Interim Inspection Report

Midland Fertility Services
0008

Date of Inspection: 29.03.2007
Date of Licence Committee: 20.06.2007

CENTRE DETAILS

Centre Address	Midland Fertility Services 3rd Floor Centre House Court Parade Aldridge WS9 8LT
Telephone Number	01922 455911
Type of Inspection	Interim
Person Responsible	Dr. Gillian Lockwood
Nominal Licensee	Anna Kavanagh
Licence Number	L0008/12/a
Inspector(s)	Dr. Neelam Sood
	Mr. Tony Knox
	Mr. Andy Glew
Licence expiry date	31/07/2008

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About the Inspection:
This inspection visit was carried out on 29/03/2007 and lasted for 7 hours. The report covers the pre-inspection analysis, the visit and information received between 2005 and 2006.

The purpose of the inspection is to ensure that centres are providing a quality service for patients in compliance with the HF&E Act 1990, Code of Practice and to ensure that centres are working towards compliance with the EU Tissue and Cells Directive 2004/23/EC. Inspections are always carried out when a licence is due for renewal although other visits can be made in between.

The report summarises the findings of the interim inspection highlighting areas of good practice, as well as areas where further improvement is required to improve patient services and meet regulatory requirements. It is primarily written for the Licence Committee who make the decision about the centre's licence renewal application. The report is also available to patients and the public following the Licence Committee meeting.

At the visit the inspection team assesses the effectiveness of the centre through five topics. These are:
How well the centre is organised
The quality of the service for patients and donors
The premises and equipment
Information provided to patients and to the HFEA
The clinical and laboratory processes and competence of staff.

An evaluation is given at the end of each topic and for the overall effectiveness of the centre:
No Improvements Required – given to centres where there are no Code of Practice, legal requirements, recommendations or conditions that need to be imposed.
Some Improvements Required – given to centres that are generally satisfactory but with areas that need attention. Recommendations will usually be made to help Persons Responsible to improve the service.
Significant Improvements Required – given to centres that have considerable scope for improvement and have unacceptable outcomes in at least one area, causing concern sufficient to necessitate an immediate action plan or conditions put on the Licence.

The report includes a response form for the Person Responsible to complete following the inspection.

The HFEA welcomes comments from patients and donors, past and present, on the quality of the service received. A questionnaire for patients can be found on the HFEA website www.hfea.gov.uk .

Brief Description of the Centre and Person Responsible

Midland Fertility Centre is located on the outskirts of a parade of shops on the top floor of an office building. Recently a purpose built education centre and administration department have been built on the second floor where all the departmental meetings are held. The centre was first licensed in 1992 and treats private and NHS patients. This is a busy IVF centre providing more than 1000 cycles of licenced treatments a year, the majority being self funded. The unit is ISO 9001 accredited.

A joint inspection with the Healthcare Commission took place last year. The Healthcare Commission reported that the centre exceeded standards in relation to patient information and protocols were considered satisfactory.

The Centre is open to patients from 7.00 am to 6.30 pm Monday to Thursday and to 5.30 pm on Friday. Only Ultrasound scans and blood tests are routinely carried out at weekends. However occasionally embryo transfers are also carried at weekends.

The centre has a good history of compliance with previous licence conditions. The centre also offers complementary therapy to its patients with hypnotic relaxation and acupuncture treatment once a week.

Activities of the Centre

Licensed treatment cycles	987	
Donor Insemination	130	
Unlicensed treatments	127	
Research	None	
Storage	Yes	

Summary for Licence Committee

The inspection team recommends the continuation of centre's licence for treatment and storage.

Risk Assessment

The current risk score is 5%

Overall judgement of the effectiveness of the centre

No Improvements required	Some Improvement required	Significant Improvement required
	X	

Evaluations from the inspection

Topic	No Improvements required	Some Improvement required	Significant Improvement required
1. Organisation		x	
2. Quality of the service	x		
3. Premises and Equipment		x	
4. Information	x		
5. Laboratory and clinical processes		x	

Breaches of the Act or Code of Practice

Breach	Action required	Time scale
None	None	None

Non-Compliance

Area for improvement	Action required	Time scale
None	None	None

Recommendations	Time scale
Written agreement / contingency plan with other units to be drawn up	3 Months
Security between Theatre and laboratory	3 Months
Quarantine dewars to be alarmed	2 Months
Air quality in the Andrology Laboratory D or barely D in Andrology laboratory.	3 Months

Proposed licence variations

None

Changes/ improvements since last inspection

Recommendation	Action taken
Update Welfare of Child form	Done
Update laboratory protocols and add Witnessing protocol with each procedure	Done
Formal rota for responding to any emergency with dewars	Done

Report of Inspection findings

1. **Organisation**

Desired Outcome: The centre is well-organised and managed and complies with the requirements of the HFE Act.

