Renewal Inspection Report

Midland Fertility Services
Centre 0008

Date of Inspection: 9 January 2008
Date of Licence Committee: 14 April 2008

CENTRE DETAILS

Centre Name	Midland Fertility Services
Centre Number	0008
Licence Number	L0008/13/a
Centre Address	Midland Fertility Services 3rd Floor Centre House Court Parade Aldridge WS9 8LT
Telephone Number	01922 455911
Type of Inspection	Renewal
Person Responsible	Dr Gillian Lockwood
Nominal Licensee	Anna Kavanagh
Inspector(s)	Allison Cummings
	Wil Lenton
	Tony Knox
Fee Paid – up-to-date	The centre is due to be invoiced.
Licence expiry date	31/07/2008
NHS/Private/Both	Both

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About the Inspection:
This inspection visit was carried out on Wednesday 9 January and lasted for 8.5 hours. The report covers the pre-inspection analysis, the visit and information received between 30 March 2007 and 8 January 2008.

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 compliant 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 licence renewal 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 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.

NB: Where there are very minor issues to be addressed these are noted in the "minor issues to be addressed" section for each topic, and this will facilitate the evaluation of 'no improvements required'. Where recommendations are made the HFEA will provide details of what needs to be addressed but not how they should be carried out as this is the responsibility of the Person Responsible.

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 Services is located in a shopping area of Aldridge, Birmingham, occupying the second and third floors of an office building. The third floor is where the centre's core activities take place whereas the second floor is used for administration, communication and education purposes. The only recent changes to the premises have been the installation of a disabled toilet.

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 licensed treatments a year, the majority being self funded. The centre is ISO 9001:2000:9001 certified. The centre appears to be well run.

The centre is open to patients from 7.30am to 6.30pm Monday to Friday and 8am to 1pm on weekends. An open evening is held each month for prospective new patients.

In February 2006, an on-line patient forum was launched. To date they have approximately 500 patients registered to the site and over 15000 items of comment. A team of moderators review the posted material on a daily basis.

The centre offers complementary therapy to its patients with hypnotic relaxation and acupuncture treatment available once a week.

Activities of the Centre

Licensed treatment cycles	928*	IVF and ICSI (with own gametes or donor eggs/sperm). IUI is now also licensed by the HFEA and the centre is expected to report their activity for 5 July – 31 December 2007 by 31 March 2008. Whilst not officially reported, the inspectorate was informed that approximately 39 IUIs have been performed since 5 July 2007.
Donor Insemination	82*	
Unlicensed Treatments/other services offered	✓	Ovulation Induction Egg sharing Full surrogacy Recruitment of egg and sperm donors Tubal patency testing (HyCosy) Surgical sperm retrieval and assessment Vasectomy reversal back-up Recurrent miscarriage screening
Storage	✓	Eggs, sperm and embryos.

* The information that we publish on our website is a snap shot of data provided to us by licensed centres at a particular time. This information may be subject to change as individual centres notify us of amendments. Before publication, we perform a preliminary validation process on the data, and ask the centres to confirm its accuracy, for which they remain responsible.

Summary for Licence Committee

The PR has responded to all agreed outcomes/actions from the previous inspection except for the formalisation of contingency arrangements for a continued patient service.

The executive recommends that the centre's licence is renewed for five years without Gamete Intra Fallopian Transfer (GIFT). Please refer to 1.Organisation: Areas for consideration for further detail.

Risk Assessment

Following the inspection, a general risk score of 16% was allocated to the centre.

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, Standard Licence Conditions or Code of Practice:

The table below sets out matters which the inspection team considers may constitute breaches of the Act, Standard Licence Conditions and/or the Code of Practice, and their recommended improvement actions and timescales. The weight to be attached to any breach of the Act, Standard Licence Conditions or Code of Practice is a matter for the Licence Committee.

