

Authority Paper

| How this paper relates to our strategy | Setting standards | <input checked="" type="checkbox"/> | Increasing and informing choice | <input checked="" type="checkbox"/> | Demonstrating efficiency, economy and value | <input checked="" type="checkbox"/> |
|--|--|-------------------------------------|---------------------------------|-------------------------------------|---|-------------------------------------|
| Paper title | Minutes of Authority meeting 17 September 2014 | | | | | |
| Agenda item | 2 | | | | | |
| Paper number | [HFEA (12/11/2014) 735] | | | | | |
| Meeting date | 12 November 2014 | | | | | |
| Author | Charlotte Keen, Information Access and Policy Manager | | | | | |
| For information or decision? | Decision | | | | | |
| Recommendation | Members are asked to confirm the minutes as a true and accurate record of the meeting. | | | | | |

Minutes of the Authority meeting on 17 September 2014 held at ETC Venues, Hatton Garden, 51-53 Hatton Garden, London, EC1N 8HN.

Members

There were 9 members at the meeting, 5 lay members and 4 professional members.

Members present

Sally Cheshire (Chair)
Professor David Archard
Sam Abdalla FRCOG

Dr Susan Price
Dr Alan Thornhill
Dr Andy Greenfield

Rebekah Dundas
Debbie Barber
Jane Dibblin

Apologies

Gemma Hobcraft
Bishop Lee Rayfield

Observers

Ted Webb (DH)
Steve Pugh (DH)

Staff in attendance

Peter Thompson
Nick Jones
Juliet Tizzard
Sue Gallone

Catherine Drennan
Paula Robinson
Rachel Hopkins

Siobhain Kelly
Charlotte Keen

1. Welcome, Apologies and Declaration of Interests

- 1.1. The Chair opened the meeting by welcoming Authority members and members of the public. This was the fifth meeting of 2014 and it was the third that had been audio-recorded. 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 Bishop Lee Rayfield and Gemma Hobcraft.
- 1.3. Declarations of interest were made by:
 - Sam Abdalla (Person Responsible at a licensed centre)
 - Debbie Barber (Part-time Nurse Specialist at a licensed centre).

2. Minutes of Authority meeting held on 9 July 2014

- 2.1. Members agreed the minutes of the meeting held on 9 July 2014 as a true record, for signature by the Chair.

3. Chair's Report

- 3.1. The Chair advised members that she had met recently with the new President of the Royal College of Gynaecologists (RCOG), Dr David Richmond, and was scheduled to meet, together with the Chief Executive, the British Fertility Society (BFS) in October. On 16 September, the Chair met with Tracey Chester, the Chair of the British Infertility Counselling Association (BICA) and had a separate meeting on the same day with Sarah Norcross, Director of the Progress Educational Trust. These meetings with key stakeholders were intended to build alliances and to seek system wide co-operation on particular issues.
- 3.2. The Chair advised members that she had been part of a panel for new member appointments to the HFEA. The Authority was seeking one new professional member to replace Sam Abdalla and one lay member to make up the complement of 12 members. The panel had made its recommendations and, given that these were Ministerial appointments, the Parliamentary Under Secretary of State for Public Health, Jane Ellison, would make her recommendations in due course.
- 3.3. The Chair, together with the Chief Executive, had attended a session for Chairs, Chief Executives and Non-Executive Directors in relation to the Honours System. On 23 September, the Chair, together with an Authority member, would be attending an event on whistleblowing and, on the same day, the Chair and the Chief Executive would be attending a workshop, hosted by Healthcare UK and the Department of Health (DH), for Chief Executives and Chairs of the DH's Arms-Length Bodies (ALBs) on ALB involvement in international revenue generation.