Summary of findings from inspection
Evidence is drawn from:

- Leadership and management
- Organisation of the centre
- Resource management
- Risk management
- Incident management
- Contingency arrangements
- Business planning
- Clinical governance
- Payment of treatment fees

Areas of firm compliance
The inspection team considered the unit to be well organised and all staff interviewed during the course of the inspection were satisfied with the support received from senior management. The centre has an excellent education programme. Documentation supplied for the inspection included an organisation chart showing main functions and lines of accountability within the unit. The PR and a number of staff commented that the organisational structure and the operational procedures of the centre are appropriate for the licensed activities provided. Key members of staff have extensive experience of working in infertility clinics and have been in their positions for a number of years. The risk assessment procedures of practices and of facilities are well documented and found in place at the unit. All areas are risk assessed separately. A very good incident reporting system to comply with HFEA and HCC was seen on inspection. The minutes of the multidisciplinary team meetings, held at the centre to discuss practice related issues are made available to all the staff members. An example of these was seen on inspection. The PR confirmed that the staff is aware of the new HFEA standards and the requirements of the EU Tissue and Cells Directive. Payments to the HFEA Finance Department are made on time.
Areas for improvement
The PR stated that currently there is no formal contingency plan in place for the unit; however, there is a verbal arrangement with other major hospitals in the area.

Executive recommendations for Licence Committee
None
Areas not covered on this inspection
All areas covered

Evaluation
Only one improvement required

2. Quality of service

Desired Outcome: Patients receive a good standard of service, appropriate treatment and are treated with courtesy and respect.

Summary of findings from inspection:

- Live birth rates
- 'Welfare of the Child' arrangements
- Confidentiality (including safe storage of patients' records)
- Choice of treatments
- Privacy and dignity of patients
- Complaint handling
- Patient feedback and satisfaction
- Counselling facilities and services
- Donor selection
- Egg sharing and surrogacy
- Protection of children arrangements (for patients under 18yrs)

Live Birth Rates
The IVF/ICSI and FET success rates for all age groups are higher than the national average. Latest pregnancy results for January 2007 also appear to be well above the national standard including FET.
Areas of firm compliance
The patient information provided to the inspection team included information on success rates and is up to date. Patients are being informed that blastocyst transfer is available. Blastocyst transfer is being used as a way of moving towards transferring a single embryo in treatment cycles. The inspection team was informed that success rates for the centre are reviewed on a regular basis. Responses to the HFEA patient questionnaire revealed that patients at this centre are more satisfied than average with all aspects of the centre and their treatment. Two patients were interviewed on the day of inspection and the responses were positive about the quality of service they had received. The patients informed the inspection team that privacy and confidentiality about their treatment is well maintained. A news letter is also produced for patients, via the clinic website. A moderated 'on-line; forum is available to patients where they may share experiences. The complaint data base was reviewed during inspection. All of the complaints made last year have been resolved except one. An audit of counselling services provided to the inspection team. The Counsellor commented that she feels part of the team and is updated on changes within the centre. She attends multidisciplinary team meetings and stated that her CPD was up to date and evidence of this was provided during the inspection.

The Quality Management System was good. The inspection team noted that the medical records are stored in a dedicated area with only members of the centre having access to them.

The centre is currently importing sperm from abroad and submitting applications for special directions at the appropriate time.

An open day is held monthly, during which prospective patients are given information on the services available at the centre. At least one member of staff from each discipline attends the open day.

Individual performance for each staff member is also reviewed.

Firm compliance was assessed by the inspection team in this section.

Areas for improvement
None

Executive recommendations for Licence Committee
None

Areas not covered on this inspection
All areas covered

Evaluation
No improvements required

3. Premises and Equipment

Desired outcome: The premises and equipment are safe, secure and suitable for their purpose.

Summary of findings from inspection:

- Suitable premises
- Storage facilities for embryos and gametes
- Safe equipment, servicing and maintenance
- Prevention of incidents/ accidents

Areas of firm compliance
The centre is fit for the purpose; the door to the unit remains locked and access is via keypad lock. The administration team has recently relocated to the second floor. An education centre, library and conference room and a separate dining area for the staff has been created which was found to be satisfactory. A complaints poster, the centre's licence and counselling poster were seen in the reception area. Storage dewars are housed within the embryology laboratory. All dewars were appropriately alarmed except the quarantine tanks. A low oxygen alarm was also seen to be in place. There is a back-up generator in place which is tested regularly. All equipment is serviced regularly and a service log is maintained showing all agreements and calibration certificates. All incubators are alarmed. The labelling system in the laboratory is acceptable with three or more identifiable indicators. The dishes are labelled on the top and bottom. Traceability of products carried out and CE marked dishes and products are used in the laboratory wherever possible. An emergency trolley is situated in the corridor outside the main operating theatre where egg collections, replacements and IUIs are performed. It was evident that this had been checked on a daily basis.
Areas for improvement
The security of the laboratory (due to an unlockable hatchway between Operating theatre and laboratory) needs to be reviewed. Air quality certificates seen – D or barely D in Andrology laboratory. (The PR stated that a new laboratory is going to be built during 2008 to completely fulfil EUTD standards. The current laboratory will be brought into compliance during 2007.

