



## Minutes of the Authority meeting on 14 September 2016 held at ETC Venues, Victoria, 1 Drummond Gate, London SW1V 2QW

Members present	Sally Cheshire (Chair) Professor David Archard Rebekah Dundas Dr Andy Greenfield Yacoub Khalaf Margaret Gilmore	Anita Bharucha Ruth Wilde Dr Anne Lampe Anthony Rutherford Kate Brian
Apologies	Bishop Lee Rayfield	
Observers/Presenters	Ted Webb (Department of Health) Jeremy Mean (Department of Health)	
Staff in attendance	Peter Thompson Nick Jones Juliet Tizzard Catherine Drennan Paula Robinson	Sharon Fensome-Rimmer Sara Parlett Andrew Leonard Paula Nolan 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 2016. 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.
- 1.2. Apologies were received from Bishop Lee Rayfield.
- 1.3. Declarations of interest were made by:
  - Kate Brian (Regional organiser for London and the South East for Infertility Network UK)
  - Yacoub Khalaf (Person Responsible at a licensed centre)
  - Anthony Rutherford (Consultant in Reproductive Medicine and Gynaecological Surgery at a licensed centre)
  - Ruth Wilde (Senior Fertility Counsellor at a licensed centre).

## 2. Minutes of Authority meeting held on 6 July 2016

- 2.1. Members agreed the minutes of the meeting held on 6 July subject to minor amendments, for signature by the Chair.

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### 3. Chair's report

- 3.1. The Chair welcomed Jeremy Mean from the Department of Health as the HFEA's new sponsor, since Ted Webb, the HFEA's sponsor for the past 14 years, was retiring. The Chair expressed her thanks to Ted on behalf of members, and HFEA colleagues, for all his support over the years.
- 3.2. The Chair also thanked Sue Gallone, the Director of Finance and Resources for both the HFEA and the HTA, as Sue was also retiring. Although Sue was unable to attend the Authority meeting, the Chair expressed her thanks to Sue for all her hard work which had been much appreciated and wished her well for the future.
- 3.3. Finally, the Chair thanked Professor David Archard, who was leaving and who was also the HFEA's longest serving member. David had been instrumental in advising the Authority on all matters to do with ethics and law and had played a major part in how the HFEA handled preimplantation genetic diagnosis (PGD), as well as working on mitochondrial donation and developing the Statutory Approvals Committee (SAC) from its infancy. Through his expert Chairing of SAC, the Chair felt that David had made a huge difference to the Authority and both she and the Chief Executive expressed their thanks to David for his valuable input during his time as an Authority member.
- 3.4. The Chair provided members with a summary of events that she had attended with organisations in the IVF sector and the wider health and care system since the last Authority meeting.
- 3.5. On 12 July, the Chair chaired the Remuneration Committee, more detail of which would be covered under item five on the agenda.
- 3.6. On 20 July, the Chair attended the Department of Health's arm's length bodies (ALBs) chairs and non-executive directors (NEDs) summer conference.
- 3.7. Finally, the Chair advised members of the public that the HFEA would mark its 25<sup>th</sup> anniversary at an event taking place on 15 September. The HFEA was the first statutory regulator of IVF and human embryo research in the world and it was testimony to all those involved that it had stood the test of time so well and was considered to be the standard against which regulation in the field was judged. The event would provide a chance to celebrate those achievements in more details with past colleagues and some of the HFEA's most important stakeholders.

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### 4. Chief Executive's report

- 4.1. The Chief Executive advised members that on 12 July he had also attended the HFEA Remuneration Committee and provided recommendations on the Senior Managers' performance pay award.
- 4.2. On 21 July, the Chief Executive attended a meeting of the Health and Social Care Leadership Scheme which brought together the Department of Health and all of the Chief Executives of the health sector's ALBs to identify senior talent within the system. Members were aware that both the Director of Compliance and Information and the Director of Strategy and Corporate Affairs had been selected onto the programme.
- 4.3. On 28 July, the Chief Executive advised members that he was part of an interview panel for the shared Director of Finance and Resources for the HFEA and HTA, following the retirement of Sue

Gallone. The Chief Executive was pleased to inform members that Richard Sydee had been appointed and he would join the HFEA and HTA on 1 November.

