

## Authority paper

<b>Strategic delivery</b>	<b>Setting standards</b> <input checked="" type="checkbox"/>	<b>Increasing and informing choice</b> <input checked="" type="checkbox"/>	<b>Demonstrating efficiency, economy and value</b> <input checked="" type="checkbox"/>
<b>Paper title</b>	Minutes of Authority meeting 8 July 2015		
<b>Agenda item</b>	2		
<b>Paper number</b>			
<b>Meeting date</b>	16 September 2015		
<b>Author</b>	Charlotte Keen, Information and Access Policy Manager		
<b>For information or decision?</b>	Decision		
<b>Recommendation</b>	Members are asked to confirm the minutes as a true and accurate record of the meeting		

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

#### Members

There were 10 members at the meeting, 7 lay members and 3 professional members.

#### Members present

Sally Cheshire (Chair)  
Dr Susan Price  
Professor David Archard  
Dr Andy Greenfield

Anthony Rutherford  
Dr Alan Thornhill  
Bishop Lee Rayfield  
Kate Brian

Margaret Gilmore  
Anita Bharucha

#### Apologies

Yacoub Khalaf  
Rebekah Dundas

#### Observers

Ted Webb (DH)  
Steve Pugh (DH)

#### Staff in attendance

Peter Thompson  
Nick Jones  
Juliet Tizzard  
Sue Gallone

Catherine Drennan  
Paula Robinson  
Suzanne Hodgson

Rosa Wotton  
Joanne McAlpine  
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 to the fourth 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.
- 1.1. Apologies were received from Yacoub Khalaf and Rebekah Dundas.
- 1.2. 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)

## **2. Minutes of Authority meeting held on 13 May 2015**

- 2.1. Members agreed the minutes of the meeting held on 13 May subject to minor amendments. The Chair agreed to sign the minutes as amended.

## **3. Chair's report**

- 3.1. The Chair informed members that, since the last Authority meeting, she had attended a range of events with organisations in the IVF sector and the wider health and care system.
- 3.2. On 27 May the Chair, together with the Chief Executive, had their annual accountability meeting with Felicity Harvey, Director General of Public Health and the HFEA's senior sponsor, and her team at the Department of Health. The meeting was to review the HFEA's performance over the 2014/15 business year and to identify key priorities for 2015/16. The meeting went well. The Department was pleased with the work the HFEA was doing and would continue to give the support required in order for the HFEA to achieve its objectives.
- 3.3. The Chair and the Chief Executive, together with members of the Senior Management Team and the Chief Inspector, continued with their programme of visits to clinics outside of the regular inspection schedule in order to hear from clinics what they felt they did well and where they thought improvement was needed. These visits would then enable the HFEA, as the regulator, to consider how to help improve the quality of care across the sector.
- 3.4. On 29 May, the Chair and the Chief Executive visited the Leeds Centre for Reproductive Medicine, where Anthony Rutherford, Authority member, is a senior clinician. The Chair advised members that on the same day she gave a talk on delivering outstanding practice and patient care at the Northern Fertility Nurses Conference in Leeds.
- 3.5. On 22 June, the Chair and Chief Executive visited the Lister Fertility Clinic, where Sam Abdalla, a former Authority member, was currently the Person Responsible. On 1 July, the Chair and the Chief Executive visited the Assisted Conception Unit at Guy's Hospital, the largest preimplantation genetic diagnosis (PGD) unit in the country, led by Authority member, Yacoub Khalaf.
- 3.6. The Chair expressed her thanks to the Person Responsible and all of the staff at each clinic for their warm welcome and for taking the time to explain their work.

- 3.7. Finally, on 23 June, the Chair informed members that she had chaired the HFEA Remuneration Committee, with two Authority members in attendance, to confirm the pay remit and proposed rewards for staff based on 2014/15 performance.

