Licence Renewal Inspection Report for Treatment and Storage Centres

Assisted Reproduction and Gynaecology Centre 0157

Date of Inspection: 14th November 2007
Date of Licence Committee: TBC

TRIM:

CENTRE DETAILS

Centre Address	13 Upper Wimpole Street London W1G 6LP
Telephone Number	0207-486-1230
Type of Inspection	Renewal Inspection
Person Responsible	Mr. Mohamed Taranissi
Licence Number	L0157-19-a
Inspector(s)	Tony Knox Stephanie Sullivan Wil Lenton Angela Sanford
Fee Paid - date	At the time of generating this report, the renewal fee had not been paid.
Licence expiry date	19th January 2008

Index

About the Inspection:
This inspection visit was carried out on 14th November 2007 and lasted for 8 hours. The report covers the pre-inspection analysis, the visit and information received between 1/10/2006 and 31/10/2007.

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 Assisted Reproduction and Gynaecology Centre is privately owned and has been licensed to provide fertility treatments since 1995. Patients attending this unit are self-funded.

Activities of the Centre

Data obtained from the HFEA Centrepede database 1/1/06 – 31/12/2006

Licensed treatment cycles	IVF ICSI FET	251 518 92
Donor Insemination		20
Unlicensed treatments	Ovulation Induction	
Research	NO	
Storage	YES	

Summary for Licence Committee

The breaches and areas of non-compliance highlighted in this report reflect the views of the inspector/inspection team. The weight to be attached to these is a matter for the licence committee to consider.

Risk Assessment

The centre was awarded a risk score of 19% following assessment of compliance against the EU Tissue and Cells Directive. An application to vary the centre licence to include previously unlicensed treatments was granted in accordance with this assessment.

The centre's last general risk assessment was calculated at 42%. A repeat assessment was conducted following this inspection which provides the centre with a current risk score of 32% which is considered to be medium risk.

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: In the opinion of the inspection team, the following breaches have been identified: -

Breach	Action required	Time scale
All treatments provided by the centre must be reported within designated timescales as per D2007/7 and S.4.2.12. (See section four).	All licensed treatments undertaken by the centre must be reported to the HFEA within designated timescales.	Immediate.
A three embryo transfer was found to have been conducted on a patient under the age of 40 years. (G.8.5.1). (See section five).	No more than two embryos should be transferred to women under the age of 40 years.	Immediate.
Licensed embryo practitioners' report for 2006 had not been received at the HFEA nor details of any PGD cases performed for the period of 2007 prior to inspection (CH(06)03) and D2003/1. (See section five).	All relevant information pertaining to licensed embryo practitioners working within the centre and documentation pertaining to PGD cases performed for 2007 to be submitted to the HFEA for inspection.	Immediate.
All third party agreements should be available for inspection (S.3.1.27, G.2.1 and A.5.5). (See section one).	Centre is required to have documented third party agreements in place, and should chase any and all outstanding third party	Immediate

	agreements to ensure that a documented copy is available on site.	

Non-Compliance

Area for improvement	Action required	Time scale
None		

Recommendations	Time scale
The independent counsellor be provided with an agenda in advance of the regular multidisciplinary meetings and with a copy of the minutes of those meetings whenever she is unable to attend. (See section two).	Immediate.
To provide more detailed information within the centre contingency policy for unexpected cessation of service. (See section one).	Three months.
During the course of the inspection, it was noted that the centre store gametes and embryos together within the same dewar. Recommendation is made to assess the potential risks associated with this practice and the possibility of cross-contamination	Three Months
Witnessing protocol to be reviewed and amended to accurately reflect all witnessing steps currently being performed within the laboratory. (See section five).	Six months.
To amend storage dewar audit reports to include dewar assignment, content, number of samples contained within each dewar, discrepancies found and actions taken to rectify errors. (See section five).	By next inspection.