Executive recommendations for Licence Committee
None
Areas not covered on this inspection
All areas covered

Evaluation
Some improvements required

4. Information

Desired outcome: Information is relevant, clear and up to date for patients and the HFEA

Summary of findings from inspection:

- Information management
- Information to patients and donors
- Information to the HFEA registry and updates
- Consent
- Protocols
- Record keeping

Outcome of audit of records
Ten sets of patients' notes were reviewed during the inspection. Overall the notes were found to be well organised with all the relevant documents being in place. However some errors were identified and these were discussed with the centre's staff.
Areas of firm compliance
The centre's information management system was considered to be of a high standard by the inspection team. Patient information and protocols submitted before inspection were reviewed by the inspection team and found to be satisfactory. The following information was seen by the inspection team on the day of the visit:- • Training records of all the staff • Three embryo transfer log book • Patient information policy • Staff rota • Quality audit conducted report • Training log including induction plan • Counselling audit • Complaints and adverse incident policy • Alert file Records were found to be well organised and were made available to the inspection team as required. The two patients interviewed stated that they had received excellent information about their treatment, which was comprehensive and timely. Registry at HFEA reported no problems with the reporting of data. Firm compliance was assessed by the inspection team in this section.
Areas for improvement
None

Executive recommendations for Licence Committee
None
Areas not covered on this inspection
All areas covered

Evaluation
No improvements required.

5. Laboratory and Clinical Practice

Desired outcome: Staff are competent and recruited in sufficient numbers to ensure safe clinical and laboratory practice.

Summary of findings from inspection:

- Assessment of patients and donors
- Safe handling systems
- Procedures in practice
- Laboratory processes and practice
- Clinical practice
- PGD/ PGS
- Recruitment and retention of staff
- Staff competence, qualifications, training and CPD

Full time equivalent staff (need to be filled up by PR)

GMC registered doctors	3.4
NMC registered nurses	7.5
HPC registered scientists	3.5
Scientists working towards registration	2
Support staff (receptionists, record managers, quality and risk managers etc)	14.5

Summary of laboratory audit
The Laboratory audit was found to be impressive and with no errors. Yearly audits are undertaken for both sperm and embryo banks.
Summary of spot check of stored material
A spot check of stored material was conducted during the course of the inspection. Two samples were checked from records to dewars and vice versa. No errors were found. All laboratory records were found in good order.
Areas of firm compliance
The centre has protocols in place for the assessment and screening of patients seeking treatment which were considered to be satisfactory by the inspection team. All laboratory procedures had written protocols in place which were version controlled. Quality control procedures found in place for semen assessments and for safe handling procedures of the patients' samples. All staff interviewed had personnel files and reported that they were provided sufficient opportunities and funding for their individual CPD requirements. All staff assured the

inspection team that they are happy with their work load. Embryology staff are given the opportunity to go on courses and attend BFS / ACE meetings. The PR reported that they have excellent training facilities in house. An induction programme for new staff is in place.

Evidence of communication between the clinical and laboratory staff was observed on the day on inspection.

The witnessed protocols seen for all procedures including disposal of gametes. The freezing records were found to be witnessed with a clear location of straws.

Areas for improvement
The Quarantines dewars needed to be alarmed.

Executive recommendations for Licence Committee
None

Areas not covered on this inspection
All areas covered

Evaluation
Some improvements required

Report compiled by:

Name…Dr. Neelam Sood

Designation…HFEA Exective

Date……18/ 04/2007

Appendix A: Centre Staff interviewed

Seven members of the staff along with two patients interviewed by the inspection team.

Appendix B: Licence history for previous 3 years

Appendix C:

RESPONSE OF PERSON RESPONSIBLE TO THE INSPECTION REPORT

Centre Number……0008……

Name of PR……Dr. Gillian Lockwood……

Date of Inspection……29 March 2007……

Date of Response……22 May 2007, Received in HFEA on 31 May

Please state any actions you have taken or are planning to take following the inspection with time scales

Security hatch to be secured with a lock to enhance security (2 months)

Individual quarantine dewars to be replaced with larger models which can be effectively alarmed (rolling programme already begun)

We are currently in discussions with a specialist business recovery team about developing secure strategies to protect patients, treatments and gametes and embryos in the case of significant failure of plant, premises or equipment. This will become operational when the new DMS (electronic data management system) is operational. In the meantime our current contingency plans involving data back-up and arrangements with other local licensed centres continue.

I have read the inspection report and agree to meet the requirements of the report.

Signed……

Name……Dr. Gillian Lockwood……

Date……31 May 2007…Submitted by PR……

2. Correction of factual inaccuracies

Please let us know of any factual corrections that you believe need to be made (NB we will make any alterations to the report where there are factual inaccuracies. Any other comments about the inspection report will be appended to the report).

We also welcome comments about the inspection on the inspection feedback form, a copy of which should have been handed out at the inspection. If you require a copy of the feedback form, please let us know.

Please return Appendix C of the report to:
Regulation Department
Human Fertilisation & Embryology Authority
21 Bloomsbury Street
London
WC1B 3HF