Authority paper

Strategic delivery	Setting standards ☑	Increasing and informing choice ☑	Demonstrating efficiency, economy and value ☑
Paper title	Minutes of Authority meeting 21 January 2015		
Agenda item	**2**		
Paper number	[HFEA (11/03/2015) 745]		
Meeting date	11 March 2015		
Author	Charlotte Keen, Information and Access 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 21 January 2015 held at ETC Venues, Hatton Garden, 51-53 Hatton Garden, London, EC1N 8HN.

Members
There were 8 members at the meeting, 5 lay members and 3 professional members.

Members present

Sally Cheshire (Chair)	Dr Alan Thornhill	Debbie Barber
Gemma Hobcraft	Dr Andy Greenfield	Kate Brian
Dr Susan Price	Rebekah Dundas	

Apologies

Professor David Archard	Jane Dibblin	
Bishop Lee Rayfield	Anthony Rutherford	

Observers

Ted Webb (DH)	
Steve Pugh (DH)	

Staff in attendance

Peter Thompson	Catherine Drennan	Matthew Watts
Nick Jones	Joanne Triggs	Joanne Anton
Juliet Tizzard	Sam Hartley	Charlotte Keen
Sue Gallone		

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 first meeting of 2015. The Chair also welcomed Kate Brian to her first Authority meeting and new members Margaret Gilmore and Yacoub Khalaf who were observing the meeting and would take up their roles on 1 April 2015.

1.2. Apologies were received from Professor David Archard, Bishop Lee Rayfield, Jane Dibblin and Anthony Rutherford.

1.3. Declarations of interest were made by:

- Debbie Barber (Part-time Nurse Specialist 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 12 November 2014

2.1. Members agreed the minutes of the meeting held on 12 November subject to one minor amendment. 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 meetings with organisations in the IVF sector and the wider health and care system. On 18 November, the Chair met with the new Chair of the Human Tissue Authority (HTA), Sharmila Nebhrajani OBE, and on 21 November, she attended the Royal College of Obstetricians' and Gynaecologists' (RCOG) Annual Dinner.

3.2. On 27 November, the Chair and the Chief Executive, together with other members of the HFEA, had attended the Manchester workshop on Consent and Multiple Births which was well attended and well received. On 2 December, the Chair attended an event for all arm's length body (ALB) Chairs and Non-Executive Directors (NEDs) in the health and care sector and on 3 December she participated in media training along with other members of the Executive. The Chair advised members that another session of this training would take place on 23 February for other HFEA staff and members who had enrolled.

3.3. Finally, on 10 December, the Chair and Chief Executive met with Dr David Richmond, the President of the Royal College of Obstetricians and Gynaecologists (RCOG), in order to discuss how the HFEA and the RCOG could work together on a range of issues.

4. Chief Executive's Report

4.1. The Chief Executive advised members that on 18 November he had participated in a Hubbub Leadership Panel event, part of the wider Hubbub Leadership Development Programme aimed at people in middle and more senior management roles, with a view to developing leadership skills and behaviours and to provide a talent pool of credible candidates for future recruitment campaigns for senior and executive posts across the sector.

4.2. On 20 and 21 November, the Chief Executive had attended the Association of Chief Executives Conference and on 2 December, he presented a talk to a Progress Educational Trust Conference entitled "What should the HFEA do about the cost of IVF?" A write up of that session was available in BioNews.

4.3. The Chief Executive advised members that on 4 December he had attended the annual workshop held with the sector on pre-implantation genetic diagnosis (PGD) and on 9 December he had attended the National Information Board Leadership meeting. On 19 December, the Chief Executive had attended the final meeting of the Regenerative Medicines Expert Group and on 8 January he had attended the Association of Clinical Embryologists (ACE) and the British Fertility Society's (BFS) annual conference. The Chief Executive expressed his thanks to both ACE and BFS colleagues for their warm welcome.

4.4. The Chief Executive advised members that the Executive had undertaken a short staff survey shortly before Christmas. There had been some positive feedback from staff together with some very thoughtful comments. The survey had looked at communications (which were working well although results indicated there was room for improvement) and strategy (where the majority of staff were aware of the strategy but some were less clear about how it related to their specific roles).

4.5. The survey had also looked at morale and capacity and the Executive acknowledged that it was evident staff morale had dipped somewhat with more members of staff feeling overloaded. The Information for Quality (IfQ) Programme was also causing capacity problems. The results had been discussed with the Senior Management Team (SMT) and the Corporate Management Group (CMG) and would be circulated to staff later in the week.

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. The HFEA report 'Fertility treatment 2013: trends and figures' was published on 17 December 2014 and there had been coverage in the Daily Mail and the Times. It was expected that this report would continue to be cited throughout the year.