- 4.4.** On 8 September, the Chief Executive attended a National Information Board (NIB) Leadership meeting. 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.
- 4.5.** Press coverage: the Chief Executive advised members that there had been relatively few news stories in which the HFEA had been quoted or cited directly since the last Authority meeting. However, there had been a number of stories on assisted reproduction featuring facts and figures from the HFEA's Register, details of which had been circulated to members.
- 4.6.** It was anticipated that, with the schedule of projects and events coming up in the next couple of months, media interest in the sector would resume.

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

- 5.1.** The Deputy Chair of the Statutory Approvals Committee (SAC) reported that the committee had met on 5 and 25 August. There had been five preimplantation genetic diagnosis (PGD) applications on 5 August, four of which were approved and one refused, together with two Special Directions applications for export, both of which were approved. At the meeting on 25 August, there had been two PGD applications, both of which were approved.
- 5.2.** The Chair of the Licence Committee reported that the committee had met on 14 July and 9 September. On 14 July, the committee considered and approved a research renewal licence application, agreed the continuance of a licence following an interim inspection and noted an unannounced inspection and an executive update. On 9 September, the minutes of which had not yet been published, the committee considered two licence renewal applications, a variation of objectives, an update on legal parenthood and a paper from the Scientific and Clinical Advances Advisory Committee (SCAAC).
- 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 on 15 and 29 July, 12 and 24 August and 9 September. For the first four meetings, the panel had considered 12 items in total, two of which were adjourned and the rest of which were approved. There were three renewal licence applications; four interim inspection reports; four licence variations and one new licence application. At the meeting on 9 September, the minutes of which had not yet been published, the panel had considered nine items. There were three renewal licence applications; one interim inspection report; four licence variations and one new licence application.
- 5.4.** The Chair provided more details of the Remuneration Committee mentioned earlier in the meeting. The committee met on 12 July to consider proposed pay awards for staff, directors and Chief Executive, together with an appraisal of their performance. The Chair expressed her thanks to all HFEA staff for their valuable contribution to the organisation.

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## 6. Strategic performance report

- 6.1. The Director of Strategy and Corporate Affairs advised members that the HFEA annual conference for 2017 would be taking place on Thursday 16 March at the Inmarsat Global Conference Centre in London.
- 6.2. The Director of Compliance and Information provided a brief summary of three issues within his Directorate which were highlighted in the Strategic Performance Report. Firstly, in June, the HFEA had a serious power outage in the building which also affected the National Institute for Clinical Excellence (NICE) and the British Council. This inevitably had an impact on the HFEA's work and the business continuity plan was invoked. As the servers were affected, this meant that staff had been unable to access the secure document storage system and subsequently this had had an effect on key performance indicators. Lessons have been learned as regards the implementation of the business continuity plan which will be useful for future eventualities.
- 6.3. The Director of Compliance and Information also acknowledged that there had been issues around the telephony systems which inevitably had an impact on the work of the committees where video conferencing was used on a regular basis. Work was ongoing to rectify these problems.
- 6.4. The Strategic Performance Report also highlighted delays with reports being sent back to clinics following inspection, although those delays were for valid reasons.
- 6.5. In the absence of the Director of Finance and Resources, the Chief Executive gave an overview of financial performance. Although it was early in the financial year, looking at the June figures, two facts stood out, one of which was a significant increase in the treatment fee income against that which had been forecast. There was no obvious reason for this, and no evidence of a pattern, but the Executive were very sighted on the increase and would continue to monitor the position.
- 6.6. The Chief Executive advised members that, on the whole, expenditure was as forecast although there had been an overspend of 35% in the legal budget. The legal budget was always difficult to predict and it was likely that the budget would right itself over time.
- 6.7. The Chair informed members that the expert panel, who had previously met and reported on progress with mitochondrial donation techniques, had been working on a report which should be ready for publication in the near future. The Chair of the expert panel advised members that the panel had published a request for evidence and the panel was now in the process of considering that evidence and writing the report in light of that consideration. The panel had met at the end of July and would be meeting again on 16 September. The report would focus on new evidence relating to the safety and efficacy of mitochondrial donation techniques that had come to light since 2014. The Chair of the expert panel advised members that it was anticipated the report would be ready for publication by the end of the year.
- 6.8. Following a discussion, members noted the latest strategic performance report.

