

Minutes of the Authority meeting on 11 May 2016 held at 10 Spring Gardens, London, SW1A 2BU

Members present	Sally Cheshire (Chair) Professor David Archard Dr Andy Greenfield Bishop Lee Rayfield Kate Brian Rebekah Dundas	Yacoub Khalaf Margaret Gilmore Anita Bharucha Ruth Wilde Dr Anne Lampe Anthony Rutherford
Apologies	Full attendance of members	
Observers/Presenters	Steve Pugh (Department of Health)	Dr David McLernon (University of Aberdeen)
Staff in attendance	Peter Thompson Nick Jones Juliet Tizzard Catherine Drennan	Paula Robinson Joanne McAlpine Charlotte Keen

Members

There were 12 members at the meeting, 8 lay members and 4 professional members

1. Welcome, apologies and declarations of interest

- 1.1.** The Chair opened the meeting by welcoming Authority members and members of the public to the third meeting of 2016 and the first to be held at the HFEA's new offices at Spring Gardens. 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.** Declarations of interest were made by:
- Kate Brian (Regional organiser for London and the South East for Infertility Network UK)
 - Yacoub Khalaf (Person Responsible at a licensed centre)
 - Anthony Rutherford (Consultant in Reproductive Medicine and Gynaecological Surgery at a licensed centre)
 - Ruth Wilde (Senior Fertility Counsellor at a licensed centre).

2. Minutes of Authority meeting held on 9 March 2016

- 2.1.** Members agreed the minutes of the meeting held on 9 March as a true record, for signature by the Chair.

3. Chair's report

- 3.1.** The Chair provided members with a summary of events that she had attended with organisations in the IVF sector and the wider health and care system since the last Authority meeting.
- 3.2.** On 15 March, all Department of Health arm's length bodies (ALBs) were invited to a Policy seminar and on 24 March the HFEA held its annual conference which was a great success. Over 200 representatives from clinics attended the event and the Chair expressed her thanks to all members who were present on the day, together with the many staff who helped organise it and to everyone across the sector who attended.
- 3.3.** On 20 April, the Chair attended the ALBs' Ministerial round table discussion and on 4 May she chaired the Multiple Births Stakeholder Group meeting.

4. Chief Executive's report

- 4.1.** The Chief Executive advised members that, on 15 March and 20 April, he attended two National Information Board (NIB) Leadership meetings. The NIB was an initiative led by the Department of Health involving all of the health sector ALBs to make significant changes to the way in which information was used within the health and care system. The HFEA's role was limited given its specialist remit although it was appropriate that it was involved.
- 4.2.** On 11 April, the HFEA moved offices from Finsbury Tower to 10 Spring Gardens and, despite a few teething problems, the move went well. The Chief Executive expressed his thanks to all staff involved in the move.
- 4.3.** On 26 April, the Chief Executive attended the third meeting of the Health and Social Care Leadership Scheme which brought together the Department of Health and all of the Chief Executives of the health sector ALBs to identify senior talent within the system. Members were aware that both the Director of Compliance and Information and the Director of Strategy and Corporate Affairs had been selected onto the programme.
- 4.4.** Also on 26 April, the Chief Executive, together with the Director of Compliance and Information, met colleagues from the National Institute of Clinical Excellence (NICE) to better understand the international work that NICE had developed. The Chief Executive reminded members that the Executive had been in discussions with Healthcare UK about how best to promote UK healthcare overseas.
- 4.5.** On 29 April, the Chief Executive, together with the Director of Compliance and Information, met the Chief Executive of the Private Healthcare Information Network (PHIN) to consider how best the new data reporting requirements that the Competition and Markets Authority (CMA) placed on private IVF clinics could be delivered without unnecessary duplication.
- 4.6.** The Chief Executive reminded members that, at the last Authority meeting, he had advised them that the triennial review, which had looked at the functions of the organisation and whether those functions were carried out in the most efficient way possible, would have been signed off by the time of the May meeting. That had not been possible, which was not to indicate that there were problems with the HFEA's triennial review report, but rather that the Ministerial sign-off process was complex.