4.8. The HFEA report on adverse incidents for 2013 was published on 11 December 2014 and was the second such report of the year with a report for 2010-2012 having been published back in July 2014. There had been very little initial coverage of the report, although the Mail had written a piece in January 2015 on two Grade A incidents which had occurred at one clinic. This had also been followed up by the Nottingham Post the following day. The Chief Executive advised members that it was important to note that all the clinics involved in the four reported Grade A incidents mentioned in the report had been made aware in advance that it was due to be published. Whilst the HFEA was committed to openness and transparency and considered publication part of its broader public duty, such reports were not about naming and shaming clinics and it was only fair to prepare clinics for any possible media coverage.

4.9. There had been considerable coverage in December about the Government's decision to lay Regulations which, if passed, would allow mitochondrial donation in the UK.

4.10. Other HFEA references: the Chief Executive advised members that the HFEA had been approached by Woman's Hour to participate in a piece in relation to a Radio 4 show on what the programme had called "super donors". The Director of Strategy and Corporate Affairs had attended the programme in order to talk about the rules governing sperm donation and to remind listeners that the best way to obtain safe, effective treatment was at a licensed clinic. Both the Woman's Hour episode and the sperm donor programme were available on iPlayer.

5. Directorates' Report

5.1. The Director of Compliance and Information provided members with a general overview of work currently being undertaken within his Directorate. He advised members that, on the whole, performance was good, although there were inevitably pressures on staff particularly with the IfQ Programme and the recent turnover of staff. Traditionally January to April was a particularly busy time for the Directorate and the Director of Compliance and Information expressed his gratitude to the Inspectors within his team for their hard work.

5.2. The Director of Strategy and Corporate Affairs provided members with an overview of work currently ongoing within her Directorate. She informed members that the Fertility Trends Report, to which the Chief Executive had referred earlier in the meeting, had been published in December 2014. The report showed that there was a continuing rise in the overall number of IVF cycles in the UK, with more undertaken in 2013 than ever before. The HFEA's 'One at Time' campaign to reduce multiple births was shown to have had a good impact, with a downward trend in multiple births, although the target of 10% had not yet been reached, with multiple births occurring in 16.9% of treatment cycles in 2012, down from 18.8% in 2011.

5.3. The Director of Strategy and Corporate Affairs advised members that if both the House of Lords and House of Commons ultimately approved the Mitochondrial Donation Regulations, they would be expected to come into force in October 2015. The Executive would design a licensing process in order to be ready to receive an application to carry out mitochondrial donation after that date. The Chair emphasised that the HFEA already had immense experience and good processes in place and a number of people had already expressed their confidence in the HFEA having the right expertise to design a process for handling mitochondrial donation applications.

5.4. The Director of Strategy and Corporate Affairs reminded members that the HFEA Annual Conference was scheduled to take place on Tuesday 17 March at ETC Venues, St Paul's, in London. The conference would be opened by a key note speech from the Chair of the Authority and there would be a selection of five different themed workshops to attend.

5.5. The Director of Finance and Resources advised members that the finance team were currently preparing month nine accounts and this would be consolidated with the Department of Health's accounts. Following an extensive review of budgets and a look at the forecast situation for the end of the current financial year, the indications were that the HFEA was now facing a deficit of around £250,000, partly due to the income from treatment fees dipping below what had been forecast by about £50,000. The deficit had also been exacerbated by unexpected legal fees. The deficit would be met by the contingency fund from the reserves. Going forward, the Director of Finance and Resources advised members that reserves would reduce considerably. The Chair asked the Director of Finance and Resources for an update to be brought to the Authority meeting in March.

5.6. Following a discussion, members noted the updates and summarised Directorates' Report.

6. Committee Chairs' Update

6.1. In the absence of the Chair of the Statutory Approvals Committee (SAC), the Deputy Chair of the committee reported that it had met on 20 November and 11 December. There had been six PGD applications in November, all of which were approved. There had been a further two PGD applications in December, both of which were also approved. There were no Special Directions for consideration at either meeting.

6.2. The Chair of the Ethics and Standards Committee (ESC) advised members that the committee had met on 3 December and 14 January. The Executive had provided the committee with an update on changes to consent forms, the HFEA Code of Practice and General Directions – all as a result of recent sector workshops on consent – and other regulatory issues which the Executive had been aware of.

6.3. The Chair advised members that the Executive had also provided the committee with an update on two new EU Directives coming into force in the next 18-24 months. The first related to a Single European Code that would need to be applied to all tissues and cells across the EU to ensure traceability, although the legislation had a number of exemptions which could be applied. The other directive related to ensuring the quality and safety of tissues and cells imported into the EU, which looked to set out a number of requirements of both clinics and national competent authorities before a clinic established an importing relationship with any clinic outside the EU. Again, there were a number of exemptions that were available to apply and the Executive would keep the Authority members up to date on progress.