Breach	Action required	Time scale
Standard 9.4.2 (c) notification of the HFEA, by the Person Responsible, of Adverse Incidents and the subsequent provision of a confirmation/conclusion report.	Notification of the HFEA of adverse incidents.	With immediate effect
Standard 7.7.1 – procedures for home procurement should be documented.	Establish a protocol for home procurement of partner samples.	30 April 2008
The storage dewars are not fitted with low nitrogen alarms nor with temperature monitoring devices, thus monitoring of storage temperatures is not performed. This is potentially contrary to Code of Practice, 7th edition, S.6.3.7, and Licence Conditions A.10.20 – A.10.21, which require critical parameters related to the storage conditions of gametes and embryos (temperature; humidity; air quality) to be defined, controlled, monitored and recorded.	To risk assess the lack of monitoring on the storage dewars. To cost and consider replacing the storage dewars with low nitrogen alarms and temperature monitoring devices if risk assessment indicates such control measures are required.	30 April 2008

Non-Compliance

Area for improvement	Action required	Time scale
None.		

Recommendations	Time scale
Formally document the proposed contingency plans for continuation of a patient service.	30 April 2008

Proposed licence variations by last Licence Committee

None.

Changes/ improvements since last inspection

Recommendations	Action Taken
Written agreement / contingency plan with other units to be drawn up.	The executive set a three month timescale for the centre to make improvements. The PR reported that there is an informal agreement with the CARE group and this will be formalised shortly.
Security between theatre and laboratory.	The executive set a three month timescale for the centre to make improvements. The premises were inspected and the security appeared to be adequate.
Quarantine dewars to be alarmed	The executive set a two month timescale for the centre to make improvements. For reasons described in section 3, these have still not been alarmed.
The background air quality in the laboratory should be tested to make sure it meets Grade D. This recommendation was made in preparation for complying with the EUTCD.	The executive set a three month timescale for the centre to make improvements. The air quality testing reports seen on the day of inspection meet the conditions of their licence.

Additional licence conditions and actions taken by centre since last inspection

Date	Action taken
	Complied Y/N
	Complied Y/N
	Complied Y/N

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:

1. Leadership and management
2. Organisation of the centre
3. Resource management
4. Risk management
5. Incident management
6. Contingency arrangements
7. Business planning
8. Clinical governance
9. Payment of treatment fees
10. Third party agreements

Areas of firm compliance
• The PR has submitted their Person Responsible Entry Programme to the executive. The responses have given the executive no cause for concern. • Minutes of regular team meetings for each discipline were seen.
Areas for improvement
• No incidents have been reported since 2006. An electronic 'events log' was reviewed by the inspectorate. It contained both incidents and complaints. A separate log of OHSS cases is also kept and on review it was found that a small number of patients required prolonged hospitalisation resulting from OHSS. These adverse incidents should have been reported to the HFEA as per S.9.4.2. The PR agreed to this recommendation.
Areas for consideration
• The centre did have approximately 15 Primary Care Trust (PCT) contracts until the middle of last year. At that time, some of the PCTs combined and now the centre has contracts with approximately nine. It was noted in the interview with the PR that changes within the NHS have meant that patients should now be seen for treatment within 18 weeks. This may have an impact on referrals to the centre as the PCTs will be trying to clear their waiting lists much quicker. • Attendance records for team meetings were seen. If meetings could not be attended, the form also included an area for signing that the minutes have been read. However, these forms were seen to be incomplete. This was raised at the feedback meeting and it was explained to the inspectorate that they had tried to enforce this within the centre by introducing the attendance forms but, with continued non-compliance, they had placed the onus on the staff themselves to ensure that they were up to date. The inspection team explained that it is the centre's responsibility to ensure that there is an effective means for communicating information to staff and how they achieve that is a matter for their own discretion.

- It was noted on the 2007 inspection report that the centre had contingency plans, but was developing an electronic data management system that would enhance their contingency planning. Licence Committee minutes of August 2007 indicated that this recommendation had been met. The inspection team recommended that the PR formalise the centre's contingency arrangements with the CARE Group.
- The inspection team had a discussion with the PR regarding the centre's licence for GIFT. It was concluded that GIFT had been included on the licence but this was an administrative error on the part of the HFEA at the time. The inspectorate was informed that general anaesthetics are not performed on the premises and GIFT is therefore not undertaken.

Executive recommendations for Licence Committee
The Licence Committee is asked to endorse the recommendations made in relation to the areas for improvement cited above.
Areas not covered on this inspection
None.

