changes since then.

- 11.2.** The Director of Finance and Resources advised members that the HFEA had reduced costs since 2010 and had made efficiencies over the last five years, absorbing inflation as well. However, it was now clear that fees would no longer meet the HFEA's costs from 2016, mainly due to treatment numbers falling, increasing numbers of eSET discounts, and accommodation costs. It had therefore become necessary to consider the fee levels required going forward.
- 11.3.** The Director of Finance and Resources explained that, each year, the HFEA considered the total funding required, reflecting future needs and making efficiencies where possible. The HFEA determined how much was to be funded by GIA and how much by licence fees. The amount of GIA required was based on a long-standing agreement with the Department of Health regarding what GIA funded, which was embedded in the HFEA's costs model. The structure of fees, as set out in Annex 1 of the paper, was well established.
- 11.4.** The Director of Finance and Resources advised members that the funding required for the next financial year was £5.3m, slightly less than the 2015/16 budget. This included an assumed additional £90k for accommodation costs after the office move. On this basis, the HFEA model indicated that the HFEA would require GIA administrative funding of £938k and £4,372k from fees.
- 11.5.** The Director of Finance and Resources provided members with an overview of the fees structure, based on 2015/16 rates and confirmed that the HFEA proposed to retain the current structure for charging fees. The Director of Finance and Resources stressed that the IVF treatment fee of £75 within the fees structure was the vast majority of the HFEA's income. It was therefore proposed that all fees except IVF treatment would remain unchanged. Around £70k of the cost of regulating would be recovered from fees that were not for IVF treatments and in order to recover the remaining costs of £4,302k from IVF treatments, it was necessary to estimate future numbers of treatments. This was very hard to predict. The best estimate at present was around 55,000 treatments in 2016/17, which reflected recent decreases and assumed the numbers would continue at that level.
- 11.6.** The Director of Finance and Resources provided members with an overview of the eSET discount, where the HFEA did not charge for subsequent transfers from the same batch of eggs after an initial single embryo transfer. The discount was introduced in 2012 to encourage eSET and to help reduce the number of multiple births. Since then, there had been good progress with eSETs with the number increasing significantly and multiple births falling to 17%. It was important to note there was now accepted evidence that eSET led to better pregnancy rates and had been embedded into clinical practices. This suggested that the eSET discount was not necessary to drive behaviour and, in addition, the HFEA was aware that the eSET discount can be complex to administer for clinics.

- 11.7.** If the Authority agreed to remove the eSET discount, the HFEA would need to maintain clear messages in relation to the continued drive in reducing multiple births in order for clinics to achieve the target of 10%. The HFEA would continue to monitor multiple births and maintain a strong focus on clinics' performance in this area. Removal of the eSET discount was also an opportunity to decrease complexity, which was one of the main focuses of the IfQ programme.
- 11.8.** The Director of Finance and Resources provided members with a summary of stakeholder views. On the proposed increase in fees, it was completely accepted as necessary and understandable. The Fees Group, in particular, had appreciated the HFEA's transparency about funding and costs. It was, however, acknowledged that fees should be reviewed every year and adjusted to reflect needs and any surpluses from the previous year. The Fees Group felt that the changes should be introduced for treatments started after 1 April 2016, as opposed to embryo transfer, and that this change would require three months' notice for clinics to implement.
- 11.9.** The Director of Finance and Resources provided members with a summary of stakeholder views on removing the eSET discount. It was felt by the Fees Group that this might be seen as contradictory to the focus on reducing multiple births. However, it was important to note that although the eSET discount might be perceived as a possible incentive, it was the clinical decisions on whether eSET took place that ultimately mattered, so the discount itself should not be driving behaviour.
- 11.10.** The Director of Finance and Resources advised members that if eSET was to be removed, to recover the funding required from treatment fees, using the estimate of 55,000 treatments and taking into account uncertainties in funding and treatment numbers, the HFEA proposed to round the treatment fee to £80 from the current charge of £75. The alternative was to increase IVF treatment fees to £90 and retain the eSET discount.