6.4. The Chair of the Audit and Governance Committee (AGC) advised members that the committee had met on 10 December. Aside from the usual standing items, there had been reports from the Director of Compliance and Information on Regulatory and Register management and an update on the IfQ programme. The Head of Business Planning presented an item on the Strategic Risk Register and the Head of HR provided members with a report on the HFEA's updated policy on whistleblowing. Progress on both internal and external audits had been provided together, with an item on resilience and business committee management from the Director of Finance and Resources, and an action plan following the annual review of committee effectiveness from the Head of Governance and Licensing.

6.5. The Chair of the Licence Committee advised members that the committee had met on 15 January. At the meeting, the minutes of which had not yet been published, the committee considered an application for an initial research project, two treatment and storage renewals, one of which had been adjourned from the previous meeting, and a whistleblowing report from a clinic.

6.6. The Chair advised members that the Appointments Committee had also met on 15 January to consider applications for external members to sit on the Licence Committee that considers representations against licensing decisions, and on the Appeals Committee that hears appeals against decisions on representations.

7. Information for Quality - Recommendations for data, submission and publishing

7.1. The Chair of the IfQ Advisory Group introduced this item explaining that IfQ 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. The Chair of the IfQ Advisory Group expressed his thanks to all who had been involved so far.

7.2. The Regulatory Policy Manager advised members that the IfQ programme responded to one of the recommendations in the McCracken review which stated that the HFEA should proceed with a major review of information requirements to 'reduce unnecessary regulatory burden'. The programme was central to the HFEA's strategy to ensure 'high quality care for everyone affected by assisted reproduction'. It would have real significance for stakeholders, since patients would have access to better information to help them make decisions on accessing treatment and clinics would also benefit, with improved systems of data submission and the ability to access information to help them provide a better service.

7.3. The Regulatory Policy Manager reminded members that they had been updated on the progress of the programme at each Authority meeting since September 2013. The paper presented included the report of the Advisory Group and its recommendations, highlighting key points of principle for discussion, together with the results of the public consultation in 2014. The Regulatory Policy Manager advised members that he would go through the paper in sections and invite discussion and decisions at the end of each section.

7.4. The tables below record all of the decisions taken by the Authority in the course of the discussion, in relation to each area of work within the Programme. The relevant presentation and discussion points are set out beneath each table.

Table A: The Register

	Recommendation	Decision
1	To establish a dedicated standing group to assess any future requests for additions (or deletions) to the dataset, using agreed criteria	Agreed
2	Information required for the Register should only be submitted if it met at least one of the justifications (as set out by the Advisory Group)	Agreed
3	Only data that was clearly defined and that could be validated or verified should be submitted to ensure only accurate and meaningful information was held on the Register	Agreed
4	The NHS number should be a mandatory data requirement. Where unavailable, the passport number or unique ID number relevant to the patient's citizenship should be the preferred unique identifier	Agreed

Discussion Points: The Register

7.5. The requirement for the HFEA to keep a Register of Treatments stemmed from the Human Fertilisation and Embryology Act 1990 (as amended). The Register

was an extremely valuable asset to both the HFEA and its stakeholders. However, the Advisory Group was of the view that:

- the HFEA had not, in the past, been explicit about why information was required for the Register and how it was then used
- some of the information was not as clearly defined as it could be
- the data needed to be of good quality, and
- the data should continue to support research.

7.6. As there would always be differences in opinion regarding what data clinics should submit to the HFEA, due to the competing priorities of the HFEA's stakeholders, the Advisory Group had not yet settled on the specifics of the dataset and this would be agreed at their final meeting in February 2015.

7.7. Meanwhile, the Authority agreed recommendations 1-4.

Table B: Data submission

	Recommendation	Decision
5	Reduce the burden of the data submission, corrections and verification process. EDI should be redeveloped with causes of error designed out and processes streamlined	Agreed
6	Implement a system of contemporaneous validation of data fields, where possible	Agreed
7	Error reports should be improved and consolidated into a user-friendly reporting mechanism, with the ability to drill down, print out, and find exactly what and where the error is	Agreed
8	EDI should comprise of a single record of treatment	Agreed
9	EDI replacement should have the functionality to enable clinics to access and query their own data	Agreed
10	Implement a system of accreditation so that clinics would know which EPRS met good standards of data submission	Agreed
11	Training and support should be provided to clinics using EDI to ensure that data was consistently submitted in a high quality format	Agreed
12	Prioritise the implementation of a secure mechanism for the electronic submission of donor goodwill messages and pen portrait information	Agreed
13	Clinic Portal to be redeveloped so that information and reports were more accessible and co-ordinated with other tools	Agreed

	Recommendation	Decision
14	Clinic Portal and EDI should be merged into a single point of clinic contact with the HFEA, with the additional functionality of a central messaging system	Agreed
15	The successor to EDI should be robust, adaptable and functional enough that it could be used as a stand-alone data management solution, albeit not with the full scope and functionality of an EPRS.	Agreed – within the budget available

Discussion Points: data submission

7.8. The Regulatory Policy Manager advised members that clinics submitted data to the Register via either:

- the Electronic Data Interchange (EDI) – software developed by the HFEA in 2005 for clinics. Only data required for the HFEA was entered and submitted, or
- the Electronic Patients Records System (EPRS) – various pieces of software developed by clinics themselves, or by a third party, to electronically manage their records, carry out analysis/audit of their data, and submit the relevant information to the HFEA.

