Unannounced Inspection Report

Midland Fertility Services
0008

Date of Inspection: 12 February 2009
Date of Licence Committee: 28 May 2009

Centre Details

Person Responsible	Dr Gillian Lockwood
Nominal Licensee	Ms Anna Kavanagh
Centre name	Midland Fertility Services
Centre number	0008
Centre address	Third Floor Centre House Court Parade Aldridge West Midlands WS9 8LT
Type of inspection	Unannounced
Inspectors	Miss Allison Cummings
	Mr Wil Lenton
	Mrs Sherry Ebanks
Fee paid	N/A
Licence expiry date	31 July 2013
NHS/ Private/ Both	Private

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About the Inspection:

As part of the HFEA's normal business process a number of inspections each year are required to be conducted without notice to the centres selected. The centres for unannounced inspection are chosen at random.

The inspection was unannounced and randomly selected and was carried out on 12 February 2009 and lasted for approximately six hours.

The purpose of the inspection is also 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. An unannounced inspection focuses on key areas of activity and on issues which arose at the last inspection. Such unannounced inspections do not cover the breadth of issues which are investigated by licence renewal or interim inspections.

The report summarises the findings of the 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 HFEA licence Committee. The report is made 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.

Where recommendations are made the HFEA will provide details of <u>what</u> needs to be addressed but not <u>how</u> 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 <u>www.hfea.gov.uk</u> .

Brief Description of the centre and Person Responsible

Midland Fertility Services is located in a shopping area of Aldridge, Birmingham. It occupies 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 9001:2008 accredited. 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.

The centre underwent a renewal inspection on 8 January 2008. The Licence Committee granted the centre a 5 year licence without any additional conditions.

The Person Responsible (PR), Dr Gillian Lockwood, is appropriately qualified to discharge her duties, as outlined in Section 17 of the HF&E Act (1990). Dr Lockwood has maintained registration with the General Medical Council (GMC) since 1987.

Centre activities[1] for the time period 1 October 2007 to 30 September 2008

In vitro fertilisation (IVF)	475
Intracytoplasmic sperm injection (ICSI)	360
Frozen embryo transfer (FET)	230
Donor insemination (DI)	64
Research	No
Storage gametes/embryos	Yes

Centre activities[2] for the time period 5 July 2007 to 31 December 2007

Intra uterine insemination (IUI)	39

[1] This data is supplied to the HFEA by individual clinics who are responsible for its accuracy and for verifying it. The data published by the HFEA is a snapshot of the state of the Register at a particular time. 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.

[2] Activity relating to IUI with partner sperm is provided to the HFEA in the form of an annual return. This data is supplied to the HFEA by individual clinics who are responsible for its accuracy and for verifying it. The data published by the HFEA is a snapshot of the state of the Register at a particular time. 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.

Summary for Licence Committee

The Visit
This is a report of a randomly selected unannounced inspection of this centre. On arrival the Inspection team was well received by the centre personnel present. The centre was closed in order to carry out an all staff mandatory training day. As there was little patient activity, the senior management team was able to quickly and efficiently locate the documents required, provide a tour of the premises and make time for interviews. Information and documentation requested appeared to be organised and readily available. Staff were open in manner and generous with their time, returning to complete their other duties later.

Inspection Findings
Improvements should be considered relating to the following aspects of the centre's practice:
- Suitable accreditation of the laboratory to undertake the diagnosis and investigation of patients, patient partners or donors, or their gametes, embryos or any material removed from them
- Storing embryos beyond the statutory storage period
- Welfare of the child risk assessment.

Executive Recommendations to Licence Committee
The inspection team would recommend that progress in addressing the issue outlined should be made within the timescales specified. The executive recommends the continuation of the centre's licence.