Decision

- 11.11.** Following a discussion, members agreed that, from 1 April 2016:
- The IVF treatment fee that the HFEA charged licensed clinics should be increased from £75 to £80
 - The eSET discount should be discontinued
 - Other fees should remain unchanged
 - There would continue to be a clear message that focused on further reducing multiple births and a regulatory emphasis on multiple birth performance.

12. Scientific and Clinical Advances Advisory Committee: issues from the past year

- 12.1.** The Head of Regulatory Policy advised members that the Scientific and Clinical Advances Advisory Committee (SCAAC) met three times each year to consider advances in science and clinical practice, which were relevant to the Authority's work. The committee kept the HFEA up to date with a fast moving area and consisted of Authority members and external advisors
- 12.2.** The committee continued to include a broad range of clinical and scientific expertise in its membership, including:

- Obstetrics
- Gynaecology
- Embryology
- Andrology
- Clinical genetics
- Preimplantation genetics
- Stem cell biology
- Epigenetics.

- 12.3.** The Head of Regulatory Policy advised members that SCAAC carried out its horizon scanning function annually, with the aim of identifying issues that could have an impact on the field of assisted reproduction or embryo research. Issues were identified by thoroughly reviewing all journal articles from the previous year and issues were prioritised according to criteria including the HFEA's remit, potential patient demand, technical feasibility and ethical or public interest issues.
- 12.4.** Issues identified as high priority were incorporated into the HFEA's business plan and work plan for the Executive, SCAAC and the Authority.
- 12.5.** The Head of Regulatory Policy advised members that SCAAC considered three standing items on an annual basis:
- Alternative methods to derive embryonic stem (ES) cells or embryonic-like stem (ES-like) cells
 - Health outcomes in children conceived using assisted reproductive technologies
 - Embryo culture media.
- 12.6.** The Head of Regulatory Policy advised members that there were five other topics that SCAAC had looked at throughout the year and which had been identified as high priority:
- 12.7.** Fertility preservation: this had been identified as a high priority issue in February 2014 and Helen Picton, from the Leeds Institute of Cardiovascular and Metabolic Medicine, gave a presentation to SCAAC in February 2015. The theory was that freezing eggs or ovarian tissue could preserve fertility in cancer patients. There were two methods of cryopreserving eggs and ovarian tissues: slow freezing and vitrification. Eggs preferred vitrification but the surrounding cells preferred slow freezing, with varying success rates. A large number of eggs had been stored for fertility preservation in the UK, but only a small number of babies had been born so far. There had been varying degrees of success in restoring fertility. Methods included injecting or attaching strips of frozen ovarian tissues to the ovaries. Approximately 40 children worldwide had been born as a result of ovarian tissue banking followed by transplantation. Key issues for consideration going forward were, that in the case of cancer patients, ovarian transplant risked reintroducing malignant cells, although it may be possible to avoid that risk by growing primordial cells to mature eggs via *in vitro* maturation (IVM) or *in vitro* growth (IVG).
- 12.8.** Reproductive immunology: this had been identified as a high priority issue in February 2014 and Siobhan Quenby, Professor of Obstetrics at Warwick Medical School, gave a presentation to SCAAC in October 2014. An Executive paper was subsequently presented in February

2015. The theory was that some clinics offered tests and treatments which were based on the idea that immune cells in the body could 'reject' a fetus, thus preventing a successful pregnancy. It was previously thought in the sector that the embryo implanted into the endometrium, but current understanding was that the cells from the endometrium encapsulated the embryo. There was a theory that natural killer (NK) immune cells could attack the fetus and prevent implantation but it was now known that these cells were actually involved in helping the process of implantation. It was also previously thought that high levels of NK cells were associated with fertility problems because of this, but it was now known that this was indicative of wider endometrial dysfunction. In summary, there was no evidence that immunosuppressive therapies improved IVF outcomes and the theory that the immune system could reject a fetus had been widely discredited. This had all been reflected in the patient information on the HFEA website.