4. Chief Executive's Report

- 4.1. The Chief Executive advised members that he had met Max Jones, Director of Information and Analytics at the Health and Social Care Information Centre (HSCIC). The HFEA's relationship with the HSCIC was one of its newer strategic partners. The HSCIC held the main bulk of the datasets relating to NHS care in England and it was clear that, in the new health and social care system, information, and how it could be better used, was vital to the improved running of

the health and social care system in general. Increasingly the HSCIC would be required by Government to be the body that either holds information directly or sets standards for the holding of information. It was therefore important that the HFEA had a close relationship with the HSCIC as one of its key strategic partners.

- 4.2. Press Coverage: the Chief Executive summarised press coverage since the last Authority meeting, details of which had been circulated to members. Members noted that the summer months tended to be traditionally slower in news terms than the rest of the year and in part this year had been no exception, with fewer requests for interview and comment taken from the media in July and August than in the preceding few months.
- 4.3. Mitochondria: there had been a back bench debate on mitochondria in Parliament on 1 September. There was considerable press coverage on the day, most notably by the BBC, which ran a documentary and a Newsnight item. The Chief Executive advised members that it was now for the Government to decide on the shape of the Regulations themselves and any timing issues.
- 4.4. Donation: since the last Authority meeting, the issue of donation, often controversial, had been prominent, with articles in the Daily Mail, the Telegraph, the Guardian and the Evening Standard amongst others.
- 4.5. One of the stories had been about 500 donors, and had suggested that this particular sub-set of donors were disproportionately responsible for a large number of children born from donation. The story had come from a request for information under the Freedom of Information legislation and some ensuing news articles had been misleading, ignoring issues such as known donation, overseas donation and the regulatory rules in place to safeguard the system. However, most reports had correctly referred to the 10-family limit in place.
- 4.6. The other main issue was around the shortage of donors in the UK. This followed on from a number of reports focusing on imports of sperm from Denmark. The Director of Strategy and Corporate Affairs and an HFEA Policy Manager subsequently gave a number of interviews on the subject.
- 4.7. Finally, there was press interest in an announcement that a National Sperm Bank was to be established, an initiative between the National Gamete Donation Trust (NGDT) and Birmingham Women's Hospital. It was not yet functioning and there would be subsequent discussions with the HFEA about any regulatory issues.

5. Directorates' Report

- 5.1. The Director of Compliance and Information provided members with a general review of the key performance indicators. Members noted that performance had been good overall for all the key performance indicators including licensing, the administration and processing of PGD applications and corporate performance.
- 5.2. The Director of Compliance and Information advised members that, on the Compliance side, there had been a number of resignations from the team over the summer. The organisation of the team, consistent with the strategy agreed by the Authority in July, had been finalised in order for the team to be better focused; Research Regulation, Clinical Governance and Inspections had been brought together under the Chief Inspector, previously the Head of Inspection.
- 5.3. The Director of Compliance and Information advised members that the Directorates' Report itself identified a large increase in June and July in Pre-Implantation Genetic Diagnosis (PGD) applications and an increase in the complexity of those applications. A workshop was planned in December with