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
The centre's laboratory performs diagnostic analysis of blood samples that is not accredited by CPA(UK) Ltd or any other body.	The PR should ensure that diagnostic analysis of blood samples takes place in laboratories which are suitably accredited to comply with Standard 7.8.2. The PR should seek local advice on the requirement for clinical pathology accreditation (CPA) of the laboratory's diagnostic facilities. The outcome of the review should be communicated to the HFEA by 30 May 2009. If accreditation is considered required then a timeline for completion of accreditation should also be submitted to the HFEA.	30 May 2009
An audit of stored material indicated that some material had been stored without effective consent: In one instance the embryos belonging to one couple were frozen 4 December 2002, consented for five years to 4 December 2007 but the embryos were discarded in February 2008. In the second instance, embryos belonging to one couple were frozen on 9 January 1996, consented for 12	The PR is reminded that this is in breach of Schedule 3 8(2) of the Human Fertilisation and Embryology Act 1990 which states that 'an embryo the creation of which was brought about in vitro must not be kept in storage unless there is an effective consent, by each person whose gametes were used to bring about the creation of the embryo, to the storage of the embryo and the embryo is stored in accordance with those consents'. This is supported by Schedule 3 1: 'a consent under this Schedule must be given in writing and,	With immediate effect

years to 9 January 2008 but were discarded in May 2008.	in this Schedule, "effective consent" means a consent under this Schedule which has not been withdrawn.	
The centre was in breach of Direction 2008/5 as it had not provided a copy of their multiple birth minimisation strategy to the Authority by 31 January 2009. The inspection team therefore requested a copy of the strategy during the course of the inspection. The form of the strategy complied with paragraph 3 of Direction 2008/5.	No further action is required.	

Non-Compliance

Area for improvement	Action required	Time scale
In one health record the patient's copy of the WT consent form remained attached to the centre's copy. This was indicative that the patient had not received a copy of their consent to the use of gametes and embryos in treatment.	The centre should give a copy of the written record of consent to each person who gives consent to the use of gametes or embryos in accordance with CoP 7th Edition G.6.7.3.	With immediate effect
In one record it was noted that the welfare of the child patient history form was incomplete i.e. the section that allows centre staff to document if any further information sought, any further action taken and whether (or not) treatment was offered was not completed. The inspection team could find no other documentation of this step within the health record.	In all cases the centre should record in writing information that has been considered in respect of the welfare of the child. The centre is reminded that where further information has been sought or discussion taken place, the record is expected to reflect the views of those who were consulted in reaching the decision and the views of those seeking treatment (CoP 7th Edition G.3.5.1).	With immediate effect

Recommendations

Area for improvement	Action required	Time scale

Changes/ improvements since last inspection in January 2008

Recommendations	Action Taken
Breach: Standard 9.4.2 (c) notification of the HFEA,	Incident reporting has been

by the Person Responsible, of Adverse Incidents and the subsequent provision of a confirmation/conclusion report. Notification of the HFEA of adverse incidents. Action required: The PR should notify the HFEA of adverse incidents in accordance with requirements set out in CoP (7th Edition). Timescale: with immediate effect	demonstrated to be in line with HFEA requirements in the time since the last inspection. At the inspection, the inspection team also encouraged the reporting of any laboratory related incidents.
Breach: Standard 7.7.1 – procedures for home procurement should be documented. Action required: Establish a protocol for home procurement of partner samples Timescale: 30 April 2008	A documented procedure was provided to the inspection team at the unannounced visit.
Breach: The storage dewars were 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. Action required: 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. Timescale: 30 April 2008	In response to these recommendations, the PR stated that they had plans to ensure a system of monitoring as soon as financial conditions allowed. At the unannounced inspection visit, the director of embryology reported that a monitoring system had been purchased and that the dewars concerned would be fitted with the new system in the weeks following the visit.
Recommendation: Formally document the proposed contingency plans for continuation of a patient service. 30 April 2008	The PR assured the inspection team that the agreement is now documented.

Additional licence conditions and actions taken by centre since last inspection

None

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 the findings from the inspection of the following areas of practice:

- Leadership and management
- Organisation of the centre
- Resource management
- Clinical governance
- Risk management
- Incident management
- Alert management
- Complaints management
- Contingency arrangements
- Establishment of third party agreements
- Meetings / dissemination of information
- Payment of licence/treatment fees

