Minutes of Authority meeting 16 September 2015

Strategic delivery:	☐ Setting standards	☐ Increasing and informing choice	☐ Demonstrating efficiency economy and value
Details:			
Meeting	Authority		
Agenda item	2		
Paper number	HFEA (11/11/2015) 772		
Meeting date	11 November 2015		
Author	Charlotte Keen, Information Access and Policy Manager		
Output:			
For information or decision?	For decision		
Recommendation	Members are asked to confirm the minutes as a true and accurate record of the meeting		
Resource implications			
Implementation date			
Communication(s)			
Organisational risk	☐ Low	☐ Medium	☐ High
Annexes			

Minutes of the Authority meeting on 16 September 2015 held at ETC Venues, Hatton Garden, 51-53 Hatton Garden, London, EC1N 8HN

Members present	Sally Cheshire (Chair) Dr Susan Price Professor David Archard Dr Andy Greenfield Anthony Rutherford Dr Alan Thornhill	Kate Brian Yacoub Khalaf Margaret Gilmore Anita Bharucha Rebekah Dundas
Apologies	Bishop Lee Rayfield	
Observers	Ted Webb (Department of Health)	Steve Pugh (Department of Health)
Staff in attendance	Peter Thompson Nick Jones Juliet Tizzard Sue Gallone Debra Bloor Catherine Drennan Paula Robinson	Joanne Anton Andrew Leonard Sara Parlett Paula Nolan Joanne McAlpine Charlotte Keen

Members

There were 11 members at the meeting, 7 lay members and 4 professional members

1. Welcome, apologies and declarations of interest

1.1. The Chair opened the meeting by welcoming Authority members and members of the public to the fifth meeting of 2015. As with previous meetings, it was being audio-recorded and the recording would be made available on the HFEA website to enable interested members of the public who were not able to attend the meeting to listen to the HFEA's deliberations. This was part of the HFEA's drive to increase transparency about how the Authority goes about its business.

1.2. Apologies were received from Bishop Lee Rayfield.

1.3. Declarations of interest were made by:

- Anthony Rutherford (Consultant in Reproductive Medicine and Gynaecological Surgery at a licensed centre)
- Kate Brian (Regional organiser for London and the South East for Infertility Network UK)
- Yacoub Khalaf (Person Responsible at a licensed centre)

2. Minutes of Authority meeting held on 8 July 2015

2.1. Members agreed the minutes of the meeting held on 8 July subject to a 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 events with organisations in the IVF sector and the wider health and care system.

3.2. On 14 July the Chair attended a Ministerial meeting with the Chairs of the health sector's arm's length bodies (ALBs), together with a cyber security seminar for ALB and Executive Agency Chairs and Non-Executive Directors. On the same day the Chair, together with the Chief Executive, attended the Human Tissue Authority's (HTA) 10th anniversary review event.

3.3. The Chair reminded members that the HFEA was currently having its Triennial Review to look at the functions of the organisation and whether those functions were carried out in the most efficient way possible. As part of that review, the Chair advised that she had been interviewed by the Department of Health's review team on 29 July and thanked Authority members and members of the Executive who had also taken part in the review for their contributions.

3.4. On 9 and 10 September, the Chair, together with an Authority member, interviewed for new members of the HFEA's independent Appeals Committee. The Chair of the panel was Dame Elizabeth Filkin and the panel was looking to appoint a Chair, Deputy Chair and two lay members to the committee since the terms of office for those members who were currently sitting on the committee had come to an end. The Chair confirmed that the panel was successful in identifying four high-quality candidates, all of whom had accepted the positions.

3.5. The Chair informed members that she, together with a representative from the Department of Health and an independent person, would be conducting interviews on 17 and 23 September to recruit two new members to the Authority – a nurse or counsellor and a clinical geneticist – to replace two current members who would be stepping down after their terms of office came to an end.

4. Chief Executive's report

4.1. The Chief Executive advised members that, on 13 July, he had attended the first Department of Health led project board meeting in relation to the Triennial Review. The board was also scheduled to meet again on 22 September. A number of stakeholders and Authority members had been contacted and asked to participate in interviews and workshops, and the Chief Executive expressed his thanks to all who had taken part in the process.

4.2. On 17 July, the Chief Executive attended an Association of Chief Executives meeting with Sir Jeremy Heywood, Cabinet Secretary and Head of the Civil Service. On 3 September, he attended the National Information Board (NIB) Leadership summit meeting in Manchester. The Chief Executive reminded members that the NIB was an initiative led by the Department of Health involving all of the health sector's 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. Press Coverage: the Chief Executive summarised press coverage since the last Authority meeting, details of which had been circulated to members.

4.4. National Sperm Bank: the press office had received a lot of calls following reports that the sperm bank had only recruited nine donors.

