Human Fertilisation and Embryology Authority

Minutes of the Executive Licensing Panel

Meeting held at HFEA, Finsbury Tower, 103-105 Bunhill Row, London, EC1Y 8HF on
26 June 2015

Minutes – item no. 2

Centre 0008 (Midland Fertility Services) – Interim Inspection Report

Members of the Panel:	Juliet Tizzard Director of Strategy & Corporate Affairs (Chair) Joanne Anton Policy Manager Rachel Hopkins Head of Human Resources
Members of the Executive in attendance:	Sam Hartley Head of Governance & Licensing Dee Knoyle Committee Secretary

Declarations of interest: members of the panel declared that they had no conflicts of interest in relation to this item.

The panel had before it:

- HFEA protocol for the conduct of meetings of the Executive Licensing Panel
- 8th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- decision trees for granting and renewing licences and considering requests to vary a licence (including the PGD decision tree)
- guidance for members of the Authority and committees on the handling of conflicts of interest approved by the Authority on 21 January 2009
- guidance on periods for which new or renewed licences should be granted
- standing orders and instrument of delegation
- indicative sanctions guidance
- HFEA Direction 0008 (where relevant) and any other relevant directions issued by the Authority
- guide to licensing
- compliance and enforcement policy
- policy on the publication of Authority and committee papers

Consideration of Application

1. The panel noted that Midland Fertility Services, centre 0008, has held a licence with the HFEA since 1992. The centre provides a full range of fertility services.

2. The panel noted that the centre's licence is due to expire on 31 July 2017.

3. The panel noted that the inspection took place on 15 April 2015.

4. The panel noted that in the 12 months to 28 February 2015, the centre provided 874 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a medium-sized centre.

5. The panel noted that for IVF and ICSI, HFEA-held register data for the period 1 December 2013 to 30 November 2014 showed the centre's success rates were in line with the national average.

6. The panel noted that in 2014, the centre reported nine cycles of partner insemination with two clinical pregnancies. This was consistent with the national average.

7. For the year ending November 2014, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 25%: this means that the centre's multiple live birth rate is likely to be higher than the 10% maximum multiple live birth rate target for this period.

8. The panel noted that at the time of the interim inspection on 15 April 2015, one critical, one major and one other area of non-compliance was identified. In particular, the panel noted the non-compliances relating to medicine management and multiple births. The panel noted that since the inspection the Person Responsible (PR) has made significant progress in addressing some of the recommendations and has committed to fully implementing all of them within the prescribed timescales.

9. The panel noted that some improvement is required in order for the centre to reflect suitable practices. The centre has a quality management system in place and the PR is encouraged to continue to use it to monitor and improve the service provided.

10. The panel noted that the Inspectorate recommends the continuation of the centre's treatment and storage licence.

Decision

11. The panel had regard to its decision tree and was satisfied that the centre was fit to have its treatment and storage licence continued.

12. The panel noted the non-compliances identified at the interim inspection and urged the PR to continue making progress and fully implement all of the recommendations within the prescribed timescales. The panel encouraged the PR to continuously review the centre's practices.

13. The panel endorsed the Inspectorate's recommendation to continue the centre's treatment and storage licence.

Signed: Date: 8 July 2015
Juliet Tizzard (Chair)

Interim Licensing Report

Centre name: Midland Fertility Service Centre
Centre number: 0008
Date licence issued: 01 August 2013
Licence expiry date: 31 July 2017
Additional conditions applied to this licence: None
Date of inspection: 15 April 2015
Inspectors: Douglas Gray (lead), Gill Walsh, Shanaz Pasha (observer)
Date of Executive Licensing Panel: 26 June 2015

Purpose of the report

The Human Fertilisation and Embryology Authority (HFEA) is the UK's independent regulator of the fertility sector. The HFEA licenses centres providing in vitro fertilisation (IVF) and other fertility treatments and those carrying out human embryo research.