7.9. The process of data submission had been described by clinics as burdensome, and the reports setting out errors in data unclear. In its strategy, the Authority had agreed to demonstrate efficiency, economy and value by improving the methods uses to submit and verify data. Making changes to the data submission process would ensure that data was submitted accurately the first time, would reduce unnecessary effort, reduce transactional costs and increase satisfaction. With this in mind, the Advisory Group's recommendations would make a significant difference to the experience of clinics.

7.10. The Authority agreed recommendations 5-15, with the caveat that recommendation 15 would need to be delivered within budgetary constraints.

Table C: The website

	Recommendation	Decision
16	The HFEA website should be redeveloped with a more intuitive design to make information more user-friendly, less complex and organised around a typical user journey.	Agreed
17	Online information about donation should be developed to inform donors and recipients about the options for donation and parenthood.	Agreed – and this should also include research
18	The HFEA should improve how stakeholders access its information, ensuring it is optimised for a variety of devices (such as mobiles or tablets).	Agreed

Discussion Points: the website

7.11. The Regulatory Policy Manager advised members that the HFEA had a statutory duty to provide information to patients, donors, clinics and the general public. The HFEA's main tool for this was the HFEA website which received approximately 100,000 visits each month. The website was also central to the HFEA's strategic ambition to increase and inform choice. However, user research with patients, donors and donor-conceived people had found that although the information on the website was well written, the website itself was difficult to navigate and it did not reflect a typical patient's journey through fertility treatment. Users also found the tone and language of the website somewhat dry and unfriendly. The Advisory Group had made its recommendations with these points in mind.

7.12. Following a discussion, Authority members agreed recommendations 16-18 related to the above three areas, with the caveat that recommendation 17 should also include research.

Tables D, E and F - Choose a Fertility Clinic (CaFC) structure, information and outcome data

	Recommendation	Decision
D	**Choose a Fertility Clinic (CaFC) – Structure**	
19	Choose a Fertility Clinic should be redesigned with information set out as clearly and simply as possible, and to avoid large amounts of data being spread over several pages.	Agreed
20	Choose a Fertility Clinic should show that quality is more than pregnancy rates and facilitate comparisons.	Agreed
21	The Authority should not accept the Advisory Group's recommendation to change the name of Choose a Fertility Clinic to 'Find your fertility clinic'.	Not decided – with further discussions relating to the name during the implementation phase
E	**Choose a Fertility Clinic (CaFC) – Information**	
22	Patient feedback should be provided through the HFEA website, using the question of "Would you recommend this clinic?" via a star rating. The average rating, the number of people responding and the number of cycles	Agreed – although the Executive should give further consideration to how

	Recommendation	Decision
	the clinic carries out must also be provided. We also recommend that patients are able to choose from a number of HFEA-generated statements to summarise their experience. This could be displayed via a word cloud for each clinic. The HFEA must pilot such a system and consider whether any changes are required based on feedback.	this could be best presented
23	Self-reported information on a clinic's type of donors, and source, should be provided on Choose a Fertility Clinic.	Agreed – although the Executive should be bolder on the provision of information regarding donor gamete availability.
24	Questions regarding the transparency of treatment costs should be asked through the patient feedback mechanism.	Agreed
F	**Choose a Fertility Clinic (CaFC) – Outcome data**	
25	Live birth per embryo transferred should be the headline success rate figure on Choose a Fertility Clinic. We also recommend that the HFEA makes clear to users what this information is able to tell them.	Agreed
26	Cumulative live birth rate from one egg collection, reported over a two year period, should be the second headline success rate figure.	Agreed
27	The headline success rate figures should include not only stimulated and unstimulated cycles, but all types of treatment, such as intra-cytoplasmic sperm injection (ICSI) and pre-implantation genetic screening (PGS).	Agreed
28	The HFEA should risk adjust success rates in the future. If additional information is necessary, we recommend that it is submitted by clinics immediately to allow a large enough body of data to be built up for subsequent analysis when the tool is developed. The algorithm used to risk adjust success rates should be published in a peer-reviewed journal.	Agreed
29	Frozen embryo transfer success rates should be based on patient age at egg collection rather than at patient age of embryo transfer.	Agreed
30	The HFEA should bring forward the publishing date of clinic statistics so that patients have more up-to-date	Agreed

	Recommendation	Decision
	information.	

