Interim Inspection Report for Treatment and Storage Centres

BMI Chelsfield Park ACU
0086

Date of Inspection: 25th April 2007
Date of Licence Committee: 15th August 2007

CENTRE DETAILS

Centre Address	Bucks Cross Road Chelsfield Orpington, Kent BR6 7RG
Telephone Number	01689 877 855
Type of Inspection	Interim
Person Responsible	Leila Hanna
Nominal Licensee	Peter Harris
Licence Number	L0086/14/a
Inspector(s)	Tahir Hussain Parvez Qureshi Vicki Lamb
Fee Paid - date	Not due.
Licence expiry date	30th September 2009

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About the Inspection:
This inspection visit was carried out on 25th April 2007 and lasted for 7 hours. The report covers the pre-inspection analysis, the visit and information received between April 2006 and March 2007.

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 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, 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

The centre was first licensed for storage and treatment in 1992 and provides treatment for private patients by referral from their hospital consultant or GP. The centre is open Monday to Friday from 08:00 to 16:00 with some additional work being conducted at the weekends when required.

The centre has a good history of compliance and there are no additional conditions on the license.

The person responsible (PR) has been in the position since April 2006 and has a wide range of experience in the field of assisted conception. She is also the PR at Queen Mary's Hospital (0117) which is in close proximity.

A recent application has been received to nominate the clinical manager as the new PR.

Activities of the Centre

Statistics taken from HFEA data 1/3/06 – 28/2/07

Licensed treatment cycles	IVF ICSI FET	142 206 59
Donor Insemination		0
Unlicensed treatments	GIFT IUI	
Research		None
Storage		Yes

Summary for Licence Committee

The centre was found to be compliant in all areas and the staff are actively working towards obtaining full compliance with the requirements of the EU Tissue and Cells Directive.

The inspectorate recommends the continuance of the centres licence with no additional conditions.

Risk Assessment

The risk assessment allocated to the centre following the last inspection was rated as 16% Following the inspection on 25th April 2007, the risk assessment has been recalculated as being 11%.

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		

Non-Compliance

Area for improvement	Action required	Time scale
A record was found where the disposal of embryos was seen to be witnessed but there was no signature to confirm this.	Ensure that all relevant steps are witnessed and signed as they occur.	Immediately.

Recommendations	Time scale
It was noted that the complaints policy was not clearly visible and did not contain the contact details of the HFEA. It was recommended that this be amended in the event that a patient wishes to complain directly to the HFEA rather than to the centre.	Immediately.
It was noted that staff were trained according to specific protocols and timelines, however, it was noted that there was no specific record of competency for each discipline.	3 Months.

Proposed licence variations

None

Changes/ improvements since last inspection

Recommendation	Action taken
N/A	

Additional licence conditions and actions taken by centre since last inspection

C	None
A	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 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
Staff interviewed during the inspection stated that they were kept informed of all changes within the unit, that there was a clear organisational/management structure within the centre. All staff felt well supported by management evidence was seen of regular unit meetings and dissemination of minutes to staff. The centre was seen by the inspectorate to be well organised and staffed appropriately for the number of cycles performed. This was confirmed with staff interviewed during the inspection. It was highlighted to the PR and the clinical manager that no incidents have been reported since the previous inspection to the HFEA. The PR stated that they regularly discussed any issues that they feel may warrant an incident at the unit meetings. To date none had fallen under the remit to be raised as an incident. Risk management and clinical governance arrangements are followed with policies available as part of the main hospital. Contingency arrangements are in place with centre 0161 BMI The Chaucer Hospital in Canterbury should any emergency arise to prevent treatments being provided. The unit is also part of the BMI group and if necessary other BMI fertility hospitals will provide support. A change of PR was also discussed as a recent application has been received proposing the clinical manager take the role over as she is based at the unit full time. A PR entry programme was in the process of being submitted. The clinical manager also attends the BMI best practice group meetings where issues are discussed and raised as appropriate which may include HFEA matters, quality documentation and any other matters that may arise

Areas for improvement
None.