Licensed centres usually receive a licence to operate for up to four years and must, by law, be inspected every two years. The full inspection prior to a licence being granted or renewed assesses a centre's compliance with the law and the HFEA's Code of Practice (CoP) and Standard Licence Conditions (SLC).

This is a report of an unannounced interim inspection together with our assessment of the centre's performance based on other information. We do this at the mid-point of the licence period. For 2015-2017 the focus of an interim inspection is:

- **Quality of care:** the quality of care provided by a centre is defined by positive healthcare outcomes and a positive patient experience delivered via safe and effective care.
- **Patient safety:** patient safety is a fundamental and essential attribute to quality healthcare: without safety there cannot be high quality. Improving safety is an ethical imperative for healthcare providers and the individuals who deliver that care.
- **Patient experience**: understanding what matters to patients and improving the patient experience is crucial in delivering high quality care.

We also take into account the centre's own assessment of its service, the progress made in implementing the actions identified at the last inspection, and our on-going monitoring of the centre's performance.

The report represents a mid-term evaluation of a centre's performance based on the above. The aim is to provide the Authority's Executive Licensing Panel (ELP) with information on which to make a decision about the continuation of the licence.

Summary for the Executive Licensing Panel

The inspection team recommends the continuation of the centre's licence. In particular we note the positive comments made by patients.

The Executive Licensing Panel is asked to note that at time of the inspection there were a number of areas of practice that required improvement, including one critical, one major and one 'other' areas of non-compliance as follows:

Critical non-compliance:

- **The PR should review practices relating to the management of medicines, including controlled drugs, to ensure that medicines are stored, administered and disposed of in accordance with requirements.**

Major areas of non-compliance:

- The PR should keep the effectiveness of the centre's multiple births minimisation strategy under review, and its application and implementation to ensure that the 10% multiple live birth rate target is not exceeded.

'Other' areas of practice that require improvement:

- The PR should ensure that the centre's records of stored gametes and embryos are reviewed at regular intervals to identify those samples for which the consent is due to expire.

The PR has made significant progress in implementing the recommendations made in this report and has given a commitment to fully implementing the remainder of all of the recommendations. The centre's inspector will monitor progress towards full implementation.

Information about the centre

Midland Fertility Service was first licensed by the HFEA in 1992. The centre provides a full range of fertility services. Treatments are provided to both NHS and self-funded patients. The centre's licence was last renewed following an inspection in February 2013. In August 2014 the centre's licence was varied to change the location.

The centre provided 874 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 28 February 2015. In relation to activity levels this is a medium centre.

Details of Inspection findings

Quality of Service

Each interim inspection focuses on the following themes as they are important indicators of a centre's ability to provide high quality patient care and to meet the requirements of the law.

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period 1 December 2013 and 30 November 2014 show the centre's success rates are in line with the national average.

In 2014, the centre reported a total of nine cycles of partner insemination with two clinical pregnancies. This pregnancy rate is consistent with the national average.

Multiple births[2]

The single biggest risk of fertility treatment is a multiple pregnancy.

For the year ending November 2014, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups is 25%: this means that it is likely that the centre's multiple live birth rate will be higher[1] than the 10% multiple live birth rate target (recommendation 2).

Witnessing

Good witnessing processes are vital in ensuring there are no mismatches of gametes or embryos, and that identification errors do not occur. We were not able to observe any laboratory activities during the inspection but we were able to have discussions about witnessing with staff. Witnessing procedures described are compliant with HFEA requirements.

Consent to the storage of cryopreserved material

The storage of gametes and embryos is an important service offered by fertility clinics as it can enable patients to preserve their fertility prior to undergoing other medical treatment such as radiotherapy. The storage of embryos not required for immediate use also means that women can undergo further fertility treatment without further invasive procedures being

[1] The data in the Register may be subject to change as errors are notified to us by clinics, or picked up through our quality management systems. Centre success rates are considered statistically different from the national averages, and multiple pregnancy rates are considered statistically different from the 10% multiple live birth rate target, when $p \leq 0.002$.