- 4.7.** Further, the Chief Executive reminded members that Government Departments were required to publish innovation plans by spring 2016 and ALBs were now required to follow suit. The HFEA's draft plan had issued on 26 April and the consultation would close on 6 June. The Executive believed that the regulatory scheme in place managed to support innovation in a way which also assured public confidence; indeed it was evident that regulation in bio-sciences had actually fostered innovation rather than hindered it. It was important to note it was the UK, with its robust regulation, that had achieved world firsts like the use of mitochondrial donation in treatment and the recent decision to allow genome editing in research. The HFEA's innovation plan set out those achievements.
- 4.8.** Press coverage: the Chief Executive summarised press coverage since the last Authority meeting, details of which had been circulated to members. It had been a quiet few weeks compared to the beginning of the year, although there were two issues in particular worth reporting.
- 4.9.** Fertility Trends report: the Chief Executive advised members that the 2016 report was launched at the HFEA's annual conference, with the Chair of the HFEA talking through the key figures. There were good, strong messages in the report, not least around multiple births and, in particular, egg freezing data which had been published for the first time.
- 4.10.** Thirteen day embryos: the Chief Executive advised members that there had been widespread coverage in the press about a licensed research project at the University of Cambridge which had developed a new technique that enabled embryos to develop in vitro beyond implantation stage, allowing for the first time analysis of key stages of human development up to 13 days. The HFEA had been contacted by journalists asking whether the law, requiring that embryos were not kept beyond 14 days, should be changed. The Chief Executive emphasised that any decision to change the law was a matter for Parliament and the HFEA had therefore declined to comment. The Department of Health had confirmed there were no plans to change the law.

5. Committee chairs' updates

- 5.1.** The Chair of the Statutory Approvals Committee (SAC) reported that the committee had met on 31 March and 28 April. There had been four preimplantation genetic diagnosis (PGD) applications in March, all of which were approved. At the April meeting, the minutes of which had not yet been published, four PGD applications had been considered.
- 5.2.** The Chair of the Licence Committee reported that the committee had met on 17 March and 5 May. At the March meeting, one treatment and storage renewal application had been considered and approved. In April, the minutes of which had not yet been published, there had been one research renewal application and an executive update.
- 5.3.** The Chair of the Audit and Governance Committee (AGC) advised members that the committee had met on 16 March, and had received reports on:
- Finance and resources risks, from the Director of Finance and Resources
 - Strategic risks, from the Head of Business Planning
 - Legal risks, from the HFEA legal advisor
 - An IfQ update on managing risks, from the Director of Compliance and Information

- Updates from the Internal and External Audit teams
- The AGC training programme.

5.4. The Chair of the Executive Licensing Panel (ELP) advised members that the panel had met five times since the last Authority meeting, on 11 and 21 March, 11 and 22 April and 6 May. The panel had considered 26 items in total, all of which were approved. There were nine renewal licence applications; five interim inspection reports; one application for a new centre and a number of variations to licences and Persons Responsible.

6. Strategic performance report

- 6.1.** The Chair 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.** In the absence of the Director of Finance and Resources, the Chief Executive provided an overview of financial performance and a summary of the position coming towards the end of the financial year. A surplus of almost £500k was forecast for year-end which was partly due to a lower spend on salaries, legal costs and a late surge in treatment fees in February and March.
- 6.3.** The Chief Executive reminded members that the finance team was in the process of preparing the end of year accounts which would be submitted to AGC when the committee next met on 15 June. On 16 June the accounts would then be circulated to the wider Authority and members would have a week to respond. The Chief Executive advised members that he would need to sign the accounts by 21 June with a view to them being laid before Parliament around 27 June.
- 6.4.** The Director of Strategy and Corporate Affairs reported on the HFEA annual conference which had taken place on 24 March. There were 200 delegates (85% of whom had attended before) and 70% giving feedback were positive about the conference. The success of the conference was due to a mixed and engaging programme, including the panel discussion on 25 years of IVF regulation and the previews of the new clinic portal and the website. As mentioned earlier in the meeting the annual Fertility Trends report was launched at the conference and the Chair was able to draw out some of the key findings from the report in her opening speech.
- 6.5.** The Director of Compliance and Information summarised activities within his Directorate. The majority of staff within the Directorate were heavily involved in the IfQ programme of work. In relation to inspection and compliance activities, members were advised that the 2015/16 inspection year had been a particularly busy one, with a 40% increase year on year and a continuing rise in PGD applications. The Director of Compliance and Information also welcomed the new Chief Inspector, who had recently joined the HFEA, to the team.
- 6.6.** Following a discussion, members noted the latest strategic performance report.