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

Evaluation
No 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
Data obtained from the HFEA shows that IVF/ICSI in the age group 38 to 39, were below the national average.
Areas of firm compliance
Patients' notes are held in secure storage with access to centre staff only. Areas containing patients' notes are secure, and the centre is fully alarmed. There is a system in place to change the key codes when a member of staff leaves. There is also a system in place to identify files of patients with the same names to avoid any errors. All notes examined showed evidence that a "Welfare of the Child" assessment had been conducted appropriately. The centre currently uses the Chelsfield Park Hospital patient feedback system but is considering setting up of one for the ACU based on the Howard Warwick model. A patient interviewed during the inspection was pleased with the quality of service received and stated that the patient information provided by the centre was well explained. The patient was made aware of counselling service and there were no concerns with booking of appointments. Overall the patient's comments were positive regarding the quality of service provided by the centre. Two HFEA questionnaire responses were received. Comments returned were generally complimentary regarding the staff and treatment services provided at the centre. The counsellor was appropriately qualified and registered as a member of BICA (British infertility counselling association). She receives external supervision and is responsible for her own CPD. Counselling sessions are held one evening per week at the centre with the remaining sessions taking place at the counsellor's home. One session is offered as part of the treatment with a charge being made for any subsequent sessions.

Counselling is promoted through patient information and during consultations held with staff. Patients are able to contact the counsellor via the centre or directly by telephone as well as having access to workshops.

The inspection team was provided with an audit of the counselling service from May 2006 to March 2007. There were 34 referrals, amounting to over 70 sessions. The figures indicate a low uptake. However, since the last inspection there has been a slight increase in the number of referrals and the counsellor anticipates that the uptake rate is likely to increase with time.

Areas for improvement
It was noted that the complaints policy was not clearly visible and did not contain the contact details of the HFEA. It was recommended that this be amended in the event that a patient wishes to complain directly to the HFEA rather than to the centre. .

Executive recommendations for Licence Committee
None.

Areas not covered on this inspection
Donor selection. Egg sharing and surrogacy. Protection of children arrangements.

Evaluation
Some improvement 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
Since the last inspection, the unit has acquired a room which is used for scanning and consulting and this room also incorporates a male production room. Access to the laboratory area is secured by keypad access, and is alarmed. All dewars contained within the area are individually alarmed and connected to an autodial facility. A low oxygen monitor is in place and was seen to have been tested regularly. Incubators were found to be alarmed and evidence was seen that regular monitoring of temperature had been performed. Evidence was provided to the inspectorate showing that all critical equipment had been serviced and maintained in accordance with manufacturers' recommendations. Calibration certificates for all equipment were also provided for examination by the inspectorate and were seen to be complete. An emergency crash trolley was found to be well equipped and checked regularly.
Areas for improvement
The newly acquired male production room was viewed to be in need of decoration by the inspectorate. It was also noted that there was a requirement for additional office space.
Executive recommendations for Licence Committee
None.
Areas not covered on this inspection
All areas covered.

Evaluation
Some improvement 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
The last operational audit conducted at the centre was performed in February 2007 and was reported to the centre just before the inspection visit. The audit concluded that the centre needed to review its systems for reporting treatments to the HFEA. During the inspection visit it was witnessed that the centre had taken positive steps to implement the necessary changes. Fourteen sets of patient records were examined during the course of the inspection. One error was noted; however this was clarified at the feedback meeting.
Areas of firm compliance
Information provided to patients and donors is written clearly and is easily understood. Staff at the centre noted that they were available to verbally explain the information should patients be confused about any aspect of their treatment, at any time. The HFEA Registry Department reported no problems with reporting of data prior to the inspection. All notes examined provided evidence that correct consents had been obtained from patients prior to their treatment. This also included consent to communicate with the patients GP and evidence of an appropriate "Welfare of the Child" assessment. The patients' records inspected were found to be well structured. The protocols viewed at the centre were version controlled. The centre has a working quality management system (QMS) in line with ISO standards and EUTD requirements. ISO 9001:2000 accreditation was achieved in August 2006.
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

GMC registered doctors	3
NMC registered nurses	3
HPC registered scientists	2
Scientists working towards registration	1
Support staff (receptionists, record managers, quality and risk managers etc)	5

Summary of laboratory audit
No discrepancies noted.
Summary of spot check of stored material
No discrepancies noted.
Areas of firm compliance
Patients are assessed and screened in accordance with the centre policies and procedures, which were considered as satisfactory by the inspectorate. In the event that witnessing procedures are required at weekends, arrangements are made with either the practice manager or a nurse to attend the centre to perform this function. It was seen that all staff attend various meetings held at the centre and have access to the minutes of these meetings. Staff were seen to be aware of the complaints, incidents reporting procedure and of the HFEA alerts. All staff interviewed stated they were well supported in their CPD requirements. Staff files contain evidence of all staff registration details which were seen to be complete and up to date. Policies for staff training and induction were provided during the course of the inspection which were considered by the inspectorate to be fit for purpose. All laboratory records including maintenance and servicing schedules were seen to be in good order.

Air quality is being monitored within the laboratory and treatment areas and it was reported that Grade A air is being obtained within the existing horizontal flow cabinets used in the laboratory and above background Grade D is being obtained in the treatment areas and main laboratory.