[2] The HFEA use a conversion factor of 1.27 to convert the 10% multiple live birth rate (MLBR) target to a multiple pregnancy rate (MPR) target of 13%.

performed. During the inspection we reviewed the centres procedures for ensuring gametes and embryos are stored in accordance with the consent of the gamete providers.

During inspections in 2009, 2011 and 2013, we observed gametes and/or embryos that were in storage beyond the date for which consent had been given. At the current inspection, all gametes and embryos were within their consented storage period. However we had some concerns there did not appear to be a regular schedule, or sufficient resources available to implement the schedule, to identify gametes/embryos for which the consent period was coming to an end (recommendation 3). Taking into consideration our previous recommendations, our concern was that lack of sufficient oversight could contribute to gametes/embryos remaining in storage after consent to storage had expired.

Staffing

Having the right numbers of staff, competent to carry out highly technical work in a non-pressured environment is important in infertility services. Staffing levels observed in the course of the on-site inspection appeared to be suitable for the activities being carried out.

Quality Management System (QMS)

It is important that clinics audit all of their practices at least every two years to ensure they are delivering the expected quality of service, that standard operating procedures are followed and that the centre's processes meet regulatory requirements. It is also important that these audits are robust and that any changes that are identified as required are implemented as this helps ensure that clinics continuously improve.

The effectiveness of the centre's QMS was assessed by reviewing the following audit reports: witnessing, consent to storage, and medicines management. Midland Fertility Service's procedures for auditing and acting on the findings of audits are partially compliant with requirements. The following non-compliance was noted:

- There was no audit of the controlled drugs register against approved protocols or regulatory requirements to ensure that the record of the use of controlled drugs is accurate and complete and that this record correlated with the record made in the patient's primary record;
- Whilst we saw evidence that corrective actions identified following an audit of witnessing had been implemented, there was no documented record of this including the date on which these actions were taken.

Medicines Management

It is important that a clinic follows best practice for medicines management both to protect patients and ensure that medicines are stored, administered and disposed of in the correct way. We reviewed the centre's processes for medicines management and the safe storage, disposal and administration of medicines.

We observed a number of practices relating to the general management of medicines that required improvement:

1. We observed two tablets on the pharmacy store room shelving that had been cut from the original packaging and were no longer identifiable (medicine name, dose or expiry date). The use of medicines that can not be confidently identified poses a

significant risk to the safety of patients. Staff acknowledged that these tablets should not have been in their stock.
2. We observed a sheet of labels for midazolam (a drug used for conscious sedation) on which the dose had been written over to the extent it was no longer legible. These labels were used to label syringes prior to administration and there is potential for these labels to cause confusion to those administering the drug.
3. In one out of five patient records reviewed, we observed a form recording the administration of an intravenous medicinal product on which the date of administration, the person administering it and the name of the second person checking the drug was not recorded.
4. We observed that nurses regularly dispensed medicines. Neither the nurses that were dispensing nor the health care assistants assigned to check what is dispensed, have received specific training in the dispensing of medicines, nor was there oversight of this practice by a registered pharmacist.
5. The practice of decanting medicines from their original packaging to a hand labelled bottle was described to us. The senior nurse described that this was done when a part packet of tablets was required and therefore a full description of the medicine, dose or expiry date was not visible on the original packaging. Whilst there is no guidance that specifically advises against this practice, we were however concerned that the lack of suitable training of staff at the centre introduced an element of risk, for example medicines being incorrectly labelled.