7. Strategy 2017-2020

- 7.1.** The Chair introduced this item, the aim of which was to encourage an early and open discussion about possible strategic priorities for 2017-20.

- 7.2.** The Director of Strategy and Corporate affairs summarised the proposed timeline for the new strategy, commencing with early discussions with Authority members and staff, and ending with publication of a new three year strategy document next April. The timeline would incorporate some internal discussions and planning, engagement with stakeholders in the autumn and winter, development of the actual document, and launch at the annual conference.
- 7.3.** The current HFEA strategy had a central vision: high quality care for everyone affected by assisted reproduction. The vision was simple and compelling, with HFEA staff identifying with it, stakeholders associating the HFEA with it, and patients agreeing it should be the main focus of the HFEA.
- 7.4.** The Director of Strategy and Corporate Affairs reminded members that the strategy had been organised around three areas: information, quality and value. It had been acknowledged at the time that the HFEA not only had to respond to wider political issues like the Francis review, but also needed, as an organisation, to take a technological step forward. The services and systems in place were out of date, hampering the organisation's ability to act. The strategy therefore had a strong theme throughout of service innovation and change. IfQ, once delivered, would enable the HFEA to use those services to further improve the quality of care.
- 7.5.** As the HFEA came into the final year of the current strategy, the organisation needed to think further ahead to the next phase of its strategy through to 2020 and consider what would shape its thinking over the coming months and years, taking into account the wide environment, including:
- The sector
 - Patient experience in clinics
 - The wider health system
 - The surrounding politics and economics
 - How the HFEA could use its systems and information to give a good quality service to the public, patients, the sector and the Government.
- 7.6.** It was also important to note that the HFEA would have new quality factors and drivers in place by April 2017, including:
- A new Register and data dictionary
 - Better quality Register information
 - Better published information – including from patients – about clinic performance
 - A wider range of information for patients and the public on a range of topics
 - More interactive engagement channels, including the website and clinic portal
 - Incentives for clinics via the transparency of 'inspector ratings' etc.
 - More published measures and benchmarking.
- 7.7.** The strategy needed to strike a balance between allowing both the environment and stakeholders to shape the HFEA's thinking, and recognising the organisation should lead with its own clear vision for change. Believing that high quality care for everyone affected by assisted reproduction should remain the HFEA's vision, consideration needed to be given to what that would mean for the next strategy.

- 7.8.** The Head of Business Planning set out some early thoughts on what themes the next strategy might focus on. Members noted that this was not an extensive or exclusive list, but reflected recent discussions and developing trends, and the increased quality of the HFEA's information infrastructure and provision after IfQ.
- 7.9.** There were areas of the current strategy that the HFEA would like to build on, including:
- Support for patients whose treatment has been unsuccessful
 - Treatment 'add-ons' (treatments such as additional drug regimes that are claimed to increase the chances of a successful pregnancy)
 - Clinics' lifelong role as information providers
 - Commissioning of IVF services (while recognising the limits of the HFEA's remit)
 - Making more use of the information held by the HFEA
 - Making good use of improved communication channels.
- 7.10.** Potential new areas of focus included:
- Treatment costs
 - Further gains from IfQ and the resulting improvements in the HFEA's information systems
 - Genetics/genomics (a growth area).
- 7.11.** The Head of Business Planning asked members to think about their personal experiences and interactions such as going to clinics, talking to clinic staff and patients, and attending the conference and to consider where the HFEA should focus its efforts in 2017-20. In particular, members were asked for their initial views on:
- The vision
 - The future landscape and operating environment
 - The ideas for future focus
 - The proposed process/timetable.
- 7.12.** Members agreed that the proposed timetable and process were suitable, and that the overall vision should remain.
- 7.13.** There was strong support for the HFEA to address treatment add-ons, given the lack of scientific evidence for many such treatments. It was also recognised, in relation to this and other issues, that public understanding of science was limited, and often not well served by the media. There could be an educative role for the HFEA in articulating difficult scientific concepts more clearly and without bias or sensationalism.
- 7.14.** In relation to commissioning and the costs of treatment, members were concerned at the lack of consistency across the UK, and the pressures on NHS clinics. Access to treatment was an issue. It was also felt that this lack of consistency was a general theme, seen across a range of fronts: quality of care, access to treatment, the quality of the information people receive when they first realise they may be infertile, and costs. Although the HFEA did not have any direct economic regulatory powers, there may still be actions the HFEA could take that would help to improve the current situation.