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## 7. Information for Quality: update

- 7.1. The Director of Compliance and Information explained that the IfQ programme was a comprehensive review of the information that the HFEA held, the systems that governed the

submission of data, the uses to which it was put and the ways in which the information was published. It included:

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

**7.2.** The Director of Compliance and Information explained that this presentation was to update members on:

- Progression to public Beta for 'Release One' products and plans for a fully live HFEA website and Clinic Portal
- Progress in relation to 'Release Two' (the data submission system)
- Programme timelines and budget.

**7.3.** Approvals progress: the Director of Compliance and Information reminded members of the stages that government IT programmes must progress through:

- 'alpha' (build a prototype, test it with users and learn from it)
- 'beta' (scaling up, a working model)
- 'public beta' (going public with a beta version, receiving feedback and preparing to go live)
- 'live' (a tested solution ready to release and then continuously improved).

**7.4.** The Director of Compliance and Information reminded members that, at the July meeting of the Authority, it was noted that the website had been launched on 5 July 2016 in a private version of beta for clinics only to access. This step was taken to enable clinics to familiarise themselves with the presentation of their CaFC data on the website, and to use the Clinic Portal, for a three-week period prior to full beta public launch.

**7.5.** The Clinic Portal was released to public beta one week later on 12 July 2016, and further developments and improvements would continue throughout the beta phase. User feedback would also be sought, including a structured session in early September in a 'laboratory' setting where users would be able to feed back their experience directly to the HFEA's contractor. The Government Digital Service (GDS) assessment of the Clinic Portal to enable progression to 'live' was scheduled for October 2016.

**7.6.** It was originally planned to make the beta version of the website available to the public a few weeks after showing it to the clinics. However, the HFEA was prevented from doing so due to an injunction granted by the High Court on 14 July, following an application brought by a clinic. The injunction was subsequently lifted and the website proceeded to public beta on 12 August 2016.

**7.7.** The feedback from public beta would be one element of the evidence that would inform the decision on the final shape of the new website. The IfQ Advisory Group would be invited to meet

again in order to help inform the set of recommendations that would be put to members at the next meeting in November 2016.

- 7.8.** The Director of Compliance and Information advised members the Executive felt that, with the judicial review pending, it would make sense to postpone the GDS assessment until any legal disputes were resolved. The GDS 'live' assessment was therefore scheduled for late January 2017.
- 7.9.** Members noted that there were two operational issues as a consequence of this delay:
- The current HFEA website content management system was dated and no longer supported by the original supplier, which would lead to instability from time to time. This had been managed to date but this risk remained as long as it remained as the HFEA's official site
  - There had been a concentration of resources in preparing the website for beta launch. This reallocation of resources had had an effect on planning assumptions, in particular relating to development work necessary for 'Release Two' – the data submission module.
- 7.10.** Progress on 'Release Two': the Director of Compliance and Information advised members that substantial work had been completed on all the necessary processes and proof of concept such that development work and design work could progress at pace. However, the additional work set out above meant that the end of October 2016 release expectations for EDI users (those clinics submitting directly to the HFEA) was unlikely to be met. A revised plan was now being developed.
- 7.11.** The Director of Compliance and Information advised that the data migration and cleansing work was a little behind schedule, also as a result of diversion of some resources. Data cleansing work remained primarily focussed on dealing with 'severity one' issues, with all issues expected to be resolved in September. If necessary, the data migration of the existing, cleansed database to a new structure could still occur by October 2016.
- 7.12.** Arrangements to provide assurance services for the data migration was now in place and an expert in data migration had been commissioned to provide a review of all the steps the HFEA had taken, and would take, prior to transfer.
- 7.13.** Whilst most clinics had been cooperative in fixing errors, there were issues with some clinics failing to deal swiftly with requests and the Executive continued to monitor progress closely.
- 7.14.** Timelines and budget implications: the Director of Compliance and Information reminded members that a revised programme plan had been finalised and signed off by the IfQ Programme Board in January 2016, in line with the overall £1.134m agreed by the Authority. On 24 May, the Senior Management Team (SMT) decided to allocate an additional £90k to the overall Programme budget to ensure that critical staff were retained on the team.
- 7.15.** The variance in September was explained by an underspend originally forecasted for the security consultant and this underspend should balance in the coming months once the work was completed and invoiced.
- 7.16.** Following a discussion, Authority members noted:
- Progress since the last Authority meeting
  - The revised timelines in relation to the website and 'Release Two' – the data submission system



- Programme timelines and budget implications.