Proposed licence variations

None

Changes/ improvements since last inspection

Recommendation	Action taken
Cryopreservation dewars were not fitted with low nitrogen level alarms or auto-dial facility	All dewars were seen to be fitted with appropriate alarms and were connected to an autodial facility.
In three sets of notes reviewed during the	Witnessing sheets were seen to have been

inspection, witnessing sheets were absent or incomplete.	included in all sets of notes reviewed on the day. It was noted that the policy for witnessing however did not accurately reflect the witnessing steps being performed. Recommendation was made to review the policy in line with current practice. (See recommendations above).
Errors in consent forms and 'Welfare of the Child' assessments were observed in five of the nine sets of patient records reviewed.	A review of ten patient records was made in which evidence was included that a suitable 'Welfare of the Child' assessment had been conducted and all consent forms were complete.

Additional licence conditions and actions taken by centre since last inspection

C	None
A	

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
• A documented organisation chart is available for the centre, which was provided pre-inspection. The organisation chart clearly identified the reporting structures within the centre. All staff interviewed are aware of the reporting structure and of their individual responsibilities. • The PR confirmed verbally that staff were appropriately qualified and employed in sufficient numbers to ensure patient safety for the treatment cycles performed. • Risk assessments were evidenced for 2007 including fire, health and safety, labelling of gametes and embryos and the transport of gametes between centres. • There is an incident reporting policy and procedure in place, which all staff interviewed were aware of. There was evidence in the laboratory meeting minutes that incidents had been discussed amongst the laboratory team. • The centre has developed a robust quality manual. This contains a full listing of all policies and procedures developed for the centre. All policies and procedures were seen to be version controlled with a review date. A full listing of all policies and procedures is held centrally and is available to all staff. The Quality Manager confirmed that all policies and procedures are reviewed annually. It was noted that the centre has resourced two external consultants to assist with the development of the quality system and internal processes which is currently ongoing. Evidence was provided of minutes taken at the last general clinical governance staff meeting held in May 2007.
Areas for improvement
• There has been a documented contingency policy in place since 1995 for the unexpected cessation of services. A review of this policy revealed that it contained no specific details of which other licensed treatment centre would be used in the event of cessation of services at the ARGC, or the type of service provision that would be provided. It was agreed with the PR that the policy would be amended to include these details. • The Quality Manager produced a folder containing general third party agreements. It was noted that not all agreements had been signed and returned from the various service suppliers despite efforts made on the part of the Quality Manager to obtain these. It was

agreed that further efforts would be made to ensure compliance. Explanation was also given that some third party agreements were held within the laboratory by the senior embryologist. An inspection of the agreements within the laboratory revealed that a third party agreement was currently being generated with an external company employed to check the laboratory incubators and with an external company employed to perform the centre air quality monitoring. It was agreed that efforts would be made to ensure these were completed within the near future.

- The Finance Department at the HFEA reported the average time for the payment of invoices generated for treatment fees to be 75 days.
- The finance Department at the HFEA noted that treatment cycles had not been reported for the centre for September or October 2007. (See areas for improvement section on page 16 of this report).

Executive recommendations for Licence Committee
None

Areas not covered on this inspection
All areas covered.

Evaluation
Some 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 Centrepede database for the period 31st March 2002 – 1st April 2005 (cumulative) show IVF/ICSI rates to be higher than the national average in the age range 40 – 42 and to be significantly above the national average success rates for age ranges below 35 to 39 years. For the same period, frozen embryo transfer rates were noted as being significantly lower than the national average for the age group 40 – 42, above the national average for age range 35 – 39, and significantly above the national average for age range below 35. Donor insemination rates are shown as being significantly below the national average for age ranges below 35 and between 40 – 42 but above average between 35 and 39. Data obtained from the HFEA Centrepede database for 1st January 2005 – 31st December 2005 show the following success rates: - IVF - 59.87% ICSI - 44.83% IVF Frozen - 18.75% ICSI frozen - 30.30% The PR noted that donor insemination treatments are performed rarely at the centre due to the scarcity of supply within the UK.
Areas of firm compliance
• Evidence was provided in the notes audited that a suitable and sufficient "Welfare of the Child" assessment had been completed for all patients accepted for treatment at the centre. The PR noted that any potentially contentious cases would be discussed internally prior to a decision being made on whether to treat or not. It was further noted that although the centre does not have regular access to an ethics committee, this could be arranged at short notice should it be required. The PR noted that to date, no treatments have been refused on the grounds of "Welfare of the Child".