#### **4. Chief Executive's report**

- 4.1. The Chief Executive advised members that on 10 June he attended the Audit and Governance Committee (AGC) as part of the end-year accounts and annual report sign-off process. The HFEA Annual Report was subsequently laid before the Houses of Parliament and published on the HFEA website. The report was different to previous years in that it had been stripped down to the essential statutory requirements. In the past, the Executive had set the report in a wider context with an introduction from the Chair and the Chief Executive, but it was now felt that such commentary could be more effectively delivered through other avenues.
- 4.2. On 17 June, the Chief Executive attended the National Information Board's (NIB) Leadership Summit meeting. The NIB was an initiative led by the Department of Health involving all of the health sector's arm's length bodies (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.
- 4.3. Last week, the Chief Executive advised members the Government had announced to Parliament that the HFEA would be subject to a triennial review, together with several other health ALBs. 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.
- 4.4. The HFEA had, of course, already been reviewed twice very recently and the Chief Executive emphasised that the terms of reference of the triennial review would not reopen the fundamental decisions that were reached in either the McCracken review in 2013 or the 2012 review conducted by the Government. The Chief Executive reminded members that the McCracken review had explicitly looked at whether or not the HFEA should merge with the Human Tissue Authority (HTA), and concluded that it should not. The 2012 review had looked at whether the responsibilities of the HFEA should transfer to the Care Quality Commission (CQC) or the Health Research Authority (HRA), and had also concluded that they should not.
- 4.5. The Chief Executive emphasised that all public bodies should be subject to scrutiny and the Executive would approach the review in an open and constructive spirit. The review process should take no more than six months. A call for evidence had been issued on the Department of Health's website and had been publicised in Clinic Focus. The Chief Executive welcomed two members of the review team from the Department of Health who were observing the meeting.
- 4.6. Press Coverage: the Chief Executive summarised press coverage since the last Authority meeting, details of which had been circulated to members.
- 4.7. A court case involving the HFEA had recently concluded in the High Court. The case involved a couple who wished to export their deceased daughter's eggs to the USA for possible future use. The HFEA's Statutory Approvals Committee (SAC) had considered the application on three separate occasions in response to evidence that was brought by the couple, but on each occasion SAC were of the view that there were sufficient issues with the daughter's consent, such that the

law meant they should deny granting an export licence. The couple then decided to go to the High Court for a judicial review, and following a detailed judgement, a judge ruled that, on all three counts, the decision of SAC was correct. At the same time, the judge denied the couple permission to seek leave to appeal and the claimants had now appealed directly to the Court of Appeal asking it to overturn the judge's decision. The Court of Appeal would now decide whether to grant leave to appeal.

- 4.8. Although the case had been widely reported both in the UK and across the world, the HFEA felt it was inappropriate to comment further, given the distressing nature of the case, other than a prepared statement, and had turned down a number of interview requests on the grounds that neither the HFEA nor, more importantly, the couple, would benefit from extended coverage of the case.
- 4.9. The Chief Executive advised members that Kate Brian, an Authority member, had recently completed a documentary for Radio 4 on the birth of the national sperm bank and its first few months of life. It was an insightful piece that painted a mostly positive picture of events, without ignoring the difficulties and complexities that came with such a project. The Chief Executive advised members that the programme was still available on BBC iPlayer.

## **5. Committee chairs' updates**

- 5.1. The Chair of the Statutory Approvals Committee (SAC) reported that the committee had met on 28 May and 25 June. There had been five PGD applications in May to consider. Three were approved as submitted, one was approved on an individual basis and the other was approved in respect of a number of types but not all of the types contained in the application. In June there had been three PGD applications and one request for Special Directions; the minutes of these decisions had not yet been published.
- 5.2. In the absence of the Chair of AGC, the Director of Finance and Resources advised members that the committee had met on 8 July and, aside from the usual standing items, had received reports on:
- The HFEA People Strategy and HR Risks, from the Chief Executive
  - An IfQ update from the Director of Compliance and Information
  - The strategic risk register from the Head of Business Planning
  - The audit completion report from the National Audit Office
  - A progress report and the annual assurance statement from DH Internal Audit
  - Information assurance from the Director of Finance and Resources
  - The annual report and accounts, including the governance statement, from the Head of Finance.
- 5.3. The Chair of the Scientific and Clinical Advances Advisory Committee (SCAAC) advised members that the committee had met on 10 June and welcomed three new members: Sheena Lewis, Professor of Reproductive Medicine at Queen's University, Belfast; Jane Blower, an embryologist at Leicester Fertility Centre; and Professor Gudrun Moore, a specialist in molecular medicine at Great Ormond Street hospital.
- 5.4. The committee received an update on alternative methods for deriving embryonic stem cells and embryonic-like stem cells, an update to the guidance on