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## 8. Strategy 2017-20

- 8.1.** The Head of Business Planning presented this item and advised members that the Executive had prepared an early outline of the strategy which had been informed by workshops and discussions with both Authority members and staff. The Head of Business Planning emphasised that this was a draft outline strategy for discussion with stakeholders during the autumn.
- 8.2.** Members were asked for their thoughts on whether the Executive had taken the right approach in the following areas in particular:
- Setting the strategy around the different needs of patients and donors through the various stages of treatment and donation
  - Including donor conception issues in with fertility treatment and that the Lifecycle campaign should come to an end, whilst continuing to use the good work the campaign had produced
  - Data and embryo research – whether to focus on facilitating patient choice in this area or to promote research and innovation and increasing consent rates.
- 8.3.** The Head of Business Planning advised members that the centre of the new strategy would be the HFEA's ongoing vision for high quality care for everyone affected by assisted reproduction. Based on research during the current strategy, the Executive had identified stages along the patient and donor pathway, setting out their needs at each stage and considering their interaction points with clinics and the HFEA. Members noted that patients and donors were not the HFEA's only stakeholders but they should be the main focus.
- 8.4.** The Head of Business Planning provided a summary of those stages. These were set out in more detail in the draft strategy together with what the HFEA wanted to achieve for patients and what patients should be able to do at each stage:
- Researching fertility treatment or donation
  - Making contact with a clinic and starting to make initial decisions
  - Having treatment or being an active donor
  - After treatment or donation.
- 8.5.** There were three main areas of strategic focus, under which the paper identified what the Authority believed should change, how this could be accomplished (through what tactics), and with what outcomes or measures of success. The three main areas were:
- Consistent support and outcomes for patients
  - Safe, ethical, effective, proven treatment
  - Improving standards through intelligence.
- 8.6.** The Head of Business Planning emphasised that post-IfQ and at the end of the current strategy, the HFEA would have the following tools and resources available in order to help deliver the strategy, including but not exclusively:
- New information for patients and donors on treatments, options and finding a clinic



- Easy-to-understand measures of quality in clinic services
- Patient ratings system for clinics
- Simpler data submission and clinic performance system
- A new register, enabling better analysis of treatments, outcomes and trends in clinical practice.

- 8.7.** Members noted that the proposed strategy had situated its ambitions for donor conception patients and for donors within several strands relating to support throughout treatment, good experience of care and evidence-based, effective treatments. The Lifecycle campaign was originally needed to reach new audiences (such as those thinking about going abroad for treatment). However, with the HFEA's new website and tone of voice, and a willingness to reach that wider patient audience, there was much less justification for a dedicated donation campaign and the resources to support it.
- 8.8.** The Head of Business Planning advised members that, in relation to the whole area of new and emerging treatments and developing science and whether those were evidence-based yet – or at all – there was often poor, misleading or sensationalised media coverage. Unfortunately, some of the available scientific information required a lot of expert interpretation to make it accessible to people without any scientific background. Consequently, part of the strategy would be to increase patients' understanding of subjects such as emerging new treatments or genetics and genomics, and to ensure that patients are given the right treatment for them. Members noted that the HFEA already had in place a mechanism for assessing the evidence of effectiveness, with a scientific committee in place, and the intention was regularly to update all the scientific and treatment information on the HFEA website, making it as easy to understand as possible.
- 8.9.** The Head of Business Planning advised members that, as part of its role as a regulator, the HFEA could 'raise the bar' by driving up sector standards through its regulatory work, to encourage greater consistency and excellence between clinics and within clinics, and being directive and challenging when necessary and proportionate to do so. The HFEA would also sometimes need to 'push the bar', setting new standards or higher standards and expectations, where there were perhaps none before, in response to new developments or new trends in the sector.
- 8.10.** The Head of Business Planning provided members with a summary of next steps, which would include stakeholder engagement via meetings in the autumn and winter and through a continuing conversation with staff. Focus groups with patients were also planned for the winter. Members would be presented with the stakeholder feedback so far at a workshop prior to the November Authority meeting, to shape the final draft strategy ready for sign-off at the January 2017 Authority meeting. The plan was to publish the strategy in April 2017, with a launch at the annual conference in March.
- 8.11.** The main points that emerged from the discussion were that members particularly welcomed the focus on patients. Members were of the view that it was important to ensure that the HFEA's continued commitment to donors and donation was clear throughout the strategy. There could be a risk that the HFEA was perceived as no longer being committed to donation issues because there was no longer a specific separate section about donation in the strategy, especially since the Lifecycle work was also coming to an end at the same time.