4.5. Genome Editing: the Chief Executive advised members that there had been a public statement by high-profile scientists, calling for an open debate on genome editing in a treatment context. The Chief Executive emphasised that the so-called CRISPR[1] technique had been legal in a research context in the UK since 2009, although use of such techniques in treatment remain illegal.

4.6. Egg freezing: the Chief Executive advised members that egg freezing had been one of the most popular topics in the press throughout 2015, and it had recently been picked up again by Professor Robert Winston. The HFEA had also received enquiries about the data it held.

4.7. Legal parenthood: the Chief Executive advised members that there had been some press coverage since the judgment by the President of the Family Court granting the families concerned legal parenthood. The cases followed errors made by some clinics in taking consent, after the law had been changed in 2009 to allow the partners of women, who were neither married nor in a civil partnership, and having treatment with donor sperm, to become the legal parent at birth. These hearings had no doubt been very stressful for the families involved and the judgment was clearly welcome news for them.

4.8. As the regulator, the HFEA had worked hard to make sure that clinics understood this complex aspect of the law and, as soon as the first case of this kind had come to light, the HFEA had asked clinics to review all relevant patient records. The HFEA continued to work with the clinics involved to make sure affected patients were contacted and offered the support and advice that they needed. The Chief Executive advised members that the HFEA had also changed its focus on inspection to pay special attention to consent processes in clinics so as to ensure that they were tightened up where necessary and that staff were properly trained.

4.9. Although the primary responsibility for the errors lay with the clinics concerned, as the regulator the HFEA felt it only right to take responsibility for its role in the matter and had issued a press release to reassure both the patients involved and the public as a whole that the situation was being proactively managed. The Chief Executive advised members that he had been interviewed on the Today programme on 12 September and that had been reported in a number of newspapers.

4.10. The HFEA would also review the action it had already taken, alongside the Judge's recommendations, to minimise the risk of this happening again.

5. Committee chairs' updates

5.1. The Chair of the Statutory Approvals Committee (SAC) reported that the committee had met on 30 July and 27 August. There had been four preimplantation genetic diagnosis (PGD) applications in July to consider; three were approved and one was refused. There had been two requests for Special Directions, both of which were granted. In August, there had been four PGD applications and one novel process application, all of which were approved.

5.2. The Chair of the Licence Committee advised members that the committee had met on 16 July and 10 September. At its meeting in July, the committee approved one research renewal

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

application, noted one incident report and two changes to research objectives which had been supported by lay summaries. At the 10 September meeting, the minutes of which had not yet been published, the committee considered four research renewal applications and an initial research application, together with an update following a voluntary revocation.

5.3. The Director of Strategy and Corporate Affairs advised members that the Executive Licensing Panel (ELP) had met five times since the last Authority meeting and had considered one treatment and storage initial licence application, which was granted; four treatment and storage renewal applications, all of which were approved; eight interim treatment and storage inspections, all of which were approved; and ten variations, all of which were approved. ELP also considered one application for Special Directions to extend a research project pending renewal, one voluntary revocation, both of which were granted and, finally, considered one executive update on progress against an initial licence in a new centre.

6. Strategic performance report

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

6.2. The Director of Compliance and Information provided an overview of the way in which the HFEA strategy and the 2015/16 business plan were being implemented within the Compliance and Information team. The overarching vision of the HFEA's strategy – high quality care for everyone affected by assisted reproduction – was underpinned by the following functions within the team:

- Setting standards by:
  - Delivering the full compliance cycle to maintain standards for patients
  - Identifying and implementing ways of improving the quality and safety of care
- Increasing and informing choice by:
  - Maintaining the Register of Treatments and Outcomes and supporting clinics in reporting the data
- Efficiency, economy and value by:
  - Modifying the HFEA's way of working to ensure the organisation was responsive, agile, innovative and effective in achieving its strategic and statutory goals.

6.3. The Director of Compliance and Information advised members that the Compliance and Information team was heavily involved in the IfQ programme of work. The inspection year for 2015/16 was also more demanding than the previous year. There was also a full programme of work in processing PGD applications.

6.4. The Director of Compliance and Information informed members that there had been an increase in resilience and capability within the team following an earlier period of turnover. A number of new members of staff had been successfully recruited, with additional resource within the Donor Information team, a strong Business Support team and a full complement of Inspectors.

6.5. The Director of Compliance and Information provided an overview of the PGD application process. The team had experienced a steady increase in the volume of applications, with applications varying considerably month on month. There had been more applications than usual for this time of year and the team had already processed more applications than in the whole of 2014. Despite activity levels having increased, the applications were still being consistently processed within key performance indicators (KPI) targets, with 100% being processed within 66 days since March. The number of incidents reported by clinics has remained steady, with between 40 and 50 incidents reported each month.