- 12.9.** Preimplantation genetic screening (PGS): this had been identified as a high priority issue in February 2015 and Executive papers were presented in February and June 2015. The theory was that aneuploidy in embryos was the commonest cause of infertility in women and increased with age. By screening for, and discarding, aneuploid embryos it should be possible to improve IVF outcomes. Initially PGS had been carried out using a technique called fluorescent *in situ* hybridisation (FISH). At the time, studies showed that this technique reduced live birth rates. Since then, a number of new technologies had been developed to carry out PGS which were much more accurate than FISH and could generate a lot more genetic data. A number of clinical studies had been conducted, showing that PGS using new technologies could improve IVF outcomes, although these studies had small sample sizes and focused on good prognosis patients. SCAAC concluded that larger, well designed, randomised controlled trials (RCTs) were required to test the efficacy of PGS properly. The use of PGS in fertility treatment was controversial, since it was introduced into treatment before clinical data was available. However, SCAAC discussions were being used to update the PGS guidance note in the Code of Practice which would be updated in 2016, and to redraft the patient information on the HFEA website.
- 12.10.** Freeze-all cycles: this was identified as a high priority issue in February 2015 and Abha Maheshwari, from the University of Aberdeen, gave a presentation to SCAAC in February 2015. The theory was that ovarian stimulation may have a detrimental effect on endometrial receptivity which could negatively impact IVF outcomes. IVF success rates might be improved by freezing all embryos and allowing the endometrium to recover before any embryo(s) were transferred back. Some research suggested that pregnancies arising from the transfer of frozen thawed embryos had better health outcomes for both mothers and babies than fresh embryo transfer and that a freeze-all strategy could reduce the risk of ovarian hyperstimulation syndrome (OHSS). However, it was not known if freeze-all was a more clinically effective, safer and cost effective way to provide IVF compared to standard IVF treatment. A multi-centre freeze-all clinical trial was about to start recruiting with the outcome due to be published in February 2020.
- 12.11.** Time-lapse imaging: this was identified as a high priority issue in February 2015 and Professor Roy Homburg, a specialist in reproductive medicine and assisted conception, Andy Vail, Professor of Clinical Biostatistics at the University of Manchester, and Dr Sarah Armstrong from the University of Glasgow, gave a presentation to SCAAC in October 2015. The theory was that by monitoring embryo development using a time-lapse camera, it may be possible to

determine which embryos had the best chance of resulting in a successful pregnancy. Time-lapse imaging had been widely adopted by IVF clinics, although it was more expensive than conventional IVF. A recent Cochrane review (these are systematic reviews of primary research in human health care and health policy) had found that there was insufficient evidence to conclude that time-lapse imaging was more effective than conventional IVF. An RCT was now being planned and was currently awaiting approval for funding. The information presented to SCAAC would be used to draft patient information on the HFEA website.


- 12.12.** The Head of Regulatory Policy concluded by advising members that research into human reproduction was fast moving and SCAAC played a key role in ensuring that the HFEA kept up to date with scientific advances and that the HFEA had a key role to play in providing unbiased patient information. Consideration should also be given to how the HFEA in future could provide information to support clinical trials.
- 12.13.** Members noted and welcomed the presentation and agreed that it should be an annual item on the Authority agenda.

13. Any other business

- 13.1.** The Chair of the meeting confirmed that the next meeting would be held on 20 January 2016 at ETC Venues, Hatton Garden, 51-53 Hatton Garden, London, EC1N 8HN. Members were asked to confirm their attendance to the Executive Assistant to the Chair and Chief Executive as soon as possible.
- 13.2.** The Chair of the meeting concluded the meeting by repeating her thanks to Dr Alan Thornhill for his six years as an Authority member and his invaluable contribution to the other HFEA committees.

14. Chair's signature

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

Signature 

Chair Rebekah Dundas

Date 27 January 2016