preimplantation genetic screening (PGS) in the HFEA's Code of Practice, and a novel process application. SCAAC also received a presentation on freeze-all cycles from Dr Abha Maheshwari, consultant of Reproductive Medicine at Aberdeen Fertility Centre, and a presentation on reproductive immunology from the HFEA's Scientific and Clinical Policy Manager.

- 5.5. The Director of Strategy and Corporate Affairs advised members that the Executive Licensing Panel (ELP) had met four times and considered four renewal applications, three of which were approved and one adjourned; five interim inspections, all of which were approved; and twelve variations, all of which were approved except for two variations of research project objectives which had been referred to the Licence Committee. ELP also considered one treatment and storage initial licence application, two voluntary revocations and one Special Directions to enable continued licensed activity, all of which were granted.

## **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 success towards implementation of the strategy, the HFEA's programmes and their development, and generally the wider performance of the Authority.
- 6.2. The Director of Finance and Resources advised members that the strategic performance report included the management accounts as at the end of April 2015. The management accounts for the end of June were just being finalised. The trend of treatment fees being less than expected had continued, with a shortfall of about £73,000 on treatment fee income for the first quarter. There was currently no cause for concern as there had been similar savings on expenditure on salaries in particular, and legal expenses had been less than anticipated.
- 6.3. Quarter end discussions would shortly be taking place with each of the budget holders to consider forecast expenditure and that, together with the work the finance team were carrying out on projecting treatment fee income, should provide a clearer picture.
- 6.4. Looking further ahead, the Director of Finance and Resources advised members that consideration needed to be given to the costs incurred following the office move next financial year, and the potential impact on fees.
- 6.5. The Department of Health had awarded the HFEA a small amount of capital funding in order to refresh the IT equipment in advance of the office move. The Department had also provided cover for capital expenditure from reserves on the IfQ programme and also the support programme for donor-conceived people and donors. Discussions were still taking place with the Department of Health in relation to the extent of the cover required.
- 6.6. The Director of Strategy and Corporate Affairs reported on work being undertaken in her Directorate and performance against some of the objectives in the strategy.
- 6.7. The Director of Strategy and Corporate Affairs reminded members of the three areas of ambition within the HFEA strategy and the topics under each:
- **Setting standards**
    - Improving the quality of care.
    - Improving the lifelong experience of donor conception.
  - **Increasing and informing choice**

- Using HFEA data to improve outcomes.
  - Ensuring patients have access to high quality information.
  - **Efficiency, economy and value**
    - Ensuring the HFEA remains demonstrably good value.
- 6.8. In improving the quality of care, the Director of Strategy and Corporate Affairs advised members that the main area of work had been implementing a system for regulating mitochondrial donation, which was a cross-cutting piece of work across all Directorates in the organisation.
- 6.9. In the area of improving the lifelong experience of donor conception, the Director of Strategy and Corporate Affairs updated members on the piloting of a new counselling and support service for donors and donor-conceived people. The service which is being run under contract by PAC-UK, had been launched on 1 June 2015 and had already received referrals.
- 6.10. In the area of using HFEA data to improve outcomes, the Director of Strategy and Corporate Affairs advised members that there was an agenda item later in the meeting about the sector's performance around multiple births, which was a good example of how the HFEA could use data it collected from clinics to help them improve their practice.
- 6.11. There had been a cluster of activity around ensuring patients had access to high quality information, including:
- rewriting information for the HFEA website and changing the tone of voice
  - publishing information on new or untested treatments
  - preparing for the new website and Choose a Fertility Clinic (CaFC).
- 6.12. In the area of ensuring the HFEA remains demonstrably good value, the Director of Strategy and Corporate Affairs advised members of the change in the way the HFEA communicated by saving money on design and using lower cost social media for communications in order to improve efficiency.
- 6.13. The Director of Strategy and Corporate Affairs provided members with an overview of the HFEA's brand refresh, which included a revised logo, designs for our publications and corporate templates and a new house style for written communications. The aim of the work was to make our external communications clearer, more engaging and more cost effective.
- 6.14. The Director of Strategy and Corporate Affairs updated members on work on mitochondrial donation which included an online survey during June, asking focused questions about licensing, inspection and follow-up. This had provided high quality helpful responses. There had also been a workshop in June which looked at:
- staff competence and inspection
  - screening and eligibility of donors (age, family limit and haplotype matching, diseases and genetic conditions)
  - follow-up of children born
  - information for patients and donors
  - the case by case approval process.