- those clinics that make the majority of PGD applications to discuss with them how the system was working for them and what sort of issues they anticipated.
- 5.4. The Director of Compliance and Information advised members that, on the information side, the Donor Information Manager was also leaving the HFEA. As well as leading on Opening the Register (OTR), she had also played a crucial part in the Information for Quality (IfQ) Programme by leading the work on behalf of the HFEA on the Data Dictionary.
 - 5.5. The Director of Compliance and Information informed members that the Executive had reported to the Ethics and Standards Committee (ESC) on 3 September with some early thoughts on measuring the positive impact the HFEA had on the quality of care provided by the clinics, through feedback from inspections, and the direct relationship between the strategy and the work of the organisation.
 - 5.6. The Director of Strategy and Corporate Affairs provided members with an overview of work planned for her Directorate for the autumn. A number of workshops were planned, primarily aimed at clinic staff, on a number of different areas.
 - 5.7. There would be a series of workshops on multiple births and on consent. Four workshops would be held during November in London, Manchester, Bristol and Edinburgh where emphasis would be put on the 10% multiple births target and the HFEA's continued expectation that clinics meet this, despite the removal of the licence condition relating to multiple births. The HFEA would expect clinics to share successes and to encourage one another to use their experience to reach that target.
 - 5.8. The consent workshops would be happening on the same day as the multiple births workshops, and would be looking at some of the issues around collecting consent, primarily to storage. Posthumous use of eggs, sperm and embryos and consent to legal parenthood would also be discussed, issues which had come up in court cases over the past couple of years. Discussions would take place around how clinics take consent, with whom and at what stage of treatment.
 - 5.9. There would also be two Information for Quality consultation workshops. Members would be given an overview of these under the IfQ consultation item.
 - 5.10. The Director of Strategy and Corporate Affairs informed members that the HFEA would be present at the Alternative Parenting show in London on 20 September and the Fertility show at Olympia on 1 and 2 November, at the end of Fertility Awareness week. Ahead of the Fertility Show, the Director of Strategy and Corporate Affairs advised members that the HFEA would be using both social media and the website and the Directorate was also working on a new edition of the HFEA's "Getting Started" guide. The Directorate was also working on a themed report around donation, which would be a combination of data from the Register and more qualitative information the Executive had been gathering from clinics.
 - 5.11. The Director of Strategy and Corporate Affairs informed members that a new Head of Engagement had been appointed and the interim Head of Policy and Communications had since been appointed as the Head of Regulatory Policy. These appointments would enable the Executive to put more energy, resources and organisational commitment into the Authority's dialogue with patients and professional stakeholders.
 - 5.12. The Director of Finance and Resources advised members that a review meeting had taken place on 15 September with the Chief Executives of both the HFEA

and the Human Tissue Authority (HTA) which confirmed the shared finance staffing arrangements were working well in practice, although there were inevitably some pressure points.

- 5.13. Good progress had been made with the preparations for the Fees Group, one of the recommendations in the McCracken Report. The approach would be to set up the Fees Group as a sub-group of the Licensed Centres Panel (LCP). Initially, therefore, members of the LCP would be asked for expressions of interest. There would be a report in Clinic Focus at the beginning of October on how the Fees Group would be taken forward in order to give others the opportunity to submit expressions of interest. It was envisaged that the Fees Group would initially meet towards the end of October, possibly on the same day as LCP depending on members' preferences. The Director of Finance and Resources emphasised that there was no intention to change fees for the next financial year and discussions would be more about views on fees and issues such as how often the Authority should review fees, the timing of that and the notice needed for any changes to fees.
- 5.14. The Director of Finance and Resources advised members that the Executive had also been looking at the minimum reserves that the HFEA required in order to operate effectively. At the moment performance was reported against a bank balance that would reduce to £750,000. The work on the minimum reserves would go to the Audit and Governance Committee (AGC) at the beginning of October and discussions would then take place with DH about what the level of reserves ought to be with a view to adjusting the key performance indicator in the Directorates' Report in quarter three of the financial year.
- 5.15. The Director of Finance and Resources informed members that the Directorates' Report showed that income from clinics for treatment fees was slightly less than anticipated and the Executive would be looking at the forecast financial position in more detail in early October. Members would be provided with an update at the Authority meeting in November.
- 5.16. The Chair expressed her thanks to the Finance team and everyone across the organisation who had contributed to the HFEA Annual Report.
- 5.17. Following a discussion, members noted the updates and summarised Directorates' Report.

6. Committee Chairs' Update

- 6.1. The Chair of the Statutory Approvals Committee (SAC) reported that the Committee had met on 24 July and 28 August. There were three items in July, one to grant a licence for Human Leukocyte Antigen (HLA) and two Special Directions, one of which was adjourned and one of which was granted. There were four items in August, two Special Directions, one of which was refused and one, previously adjourned, which was granted. There were two PGD applications, one of which was granted and one refused.
- 6.2. The Chief Executive provided members with an update of the Ethics and Standards Committee (ESC) meeting held on 3 September. There were three items on the agenda: the HFEA's patient complaints handling process where it was proposed that, on inspection, more time was spent examining clinic complaints; an analysis of risk tool outputs from April 2013 to March 2014, together with a summary of inspection findings from the same period; and finally, the Regulatory and Ethical Horizon Scanning Review.