Areas of firm compliance
Leadership and management On arrival the inspection team was well received by the centre personnel present. The centre was closed in order to carry out an all staff mandatory training day. As there was little patient activity, the senior management team was able to quickly and efficiently locate the documents required, provide a tour of the premises and make time for interviews. Information and documentation requested appeared to be organised and readily available. Staff were open in manner and generous with their time, returning to complete their other duties later. **Incident management** Since the renewal inspection in January 2008 the PR has been prompt in notifying the HFEA of adverse incidents. The inspection team were shown an electronic log of all incidents and the content concurred with information reported to the HFEA. The inspection team encouraged the ongoing reporting of incidents to the HFEA. **Complaints management** The nominal licensee is responsible for complaints management. At the renewal inspection in January 2008 the inspection team was informed that the centre has recently implemented a policy change in complaint handling. The revised policy aimed to ensure that the complainant is kept informed about the ongoing progress of a complaint, especially in circumstances when delays surrounding the investigation were expected. An electronic log is maintained to capture the progress of each complaint and this was examined by the inspection team. The information contained in the log demonstrated that the centre has a robust and efficient system for handling and resolving complaints.

Contingency arrangements
At the renewal inspection in January 2008 the centre had an informal arrangement with HFEA licensed centre CARE Nottingham (0101) for the continuation of patient treatment in an emergency. Although not a mandatory requirement, the inspection team made a recommendation that the centre formally document the arrangement by 30 April 2008. The PR agreed to this recommendation and assured the inspection team this has been formally documented.

Payment of licence/treatment fees
The centre is prompt in the payment of fees to the Authority.

Areas for improvement
None
Areas for consideration
None
Executive recommendations for Licence Committee
None
Evaluation
No improvements required
Areas not covered on this inspection
Resource management Risk management Alert management Establishment of third party agreements Meetings / dissemination of information

2. Quality of service

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

Summary of the findings from the inspection of the following areas of practice:

- Quality management system
- Quality policy
- Quality manual
- Quality objectives and plans
- Quality management review/evaluation
- Feedback
- Document control
- Live birth rates

Live birth rates[1]
In the time period from the 1 January 2005 to 31 December 2007 the centre's outcomes were in line with the national average.
Areas of firm compliance
Areas for improvement
None
Areas for consideration
None
Executive recommendations for Licence Committee
None
Areas not covered on this inspection
Quality management system Quality policy Quality manual Quality objectives and plans Quality management review/evaluation Feedback Document control
Evaluation
No improvements required

3. Premises and Equipment

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

Summary of the findings from the inspection of the following areas of practice:

- Premises
- Clinical facilities
- Counselling facilities
- Laboratory facilities
- Air quality
- Management of equipment and materials
- Storage facilities for gametes and embryos
- Staff facilities
- Storage of records

Areas of firm compliance

Premises

Since the last inspection access to critical work areas within the centre are now controlled by fingerprint recognition system or key-pad locks.

Clinical facilities

A tour of the premises was provided by the director of nursing services. The premises remained unchanged since the centre's last inspection except for the scan rooms which are now also equipped to recover patients following egg collection procedures. The clinical facilities appeared to provide for the privacy and comfort of those considering donation and seeking treatment; undergoing examination and treatment; and producing semen specimens. The centre has systems for checking and documenting that the emergency clinical facilities and equipment are fit for purpose.

Storage facilities for gametes and embryos

At the renewal inspection in January 2008, the inspection team noted that it was not possible to source appropriate probes to monitor the temperature of eight quarantine dewars. The director of embryology reported that these dewars were used to quarantine donor samples rather than patient samples. Despite this, the inspection team concluded that the centre was potentially in breach of 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. The inspectorate recommended that the lack of monitoring be risk assessed and control measures be put in place as required. In response to these recommendations, the PR stated that they had plans to ensure a system of monitoring as soon as financial conditions allowed. At the unannounced inspection visit, the director of embryology reported that a monitoring system had been purchased and that the dewars concerned would be fitted with the new system in the weeks following the visit.

Storage of records

There is a separate area at the end of the clinic for the storage of records. This area also serves as a rest area for staff. The inspection team used the room to carry out documentation

reviews and the room was locked when not in use.
Areas for improvement
Laboratory facilities The centre has a laboratory that performs diagnostic analysis of blood samples that is not accredited by CPA(UK) Ltd or any other body.
Areas for consideration
None
Executive recommendations for Licence Committee
The PR should ensure that diagnostic analysis of blood samples takes place in laboratories which are suitably accredited to comply with Standard 7.8.2. The PR should seek local advice on the requirement for clinical pathology accreditation (CPA) of the laboratory's diagnostic facilities. The outcome of the review should be communicated to the HFEA by 30 May 2009. If accreditation is considered required then a timeline for completion of accreditation should also be submitted to the HFEA.
Areas not covered on this inspection
Air quality Management of equipment and materials
Evaluation
Some improvement required.