- 6.15. During the summer the Executive would be analysing the survey and workshop feedback, and drawing together recommendations for the September Authority meeting. From mid-September, the Executive would:
- implement the Authority's decisions
  - let the clinics know what the requirements would be
  - launch the application system on 29 October.
- 6.16. The Director of Compliance and Information advised members that the programme of activity in 2014/15 relating to inspections and information audits had been completed within the timeframe. The two red areas highlighted in the report related to a slight increase in the time taken to submit reports back to clinics after they had been inspected, although this demonstrated a proportionate and quality-focused approach, investing extra time where necessary in order to get the report right. The second area related to the very small number of tissue-typing applications. Given the infrequency of such applications, clinics did not always immediately submit the relevant information to enable the HFEA to process the application quickly and make a swift decision.
- 6.17. Following a discussion, members noted the presentation and the latest strategic performance report.

## **7. Strategic risk register**

- 7.1. The Head of Business Planning presented this item in a revised format in order to provide members with an overview of the risks as a complete set, showing the relative risk tolerances and residual risk scores. Five of the twelve risks were currently high and deemed above tolerance.
- 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.
  - 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 been subjected to 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 during the mitochondria project and in the course of the subsequent start-up of applications processing.
  - 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.

- 7.2. 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.
- 7.3. Following a discussion, members noted the latest version of the risk register and agreed that the new way of presenting the risks was clear and informative.

## 8. Multiple births annual update

- 8.1. The Researcher in Epidemiology and Statistics reminded members that in 2009 the HFEA, together with professional bodies and stakeholder groups, introduced a multiple births policy with the aim to reduce the multiple birth rates by promoting elective single embryo transfer (eSET). Central to that policy was the introduction of a series of targets, starting in 2009 with the maximum multiple birth rate of 24% for clinics, with the intention to reduce this in steps over a series of years to 10%, which was the current target.
- 8.2. In 2011, the HFEA published a multiple births data report, based on the 18 months of data available at the time. This had showed an initial growth in eSET, a growth in blastocyst transfers and a corresponding decline in multiple pregnancy rates in that short period of time. Since then the Executive had provided annual updates to Authority members, and also provided updates to the Multiple Births Stakeholder Group. Verified data was now available to the middle of 2014. The latest report with this data would be available on the website during the week of 13 July 2015.
- 8.3. **Shift to eSET:** in 2008, the majority of women under 35 had a double embryo transfer, but by 2013, eSET had increased significantly and double embryo transfer had decreased. There had clearly been a shift away from double embryo transfer towards eSET.
- 8.4. 86% of women under the age of 38 were now receiving eSET, with two thirds on their first cycle and another 17% on their second cycle. Whilst eSET had grown dramatically, the patient profile had remained fairly steady. About 40% of IVF treatment cycles were funded by the NHS and the remaining 60% funded by the patients themselves. Looking at fresh eSET cycles, that proportion was reversed with 61% NHS funded.
- 8.5. **Shift to blastocyst transfers:** the Researcher in Epidemiology and Statistics explained that blastocysts were embryos which had been cultured for a longer period (five to six days) in the laboratory. Previously most embryo transfers would be carried out at cleavage stage, which was at two to three days in the laboratory. There had been a significant growth since 2011 in frozen embryo transfers carried out at the blastocyst stage. It was noted that more women were able to freeze embryos and consequently more frozen embryo transfers were taking place, with a 10% growth in frozen embryo transfers between 2012 and 2013.
- 8.6. **Fresh blastocyst transfers:** the shift to eSET in relation to fresh blastocyst transfers was even more significant. In 2008, the majority were double embryo transfers and in 2013, eSET was over 50%. This was a really important change because, whilst the data showed early on that blastocyst transfers were associated with a better pregnancy rate, they were also associated with very high multiple pregnancies.