7. McCracken Update

- 7.1. The Chief Executive reminded members that the McCracken Review was “an independent review of the way in which the HFEA and HTA undertake their functions and operations, with a view to delivering greater efficiencies and giving serious consideration to a merger of the two bodies.”
- 7.2. In July 2013, the Government accepted all the McCracken recommendations and the central conclusion that the HFEA and the HTA should be retained as separate NDPBs with distinct identities. The Authority agreed its response in September 2013 and considered an update on progress in March 2014.
- 7.3. The review had been positive and concluded that “public confidence in the sensitive areas regulated by the HFEA...is high, and the regulatory arrangements play an important role in keeping it so.” However the Review had set out ten recommendations where the HFEA should seek to improve. Of those, six months on, the HFEA had completed four recommendations and the remainder were underway or planned. Now, twelve months on, the HFEA had completed seven recommendations and the remainder were partially complete or well under way.
- 7.4. The Chief Executive provided members with an overview of the progress that had been made over the last six months.
- 7.5. **Stakeholder Engagement (recommendations 4, 5 and 13):** the McCracken Review had recommended that the HFEA should take action to improve the way in which it engaged, listened and fed back to the fertility sector (recommendations 4 and 13). Work on this was now complete with a stakeholder engagement plan agreed in May 2014 and a stakeholder survey to be rerun in spring 2015. In addition, the McCracken Review had suggested the establishment of a separate Fees Review Group (recommendation 5) to ‘improve accountability and facilitate dialogue’ with fee payers. Preparations had commenced to establish such a group with the first meeting planned in October 2014, as reported by the Director of Finance and Resources earlier in the meeting.
- 7.6. **Better use of Information (recommendations 6 and 7):** the McCracken Review had recommended that the HFEA should review the information it collected and how it validated and verified that information and that this work should proceed with stakeholder engagement (recommendation 6). To that end the HFEA had established a significant programme of work entitled the Information for Quality (IfQ) Programme. This was well underway. An IfQ Advisory Group had been established in October 2013 with four expert sub-groups. An options appraisal and user research had been completed in May 2014, with a consultation scheduled from 1 October 2014 and the programme itself completed in the 2015/16 business year. In addition, the McCracken Review had recommended that the HFEA developed, in time, two additional information projects: one on making available better aggregated data for research and another on identifying the best means of providing support to donor conceived individuals when they accessed information from the HFEA Register. At its meeting in March 2014, the Authority agreed to set up a three-year pilot, which would provide counselling and intermediary support for Opening the Register applicants. The proposal envisaged entering into a contract with an external provider to supply this service and a formal procurement exercise would begin in autumn 2014. The recommendation was therefore partially complete.
- 7.7. **Regulatory Focus (recommendation 10):** the McCracken Review had recommended that the HFEA conducted a review of the balance of its regulatory

activity 'to ensure that it reflects the relative risks of the different activities it oversees'. The Authority agreed in September 2013 that the HFEA's new strategy was the most appropriate vehicle to locate such a review. This was now complete with a new three year strategy published in July which addressed the issues of regulatory focus and implementation was underway.

7.8. Authority members noted and agreed:

- The progress made over the last six months, with 7 recommendations complete out of 10
- That this would be the last update on McCracken and that the remaining actions would be reported through separate mechanisms
- That the Chief Executive would send Justin McCracken (copied to the Department of Health) the Authority paper with a covering letter.

8. Strategy Implementation

8.1. The Head of Business Planning presented this item, advising members that since the HFEA had published its new three-year strategy, it was possible to take a longer term view in the organisation's planning. It was also possible to take a more cohesive approach to strategic risk management and the monitoring of delivery.