Discussion Points: CaFC

7.13. The Regulatory Policy Manager advised members that CaFC was the HFEA's clinic search tool. It provided information about each licensed clinic, including the services they provided, success rates and inspection reports. Approximately 15,000 patients accessed CaFC in any given month to help them decide where to go for treatment.

7.14. Authority members had already agreed, through the HFEA's strategy, that the presentation of clinic comparison information on CaFC should be improved. User research found that navigation of CaFC was deep and complex, the advance search facility was overwhelming and difficult to use, statistics and the ranges provided were difficult to understand and single figure data on clinic websites was seen as more appealing and straightforward. Success rate information was also difficult to interpret and could give a false impression of a clinic's performance.

7.15. The Regulatory Policy Manager informed members that, from user research, although patients were interested in pregnancy and birth data, they saw the quality of the clinic as being about more than just its success rates and wanted more information about the HFEA's assessment of the clinic as the regulator. Presenting a broader range of information about each clinic would reduce the over-reliance on outcome data and help patients make a decision based not so much on which was the 'best' clinic, but on which was the best clinic for them. Furthermore, patients wanted to be able to compare clinics and this was an ambition in the Authority's strategy.

7.16. Following discussion, Authority members agreed with the direction of travel proposed. They acknowledged that many of the recommendations were supported by the sector, in particular, changing the headline success rate figures. Members agreed with recommendations 19-30 with the exception of recommendations 22 and 23. Some members had misgivings about the presentation of patient experience information on CaFC. There were concerns that it could be overly simplistic and prone to manipulation by clinics. Members wanted to ensure that, when such information was displayed, it was clear how representative it was, and that it did not visually dominate for users, since other information provided was also important (such as multiple births data), and there needed to be a balance in the information represented.

7.17. Members were also concerned that recommendation 23 did not include the average waiting times for donor gametes. It was explained that the Advisory Group felt that such information changed frequently and could be misleading to patients, particularly if they were after a particular type of donor (which might involve a much longer waiting time than average). Following discussion, members agreed that such information was important for patients and had been explicitly mentioned in the Authority's strategy because of this. The Executive was asked to be bolder and to consider further how to provide information on donor gamete availability.

Table G: National data

	Recommendation	Decision
31	A personalised predictive pregnancy or birth rate tool should be provided by the HFEA. It should be prospective and, where possible, be based on verifiable and validated data. There will always be a number of other individual factors at play, therefore a disclaimer should be displayed to explain to users that it is not definitive and only provides an indication of pregnancy or birth.	Agreed
32	The HFEA should provide a national cumulative live birth rate over three cycles of treatment.	Agreed

Discussion Points: National data

7.18. The Regulatory Policy Manager advised members that the HFEA could make further use of the data it held by providing additional information on a national basis. This could include providing patients with an indication of the likelihood of success over more than one cycle of treatment and developing a personalised pregnancy or birth rate predictor tool which would build on the Authority's ambition to ensure it used the data in the Register effectively and ensured patients had access to high quality meaningful information.

7.19. Following a discussion, Authority members agreed recommendations 31-32.

Table H: Anonymised Register

	Recommendation	Decision
33	The anonymised Register should be made more accessible, with further guidance on how to use it, along with clear definitions of the data fields. When individuals wish to use such information, the HFEA should request details of the research being proposed, along with their contact details to publish on its website. This will avoid duplication and promote collaboration.	Agreed

Discussion Points: Anonymised Register

7.20. The Regulatory Policy Manager asked members to note that the Advisory Group had recommended that the anonymised Register should be made more accessible, with further guidance on how to use it, along with clear definitions of the data fields. When individuals wished to use such information, the HFEA should request details of the research being proposed, along with their contact details to publish on its website. This would avoid duplication and promote collaboration.

7.21. Authority members agreed recommendation 33.

Table I: Consent process

	Recommendation	Decision
34	The HFEA should look at what can be done to improve the consent process.	Noted

Discussion Points: Consent process

7.22. The Regulatory Policy Manager asked Authority members to note the Advisory Group's recommendation that the HFEA look at what could be done to improve the consent process, in light of ongoing work the Executive is undertaking at present regarding consent.

7.23. Authority members noted recommendation 34.

IfQ Resourcing

7.24. The Director of Compliance and Information reminded members that the IfQ programme encompassed:

- The redesign of the HFEA website and CaFC
- The redesign of the "Clinic Portal" (used for monitoring performance and interacting with clinics), and including within it data submission functionality, currently provided in the HFEA's separate EDI system, used by clinics to submit treatment data to the HFEA
- A revised dataset and data dictionary approved by the Standardisation Committee for Care Information (SCCI)
- A revised Register which would include the migration of historical data contained within the existing Register
- The redesign of the HFEA's main internal systems that comprise the Authority's Register and supporting IT processes.