- 8.7. **Pregnancy and multiple pregnancy rates:** the pregnancy rate had stayed fairly steady from 2008 but had recently started to increase and was now up to about 34 to 35%. The multiple pregnancy rate had steadily declined and currently stood at around 16%.
- 8.8. The Researcher in Epidemiology and Statistics provided members with a summary of a comparison of pregnancy rates for the number of embryos transferred and the stage at which it was carried out. The important thing to bear in mind was the multiple pregnancy rate. For eSET, the multiple pregnancy rate was under 2% at both cleavage and blastocyst stage, whereas for double blastocyst transfer the multiple pregnancy rate was over 40% and about 33% for cleavage stage. There was therefore a lot of risk associated with a double blastocyst transfer but very little gain in terms of a higher pregnancy rate.
- 8.9. **Cumulative rate, first fresh cycles started 2013:** the data in the HFEA register now allowed the Executive to track women through the whole of their treatment. The data showed that the pregnancy rate was slightly higher for eSET, but with a multiple pregnancy rate of around just 2%, compared to 32% following a double embryo transfer.
- 8.10. The Researcher in Epidemiology and Statistics provided members with a summary of the conclusions of the findings in the updated report.
- Findings showed that the strategies pursued by clinics, in line with HFEA policy, had been a clear success with the multiple pregnancy rate after IVF dropping from one in four to one in six and continuing to decline, while the pregnancy rate was increasing.
  - There had been a swift cultural change in IVF which had tangible health benefits for patients and their babies.
  - Younger women on their first cycle who had an eSET had a higher pregnancy rate than those that had a fresh double embryo transfer.
  - When this was followed by a subsequent single frozen embryo transfer, the pregnancy rate was higher still, but the multiple rate remained very low.
  - Routinely collected data had successfully influenced change and improved outcomes.
- 8.11. The Researcher in Epidemiology and Statistics advised members that this had been a joint effort and expressed her thanks to the professional bodies, clinicians and scientists, patient groups and patients involved in making this policy a success.
- 8.12. Following a discussion, members noted the information given in the multiple births report.

## 9. Opening the register (OTR) update

- 9.1. The Donor Information Manager presented this item and reminded members that the HFEA strategy put patients (including donors and donor-conceived people) and the quality of care they received at the centre of its work. The OTR service was therefore fundamental in the achievement of the following strategy objectives and recent developments and improvements in this area of work contributed further to this aim.
- **Our vision: high quality care for everyone affected by assisted reproduction. This encompassed:**