8.2. Through recent discussions at the Corporate Management Group (CMG), the Executive had reviewed the current HFEA Business Plan for 2014/15 in light of the strategy. The revised document, realigned to correspond to the areas of the strategy, had been circulated to members separately and would be published shortly. CMG had also begun to consider the range and timing of the work that would be required in order to address the whole strategy across the next three years with the HFEA's vision statement – 'high quality care for everyone affected by assisted reproduction' – underpinning all of that work.

8.3. Alongside the development of future business plans, the Executive would be redeveloping other documentation and processes in order to manage strategic risks effectively and monitor performance and progress, including a review of the high level risk register to ensure it accurately reflected the real risks to delivering the HFEA's vision and strategic objectives. This would be progressed through CMG in the next few months.

8.4. The Head of Business Planning advised members that, as mentioned above, work had already commenced on revising the 2014/15 business plan in order to ensure it was aligned to the elements of the strategy. This would be re-published imminently. The next step would be to write the 2015/16 business plan which would be drafted in time for the Authority meeting in November; and early consideration was also being given to the outline of the 2016/17 business plan.

8.5. In relation to risk assurance and monitoring, the Head of Business Planning advised members that the Executive would report back to AGC and the Authority on the review of the high level risk register. As well as reviewing the content of the risk register, the Executive would also take the opportunity to address several of the recent internal audit recommendations for improving the risk register and the wider risk system, including developing a risk assurance mechanism and reviewing the way in which operational risks were recorded and monitored. A structural review of the Directorates' Report would also be carried out which would be presented for initial discussion at CMG.

- 8.6. Between October and December, CMG would then focus on developing an additional new dashboard of overall strategic indicators, to be included in the summary received by the Authority, which would provide an ongoing picture of strategic progress and performance.
- 8.7. The Head of Business Planning provided members with an overview of Annex A of the paper, which set out the strategic implementation across the business plans for 2014-17 and identified all the activities in the business years, divided into sections and mapped against the strategy, which was available on the HFEA website.

Decision

- 8.8. Following a discussion, Authority members noted and approved:
 - The broad three year plan set out in Annex A of the paper. The draft business plan for 2015/16 would subsequently be prepared for consideration at the November meeting
 - The other developments planned to refresh and improve the HFEA's strategic risk management and assurance mechanisms as set out in section 3 of the paper.

9. Update on People Strategy

- 9.1. The Head of Human Resources provided members with a brief summary of progress in relation to the HFEA's People Strategy and the activities planned and underway. The People Strategy's vision was for the HFEA to "be an outstanding organisation with high-performing, motivated and flexible staff, who work together with shared purpose, putting patients and donor conceived people at the heart of their work, and ensuring quality in all that we do. This will enable the HFEA to be successful in making a positive impact for patients and donors by achieving its corporate objectives, while responding effectively to future challenges."
- 9.2. The Head of Human Resources advised members that all the activities would focus on three strategic themes for staff: developing, performing and innovating. All three strategic themes combined would ensure excellence for staff and the organisation.
- 9.3. The Head of Human Resources confirmed that the HFEA had now signed up to Civil Service Learning as a learning and development provider. The website provided a number of learning modules and material online but also provided access to cost effective, face to face training. All members of staff throughout the organisation would also be undertaking a personal development day – Insights Discovery - during September and early October, which used a simple and accessible four colour model to understand an individual's preferences and those of colleagues. This would then feed into the all staff away day, scheduled for Monday, 20 October.
- 9.4. The Head of Human Resources informed members that the HFEA was in the process of adopting the Civil Service Competency Framework, which would give staff a benchmark that they could reflect on about the level of their performance and their own future development needs in the context of the desired competencies for each individual role.
- 9.5. The all staff away day would be an opportunity for staff to:
 - Celebrate success and reflect on achievements