We observed a number of practices relating to the management of controlled drugs that required improvement:

1. There was no regular check of controlled drugs stock against the balance as recorded in the controlled drugs register.
2. We observed omissions from the controlled drugs register of medicines used, including the date of administration, the dose dispensed / administered, and witness signature. In addition, the dose administered was not routinely recorded although the amount dispensed was; this meant that any unused portion of the medicine was not traceable. The discard of the unused portion of any drug dispensed was not routinely witnessed by a second person or recorded.
3. There was no audit of the controlled drugs register against approved protocols or regulatory requirements to ensure that the record of the use of controlled drugs is accurate and complete and that this record correlated with the record made in the patient's primary record. It is important that the use of controlled drugs is audited and action is taken if necessary.

Our observations caused us sufficient concern that on the day of the inspection we asked the centre to take immediate action. Confirmation was received within a week that actions we had requested had been taken. Our recommendation takes this into account (recommendation 1).

Infection Control

Having suitable procedures in place to ensure that patients experience care in a clean environment is important, as well as ensuring that both patients and staff are protected from acquiring infections. During the inspection, we assessed compliance with infection control guidance by observation and found that the centre's procedures were compliant with guidance.

Equipment and Materials

It is important that products (known as medical devices) that come into contact with gametes and/or embryos are approved for use in treatment to ensure the safety of gametes and embryos and patients. The approval of such products is denoted by the issue of a 'CE mark'. The CE mark status of the following medical devices was reviewed in the course of the inspection: media, plastic ware. The centre is compliant with requirements to use CE marked medical devices wherever possible.

Patient experience

During the inspection visit we spoke to one patient who provided feedback on her experiences and observed interactions between centre staff and patients. A further 14 patients also provided feedback directly to the HFEA in the time since the last inspection. Feedback was generally positive, with 10 of the individuals providing written feedback commenting that they had compliments about the care that they received, and that they felt that staff were caring and supportive.

On the basis of this feedback and observations made in the course of the inspection it was possible to assess that the centre:

- has respect for the privacy and confidentiality of patients in the clinic;
- gives prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions;
- maintains an effective system for responding to patient phone calls.

Monitoring of the centre's performance

In addition to commenting on evidence gathered on the inspection it is important to report on the centre's performance since the granting of the licence based on other evidence available to us.

Compliance with HFEA standard licence conditions

From the information submitted by the centre in their self assessment questionnaire and from observations during the visit to the centre, the inspection team identified no further non-compliances.

Compliance with recommendations made at the time of the last inspection

Following a renewal inspection in 2013 recommendations for improvement were made in relation to one critical and seven major non-compliances and four 'other' areas of practice that required improvement. The PR provided evidence that all these were implemented within the agreed time frames.

On-going monitoring of centre success rates and risk tool alerts

During the period since the last inspection, the centre received five alerts relating to multiple pregnancy rates and they responded to these. A recommendation has been made relating to the centre's clinical multiple pregnancy rate (see recommendation 2).

Provision of information to the HFEA

Clinics are required by law to provide information to the HFEA about all licensed fertility treatments they carry out. This information is held in the HFEA Register. The clinic is compliant with requirements to submit information to the HFEA.

Legal parenthood

The partners of women treated with donated gametes or embryos, where the couple are not married or in a civil partnership, must give written consent in order to become the legal parent of any child born. If this consent is not documented properly or if proper information is not provided or counselling offered prior to both parties giving consent there may be doubt about the effectiveness of the consent and in some cases it may be necessary for a patient couple to obtain a court declaration to establish legal parenthood.

In February 2014, HFEA asked all centers to audit their procedures for giving patients an opportunity to consent to legal parenthood to ensure they are suitable, to report the findings of the audit to us and to respond to those findings. A report of the audit was submitted within the required timeframe and the clinic have acted on their findings. During the inspection, we reviewed the centre's audit and found that it had been performed according to the method specified by HFEA.

Annex 1

Areas of practice that require the attention of the Person Responsible

The section sets out matters which the Inspection Team considers may constitute areas of non compliance. These have been classified into critical, major and others. Each area of non-compliance is referenced to the relevant sections of the Acts, Regulations, Standard Licence Conditions, Directions or the Code of Practice, and the recommended improvement actions required are given, as well as the timescales in which these improvements should be carried out.