6.6. The Director of Compliance and Information advised members that, in order to assure the quality of the information held by the HFEA , the Information team carried out two updates of Choose a Fertility Clinic (CaFC) each year, where clinics were required to verify their data. The Information team also played a role in checking the quality of information held at clinics, and the audit team accompanied the inspectors on about 25 inspections a year and reviewed a sample of around 250 patient records at each of those sites. The HFEA also had an obligation to validate its fee income to the National Audit Office (NAO) by checking 1,000 cycles a year to ensure that those cycles reported were carried out.

6.7. The Director of Compliance and Information advised members that the Information team also provided advice and support to clinics, dealing with about 375 email and 85 telephone queries each month. The IfQ programme should help to streamline some of this activity with a much more straightforward system for clinics to interact with.

6.8. The Director of Compliance and Information reminded members that they received a report at their meeting in July on Opening the Register. Members noted that the Donor Information team received on average about 25 applications a month seeking further information, which was a 20% increase on the previous year. In order to improve that experience and outcomes for applicants, the Executive had embarked on a number of policy initiatives, including launching a support service in April 2015.

6.9. The Director of Compliance and Information advised members that the team also provided an IT support service to both clinics and colleagues which included:

- Clinic IT support
  - Running the Electronic Data Interchange (EDI) helpdesk
  - Taking approximately 30 calls per week
- Helpdesk calls for HFEA staff:
  - An ‘office hours’ service to keep the computers and systems running
  - Around 40 formal user generated requests a week
  - Around 25 informal requests a week.

6.10. The Director of Finance and Resources advised members that the Finance team were meeting all of their performance indicators, in particular those on prompt payment and recovery of debts. In terms of the HFEA’s financial position, the strategic performance report included the management accounts as at the end of June 2015. The position at the end of August was quite similar, with the trend of treatment fees being less than expected continuing. 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.

6.11. Looking ahead to the budget position for the next financial year, the Director of Finance and Resources advised members that the HFEA had not been subject to the spending review requests to model savings of 40% and 25%. Nevertheless, it was still important to look for efficiencies. There was also an uncertainty about the costs for the next financial year and consideration needed to be given to the costs incurred following the office move next spring, and the potential impact on fees, which needed to be increased in 2016. Over the next month or so, the Executive would be firming up its proposals on how to take that increase forward. Those proposals would be brought to Authority members at their next meeting in November. The Chair emphasised that it was the first time the HFEA had considered raising treatment fee income for many years, and it was unlikely that they would increase substantially.

6.12. The Director of Strategy and Corporate Affairs advised members that, in relation to the strategic performance report, the only issue to note was that there had been a slight reduction in visits to the HFEA website. It was likely that this was, in part, due to communications staff focusing on designing the new website.

6.13. The new refreshed brand identity had been rolled out, making it more clear and recognisable. New leaflets and guidance would be produced incorporating the new identity in time for the alternative parenting show on 19 September and the fertility show scheduled to take place in the first week of November. Both events were an opportunity for the HFEA, as the regulator, to meet prospective patients, donors and recipients of donor gametes face to face, and to provide them with information. The Director of Strategy and Corporate Affairs expressed her thanks to the Communications team for their hard work. The Chair asked for the dates of the alternative parenting show and the fertility show to be advertised on the HFEA website and the Director of Strategy and Corporate Affairs agreed to send a note to members following the shows to provide them with feedback.

6.14. Following a discussion, members noted the presentation and the latest strategic performance report.

7. Regulating mitochondrial donation

7.1. The Chair introduced this item and reminded members that, back in February 2015, Parliament approved Regulations to allow techniques to prevent serious mitochondrial disease. The HFEA had therefore been required to develop a licensing process which would come into effect on 29 October 2015.

7.2. The Policy Manager reminded members that on 29 October, the UK would be the first country in the world to regulate mitochondrial donation for the avoidance of serious mitochondrial disease. This had been a result of extensive work over the last four years, carried out by researchers, campaigners, policy makers and other stakeholders alike. Since the Regulations were passed earlier this year, the HFEA had been tasked with designing a regulatory framework within which the HFEA could put the law into practice. That framework would comprise of three stages that a clinic wishing to offer mitochondrial donation would have to follow. The Policy Manager advised members that the three stages were:

- How to seek approval to carry out mitochondrial donation
- How to run a good quality service

- The clinics' obligations following treatment.

7.3. The Policy Manager advised members that the new regulatory framework would be communicated to clinics on 29 October 2015, when the Regulations came into force. The first stage would be to set out how the clinic would apply to the HFEA to be licensed in order to carry out mitochondrial donation. As with any new treatment, it was important that the treatment must be judged to be safe and effective before it was made available. The HFEA expert panel had considered the safety and efficacy of the two techniques of maternal spindle transfer (MST) and pronuclear transfer (PNT) in three reports and it had recommended that a number of tests should be completed before treatment could be offered. Accordingly, once those tests had been carried out, the panel had been satisfied and the Authority had accepted their recommendations, the formal licensing process could then begin.