- support for patients, donors and donor-conceived people
  - excellent service and information from the HFEA.
  - **What we will do:**
    - We will improve the lifelong experience for donors, donor-conceived people, patients using donor conception and their wider families.
  - **How we will work:**
    - We will make the quality of care experienced by patients, donors and donor-conceived people our central priority and the primary consideration in our decision making.
- 9.2. The Donor Information Manager provided a summary of OTR applications received over the last five years. There had been a 20% increase during 2014, with parents and donors being the main groups applying. Since processes for dealing with such applications had developed and become more rigorous over time, they inevitably now took longer to process. Between January and June 2015, the OTR team had dealt with and responded to 136 applications.
- 9.3. In addition, the Donor Information Manager advised members that 79 donor-conceived individuals had joined the Donor Sibling Link (DSL), the HFEA's voluntary contact register, since its launch in 2010. Under this scheme, registrants agreed to the HFEA sharing their name and contact details with any of their donor-conceived genetic siblings who had also joined. The number registering was still small, with 11 per year in 2011 and 2012, but increasing to 21 per year in 2013 and 2014, but registration was likely to grow significantly in the coming years.
- 9.4. The HFEA had also received 149 applications from anonymous donors (those who donated after 1991 but before 1 April 2005) to remove their anonymity. Over the last three years, there had been a slight increase in re-registering although numbers were disappointingly low with only 12 applying in 2014.
- 9.5. In 2013, the HFEA received its first application for identifying information from an adult donor-conceived individual with an identifiable donor. In total, six applications of this nature had been received; two each year so far, and earlier this year the HFEA had its first DSL match. In each of these cases the HFEA offered and coordinated (where requested) support and intermediary assistance to the donor-conceived individuals and donors concerned.
- 9.6. The Donor Information Manager advised members that there had been significant progress and policy developments in OTR request handling over the last three years, which were set out in more detail in the paper. These included:
- a steer on key operational issues from the Authority in June 2012
  - development of a redaction framework for OTR staff
  - website content created in 2013 to enable past applicants to check if their donor had re-registered as identifiable
  - development of a guidance pack for clinics to improve the sharing, quality and disclosure of donor information.
- 9.7. The Donor Information Manager provided members with an overview of the HFEA's pilot support and intermediary service, which was identified as a high priority by a group of key stakeholders in June 2013. In July 2013, the Authority approved recommendations to work with stakeholders to scope out models for a

three year pilot and explore, at the same time, what specialist support should be provided for other people affected by donation.

- 9.8. Since then, the HFEA had worked closely with stakeholders to develop a service which provided both of these recommendations. As mentioned earlier in the meeting, a contract was subsequently awarded to PAC-UK, an adoption support agency with relevant expertise and suitably qualified staff. The HFEA had delivered two days of training to PAC-UK in May 2015 and created a suite of leaflets to complement, or act as an alternative to, the service. The service was then launched as a pilot on 1 June 2015.
- 9.9. As part of the OTR process, applicants were supplied with a link to an online confidential feedback questionnaire. The Donor Information Manager provided members with a summary of those survey responses.
- The majority of respondents discovered they could apply for information from the HFEA register through the HFEA website, with others finding out through sources such as their clinic.
  - Only a quarter of respondents said they had spoken to someone at the HFEA before applying, although 100% of those rated this experience as helpful or very helpful.
  - Expectations among respondents varied in terms of the amount of information they received. 58% considered it adequate, 26% did not have any expectations, 16% expected to receive more information and 2% expected to receive less information.
- 9.10. The survey also gave respondents the opportunity to add any further comments they had on the information they had received or the process itself, and the majority stated that they had found the process straightforward, efficient and speedy, and were grateful for both the existence of the OTR service and the high level of service received.
- 9.11. Following a discussion, members noted:
- the significant policy and process developments over the last three years to the OTR service, which were in line with delivering the HFEA 2014-2017 strategy
  - the trend showing increases in the number of applications
  - the positive feedback received about the OTR service provided by the HFEA.

## **10. Information for quality: update and data dictionary**

- 10.1. 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 way in which the information was published.
- 10.2. The Director of Compliance and Information explained that IfQ was a critical component of the HFEA's strategy and encompassed:
- the redesign of the HFEA's website and Choose a Fertility Clinic (CaFC)
  - the redesign of the 'Clinic Portal' and combining it with data submission functionality that was currently provided via the HFEA's separate Electronic Data Interchange (EDI) system
  - a revised dataset and data dictionary approved by the Standardisation Committee for Care Information (SCCI)