- Think about the new Strategy and what it means for staff in their individual roles
 - Look at what the future holds and what opportunities and challenges there may be
 - Develop ideas about how staff could work together for continued success.
- 9.6. Looking ahead, all staff would have (as usual) a six month review in October/November as part of the HFEA's performance and development plan. This would provide an opportunity to reflect on personal objectives, how they would feed into the HFEA Strategy and which Civil Service competencies were applicable to individual roles, with a view to having clear objectives and identified competencies firmly in place by the start of the new personal and development plan year.
- 9.7. The Head of Human Resources advised members that, to support the HFEA People Strategy, HR policies and processes would be reviewed. There would also be strong emphasis and focus on performance, management, leadership development and talent management, which was particularly important for staff given the small size of the organisation and to enable them to have opportunities for career progression elsewhere if that was their development goal.
- 9.8. Members noted the presentation and the proposed timescales for implementation. The Chair thanked all HFEA staff for their hard work and contribution to the organisation.

10. National Information Board

- 10.1. The Director of Compliance and Information presented this item, advising Authority members that the creation of the National Information Board was a DH led initiative, which:
- Had responsibility for defining and agreeing the strategy requirements and priorities for 'informatics' across the health and care system
 - Ensured system leaders worked collectively to guarantee successful delivery of the system-wide Information Strategy
 - Steered the priorities and commissioning of technology and other services delivered by the Health and Social Care Information Centre (HSCIC) and other ALBs and system partners.
- 10.2. The National Information Board's mission was to "put data and technology to work to the best advantage of patients, professionals, citizens and taxpayers".
- 10.3. The Director of Compliance and Information advised members that the Board's measurement of success would focus on six outcomes:
- Service user experience, focussing on information, transactions and self-care
 - Generating user demand amongst the key user groups such as the elderly and the chronically ill
 - Transforming professionals and services through training and education
 - Providing an 'open' framework of infrastructure and standards to support local and national innovation
 - Providing consistent, ubiquitous, reliable information for decision making by professionals, commissioners and service users

- Enhancing staff skills and productivity.
- 10.4. The Director of Compliance and Information advised members that the IfQ Programme was consistent with the National Information Board's overall aims, although it may be necessary to adjust the programme in the light of things which could emerge from the Board's priorities. The HFEA had also been at the forefront of providing information for the public with Choose a Fertility Clinic and making information available for research.
- 10.5. It was important for the HFEA to build on and maintain strategic relationships with other organisations in the system, such as HSCIC and the Government Digital Service (GDS), recognising where the organisation could add value. The HFEA would also be asked to sign up to the National Information Strategy to be launched later in the year. The HFEA's *informatics* proposals would need to be put to scrutiny of the Board and its sub-committees, which could impact on current plans.
- 10.6. Following a discussion, Authority members noted the presentation and the HFEA's involvement in the National Information Board.

11. Information for Quality Consultation

- 11.1. The Director of Strategy and Corporate Affairs presented this item and reminded members that the IfQ Programme was a large programme of work to transform the way in which the HFEA defined the data it requires, the way in which clinics submit that information to the HFEA and the uses to which the organisation put it. This had been one of the key recommendations in the McCracken Report, as mentioned in item 7 of the agenda, together with another recommendation on how the HFEA worked with its stakeholders.
- 11.2. The Director of Strategy and Corporate Affairs advised members that, in order to widen the discussion, the HFEA was publishing a consultation document in relation to the IfQ Programme on 1 October with a view to seeking stakeholders' - and others' - views on the proposals to transform the way in which the HFEA collected, used and published information to benefit patients, the public and clinics.
- 11.3. The proposals within the consultation had been informed by:
- **Four Expert Groups** covering what data the HFEA collected and how it was defined, how clinics submitted data to the HFEA, data reporting and publishing information for patients. Those groups had drawn up plans and issues for consultation
 - **Advisory Group** – a dedicated group with a range of expertise, which had considered recommended plans and issues from the Expert Groups on 3 September
 - **User Research** into how the HFEA's audiences used its information and systems, which had been carried out by Fluent Interaction.
- 11.4. The Director of Strategy and Corporate Affairs advised members that the consultation document had been split into three main areas, with a series of questions contained within the consultation document in relation to each area. The three areas were:
- The information the HFEA collected – what the dataset should include and why