- 8.12.** Members also agreed that the final published strategy document should be short, focused and concise, and include clear strategic objectives below the vision level.
- 8.13.** Members welcomed the focus on embryo research. They felt, however, that it was important to substantiate that the HFEA had the capacity and capability to deliver the resulting work.
- 8.14.** Following the discussion, members approved the early outline of the strategy, subject to the necessary revisions and amendments raised, prior to further discussion with stakeholders in the autumn.

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## **9. Compliance activities 2015/16: a review**

- 9.1.** The Chief Inspector introduced this item and advised members that the paper was the second annual report on compliance activities. The paper included:
- an overview of the type and number of non-compliances found on inspection or identified through the HFEA's risk-based assessment tool (RBAT) or other reporting mechanisms
  - a review of the actions taken in the inspection year April 2015 to end of March 2016 to promote compliance by licensed clinics and research centres with the HFE Act 1990 (as amended)
  - an assessment of the effectiveness of the regulatory methods employed by the HFEA and the extent to which they had an impact on the sector.
- 9.2.** 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 2015 and 31 March 2016, and a comparison with the 2014/15 inspection findings.
- 9.3.** 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:
- 84 inspections at clinics: 35 treatment and or storage renewal inspections, 36 treatment and or storage interim inspections and 13 additional inspections in 2015/16, an increase of 60% on the previous year
  - In addition, 18 inspections at research centres were carried out
  - 445 recommendations for corrective action at treatment centres in 2015/16 with 373 having been fully implemented as at 26 July 2016 (84%)
  - 264 recommendations to correct higher risk critical and major non-compliances with 222 of those implemented as at 26 July 2016 (84%).
- 9.4.** The Senior Inspector advised members that, in post-inspection feedback, 93% of respondents inspected in 2015/16 agreed that inspection had promoted improvement to the way their clinic carried out its work. Generally, less than 90% of respondents were happy with the preparation, delivery and reporting of their inspection. This data suggested that the inspection team were delivering the objective to improve the quality and safety of patient care as set out in the HFEA's strategy.

- 9.5.** The Senior Inspector advised members that in 2015/16 the HFEA found the sector more compliant than the previous year. This conclusion was based on inspectors finding fewer non-compliances per inspection in 2015/16 than in the previous year. Another finding was that the improvement in non-compliance was seen across virtually all areas of practice except two: medicines management and legal parenthood consent. The increase in prevalence in these areas was thought to be related to the increased regulatory focus on these areas of practice.
- 9.6.** The medicines management non-compliances comprised four critical, 28 major and nine other non-compliances. Seven had not yet reached their implementation deadlines as at 26 July. The remainder had all been corrected. In many cases the non-compliances reflected problems in medicines management documentation and practices which were contrary to professional body guidelines or relevant legislation, and thus their severity had been elevated. The four critical non-compliances involved multiple failings which had given significant and immediate cause for concern and the inspection team had ensured corrective actions to address them were swiftly implemented.
- 9.7.** The legal parenthood non-compliances comprised two critical and five major non-compliances. All had subsequently been addressed.
- 9.8.** 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.
- 9.9.** 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.
- 9.10.** 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.
- 9.11.** Clinics' performance in 2015/16 had worsened compared to the previous year in relation to the submission of critical treatment information, but this was mainly due to the activity being undertaken by key teams within the HFEA, relating to IfQ developments. The number of alerts relating to invoice payments had significantly decreased, suggesting the clinics' performance in meeting the enhanced performance expectations had been successful. Further, in relation to success rates and multiple birth rates, the volume of alerts had remained constant, albeit that the population of clinics receiving these alerts had changed, suggesting an improvement in performance by some.
- 9.12.** Of the ten clinics receiving the highest number of alerts last year, five of those clinics remained in the same category. This suggested either difficulties that could take time to improve, or limitations in terms of those clinics' culture of improvement. It was clear that some refocusing of performance

in relation to some clinics' multiple birth minimisation plans was necessary to move the overall sector average performance closer to the 10% target.