- a revised Register, to include the migration of historical data contained within the existing Register
  - redesign of the HFEA's supporting IT infrastructure.
- 10.3. The Director of Compliance and Information advised members that, given the importance of the programme to the Authority's strategy, updates on progress were provided to each meeting of the Authority and approval for direction and actions sought. This update, in particular, introduced the concept of an overriding vision of the work in three main parts, addressed progress in technical services and considered consequences for organisational change.
- 10.4. **The website:** the Director of Compliance and Information advised members that the HFEA website represented the organisation's personality, style and tone and would embody the HFEA's refreshed brand, with links to HFEA social media channels. The website would be updated on a regular basis, with less text and more interactive elements.
- 10.5. The website also encompassed the work on CaFC, although the Director of Strategy and Corporate Affairs would discuss this area in more detail at item 11 on the agenda.
- 10.6. **The clinic portal:** the clinic portal would be the key window to the HFEA for clinics. There would be a seamless transition from a password protected website to the portal, which would provide useful information about requirements placed on licensed clinics and their key staff. It would make the risk tool accessible together with other useful publications. The portal would also enable clinics to access information about their own performance.
- 10.7. A key component of the clinic portal was the way in which clinics submitted data to the HFEA. The new clinic portal would provide an easier and more pleasant way for clinics to submit their data and users would be able to adapt the system around their work rather than their processes being determined by the HFEA system. It would also prevent simple errors by having a real-time verification facility.
- 10.8. **HFEA internal systems:** an IT strategy would be implemented which supported all the IfQ developments and provided economic and efficient hosting and storage arrangements, utilising the benefits of the 'cloud' as appropriate. The IT strategy would provide business continuity and security, with desktop services meeting high service standards, and would be based on simplicity and 'agile' development principles. Once the development phase of IfQ was complete, where contracts with suppliers were in place to allow for minor improvements, there would be a move to a more evolutionary approach where business leads within the organisation would understand from their knowledge of user feedback what improvements to systems were needed and would bid for resource accordingly using a business case approach.
- 10.9. The Director of Compliance and Information provided a summary of the procurement process.
- The Authority had agreed the budget for 2015-16 of £1.134m.
  - The procurement process had been conducted by the Crown Commercial Service with two preferred suppliers selected.
  - Progression from each phase – Alpha, Beta, and Live - was dependent on performance requirements being met, with the Chief Executive approving

progress to each phase on the basis of a recommendation from the IfQ Programme Board.

- In addition the Board would recommend approval to stages of expenditure within these phases and expenditure would be signed off by both the Director of Compliance and Information and the Director of Finance.
- All approvals would be reported to the Audit and Governance Committee.
- A substantial contingency of around 20% of budget was also protected, which was considered both prudent and best practice.
- Approval from the Department of Health and the Government Digital Service was necessary to progress from Alpha to Beta with the development of a public service digital interface having to meet necessary standards.

10.10. The Director of Compliance and Information reminded members that the Gateway Review which had been highlighted at the previous Authority meeting, had advised of the need to have increasing regard to the consequences of the programme for the HFEA's ways of working, and in turn the implications on teams. There was also the expectation of substantial external impact, with the benefit of a significant technological investment felt by a range of stakeholders.

10.11. The period between July and November would be intensive and focused on research, development and testing, with a group of internal and external users involved in that process. There would be increased stakeholder engagement, with a stakeholder group meeting taking place on 29 July.

10.12. In terms of ways of working, agile development encouraged seeing change as evolutionary and ever-present. Consequently, continued engagement with staff was ongoing since different ways of working would inevitably necessitate changes to some roles within the organisation.

10.13. Following a discussion, members:

- approved the vision for change which would guide all of the work
- noted the progress as regards procurement of third party suppliers in line with corporate and Government approval process, and associated costs
- noted that progression from the alpha stage was dependent on external approval (with an update report provided to members at that point)
- noted the arrangements informing organisational change resulting from the realisation of the IfQ Programme.

## **11. Choose a fertility clinic (CaFC)**

11.1. The Director of Strategy and Corporate Affairs reminded members that, at their meeting in January 2015, members had agreed that the quality of a clinic should be measured in a multi-dimensional way, through patient feedback, inspection findings and success rates. Members asked the Executive to consider the details in more depth and the presentation and paper sought to update members on progress.