How to seek approval to carry out mitochondrial donation

7.4. Before any HFEA-licensed clinic could undertake mitochondrial donation for treatment purposes, it must follow a two-stage process, which had been developed in line with the requirements of the Regulations:

- The clinic would need to apply to vary its licence to include specific permission to carry out MST and/or PNT. Such applications would be considered by the Licence Committee and, if the application was approved, the clinic would be licensed and it would not need to repeat this step unless certain circumstances changed – for example if the clinic wished to seek approval to change its embryologist(s).
- The clinic would need to apply for approval to treat a specific patient. Such applications would be considered by the Statutory Approvals Committee (SAC). This step must be completed for each individual patient, and details concerning this were set out in paragraphs 2.14-2.16 of the paper.

7.5. The Policy Manager advised members that General Directions 0008 set out the necessary evidence needed to support a licence variation and would need to be revised to take into account mitochondrial donation requirements. These directions would require the clinic's Person Responsible (PR) to submit the following evidence:

- Suitable validation of their clinic's equipment and processes
- The clinic's process for monitoring children born following mitochondrial donation (where patients consented to follow-up)
- The competency of the clinic staff and suitability of its premises and processes with specific reference to MST and/or PNT
- The competency of the clinic's MST/PNT embryologist(s)
- Any other information that may demonstrate competency.

7.6. These proposals would require changes to the Authority's Standing Orders, highlighted at Annex two of the paper. Those changes would require a formal vote by Authority members.

7.7. Before the HFEA could issue a licence specifically permitting the clinic to carry out mitochondrial donation, the clinic must acknowledge the licence conditions in the usual manner. The Policy Manager advised members that the new licence conditions specific to mitochondrial donation were set out in paragraph 2.12 of the paper.

Decision

7.8. Following a discussion, members approved, subject to minor amendments:

- The regulatory approach to clinics applying to vary their licence to perform mitochondrial donation
- The individual patient approval process
- The new licence conditions
- The necessary amendments to General Directions 0008 (information to be submitted to the HFEA as part of the licensing process) and revisions to the Standing Orders.

7.9. Members also formally delegated the later amendments to General Directions 0008 and the Code of Practice, to include (but not be limited to) performance indicators for MST/PNT embryologists, to a sub-set of Authority members, in accordance with its powers under section 6.6 of the Standing Orders.

How to run a good quality service

7.10. The Policy Manager advised members that, once a clinic had been licensed to carry out mitochondrial donation and a patient approved for treatment, the clinic would be required to run a good quality service in line with the new regulatory requirements. Putting this in place would entail:

- A registration process
- The use of new consent forms
- A specific, stand-alone Code of Practice guidance note
- Amendments to General Directions.

7.11. The Policy Manager provided an overview of the proposed approach to obtaining patient, partner, and donor consent. The HFEA was proposing to introduce separate consent forms for patients seeking mitochondrial donation and for donors. These forms would reflect the specific information needs of such patients and donors as opposed to standard fertility treatment patients.

7.12. The Policy Manager also asked members to consider an approach to the disclosure of non-identifying information about mitochondrial donors to patients and parents following mitochondrial donation. Members were also asked to consider whether to introduce a similar policy as that for gamete donation, whereby a patient or parent could seek certain non-identifying information about the mitochondrial donor from the clinic or from the HFEA. The HFEA, however, did not propose introducing the same guidance to clinics to encourage the disclosure of that information in the same way as for gamete donation.

Decision

7.13. Following a discussion, members approved:

- The approach for how clinics should run a good quality service, including new guidance, directions, use of new consent forms and the information clinics would submit to the HFEA
- The approach to obtaining consent and the disclosure of non-identifying information
- The mitochondrial guidance note
- Amendments to General Directions 0001 (gamete and embryo donation), 0005 (collecting and recording information for the HFEA) and 0007 (consent).

What to do after treatment

7.14. The Policy Manager advised members that, following treatment, clinics would need to ensure that they continued to comply with their obligations under the new regulatory framework. All clinics would be required to have in place a documented process for monitoring children born following mitochondrial donation, where patients had consented to follow-up. In addition, clinics would need to submit an annual report on patient uptake of follow-up studies and non-patient specific information on the outcomes.

7.15. In relation to the export of MST or PNT eggs or embryos, the Policy Manager advised members that the Regulations did not prevent post MST or PNT eggs or embryos (created following the authorisation by the Authority) from being exported. The Executive felt that the export of post MST or PNT eggs or embryos should not take place under General Directions, but that a specific requirement should be included in General Directions 0006 (imports and exports) to reflect the need for clinics abroad to have equivalent expertise and mechanisms in place. The approval of such an amendment would be delegated to the sub-group of members referred to in paragraph 7.9 above.