7.25. The Director of Compliance and Information advised members that the programme would fully meet the relevant recommendation in the McCracken Review. The initial business case, which had been submitted to the Department of Health in February 2013, had identified the following investment objectives:

- A clear and consistent data dictionary
- A reduction in time of 20% spent by clinics in order to meet the HFEA's requirements
- A reduction of errors from 600 to 200 per month
- A reduction in cost of maintaining the Register by £100,000 per year
- Enabling the production of information for Parliamentary Questions (PQs) and Freedom of Information (FOI) requests to 3 days in 90% of cases
- Information systems that were 'fit for purpose' thus driving further efficiencies
- Making public information more accessible

- The HFEA's content management system would support broader information about clinic performance.

7.26. The Director of Compliance and Information advised members that from the inception of the programme in October 2013 through to the end of March 2015 expenditure was projected to be £720,000, as previously approved by the Authority. This included the following activity areas:

- £110k on engagement and consultation
- £78k on researching user needs
- £79k on technical appraisal
- £75k on business requirements for a new system
- £12k on secure data migration
- £368k on supporting the Programme.

7.27. The Director of Compliance provided a summary of future indicative expenditure of £1.1m, subject to the Department of Health's approval and the tendering process being complete by the end of March 2015:

- £225k on the HFEA website to go live from October 2015
- £380k on a Clinic Portal – with the Clinic Portal going live from October 2015 and a Clinic Portal with a submission system live from March 2016
- £300k on a new Register and supporting HFEA systems from March 2016
- £200k on programme management costs.

7.28. This expenditure of £1.1m, together with the £720,000k outlined above, brought the overall programme budget to just over £1.8m compared to an initial approval which had been based on an outline business case in October 2013 of £1.2m. The revised figure includes a sum for contingency and a much better understanding of costs following an extensive discovery phase.

7.29. The Director of Compliance and Information advised members that the Internal Audit report which had been presented to AGC in December 2014 had identified the following risks:

- consistency with overall IT strategy
- delays in time and cost overruns
- a clearer breakdown and profiling of costs
- supplier performance
- data migration
- staffing and capability
- clinic dependency for some benefits realisation.

7.30. Members noted that the required outline Business Case had been submitted in December 2014 and was subject to Department of Health and Government Digital Service approvals. Members also noted the likely expenditure to the end of March 2015.

Decision

7.31. Following a discussion, Authority members approved the overall and revised budget of £1.85m to the Programme completion date of 31 March 2016

(£720,000 committed to date with a further £1.1m expenditure in the 2015/16 financial year) and to receive progress reports on this expenditure at each meeting of the Authority.

8. Communications Strategy

8.1. The Head of Engagement presented this item which would inform members on the direction of travel for communications at the HFEA during the next two years. The Head of Engagement reminded members that the HFEA's existing communications strategy had been published in 2013 before the corporate strategy for 2014-2017 had been developed. With the strategy now in place, the Executive felt it was the right time to review the HFEA's approach to engaging with patients, professional stakeholders, staff and the media.

8.2. **How have we done so far?** The Head of Engagement advised members that improvements to existing communications had been very much informed by the McCracken Review and focused primarily on how the HFEA engaged with professional stakeholders. Whilst there was still work to do in this area, the HFEA's relationship with clinic staff and its professional stakeholders had improved markedly. The Executive had made improvements so far by:

- Understanding patients' needs as it was clear that patients wanted to know more about the HFEA and the information it provided early in their IVF journey
- Changing the tone of voice by becoming more open, transparent and approachable in social media and press publications without losing the need to be authoritative and firm
- Improving digital communications, press and publications with visits to the website up by 41% from 2013 to 1,255,000 in 2014. The number of followers on Twitter had increased by 27% over the year to 1,943, with over 260 media enquiries over the year and over 2,000 references to the HFEA in the press and publications. The HFEA had also issued ten press releases during the course of the year
- Improving relationships with stakeholders by reinstating the HFEA Annual Conference, running a number of workshops for clinics, including consent and multiple births, and by attending more conferences. This had created better engagement from professional stakeholders and patient representatives as evidenced by the strong interest in the HFEA's strategy consultation in spring 2014. All of these actions had helped enhance the awareness of the HFEA
- Redeveloping the HFEA website and CaFC had also been a major step forward in communications terms.

8.3. **Where do we want to be?** The Head of Engagement advised members that the main focus for the HFEA was to be more engaged with patients and professionals, with patients being better informed and for them to receive information early in their IVF journey, and to continue to build better working relationships with professional stakeholders.

8.4. **How are we going to get there?** The Head of Engagement advised members that:

- The HFEA website and CaFC would be redeveloped.
- The HFEA's social media activity would be further developed.

- There would be continued HFEA attendance at shows and exhibitions such as the Fertility Show and the Alternative Parenting Show in order to continue to raise the HFEA profile.
- Consideration would be given to the use of press releases, how to distribute them and how to use them in other channels by perhaps cross-referencing them in social media and other social events.
- HFEA internal communications would be reviewed following the results of the staff survey.