11.2. The Director of Strategy and Corporate Affairs showed members how CaFC was currently presented. The general assessment was that the design had become outdated and did not succeed in highlighting the more important feature of a page. There was no overall sense of the quality of a clinic, information was buried and hard to find and patients found that success rate information, while

- statistically correct, was confusing to the extent that some patients preferred the simpler presentation on clinic websites.
- 11.3. The Director of Strategy and Corporate Affairs reminded members that, having taken on board most of the recommendations from the IfQ Advisory group presented to them in January, members agreed that they wanted CaFC to offer:
- a better balance between statistical and non-statistical information
  - easier comparison between clinics
  - non-statistical information that included inspection findings, patient reviews and the availability of donated eggs, sperm or embryos
  - a patient review feature which should not consist of free-text feedback
  - information about the availability of donated eggs, sperm or embryos consisting of types of donors available, the source and waiting times for treatment
  - top-line statistical information consisting of births per embryo transferred, followed by the cumulative success rate.
- 11.4. Since then, the Executive had set up two work streams, one on statistical information and one on non-statistical information, to take this work forward. The two groups had subsequently drafted a comprehensive set of recommendations which had recently been approved by the IfQ programme board.
- 11.5. In relation to statistical information, the Executive recommended that:
- cumulative success rates per egg collection should be shown over a two year period
  - data ranges needed to balance statistical reliability with ease of understanding, potentially increasing sample sizes by:
    - reducing age stratification from 6 to 2 - under 38, and 38 and over
    - using a measure which contained more types of cycles.
- 11.6. The Director of Strategy and Corporate Affairs advised members that further consideration was required in relation to the presentation of data ranges, possibly in a much more graphical, visual way than the current numerical way. Ultimately, options would need to be tested out on users to find the best solution. The important issue was to try and present fair, comparable data in such a way that it was statistically reliable but also understandable to users.
- 11.7. The Director of Strategy and Corporate Affairs advised members that, when inspectors carried out an IVF clinic inspection, they split the areas of focus into four areas:
- the protection of the patient, and children born following treatment
  - the experience of patients
  - the protection of gametes and embryos
  - how the centre looked after important information.
- 11.8. Inspectors did not consider it appropriate to have an overall inspection score for a clinic, although they did anticipate being able to give an inspection score in each of the four areas of practice. Inspectors had been asked to consider how they could reduce the areas to three, without changing the format of the current inspection reports, in order to summarise inspection findings using a traffic light system to show clinics' levels of compliance with regulatory requirements.

- 11.9. In relation to patient feedback, the Executive recommended the following approach, although further consideration was required following user testing:
- asking five short questions to derive five ratings
  - a 1-5 rating shown for each area, plus an averaged overall rating
  - showing the number of reviews
  - providing a link to the inspection questionnaire.
- 11.10. The Director of Strategy and Corporate Affairs advised members that for waiting times for donor conception treatment, the Executive recommended that CaFC should show how available egg, sperm and embryo donors were in a particular clinic, together with four general time periods. Again, this proposal would need to be tested out on users.
- 11.11. The newly formed stakeholder group would be meeting at the end of July and every month during the autumn period in order to help further refine the proposals in relation to CaFC. The Executive would then give members an update on progress in the autumn.
- 11.12. In discussion, some members expressed concern over the suggested reduction in the age bands from six down to two. A member also pointed out that such statistics were historical data in relation to a clinic's performance and as such should not be presented as a predictive tool. It was agreed that this issue was best resolved through testing with users. More generally, members noted the progress made on the CaFC review and gave their endorsement to the proposals and direction of travel, including the commitment to testing out the concepts in order to work out how the Executive could improve the proposals.

**12. Any other business**

- 12.1. The Chair confirmed that the next meeting would be held on 16 September 2015 at ETC Venues, Hatton Garden, 51-53 Hatton Garden, London, EC1N 8HN.

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

Chair

S Chestnut

Date

17/9/15