7.16. The Policy Manager advised members that consequential changes following the introduction of the new Regulations had been made to the existing guidance in the Code of Practice. These changes were not substantial but were required to ensure accuracy across the Code of Practice.

Decision

7.17. Following a discussion, members approved:

- The regulatory requirements for clinics following mitochondrial donation treatment
- The approach to the export of eggs or embryos
- The consequential changes to the Code of Practice
- Amendments to General Directions 0005 (collecting and recording of information for the HFEA) and 0012 (retention of records).

7.18. It was agreed that, in relation to the approach to follow-up reporting for monitoring children following mitochondrial donation, where patients had consented to follow-up, the Executive should consider this further. Members emphasised that clinics should have robust follow-up mechanisms in place and that patients should be encouraged to consent to the follow-up of children born following mitochondrial donation. The approach would therefore be discussed further and agreed by a sub-group of members.

7.19. Members also approved (with a formal unanimous vote) the necessary revisions to the Standing Orders to take into account the mitochondrial donation approval process at Annex two of the paper.

7.20. Members also voted unanimously for the Standing Orders to be amended to increase the number of members attending the Audit and Governance Committee (AGC) from four to five in order to ensure less risk to quoracy.

8. Business Plan 2016/17: outline objectives

8.1. The Head of Business Planning reminded members of the timetable for the implementation of the 2015/16 business plan and the development of the 2016/17 business plan. The business planning cycle commenced each year in August, with development of the draft plan occurring from September through to December. During October, when the delivery cycle had reached the end of quarter two of the financial year, a review took place to consider progress against the current business plan. This was an opportunity to either re-publish the current plan if any changes were required, or identify what would need to be continued through to the next financial year. The HFEA strategy was also considered, with a three year delivery outline having previously been agreed by the Authority in 2014.

8.2. The Corporate Management Group (CMG) also considered current and future aims, what activities these required and what resources would be needed to deliver them. The Head of Business Planning advised members that, in December, the Department of Health would need to receive a first draft of the business plan for 2016/17, which meant that the draft would be brought to members for consideration at their meeting in November. From January through to April 2016, there would be an iterative process, where discussions took place with the Department of Health about the draft plan, identifying anything that the sponsors or Ministers would like changed or incorporated. The aim was to finalise the plan and associated budget in order for it to be signed off in March and published in April 2016.

8.3. The Head of Business Planning provided members with an overview of the main points and activities proposed for the 2016/17 business plan, which were set out in more detail in the paper. The activities continued to focus squarely on achieving the HFEA's vision of 'high quality care for everyone affected by assisted reproduction'. All the HFEA's statutory work was included (regulation and information provision) and the IfQ programme would be a major part of the plan over the remainder of the current business year and for much of the next. The plan would reflect the HFEA's continued emphasis on being a high-value, high-quality public body.

Decision

8.4. Members approved the outline as a basis for drafting the 2016/17 business plan and noted that the full draft would be presented to them at their meeting in November.

9. Information for Quality update

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

9.2. The Director of Compliance and Information provided an overview of progress thus far. The procurement process of selecting suppliers was now complete and suppliers had started purposefully, working on five outward facing elements of the programme. The HFEA was adopting an Agile methodology. The work had been organised successfully, and three 'sprints' (usually a two week period of activity) had now been completed, including a phase called Discovery+ where users' expectations of the new systems were finalised.

9.3. The Director of Compliance and Information reminded members that the externally facing part of the IfQ programme could not proceed beyond the 'Alpha' stage (proof of concept) until further approvals in line with Government Digital Service standards had been granted by the Department of Health. Alpha stage development had now commenced and was expected to last for eight weeks, with a formal decision expected in November 2015. In advance of that, in order to make the process as smooth as possible, the Executive had been in active discussions with colleagues at the Department of Health who were content to provide informal indications along the way.

9.4. The Director of Compliance and Information provided an overview of managing the key risks. It was acknowledged that the programme was very ambitious in terms of what was being achieved with the available resources. The main contractor, Reading Room, had made good progress. The HFEA's internal teams were also heavily involved in development. Specialist, additional, expertise would, however, be required for certain aspects such as IT security and cloud infrastructure.

9.5. The Director of Compliance and Information reminded members that data migration was a key risk to the programme, with 20 years' of treatment data being transferred to the new Register structure. It has always been emphasised that the HFEA would not implement a new system of data submission until the data migration strategy had been completely satisfied. This commitment inevitably introduced a degree of uncertainty as regards a published timetable for implementation.