Critical areas of non-compliance

A critical area of non compliance is an area of practice which poses a significant risk of causing harm to a patient, donor, embryo or child who may be born as a result of treatment services. A critical area of non-compliance requires immediate action to be taken by the Person Responsible.

Area of practice and reference	Action required and timescale for action	PR Response	Executive review
1. The centre's processes for medicines management and the safe storage, disposal and administration of medicines were not compliant with requirements. (Section 27, The Misuse of Drugs Regulations, 2001;	The PR should review practices relating to the management of medicines, including controlled drugs, to ensure that medicines are stored, administered and disposed of in accordance with legislation and best practice guidance. On 17 April 2015 we wrote to the centre asking for immediate action to be taken with respect to the observations made	In addition to all the 'with immediate effect' changes that Heidi outlined in her email to you of 24th April , the audit of the controlled drugs register has been performed and will be undertaken regularly. The review by a qualified pharmacist with a special interest in reproductive medicine (Mr Harmohn Laehri MRPharmS) covered the entire area of pharmacy practice and medicine management as	The PR's summary of their expert review provides assurance that significant progress has been made. As advised, the PR should aim to audit compliance against revised practices within three months. A summary report of these audits should be forwarded to their inspector by 22 September 2015. Also, as requested in our 17 April 2015 email, a copy of the centre's

The Controlled Drugs (Supervision of Management and Use) Regulations, 2013; Nursing & Midwifery Council, Standards for Medicines Management, 2010; standards 4 and 26. SLC T36.)	during the inspection. This included checking that all medicines and labels used for medicines were clearly identifiable; to implement a stock check of controlled drugs and conduct an audit of their use; and ensure records relating to the administration of medicines, including the controlled drug register, were completed with all information that was required. The practice of decanting medicines from their original packaging to manually labelled bottles was to cease subject to the risk of this practice being assessed by a registered pharmacist. On April 24 2015 the centre responded indicating that the above actions had been taken or initiated, as appropriate. The PR should now initiate an investigation to identify how and or why requirements for compliant medicines management have not been adhered to. A summary report of the findings should be sent to	undertaken at the clinic. He made numerous recommendations which we are implementing as rapidly as possible. The principle recommendations were that : Monthly expiry audits should be implemented : This has been done Medication must remain in the manufacturers or pharmacy's original packaging at all times : done Medications that can be obtained without undue difficulty or delay from a community pharmacy should not be routinely prescribed and dispensed by the medical staff. Implemented. Patients requiring low value, non urgent items will have a private prescription written. This will have no cost implications for patients, but may inconvenience them. Time critical or specialist drugs may continue to be prescribed and dispensed by the clinical team (with appropriate training and checking) but extension and/or dosage changes of medicines require a Dr's prescription (via an emergency specific patient directive) if 'out of core hours' . Implemented The Care Quality Commission	audit of the controlled drugs register against records of the administration of that medicinal product in patient notes should be forwarded to their inspector by 24 June 2015. We encourage the PR to continue their investigation and we will further discuss this with the PR during a planned follow-up meeting early June 2015.

	their inspector by 24 May 2015. The PR should also commission a review of pharmacy practice and management of medicines by an independent registered pharmacist. It is expected that this review should be completed by 24 May, and a summary report, including corrective actions and the timescale for their implementation should be sent to the centre's inspector. Within three months of the implementation of corrective actions the centre should complete an audit of practice to ensure that corrective actions are being effectively implemented and have ensured on-going compliance with requirements.	should be informed of the identity of the CD Accountable Officer (Heidi Birch) via their portal and a list of authorised witnesses for the destruction of CDs should be maintained. Implemented. Both the CQC and the Home Office had inspected the site prior to licensing in 2014 and had not pointed out these requirements.	