8.5. **How will we know we are successful?** The Head of Engagement advised members that, in order to measure the level of effectiveness and success, evaluations would be carried out of:

- social media and website statistics
- press coverage
- patient feedback.

8.6. The Head of Engagement informed members that she would provide regular reports to the Authority.

8.7. Following a discussion, Authority members supported the direction of travel set out and noted and agreed with:

- Patients being more informed coming into clinics.
- The HFEA making more effective use of social media.
- Continued engagement with professional stakeholders.

8.8. Authority members also agreed with the suggested methods of evaluation and measuring effectiveness.

9. Consent update

9.1. The Policy Manager reminded members that, at their meeting in November 2014, they had agreed a number of measures to address issues raised by the Elizabeth Warren court case, particularly around consent to storage and posthumous use and storage. These measures included:

- Regulatory changes to the HFEA's Code of Practice and consent form changes.
- Information provision – improved patient and clinic information.
- Cultural changes – engagement at workshops and other channels to promote key messages.

Regulatory and Information Changes

9.2. The Policy Manager advised members that the Code of Practice had been updated – as agreed by the Ethics and Standards Committee – to clarify requirements in relation to:

- storage periods
- restricting storage periods
- posthumous medical opinion for extending storage.

9.3. Changes to consent forms in order to improve usability included:

- Changes to the format of storage sections.

- Forms had been reviewed to make sure the language used was patient-focused, consistent and easy to understand.
- Other amendments following feedback, including changes to the consent to disclosure form.

9.4. The Policy Manager advised members that, in order to explore and understand further how clinics obtained consent, the Executive had held a number of best practice workshops around the country. These workshops had attracted a high turn-out across clinics with approximately 180 attendees. The majority of attendees had been fertility nurses who were involved in obtaining consent. Kate Gallafent QC had delivered a compelling presentation about the importance of consent and the Senior Infertility Nurses Group gave a presentation on good practice. Delegates had discussed patient scenarios and the challenges of obtaining patient consent and the Executive had received positive feedback from the workshops.

9.5. The Policy Manager informed members that the main issues identified from the workshops were:

- A mixture of practices existed for taking consent and for the time dedicated to the process. There were examples of good practice but some clinics saw consent as a 'tick box' exercise.
- Confusion around storage periods and who qualified for extended storage.
- The difficulties clinics faced staying in contact with their patients and the perceived risks of allowing patients to consent for long periods.
- How to use forms where patients changed their minds about storage periods.

9.6. The Policy Manager provided members with a summary of the key messages the HFEA conveyed at the workshops, which included:

- The fact that a patient providing informed consent was one of the most important principles in healthcare.
- Clinics played a crucial role in obtaining patient consent. Conversations with patients could sometimes be challenging and could take time but it was each clinic's responsibility to ensure consent was taken well.
- Clinics should be able to demonstrate that they treated their patients as individuals. It was the quality of the consent conversation that was important.
- HFEA consent forms did not hold all of the necessary information to enable patients to give informed consent. New changes to consent forms would make them more user-friendly.

9.7. The Policy Manager advised members that future work comprised:

- Communication to clinics in the HFEA's February edition of Clinic Focus, including a Chair's letter, updates to the Code of Practice and consent forms, and a consent workshop report.
- An updated guide to consent forms and patient information for 1 April 2015.
- A key message at the HFEA Annual Conference in March 2015.
- Consultation with relevant stakeholder groups to produce a separate oncology consent form for 1 October 2015.

9.8. Following a discussion, members noted the presentation and planned work around consent, with a suggestion that additional training could perhaps be provided for clinics on the issue of taking consent and the importance of treating specific groups of patients, such as oncology patients, compassionately.

10. Register Research Applications

10.1. The Researcher in Epidemiology and Statistics presented this item and advised members that the HFEA Register Research Panel (RRP) had been set up in 2010 after the law changed to allow the disclosure to external researchers of patients' identifying information. The Authority remained the statutory Oversight Committee and therefore had a duty to exercise oversight of the work of the RRP.

10.2. Since the RRP was established, seven studies had been approved, two of which had now been published in peer reviewed journals. The first of these was the University College London's (UCL) study looking at cancer in children born after IVF, the results of which had been presented to Authority members in September 2013 by Professor Alastair Sutcliffe, and had subsequently been published in the New England Journal of Medicine in November 2013.

10.3. The second was a preliminary paper published by a team in Nottingham, who were looking at the effect of a patient's ethnicity on the success of assisted reproduction technologies. The full analysis of Register data relating to this study was scheduled to be published in another high impact journal later in the year.

10.4. Since the last report to Authority members in November 2013, the Panel had received no new applications but was expecting at least two in the next few months. However, the excellent quality of work performed demonstrated the value of the Register and allowing researchers access to it.

10.5. The Researcher in Epidemiology and Statistics advised members that, in relation to extant studies, there were two which had merged, in relation to mortality and general health in children born after IVF, carried out by UCL.