Evaluation
Some improvements 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:

1. Quality Management System
2. Quality Policy
3. Quality Manual
4. Quality objectives and plans
5. Quality Management review/evaluation
6. Monitoring and resolution of complaints
7. Staff suggestions
8. Live Birth Rates
9. Counselling
10. Patient feedback
11. Welfare of the child

Live Birth Rates

The clinical pregnancy rates reported below were taken from a report run prior to the inspection date*. As the centre's inspection occurred at the beginning of the year it is possible that more clinical pregnancies will be reported. Please see the table below:

	IVF	FET after IVF	ICSI	FET after ICSI	DI
Clinical pregnancy rate per treatment cycle started: 01/01/07-31/12/07	26.60%	27.78%	31.62%	44.44%	12.99%
Live birth rate per treatment cycle: 01/01/06 - 31/12/06	20.40%	26.61%	22.38%	33.01%	6.92%

*HFEA verified data from March 2002 to April 2005 indicated that the success rates for all licensed treatments and for all age bands were in line with the national averages. The information that we publish on our website is a snap shot of data provided to us by licensed centres at a particular time. This information may be subject to change as individual centres notify us of amendments. Before publication, we perform a preliminary validation process on the data, and ask the centres to confirm its accuracy, for which they remain responsible.

Patient feedback

35 patient questionnaires were returned to the HFEA prior to the inspection. Relevant to the activity of the centre, this is a small number. Together with this information and patient interviews held on the day of inspection, a number of themes were brought to the attention of the inspectorate.
Some positive comments included:

- Patients treated with respect and dignity
- Confidentiality maintained
- Staff both supportive and professional
- Information received in both verbal and in written form was easy to understand

Patients highlighted some issues including:

- Patients are not always able to liaise with their primary nurse or to consistently see the same members of the nursing team
- Telephone access to reception – at busy times patients may have to wait longer than they would expect.

Areas of firm compliance

- A quality management system has been in place for many years. The inspectorate saw evidence of their BS EN ISO 9001:2000 certificate and noted the centre was last externally reviewed in September 2007.
- If the main counsellor is not available, there are three other counsellors who can be accessed to ensure the continuation of the service. An audit of counselling services was 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 Continual Professional Development (CPD) was up to date. Evidence of this was provided during the inspection.

Areas for improvement

None.

Areas for consideration

The inspectorate was informed that the centre has recently implemented a policy change in complaint handling. The new policy ensures that a complainant is kept informed about the progress of their complaint when there is going to be a particular delay before responding in full.

Executive recommendations for Licence Committee

None.

Areas not covered on this inspection

- Quality manual including quality policy, quality objectives.
- Staff suggestions

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:

1. General Suitable premises
2. Clinical facilities
3. Counselling facilities
4. Laboratory facilities
5. Air quality
6. Storage facilities for gametes and embryos
7. Staff facilities
8. Management of equipment and materials
9. Control of records
10. Risk assessments

Areas of firm compliance
• Overall, the premises and facilities appeared to be of a high standard. • Records for the monitoring of key equipment were seen and up to date. • Air quality requirements have been met and records of testing were shown to the inspectorate. • Evidence of traceability of laboratory consumables and media were seen. • All dewars (apart from the quarantine dewars) were found to be alarmed and connected to an auto-dialler facility. The inspectorate noted that a low oxygen monitor was fitted with an audio-visual alarm and that there is a protocol for responding to emergencies.
Areas for improvement
• The inspectorate observed that the eight quarantine dewars were not alarmed, as at the last inspection in 2007 and despite recommendations that the centre alarm these dewars. The director of embryology stated that attempts had been made to alarm them but the manufacturers had difficulties fitting the probes. It was reported that nine different donor samples were kept in the dewars and that none contained patient's samples. This is potentially contrary to S.6.3.7, and Licence Conditions A.10.20 – A.10.21, which require critical parameters related to the storage conditions of gametes and embryos (temperature; humidity; air quality) to be defined, controlled, monitored and recorded. The inspectorate recommended the lack of monitoring be risk assessed and control measures be put in place as required.
Areas for consideration
• The three embryo transfer log was seen and although not all patient dates of birth were recorded at the time of the transfer the information was sought for the inspectors and the log was completed.
Executive recommendations for Licence Committee
The Licence Committee is asked to consider a response in relation to the areas for consideration cited above.