‘Major’ area of non-compliance

A major area of non compliance is a non critical area of non compliance:

- which poses an indirect risk to the safety of a patient, donor, embryo or child who may be born as a result of treatment services;
- which indicates a major shortcoming from the statutory requirements;
- which indicates a failure of the Person Responsible to carry out his/her legal duties;
- which can comprise a combination of several ‘other’ areas of non-compliance, none of which on their own may be major but which together may represent a major area of non-compliance.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
2. For the year ending November 2014, the centre’s clinical multiple pregnancy rate was 25%. If there is no change to the centre’s multiple pregnancy rate of 25%, our analysis suggests that the 10% multiple live birth target is likely to be exceeded. The single biggest risk of fertility treatment is a multiple pregnancy. (CoP 7.1 and T2)	The PR should keep the effectiveness of the centre’s multiple births minimisation strategy under review, and its application and implementation to ensure that the 10% multiple live birth rate target is not exceeded. We acknowledge that the centre has not received a risk tool alert for five months. We will therefore continue to monitor the centre’s multiple pregnancy rate, allowing sufficient time for the centre to assess the impact of their strategy. If our data suggest that the centre are making no progress towards meeting the 10% multiple live birth target by December 2015, we will consider	The move to the new building with its ‘scrubbed air’ positive pressure system and the institution of enhanced infection control measures (separate clinical suites, theatre scrubs etc) has led to improved pregnancy rates but also a rise in multiple pregnancy rates above the target. The Laboratory Director and Director of Nursing have visited three IVF Units recently which have succeeded in maintaining pregnancy rates whilst simultaneously reducing the multiple rate. In the light of their suggestions and recommendations, our clinic has changed the criteria for Blastocyst culture and widened the criteria for Top Quality Embryo (TQE) status. I attach the new	The PR has implemented a new eSET policy and has committed to keeping their multiple pregnancy rate under review. We will continue to monitor the centre’s multiple pregnancy rate and assess progress made in December 2015.

	whether it is appropriate to take further regulatory action in accordance with our Compliance and Enforcement Policy which may entail analysis of the suitability of the centres practices in relation to multiple births (SLC T2).	criteria, which have been implemented with immediate effect. We will continue to review the pregnancy rates and multiple rate in our regular laboratory and clinical meetings.	

‘Other’ areas of practice that requires improvement

Areas of practice that require improvement are any area of practice in which failings occur, which cannot be classified as either a critical or major area of non-compliance, but which indicate a departure from statutory requirements or good practice.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
3. The PR should ensure that the centre’s records of stored gametes are regularly reviewed. (CoP 17.19 and 17.20)	The PR should ensure that the centre’s records of stored gametes and embryos are reviewed at regular intervals to identify those samples for which the consent is due to expire, allowing sufficient time for the gamete providers to be contacted. The centre’s inspector should be advised of the actions taken to ensure that this takes place in responding to this report. The PR should review the relevant SOP(s) to ensure that the procedure is sufficiently described, and review staffing arrangements to ensure that adequate resource is available to implement the SOP. An audit against this SOP should be completed and forwarded to the centre’s inspector within six months of the inspection (by 15 October 2015).	Although the bring-forward system of contacting of patients ahead of consent ‘expiry’ date is managed well and is robust, it is recognised that the physical disposal of the gametes and embryos is occasionally delayed. This is often due to the reluctance of patients to reply to correspondence and it therefore becomes a lengthy administrative procedure to complete all of our final checks prior to discarding samples. A review of the SOP plus patient literature is to be undertaken with the staff involved to try and streamline the process.. It is envisaged that more time and staff will be regularly time-tabled into the laboratory diary to fulfil this requirement.	The PR has committed more staff/time to monitor the bring-forward system. We await the outcome of the audit against the centre’s SOP(s) due by 15 October 2015.

Additional information from the Person Responsible
I hope that these comments will reassure you and the committee that we have addressed the issues raised at the Inspection. Kind regards Gill Lockwood Medical Director and PR