4. Information

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

Summary of the findings from the inspection of the following areas of practice:

- Information for service users
- Consent
- Welfare of the child
- Access to health records
- Provision of information to the HFEA register

Areas of firm compliance
Consent Five health records were reviewed. Consents were present, complete and compatible with the treatment/service provided. The records were kept in an organised manner.
Areas for improvement
Consent Although the consents were present, complete and compatible with the treatment/service provided, it was noted that in one record that the patient's copy of the WT consent form remained attached to the centre's copy. This was indicative that the patient had not received a copy of their consent to the use of gametes and embryos in treatment. **Welfare of the child** The centre uses the HFEA welfare of the child patient history form to obtain information from prospective patients to help determine whether any child born as a result of treatment might have or be at risk of serious harm. Five health records were audited In one record it was noted that the section to be completed by the centre (this section allows for the documentation of any further information sought, any further action taken and whether (or not) treatment was offered) was incomplete. The inspection team could find no other documentation of this process within the audited record.
Areas for consideration
None
Executive recommendations for Licence Committee
In all cases the centre should record in writing information that has been considered in respect of the welfare of the child. The centre is reminded that where further information has been sought or discussion taken place, the record is expected to reflect the views of those who were consulted in reaching the decision and the views of those seeking treatment (CoP 7th Edition G.3.5.1). The centre should give a copy of the written record of consent to each person who gives consent to the use of gametes or embryos in accordance with CoP 7th Edition G.6.7.3.
Areas not covered on this inspection
Information for service users

Access to health records Provision of information to the HFEA register
Evaluation
Some improvement required

5. Clinical, laboratory and counselling practice

Desired outcome: Clinical, counselling and laboratory practices are suitable and are provided by competent staff.

Summary of findings from inspection:

- Staff training and competency
- Clinical practice
  - Screening of donors
  - Three embryo transfer
- Laboratory practice
  - Procurement, distribution and receipt of gametes and embryos
  - Traceability and coding
  - Selection and validation of laboratory procedures
  - Coding/ identification of samples
  - Witnessing
- Counselling practice
  - Counselling audit
- Storage of gametes and embryos

Full time equivalent staff

Registered doctors	3.4 + 1 working 6 days pa
Registered nurses	8 (including 2 midwives)
Non NMC registered nurses/health care assistants	
Registered scientists	3.3
Scientists working towards registration	2
Laboratory support staff	
Counsellors	3 (hours as per business needs)
Support staff (receptionists, record managers, quality and risk managers, etc).	14.5

Summary of laboratory audit
Audits of stored embryos and oocytes were undertaken by the centre in 2008. The audits indicated that some material had been stored without effective consent. In one instance the embryos belonging to one couple were frozen 4 December 2002, consented for five years to 4 December 2007 but the embryos were discarded in February 2008. In the second instance, embryos belonging to one couple were frozen on 9 January 1996, consented for 12 years to 9 January 2008 but were discarded in May 2008. The laboratory manager explained to the inspection team that in both instances the centre had difficulties contacting the gamete providers and therefore embryos were disposed beyond their consented storage periods.
Summary of spot check of stored material
No spot check of stored material was carried out on this unannounced inspection.
Areas of firm compliance
Staff training and competency

When the inspection team arrived to carry out the unannounced inspection visit, the centre was closed in order to facilitate an all staff training day. The training schedule provided to the inspection team demonstrated attention to a wide range of issues including counselling; health and safety; and complaints/incident reporting.

The nominal licensee informed the inspection team that since the last inspection the centre has established a competency framework for all staff. It includes core competencies as well as operational competencies pertinent to the tasks that each staff member performs. The inspection team was informed that it is in the process of being rolled out across all 50 staff and whilst the laboratory team had already implemented the competency framework this was work has not yet been completed for nursing staff. The nominal licensee stated that competencies will be assessed yearly as part of each staff member's annual review. Each staff member has recently been issued with a folder to hold personal information relating to training and development, personal objectives, learning and evidence. A folder belonging to a nurse was selected by the inspection team and the content demonstrated the staff member had provided with three internal training days (included mandatory training along with training logs to perform early pregnancy ultrasound scanning, embryo transfers and surgical sperm retrieval. Personnel records seen for an embryologist demonstrated that their competence had been assessed.