9.6. The Director of Compliance and Information advised members that, until the necessary procurement processes and approvals had been completed, together with more detailed planning assumptions, the Executive had not thought it appropriate to put a detailed timetable into the public domain. This position was one supported by the external stakeholder group, who continued to play a vital role in an advisory capacity in the IfQ programme. The Director of Compliance and Information, however, provided members with an indicative timeline which would form the basis for external communications, and would provide clinics with a greater degree of certainty in relation to the impact on them relating to changes in the submission of treatment information.

9.7. The timetable was subject, principally, to Alpha stage approvals being granted. The full implementation of the Clinic Portal would be dependent on data migration progressing successfully. With this in mind, a timetable of February to March 2016 was indicated for 'Beta' versions of the website, Choose a Fertility Clinic (CaFC) and the Clinic Portal (without treatment submission functionality) to be launched, with a live version of the Clinic Portal subsequently being released to those clinics with a direct electronic data interchange (EDI) with the HFEA in October 2016. A slightly longer period of time would be needed for those clinics that used third-party systems.

9.8. The Director of Compliance and Information advised members that the Executive was about to start a process of engagement with clinics so they were aware in advance of the requirement to undertake some data cleansing work. The bulk of this work was expected to take place from October 2015 and completed in the spring of 2016.

9.9. Following a discussion relating to the indicative timeline, members noted that a final timeline would be published in due course. Members also noted:

- The progress made on the IfQ Programme
- That Alpha stage development had now commenced and progression for the externally facing part would be dependent on external approval.

10. Compliance activities 2014/15: a review

10.1. The Chief Inspector advised members that the paper introduced a suite of papers which analysed and commented on the impact of the HFEA's regulatory activities.

10.2. Members were advised that the first four items would be treated as one and a single discussion would take place thereafter on the issues raised. The final paper on the compliance and enforcement policy would be subject to a separate discussion.

10.3. The Chief Inspector reminded members that the HFEA's strategy for 2014-17 signalled an ambition for high quality care for everyone affected by assisted reproduction. Within the boundaries of its statutory remit, the HFEA's regulatory activities were directed to the improvement of the quality and safety of care. It was important that the HFEA, from time to time, scrutinised and challenged its regulatory approach and considered recommendations for improvement.

10.4. The cause and effect of regulatory activities were, however, difficult to measure. It was evident that the existence, production and development of the Code of Practice, which provided a set of rules to guide clinics, together with the prospect of inspection, promoted compliance. In addition to providing guidance, the Chief Inspector advised members that the HFEA also provided a framework for clinics through consent forms and the procedures that were in place for reporting information.

10.5. The Chief Inspector advised members that the HFEA also provided guidance to clinics in general and on a one to one basis, and all clinics had access to a dedicated inspector. Clinic performance was also continually monitored between inspections using a risk tool to flag up performance concerns at individual clinics. Any recommendations made at inspection were also monitored to ensure implementation.

10.6. Taking the limitations of the HFEA's statutory remit into account, the Chief Inspector advised members that the Executive aimed to keep the HFEA's regime under review and to continually evolve its regulatory approach in line with its strategic goals.

10.7. The papers presented to Authority members set out what the HFEA could measure in terms of compliance and an analysis of the outcomes of those measures in terms of success.

11. Compliance activities 2014/15: analysis of risk tool alert data

11.1. The Senior Inspector advised members that the HFEA had been using the risk based assessment tool (RBAT) to enhance the monitoring of clinics between inspection visits since April 2011. Members noted that the risk tool measured performance in relation to the following indicators:

- Outcomes in terms of both clinical pregnancy rates and clinical multiple pregnancy rates
- Submission of critical register information relating to treatments using donor gametes
- Timeliness of payment of monthly HFEA invoices.

11.2. Performance was analysed based on the information submitted to the HFEA by clinics. Where the trend analysis performed by RBAT suggested that there may be a dip in performance, an automated alert was sent to the Person Responsible (PR) and clinics were expected to act on

those alerts to investigate any possible causal factors and take corrective action if appropriate. Inspectors and/or members of the Register Information team also carried out targeted follow-up where appropriate.

11.3. The Senior Inspector advised members that the paper provided an update to the review of RBAT outputs completed in 2014 and aimed to identify trends, establish performance against the benchmark analysis undertaken in 2014, and identify actions for the future in relation to the focus of the HFEA's regulatory interventions.

11.4. The Senior Inspector provided members with an overview of the number and type of alerts issued from the risk tool, which were set out in detail in the paper.

11.5. Members noted that clinics' performance between April 2014 and March 2015 had improved in relation to success rates and timeliness in payment of fees, but had worsened in relation to submission of critical register information. However, it was anticipated that the IfQ programme would have a significant impact on the quality of register submissions.

11.6. Members also noted that alerts relating to success rates showed a more promising pattern, with the number of alerts decreasing in each area, evidence that clinics were taking action to continually improve their success rates.