Areas not covered on this inspection
None.

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:
1. General Information
2. Document control
3. Meetings and communication
4. HFEA Alerts
5. Welfare of child
6. Confidentiality and access to health records
7. Traceability and coding
8. Coding/ identification of samples
9. Information for service users/consents
10. Donor information
11. Donor registration
12. Surrogacy
13. Procurement and distribution of receipt of gametes and embryos
14. Home procurement report documentation
15. Packaging & distribution
16. Labelling of packages containing procured gametes
17. Transportation, labelling of shipping container and recall
18. Receipt of gametes

Outcome of medical records audit
• Three patient records were audited for completeness with respect to patient consent. • The audited records were seen to be well organised and information was easy to locate.
Areas of firm compliance
• The nurse manager reported that daily backup tapes are made of the patient database and stored off site in case of emergency. The inspectorate was also informed of plans to have another server prepared and made ready for any emergency involving the loss of data. This way, the second server and the back up tapes can be retrieved and used so that the patient service can be continued. • Samples of the centre's documents were found to be adequately controlled.
Areas for improvement
None.
Areas for consideration
None.
Executive recommendations for Licence Committee
None.
Areas not covered on this inspection
None.

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:

1. Laboratory and clinical processes
2. Selection and validation of laboratory procedures
3. Laboratory's documented procedures
4. Screening
5. Storage of gametes and embryos
6. Training and continued professional development

Full time equivalent staff

GMC registered doctors	3.4 + 1 working 6 days pa
NMC registered nurses	8 (including 2 midwives)
HPC registered scientists	3.3
Scientists working towards registration	2
Support staff (receptionists, record managers, quality and risk managers etc)	14.5
Counsellors	3 independent counsellors, working hours as per business needs

Summary of laboratory audit / audit of records
• An audit report of patient's own stored sperm was supplied to the inspectorate. The report identified any non-conformities present in each dewar, a record of the consequent investigation and corrective actions made in all except for a small number of instances.
Summary of spot check of stored material
• One sperm and one embryo sample was tracked from the centre's database to the dewars and vice versa. No discrepancies were found.
Areas of firm compliance
• Evidence was provided to show that staff needs for continuing professional development have been and continue to be addressed. • A 'return to work schedule' was seen for an embryologist returning from leave, an example of update training. • The laboratory team has considered the most suitable method of witnessing for their local situation. They have decided to continue with manual witnessing. A risk assessment of their chosen system has been documented and was provided to the inspectorate. • Audit tools for witnessing and transport hazards of gametes and embryos recently circulated to PR's nationally had been successfully completed and supplied to the inspectorate. • Using the witnessing audit tool recently completed by the laboratory manager, the inspectorate tracked the witnessing steps of a patient's gametes and embryos including but not limited to the steps involving gamete collection, embryo culturing and storage. No errors were noted. • Clinical ICSI data sheets for 2007 were submitted to the inspectorate. • A comprehensive evaluation of laboratory activity from August to October 2007 was

supplied to the inspectorate. The analysis included (but was not limited to) the competency assessment of operators with cross reference to the equipment used.
- A thorough analysis of clinical data from August to October 2007 captured information including (but was not limited to) egg collection and embryo transfer activity, number and grading of OHSS cases, outcome data and operator competency assessment.
- The inspectorate was informed that samples are screened as per British Andrology Society (BAS) guidelines and that patients are offered implications counselling.

Areas for improvement

- During the review of witnessing protocols, the inspectorate found that a home procurement protocol had not been established. This should be drafted in accordance with S.7.7.1.

Areas for consideration

None.

Executive recommendations for Licence Committee

The Licence Committee is asked to endorse the recommendations made in relation to the areas for improvement cited above.

Areas not covered on this inspection

None.

Evaluation

Some improvements required.

Report compiled by:

Name Allison Cummings

Designation Inspector

Date 15 February 2008

Appendix A: Centre Staff interviewed

Person responsible and 5 other staff.