- 7.15.** Members were keen to do further work to improve the experiences of people whose treatment was unsuccessful, and felt that the support given by clinics should be more holistic and not focused solely on counselling provision.
- 7.16.** Members discussed genetics and genomics, and the wider research context. Although genetics and genomics was a high profile issue, the majority of the developments at this stage were in the research field, rather than treatment. The public would naturally expect research to lead directly to the creation of new treatments, when the reality may not be so straightforward. This was also another area where the science could be difficult even for experts in the field to grasp, and so there could be a communication role for the HFEA. It was felt that both embryo research and data-based research should be central in the new strategy. It was also suggested that the HFEA should make best use of the most up to date and widely used communication channels, including social media, to reach its intended audiences more effectively – especially so as to communicate key messages to younger people.
- 7.17.** The HFEA should continue to focus on patients' core quality concerns, which remain success rates, safety, cost and donation. These should form the heart of the future strategy. 'High quality care' in the next strategic period would mean safe, supportive, effective and consistent care, backed up by well-articulated scientific and research information.

8. Presentation from David McLernon – cumulative live birth rates after one or more complete cycles of IVF¹

- 8.1.** The Chair reminded members that since 2009, HFEA Register data had been available for researchers. Professor Alastair Sutcliffe, from University College Hospital in London, presented his research to Authority members in September 2013 and the Executive had been keen to invite more researchers to share their work with the Authority and the wider public. The Chair introduced Dr David McLernon, from the University of Aberdeen. Members noted that Dr McLernon had used HFEA data with two publications to date: the first on cumulative live birth rates over one or more complete cycles of IVF; the second on a clinical prediction model that could estimate the probability of a live birth rate over multiple cycles of IVF.
- 8.2.** Dr McLernon advised members that globally, the estimated prevalence of infertility was around 9%, whilst in the UK, one in six couples experienced problems conceiving, with many going on to have IVF treatment. Worldwide, by the end of 2013, over five million people were estimated to have been born as a result of IVF, with the UK accounting for over 4% of this total.
- 8.3.** Dr McLernon explained that IVF success was generally calculated and reported on the basis of live birth rates per treatment attempt, involving either an intended fresh or frozen-thawed embryo replacement. However, in order for patients and clinicians to understand the success of a live birth over an entire IVF programme, the most appropriate way of reporting this was to estimate the cumulative chances of success per woman after a number of completed cycles. Although cumulative live birth rates following IVF had been reported at an international level, no studies

¹ Cumulative live birth rates after one or more complete cycles of IVF: a population-based study of linked cycle data from 178,898 women: <http://humrep.oxfordjournals.org/content/31/3/572.full>

had reported such rates for the UK. It was also important to determine whether cumulative live birth rates had improved over time.

- 8.4.** Dr McLernon advised members that the aims of his study were to report the cumulative rates of live birth during two different time periods in UK women, and to estimate the personalised probability of a treatment dependent live birth over multiple complete cycles of IVF, between the time of the initial consultation before IVF began until after the first fresh embryo transfer attempt.
- 8.5.** The study was conducted using records extracted from the HFEA Register of 178,898 women who had embarked on IVF treatment in the UK between 1992 and 2007.
- 8.6.** Dr McLernon explained that a total of 71,551 women commenced IVF treatment during 1992-1998 and an additional 107,347 during 1999-2007. After the third complete IVF cycle, the 'conservative' cumulative live birth rate for women who commenced IVF during 1992-1998 was 30.8%, increasing to 42.3% during 1999-2007. The optimal cumulative live birth rates were 44.6% and 57.1% respectively. After eight complete cycles the optimal cumulative live birth rate was 82.4% in the latter time period. The conservative rate for multiple pregnancy per pregnant woman fell from 31.9% during the earlier time period, to 26.2% during the latter.
- 8.7.** Dr McLernon advised members the results demonstrated that, in the last two decades, there had been a rise in cumulative live birth rates accompanied by a decline in multiple birth rates. However, most UK couples who did not conceive after their first complete cycle did not receive a further two complete NHS funded IVF cycles as recommended by NICE. If there were no barriers to continuation of IVF treatment, around 83% of women receiving IVF would achieve a live birth by the eighth complete cycle, similar to the natural live birth rate in a non-contraception practising population. This data could be used to inform policy and counsel patients commencing IVF treatment in order to prepare them both emotionally and financially for their complete IVF journey.
- 8.8.** Following a discussion, members noted the presentation and the Chair thanked Dr McLernon for taking the time to share his study with the Authority.