11.7. The small increase in the number of alerts relating to clinical multiple pregnancy rates in 2014/15 was surprising, since clinics had had since October 2012 to adjust to the 10% multiple live birth rate target. However, data for the sector as a whole showed that in 2013/14, 19 clinics had a multiple pregnancy rate that was likely to be higher than the 10% multiple birth rate target, whilst in 2014/15 this had decreased to 15 clinics. This suggested that clinics were taking action to review the effectiveness of their multiple births minimisation strategies and it was thought that the HFEA's proactive real time monitoring through RBAT had played a role in encouraging this behaviour.

11.8. The Senior Inspector advised members that the HFEA felt the risk tool provided useful and timely information to give to clinics in order to prompt them to review processes and take subsequent action where appropriate. It also helped the inspectorate to focus its activities on quality of service and prompted interaction with specific clinics.

12. Compliance activities 2014/15: analysis of inspection findings

12.1. The Senior Inspector advised members that the paper provided an analysis of non-compliances found in the course of renewal and interim inspections between 1 April 2014 and 31 March 2015, and a comparison with the 2013/14 inspection findings.

12.2. The Senior Inspector provided members with an overview of how the inspection team had been successful in meeting the objective of improving the quality and safety of care through the HFEA's regulatory activities. The analysis was set out in detail in the paper and included:

- 323 recommendations in 2014/15 with 215 having been fully implemented to date
- 185 recommendations to correct higher risk critical and major non-compliances with 137 of those implemented to date.

12.3. Members noted that in post-inspection feedback, 35 of 38 respondents inspected in 2014/15 agreed that inspection had promoted improvement to the way their clinic carried out its work.

12.4. The Senior Inspector advised members that in 2014/15 there had been 59 inspections of treatment and/or storage clinics. It was important to note that, although fewer inspections were carried out in 2014/15 than in the preceding year, there had been a higher proportion of inspections at large clinics compared to 2013/14 and a lower proportion at treatment only clinics. Large clinics tended to provide more complex treatments and, as a result, were subject to compliance with more requirements than treatment only clinics.

12.5. Members noted that there had been an increase in critical non-compliances in 2014/15. Recommendations to address all these critical non-compliances had all been fully implemented. The main reasons for this increase in critical non-compliance were:

- Inspection of different areas, including surgical procedures
- Repeat non-compliance at the same clinic upgraded from major to critical
- Sporadic or repeat non-compliance at different clinics, including storage consent and counselling.

12.6. The Senior Inspector provided an overview of some common reasons for non-compliance, which included changes of staff, premises and equipment and processes in clinics, together with understanding of the Code of Practice not being sufficiently widespread within the clinic.

12.7. The Senior Inspector advised members that the HFEA would continue to promote compliance by:

- Developing effective methodologies to inspect clinics in a focused and proportionate manner
- Monitoring the implementation of recommendations made on inspection
- Requiring clinics to have an effective quality management system and, specifically, effective audit procedures, to ensure their compliance and assure the effectiveness of improvements
- Providing advice on the Code of Practice requirements
- Liaising across the HFEA to develop regulatory tools and to flag concerns where clarity was needed relating to existing requirements
- Liaising with other regulators to clarify requirements
- Liaising with, and informing the sector, through the annual conference, workshops and clinic visits to promote knowledge of the Code of Practice requirements and to promote a culture of compliance.

12.8. Members noted that levels of compliance remained high, and the non-compliances identified during inspection related to either high risk or complex areas of practice. Inspections continued to adapt to the regulatory landscape and clinics were clearly making improvements prompted by the HFEA's regulatory activities. Post inspection feedback supported a conclusion that inspection visits led to improvements in service delivery and patient care.

13. Compliance activities 2014/15: clinical governance learning and culture

13.1. The Clinical Governance Inspector advised members that an estimated 1% of the 60,000 cycles of IVF treatment that were carried out in the UK each year were affected by some sort of adverse incident. The HFEA's definition of an adverse incident was 'any event, circumstance, activity or action which has caused, or has been identified as potentially causing harm, loss or damage to patients, their embryos or gametes and also to staff at licensed clinics.'

13.2. The Clinical Governance Inspector advised members that clinics had a statutory duty to report and analyse the cause of incidents. Similarly, the Authority had a duty to investigate and take appropriate control measures in relation to reported incidents. Reported incidents were graded using an incident grading matrix, taking into account the severity of the outcome, the potential outcome and the likelihood of it happening again. 'A' grade incidents were considered the most serious and when one was reported to the HFEA, the clinic was immediately contacted to obtain more information, in light of which the team would agree what action needed to be taken. An incident inspection was also carried out in order to ascertain why the incident happened and identify action needed to minimise the risk of a similar incident happening in the future. Following this inspection, and after the clinic had completed its own investigation, the HFEA produced a root cause analysis report. This information was then presented to the HFEA's Licence Committee which decided if any further regulatory action needed to be taken.