- All staff are required to sign a confidentiality declaration upon appointment at the centre. It was noted by the Quality Manager that training in confidentiality is also provided to all new employees during their initial induction period. Lockable storage cabinets are provided for patient notes to be stored securely within the centre. The unit itself is secured and alarmed appropriately. All computers are password protected with access restricted to authorised members of staff only.
- The centre provides a full range of licensed treatments. Patients are assessed in accordance with the centres treatment protocols taking into account information obtained from patients during consultation, from past medical history and from referral information obtained either from the patient general practitioner or hospital consultant. Additional information regarding the appropriateness of treatment is also obtained by conducting a monitoring cycle prior to a full treatment cycle commencing.
- The centre has developed their own patient satisfaction questionnaire, which is given to patients following all embryo transfers. Responses to the questionnaires are collated annually and audited by the Quality Manager. Evidence of a patient satisfaction survey was provided during the course of the inspection. Outcomes from the audit are communicated to all staff.
- The centres complaints policy and log were evidenced and considered fit for purpose and in accordance with HFEA requirements. A designated complaints officer is noted within the patient information. It was evidenced that all complaints had been handled in accordance with the centres policy.
- When required, a consulting room is made available for the purposes of providing counselling services.
- Evidence was found within the notes audited that appropriate screening in accordance with professional body guidelines is conducted on all patients and donors seeking treatment prior to acceptance.

Areas for improvement

- It was noted during the interview with the PR that the independent counsellor does not normally attend regular planned multidisciplinary meetings at the centre. It was recommended that the counsellor be provided with a copy of the meeting agenda in advance wherever possible or a copy of the minutes made from the meetings in the event that she is unable to attend. In this way, the counsellor will be made aware of any changes in practice and can (whenever necessary) provide contribution to the meetings. This was agreed by the PR.

Areas for consideration

- The counselling audit provided pre-inspection shows a low take up rate for the service, i.e. 18 counselling session for the period January 2006 – February 2007. It was noted by the PR that counselling is promoted by staff during consultation and in ongoing assessment, it was also evidenced that counselling is also promoted within the patient information packs provided to patients. The PR noted that contributory factors to the low uptake of counselling services were the fact that patients are seen daily at the centre during their monitoring phase and are therefore able to address their concerns and anxieties to staff working within the unit directly. In addition, a large number of patients have either had previous treatments elsewhere and will have received counselling services in those centre's.

Executive recommendations for Licence Committee
None.

Areas not covered on this inspection
• The independent counsellor was not available for interview. • Egg sharing is not performed at this centre. • Surrogacy. • No patient interviews were conducted during the course of the inspection. • Protection of children under the age of 18.