- 9.13.** The Senior Inspector advised members that the HFEA felt the risk tool provided useful and timely information for 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 when needed.
- 9.14.** The Chief Inspector summarised the findings of the report, what the HFEA wanted to happen going forward and how the HFEA was going to implement this.
- 9.15.** The findings of the report suggested that:
- There was an increase in inspection activity by 60%
  - The inspection process was effective, and promoted improvement
  - There was evidence that some clinics had not embedded lessons learned or embraced risk based thinking
  - There was some evidence of ineffective root cause analysis (RCA) and the absence of RCAs being documented
  - Alerts on success rates had remained consistent
  - The majority of clinics embraced single embryo transfer (SET).
- 9.16.** The HFEA wanted:
- The sector to continue to be safe and to provide a quality service which was compliant
  - The HFEA to adapt its inspection techniques to ensure the above
  - Clinics to embrace quality and lessons learned
  - Clinics to be more effective at RCA
  - Clinics to be more effective at internal audits
  - More clinics achieving the 10% SET figure.
- 9.17.** The HFEA would achieve this by:
- Maintaining a credible, effective and safe regulatory process by standardising and increasing the intensity and focus, and evolving the approach where necessary
  - Continuing the series of workshops that had been established to provide assistance to the sector and giving clinic staff a better understanding of RCA and human factors
  - Working with policy colleagues, partners and the sector on re-invigorating the multiple births strategy
  - Performing more frequent trend analysis in order to respond pro-actively.
- 9.18.** Following a discussion, members noted the inspection and monitoring work undertaken, and the effect of this on the performance of the sector. In terms of lessons, the Authority saw an opportunity to address inconsistency in performance between clinics, on a range of measures including multiple birth rates. This will require signalling to clinics that the Authority is ambitious to see further improvement not just on current standards but on a continuous improvement basis - that is 'raising' the bar and 'pushing' the bar. Members noted the report and the summary of actions set out in section four of the paper.

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## 10. Adverse incidents in fertility clinics

**10.1.** The Chief Inspector introduced this item and provided a summary of the presentation which included:

- The HFEA's vision for decreasing incidents
- A background on incidents
- The investigation process
- Root cause analysis (RCA)
- Human error
- Human factors
- Recommendations
- What the HFEA want clinics to do
- How the HFEA envisaged achieving this.

**10.2.** The Clinical Governance Inspector reminded members that the HFEA now published an annual incident report, a draft of which was included in the set of papers and would be published later in September.

**10.3.** During 2015, there were 517 incidents reported by the sector to the HFEA, an increase of 4%, although members noted there were more treatment cycles being carried out. However, there was still room for improvement in the sector and incidents and re-occurring incidents still continued to happen.

**10.4.** The Chief Inspector provided members with a summary of what constituted a good investigation, which included:

- remedial action
- RCA
- corrective action
- preventative action
- monitoring.

**10.5.** RCA was quite a simple methodology and, in healthcare, it was essential to discover and address the root cause to improve the delivery of care and to prevent or minimise its reoccurrence. The Chief Inspector advised members that human error was often identified as the root cause. However, human error (defined as 'an act or thought that unintentionally deviated from what was correct, right or true') would itself have a root cause, and it was important that the real root cause was identified so that learning and improvement could occur.

**10.6.** Following a discussion, during which the Chair emphasised that it was essential there was an improvement in clinic performance next year, members agreed that:

- The sector should continue to engage with the clinical governance team within the HFEA
- The HFEA should standardise the approach to incident investigations to maintain and increase the focus on this area of performance

- The use of 'human error' as the root cause of an incident should be avoided, since this failed to get to the true root cause.
- The fertility sector needed to adopt a more scientific and methodical approach to incident/non-conformity investigating
- A group-wide approach to lessons learned from incidents should be promoted.

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## 11. Any other business

- 11.1.** The Chair confirmed that the next meeting would be held on 16 November at ETC Venues Victoria, 1 Drummond Gate, London SW1V 2QW. Members were asked to confirm their attendance to the Executive Assistant to the Chair and Chief Executive as soon as possible.

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## 12. Chair's signature

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

**Signature**

**Chair**

**Date**