13.3. The Clinical Governance Inspector provided an overview of incidents reported to the HFEA over the previous five years. Members noted that the number of incidents had remained fairly static, and it was disappointing to note that the number of administrative, more avoidable, incidents had also remained static. In October 2010, the decision had been taken to publish 'A' grade inspection reports and Licence Committee minutes on the HFEA website. There had been some concern in the sector that such publication might be seen as a punitive measure and make clinics reluctant to report serious incidents, although it appeared that this had not, in the event, been the case.

13.4. The Clinical Governance Inspector advised members that the HFEA published its first incident report in July 2014, covering the period between January 2010 and December 2012. The report described a number of lessons learned and provided examples of improvements that had been made by clinics following incidents. In December 2014, the HFEA published its first annual incident report, which covered 2013 data, and the report covering 2014 data was due to be published today.

13.5. The analysis of the 2014 data showed that:

- Avoidable incidents were still happening, which was a recurring theme within the wider healthcare setting
- Clinics were not always conducting robust investigations or taking the incidents seriously and they must improve the quality of their investigations.

13.6. The Clinical Governance Inspector provided members with an overview of how the HFEA intended to address this. The aim was to encourage clinics to take responsibility for their own improvement. These actions included:

- Working with clinics collectively (workshops, Clinic Focus articles, annual Incidents Report)

- Working with clinics on a one to one basis to encourage them to fully engage with incident investigations
- Re-focusing inspections to look for evidence that clinics had actually learned from incidents and audits and had acted on guidance.

13.7. In summary, the Clinical Governance Inspector advised members that the HFEA aimed to keep its processes under constant review and to establish collaborative working relationships with NHS Improvement, to ensure that wider learning from colleagues working in patient safety in a healthcare setting fed into the HFEA's own ways of working. Members noted that the HFEA was:

- Seeking to influence the culture in licensed clinics so they developed an embedded learning and safety culture
- Aiming to ensure that the work of the organisation on incident oversight read across to its inspection activities.

Decision

13.8. Following a discussion, particularly around the impact of staffing levels in clinics in relation to their ability to carry out treatments effectively, members:

- Noted the papers and evidence
- Agreed with the current regulatory focus and approach
- Confirmed the future direction of the HFEA's regulatory activities
- Asked the senior management team to consider members' comments and provide an update to Authority members at a later date.

14. Compliance and enforcement policy review

14.1. The Chief Inspector advised members that the Compliance and Enforcement Policy was largely effective. The policy had been in force since 2009 and set out the actions the Compliance team should take to ensure compliance by licensed centres. The policy was part of a suite of documents which also included the Indicative Sanctions Guidance and Applications Guidance.

14.2. The proposals and recommendations for the update of the suite of documents were based on learning from recent experiences, and feedback from Authority members and committee Chairs, on the factors that should be taken into account when considering regulatory sanctions.

14.3. Minor changes were also recommended in order to:

- Rationalise the practical sequence of events
- Set out when a report would be drafted and presented to the Executive Licensing Panel or Licence Committee
- Clarify that forensic scrutiny of a clinic's practices may be undertaken when considered necessary.

14.4. The Chief Inspector advised members that revisions to the applications guidance were also required in order to:

- Emphasise the importance of the licence history that was considered

- Make risks to safety of patients, embryos or gametes central to consideration
- Consider the quality of service
- Take into account the extent to which the PR demonstrated an understanding of the need for improvement, and a commitment to improvement.

14.5. Indicative Sanctions guidance should be aligned with key risks and should be clearer that the following would be considered aggravating factors:

- Failure to ensure the safety of patients, their gametes or embryos
- The PR ceasing to be considered a suitable person
- Failure to ensure suitability of staff, or the use of proper equipment, or the suitability of premises.

14.6. The Chief Inspector advised members that the revised policy would be subject to a focused consultation and would be piloted in the next three months. Final recommendations and proposals would then be referred to the Authority in early 2016 prior to implementation in April 2016.

Decision

14.7. Following a discussion, members agreed in principle to:

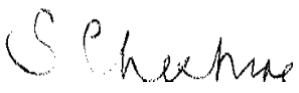
- The proposals for the revision of the Compliance and Enforcement Policy and supporting documents
- A focused consultation with the sector, stakeholders and legal advisors
- The proposal that the Licence Committee and the Executive Licensing Panel would pilot the use of the guidance
- The plan to submit the final policy to the Authority in early 2016 with implementation from April 2016.

15. Any other business

15.1. The Chair confirmed that the next meeting would be held on 11 November 2015 at ETC Venues, Hatton Garden, 51-53 Hatton Garden, London, EC1N 8HN.

16. Chair's signature

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

Signature 

Chair

Date **20/11/2015**