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. It included:
- The redesign of the HFEA's website and Choose a Fertility Clinic (CaFC) function
 - The redesign of the 'Clinic Portal' used for interacting with clinics
 - New data submission functionality
 - A revised dataset and data dictionary which would be accredited
 - A revised Register of treatments, which would include the migration of historical data contained within the existing Register
 - The redesign of the HFEA's main internal systems that comprised the Authority's Register and supporting IT processes.

- 9.2.** The Director of Compliance and Information advised members that the purpose of this presentation was to update members on:
- The forthcoming approvals processes to proceed to ‘public beta’ phase and later to ‘live’
 - Progress since the HFEA annual conference
 - Data migration and cleansing
 - Programme timelines and budget implications.
- 9.3.** The approvals process to proceed to ‘beta’ phase: the Director of Compliance and Information reminded members that the externally facing part of the programme could not formally proceed beyond ‘alpha’ proof of concept stage until approvals in line with Government Digital Standards (GDS) had been granted by the Department of Health. The first, alpha, stage assessment, undertaken by the Department of Health Digital Projects team was passed to a high standard. The second stage assessment, undertaken by the GDS (essentially a check on the first stage departmental process) had now also been passed. On 11 and 12 May, both the website and clinic portal would again be assessed and, subject to the associated approvals from the Department of Health and GDS, both products would be released to ‘public beta’.
- 9.4.** Progress since the HFEA annual conference: the Director of Compliance and Information reminded members that the HFEA website and clinic portal had been demonstrated at the Annual Conference and were very well received. The recent focus had been towards user testing, which had taken place in late April, and this had been carried out successfully with both the website and CaFC receiving a good reception from all those who tested it. Although there were a number of issues raised, these were minor additions and adjustments involving refinements and enhancements rather than fundamental changes.
- 9.5.** Data migration and data cleansing: members were reminded that there was a certain amount of data cleansing that clinics were required to carry out before the data could be migrated to the new Register. The Executive had been communicating with clinics in order to prepare them for the requirement to cleanse data, and it was hoped that the prospective benefits offered by the new system would act as an incentive. The first tranche of eight clinics identified to undertake a pilot of cleansing activity had now received notification and, given the Executive’s communication had been proactive and the volume of work for each clinic was modest, there had been no negative feedback.
- 9.6.** Whilst the recent emphasis had been on data cleansing, the Director of Compliance and Information advised members that the Executive was still progressing the paperwork needed to get the data dictionary accredited, with the submission to NHS Digital in June for a July assessment.
- 9.7.** Timelines and budget implications: the Director of Compliance and Information reminded members that a revised IfQ programme plan had been finalised and signed off by the IfQ Programme Board in January 2016, in line with the overall £1.134m agreed by the Authority. Whilst the overall budget for IfQ remained unchanged, the revised timeline would extend work, originally expected to be completed in the current financial year, into the next. This would result in approximately £450,000 within the IfQ budget being carried over into the next financial year.
- 9.8.** Authority members noted:
- The forthcoming approvals processes to proceed to ‘public beta’ phase and later to ‘live’

- Progress since the HFEA annual conference
- Data migration and cleansing
- Programme timelines and budget implications.

10. Any other business

- 10.1.** The Chair confirmed that the next meeting would be held on 6 July (venue to be confirmed). Members were asked to confirm their attendance to the Executive Assistant to the Chair and Chief Executive as soon as possible.

11. Chair's signature

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

Signature

Chair

Date