Laboratory practice

Procurement, distribution and receipt of gametes and embryos

At the previous inspection, the inspection team requested that the centre establish a documented procedure for the receipt of sperm received from patients that produced their sample at home or at another location away from the centre. At the unannounced visit, the inspection team were provided with the documented procedure demonstrating compliance with CoP (7th Edition) S.7.7.1.

Witnessing

The centre has recently purchased an electronic witnessing system. It is expected that the electronic witnessing will commence in May 2008. The inspection team were informed that the documented procedures are currently being revised to accommodate this change.

Areas for improvement

As documented in section 'summary of laboratory audit'.

Areas for consideration

Clinical practice

Multiple birth minimisation strategy

The PR recently met with other HFEA licensed centres providing IVF in the West Midlands to establish a multiple birth minimisation strategy. The centre was in breach of Direction 2008/5 as it had not provided a copy of the strategy to the Authority by 31 January 2009. The inspection team therefore requested a copy of the strategy during the course of the inspection. The form of the strategy complied with paragraph 3 of Direction 2008/5. The laboratory manager commented that multiple embryos have not been transferred to any patient who meets the criteria for single embryo transfer and therefore a summary log for capturing this data has not yet been established. No further action is required.

Storage of gametes and embryos

The centre should consider revising its' bring-forward system in order to ensure sufficient advance notice of the end of the statutory storage period (or such shorter period as specified by a person who provided the gametes) for gametes or embryos in storage (CoP 7th Edition G.9.9.1).
Executive recommendations for Licence Committee
The PR is reminded that Schedule 3 8(2) of the Human Fertilisation and Embryology Act 1990 requires that 'an embryo the creation of which was brought about in vitro must not be kept in storage unless there is an effective consent, by each person whose gametes were used to bring about the creation of the embryo, to the storage of the embryo and the embryo is stored in accordance with those consents'. This is supported by Schedule 3 1: 'a consent under this Schedule must be given in writing and, in this Schedule, "effective consent" means a consent under this Schedule which has not been withdrawn.
Areas not covered on this inspection
Screening of donors Three embryo transfer Traceability and coding Selection and validation of laboratory procedures Coding/ identification of samples Counselling practice Counselling audit
Evaluation
Some improvements required.

Report compiled by:

Name	Allison Cummings
Designation	Inspector
Date	17 March 2009

Appendix A: Centre staff interviewed

Three staff members

Appendix B: Licence history for previous 3 years

2008

14 April 2008: Consideration of renewal inspection report

A renewal inspection was carried out on 9 January 2008. The Committee decided to renew the licence for a period of five years, with no additional conditions.

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.

Appendix C: Response of Person Responsible to the inspection report

Centre Number……008……

Name of PR… Gillian Lockwood…….

Date of Inspection 12 /2/09……..

Date of
Response……7/5/09……

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

Signed……

Name Dr Gillian Lockwood
…….

Date……7/5/09……

1. Correction of factual inaccuracies

Please let us know of any factual corrections that you believe need to be made. We will make alterations to the report where there are factual inaccuracies.

Minor factual inaccuracies noted and corrected in the body of the report.

2. Please use the space below to document any comments or additional information that you would like to be considered by a Licence Committee.

We are currently applying for CPA on the basis of my experience in assay biochemistry gained during my DPhil.

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

As stated at the Inspection, this Centre was instrumental in setting up the West Midlands Consensus Strategy on multiple pregnancy minimisation. Since the 1st of January 2009 we have adhered to the protocol agreed by all the IVF Units in the West Midlands .

We welcome comments about the inspection on the inspection feedback form, a copy of which should have been provided at the inspection. If you require a copy of the feedback form, please let us know.
Please return Appendix C of the report electronically to your inspector or in hard copy to:
Regulation Department
Human Fertilisation & Embryology Authority
21 Bloomsbury Street
London
WC1B 3HF
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