Appendix B: Licence history for previous 3 years

2007

15 August: Consideration of interim inspection report

An interim inspection was carried out on 29 March 2007. In response to the inspection findings, the Committee agreed that the centre should continue with no additional conditions.

14 May: Variation of Licence under the EUTCD legislation

The Committee agreed to vary the centre's licence to incorporate the requirements of the EUTCD.

2006

21 June: Consideration of interim inspection report

A joint two day interim inspection with the Healthcare Commission was carried out on 28th February and 1st March 2006. It was agreed that the centre's licence should continue with no additional conditions.

2005

23 March: Consideration of renewal inspection report

The Committee agreed to renew the centre's licence for 3 years with no additional conditions.

Appendix C:

RESPONSE OF PERSON RESPONSIBLE TO THE INSPECTION REPORT

Centre Number 0008

Name of PR Dr Gillian Lockwood

Date of Inspection 9 January 2008

Date of Response 31 March 2008

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

Signed……

Name……

Date……

1. 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).

Factual corrections
Activities of the centre During this time period 155 Frozen embryo replacement cycles were performed (licensed treatment)

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

Actions taken or planned
Formal agreement from the CARE group has now been obtained to cover all contingencies in which patients' treatments could not be carried out due to catastrophic equipment/facility failure at the Aldridge site. Insurance cover is in place which would allow MFS staff to treat MFS patients on other licensed sites (within the CARE group) Since it has proved impossible to source appropriate probes for the existing quarantine dewars, we plan to introduce a rolling programme to replace these. This represents a significant financial outlay and will be implemented as soon as conditions allow.

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

Licence Committee Meeting

14 April 2008
21 Bloomsbury Street London WC1B 3HF

MINUTES Item 2

Midland Fertility Centre (0008)
Licence Renewal

Members of the Committee:
Walter Merricks, Lay Member – Chair
Jennifer Hunt, Lay Member
David Archard, Lay Member
Sally Cheshire, Lay Member
(present via conference telephone:)
Neva Haites, Professor of Medical Genetics, University of Aberdeen

In Attendance:
Debra Bloor, Head of Inspection
Claudia Lally, Committee Secretary

Providing Legal Advice to the Committee:
Sarah Ellson, Field Fisher Waterhouse Solicitors

Observing:
Peter Hollands, HFEA Inspector

Conflicts of Interest: members of the Committee declared that they had no conflicts of interest in relation to this item.

The following papers were considered by the Committee:

- papers for Licence Committee (36 pages)
- no papers were tabled.

1. The papers for this item were presented by Debra Bloor, Head of Inspection, and Wil Lenton, HFEA Inspector. Dr Bloor informed the Committee that this large centre carries out in the region of 1,000 treatment cycles per year and has achieved ISO accreditation. The centre is well organised with robust processes in place, for example for logging complaints and incidents. The main issue of concern for the inspection team had been the lack of low nitrogen alarms for some dewars containing donor sperm; however, there were no patient samples in the dewars concerned. Another issue identified at the inspection was that no standard operating procedure exists for when patients produce samples off-site.

2. The Legal Adviser informed the Committee that under the Code of Practice (S 6.3.7) centres are required to control, monitor and record critical storage parameters which would include nitrogen levels for stored samples. Low nitrogen

level alarms were not specifically required (other than for patients' samples in accordance with G 9.3.1).

The Committee's Decision

3. Having considered the Person Responsible's response to the report, the Committee decided that it was satisfied that the centre was doing what it can to address the issue of the low nitrogen level alarms on dewars containing donor sperm.

4. The Committee endorsed the Executive's recommendation in relation to the need for the centre to establish a standard operating procedure for when patients request to produce sperm off the premises.

5. The Committee agreed that they were satisfied as to the suitability of the Person Responsible, the centre premises and the use of suitable practices at the centre. The Committee noted that a signed application had been received from the centre and that the licence fee had been paid. The Committee further agreed that it was satisfied that it had sufficient and satisfactory information on which to make a decision on the licence renewal.

6. The Committee decided to renew the licence for a period of five years, with no additional conditions. The Committee noted that GIFT had previously been added to the centre's licence in error and agreed that GIFT would not be included on the renewed licence.

Signed…… … Date……..
Walter Merricks (Chair)