Areas for improvement
Five sets of patient records were examined for witnessing and one error was noted where the step for disposal of gametes and embryos was not signed. In-house training is provided to all members of staff and training records provided were considered to be well maintained. However some staff expressed additional training would be helpful. Evidence was seen of a refresher induction programme and staff stated that this was very useful, however, it was noted that not all disciplines had a comprehensive list of competencies achieved.

Executive recommendations for Licence Committee
None.

Areas not covered on this inspection
PGD/PGS are not performed at this centre.

Evaluation
Some improvement required.

Report compiled by:

Name Tahir Hussain

Designation Regulation Inspector

Date 15th April 2007

Appendix A: Centre Staff interviewed

Leila Hanna – Person Responsible
Judith Reid – Clinical Manager
Six other members of staff
One couple

Appendix B: Licence history for previous 3 years

2007

License Committee 2 May 2007

Variation of Licence to include EUTD standards. This was granted with no additional conditions or recommendations.

2006

License Committee 8 February 2006

Change of Nominal Licensee was approved.
Re-housing of dewars was approved.

License Committee 22 March 2006

Change of PR was approved.

License Committee 8 June 2006

Renewal of license granted for three years.

2005

License Committee 12 January 2005

Change of PR was approved.

License Committee 28 April 2005

Renewal of license granted for 12 months.

License Committee 5 September 2005

Change of PR was approved.

Appendix C:

RESPONSE OF PERSON RESPONSIBLE TO THE INSPECTION REPORT

Centre Number……086……

Name of PR……Leila Hanna
……

Date of Inspection…26th April 2007
……..

Date of response 31st May 2007
……

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

None

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

Signed …Leila Hanna
……

Name……LeilaHanna
……

Date……31st May 2007
……

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).

X4 Doctors registered with GMC Leila Hanna, John Erian, Chris Stree and Judy Reid

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

15 August 2007
21 Bloomsbury Street London WC1B 3HF

MINUTES Item 2

BMI Chelsfield Park ACU (0086)
Interim Inspection

Members of the Committee:

Emily Jackson, Lay Member – Chair
Richard Harries, Lay Member
Anna Carragher, Lay Member
Maybeth Jamieson, Consultant Embryologist, Glasgow Royal Infirmary

In Attendance:

Trish Davies, Director of Regulation
Frances Clift, Legal Adviser
Marion Witton, Head of Inspection
Barbara Lewis, Regulation Team Leader
Claudia Lally, Committee Secretary

Observing:

Allison Cummings, 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 (24 pages)
- no papers were tabled.

1. The papers for this item were presented by Tahir Hussain, HFEA Inspector. Mr Hussain informed the Committee that this is a small centre with a history of good regulatory compliance. Mr Hussain reported that two breaches were identified by the inspection team. Firstly, staff at the centre were still failing to witness the disposal of embryos and gametes in accordance with Directions 2004/4. In addition, the centre's complaints policy was not clearly visible on the day of the inspection visit and did not include contact details for the HFEA. This is a breach of paragraph 13.4 of the sixth edition of the Code of Practice which states that centres should "display notices prominently in reception areas explaining the complaints procedure". Mr Hussain reported that the centre's laboratory witnessing sheets for the disposal of gametes and embryos have now been updated and a copy sent to the Executive. Furthermore, the Person

Responsible has confirmed that the complaints policy has now been updated and is being prominently displayed.

2. These breaches were considered by the Committee, who noted with concern that a previous incidence of non-compliance with Directions 2004/4 had been reported to a Licence Committee in June 2006, at which point the Committee had been informed that the centre agreed to comply with the Directions henceforth. The Committee welcomed the information that the centre has now changed the laboratory witnessing sheets to ensure that witnesses sign their name in the event of the disposal of gametes or embryos.

3. The Committee noted that page 13 of the inspection report states that in the sample of patient notes examined the centre had in every case obtained consent from patients to communicate with the patient's General Practitioner. The Committee noted that this was consistent with good practice. In addition, they asked for the centre to be reminded that, subject to concerns about risk arising in respect of particular patients, General Practitioners ought not to be contacted routinely in the course of providing treatment, as is clear from Welfare of the Child guidance at G.3 of the seventh edition of the Code of Practice.

4. The Committee noted that only two of the HFEA patient questionnaires had been returned by patients of the centre. The Committee noted this very low rate of return and agreed that the centre should be requested to encourage the wider use of these questionnaires by patients.

5. The Committee agreed that the centre's licence should continue with no additional conditions.

Signed…… … Date……..
Emily Jackson (Chair)