10.6. There were also three further studies ongoing:

- Cancer risk and women's mortality after IVF by UCL. The analysis of the data provided by the HFEA was ongoing, and the results of this study should be published this year.
- A team in Aberdeen were working on a predictive model for IVF.
- An EpiHealth Outcomes Project carried out by a team in Manchester, the analysis of which should be complete in the first half of 2015.

10.7. Members were advised that the Executive had developed processes in order to ensure the support provided to researchers ran smoothly, although it had been a steep learning curve and it was hoped the IfQ work would assist in this area of work to facilitate that support.

10.8. Authority members (sitting as the Oversight Committee) noted the report provided to them by the RRP and asked if researchers in future could present their findings at subsequent Authority meetings, as Professor Alastair Sutcliffe had done in 2013.

11. Committee Roles and the Delegation of Functions

11.1. The Head of Governance and Licensing reminded members that, at their workshop in November, they had considered the role that they wanted to play in the future in light of the reduced and changing membership, new strategy, and

future issues emerging for the Authority. Members had given a strong steer on a number of issues and had asked the Executive to give some further thought to these. In general terms, those issues were:

- The overall approach and working practices of Authority members.
- Whether there were further delegations possible from Licence Committee to the Executive Licensing Panel (ELP).
- The approach taken to policy and ethical issues, and the implications for the Ethics and Standards Committee (ESC).
- The approval process for pre-implantation genetic diagnosis (PGD) applications.

11.2. The Head of Governance and Licensing advised members that, although the Executive had given thought to the matter of PGD applications, the implications of a move away from the current procedure would be significant and were being considered by the Executive. These considerations would be reported to the Authority at its meeting in March.

11.3. On the overall approach and working practices of Authority members, the Head of Governance and Licensing advised members that the implications of the recommendations set out in his paper and indeed the lessons learned over the past 12-18 months with the smaller Authority, meant that a more flexible approach was required to decision-making. Increased use of technology such as telephone and video conferencing at meetings and aiming to have a more coordinated approach to achieving quoracy, were particular areas for development. One potential implication of the recommendations was that public facing Authority meetings could well become more prolonged.

11.4. Turning to licensing, members were advised that the guiding principle in relation to licensing was that matters considered by the Licence Committee, which was populated with Authority members, were classified as either 'complex' or 'controversial'. The current general functions of the Licence Committee included consideration of research licence applications and renewals, Grade A incidents, whistleblowing issues and proposals to revoke a licence or take other enforcement action against clinics, all of which could be described as complex or controversial.

11.5. In addition to such items, the Licence Committee currently considered applications for new Treatment and Storage licences. Generally these were non-contentious decisions, where no licensed activity had yet occurred, and they rarely fell into the criteria of complex or controversial. The Executive therefore recommended delegation of such decisions to the Executive Licensing Panel.

11.6. The Head of Governance and Licensing advised members that the workshop discussion in October 2014 had given the Executive a steer as to how to consider the purpose and the role of ESC. Business had not always required ESC to meet in the last year and the Committee had exercised its delegated powers only twice. Given that steer, the Executive had considered the agenda items at the past four ESC meetings and suggested alternative audiences for such items, listed in the table on page 4 of the paper presented to members as a potential future model.

11.7. The Head of Governance and Licensing emphasised that the recommendation was not about looking to reduce scrutiny by Authority members on the ethical and standards issues but more about trying to find an improved and more efficient way of applying member scrutiny and members' skills and experience to the issues that required them. Consideration had also been given to some of the

other more operational decisions that ESC had taken and whether the Executive could take on some of those functions, thus freeing up time for members to concentrate on other matters.

11.8. The Head of Governance and Licensing explained that this approach was not without risks and the Executive had duly reflected on those risks. There would have to be a clear and documented way of deciding which items were considered by which particular audience in order to have a robust defence if challenged. The Executive therefore recommended abolishing ESC, with functions transferred to the full Authority, an individual Authority member or the Executive.

11.9. A member proposed, in relation to the abolition of ESC, that although it was sensible to put Ethical issues to the whole Authority for consideration and to deal with those issues in the Authority workshop forum, consideration should be given to a standing committee set up to deal with other issues such as the Code of Practice. That committee would not have the requirement to meet a set amount of times during the course of the year unless it was required to do so, and could comprise of a chair with a core group of three suitable members.

Decision

11.10. Following a discussion, Authority members agreed:

- To delegate consideration of initial Treatment and/or Storage licence applications to ELP.
- That this change should come into effect on 1 April 2015 and would be reflected in the Standing Orders from this date.
- That further consideration should be given to the abolition of ESC with thought given to the establishment of a standing committee as proposed by members and for the Executive to report back to the Authority in March.

12. Any Other Business

12.1. The Chair confirmed that the next meeting would be held on Wednesday, 11 March 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 Cleaver

Date 22/4/15