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
• The lower ground floor consists of the main theatre, a recovery area (sufficient for the provision of recovery services for between five or six patients), an embryology laboratory/ dewar storage facility and staff changing room. The ground floor consists of the main patient entrance, a waiting room, a reception area, a nursing office (containing patient notes) and patient toilets. The first floor consists of two consulting rooms, both equipped with examination couches and ultrasound scanning equipment and a male production room. The production room was seen to be equipped with a toilet cubical, and a sink and chair in the outer part of the room. The centres' second floor consists of a further two consulting rooms each containing an examination couch and ultrasound scanning machine. The premises were seen to be well maintained. All consulting rooms were seen to be equipped with privacy screens. • The cryostore contained four storage dewars. All dewars were seen to be independently locked, connected to low nitrogen level alarms, and were connected to an autodial facility. Access to the laboratory was secured by digilock system with restricted access to authorised personnel only. Low oxygen alarm systems were in place within the laboratory providing advance warning of low oxygen levels in the event of a dewar failure. • Service and maintenance logs provided evidence that all critical equipment within the laboratory had been checked in accordance with recommended protocols. Evidence was also seen that all incubator temperatures were recorded on PC. • The PR noted that during the processing stages following egg collection, developing embryos are split between incubators thereby minimising any potential risk of an incubator failure. • The centre Licence, complaints policy and quality policy were clearly displayed within the waiting room.
Areas for improvement
None
Executive recommendations for Licence Committee
None
Areas not covered on this inspection
All areas covered.

Evaluation
No 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
Ten patient records were reviewed during the course of the inspection which provided evidence that a suitable and sufficient assessment of "Welfare of the Child" had been performed, that all required consent forms had been completed and that all required screening of patients had been performed in accordance with recommended professional body guidelines. The notes were seen to be in good order.
Areas of firm compliance
• The main "working copy" of all patient information is held on computer. This is password protected and access controlled to ensure only authorised members of staff may access and change its content. • The majority of information supplied to patients either pre-consultation or during their treatment cycle was considered to be informative and fit for purpose. Two additions were recommended to the PR (See below). • Documentation requested on the day (which did not require additional compilation), was provided to the inspectors upon request indicating that the centre has an appropriate system for record keeping.
Areas for improvement
• Prior to the inspection, it was reported that no treatments had been reported as being performed during September 2007 and only one treatment reported for October 2007 to the HFEA from the centre using the HFEA computerised reporting system (EDI). This was raised in the interview with the PR. It was noted that appropriate entries of treatments performed had been entered onto the computer system within the allocated time period however, due to a lack of understanding of the system at the point of data entry, the forms had not been "uploaded" to the HFEA for inclusion. The PR noted that the forms would be forwarded to the HFEA following the inspection and that all staff using the data entry programme would be appropriately instructed in its use in the future. • Recommendation was made to include the length of time a patient may store their gametes/embryos within the information provided to patients in addition to the fact that this service is available. Recommendation was also made to include the possible side affects from drugs administered throughout the treatment process.
Executive recommendations for Licence Committee
None

Areas not covered on this inspection
All areas covered.

Evaluation
Some improvement 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	4 Full time consultants 3 Part time doctors 4 Anaesthetists
NMC registered nurses	10
HPC registered scientists	4
Scientists working towards registration	9
Support staff (receptionists, record managers, quality and risk managers etc)	1 x Independent counsellor and 7 administrative staff.

Summary of laboratory audit
The laboratory audit provided pre-inspection provided evidence that all samples held in storage had been accounted for. It was noted that the documentation for the audit however did not contain details of the date the audit was performed and by whom, the number of dewars audited, the number of samples contained within the dewars, details of the audit process, whether any anomalies had been detected during the course of the audit or any corrective actions that had been taken as a result. This was discussed with the PR and agreement was made that all future laboratory audits would be provided to include these details. (See recommendations section on page seven of this report)
Summary of spot check of stored material
One sperm sample was tracked from the log to the dewar location and one sample racked from the dewar to the log. No discrepancies were identified. One embryo sample was tracked from the log to the dewar and one embryo sample was tracked from the dewar to the log. No discrepancies were identified.
Areas of firm compliance
• All patients are assessed in accordance with the centre's treatment protocols taking into account past medical history, information obtained from both the patient and their referrer and information obtained from a pre-treatment monitoring cycle. Patients undergoing treatment are seen at the clinic daily during their monitoring phase to ensure that

treatment is personalised and adapted to each individuals treatment needs.

- All egg collections are performed using intra-venous sedation, which is administered by an anaesthetist. An emergency trolley containing resuscitation equipment is available and was seen to be checked daily by means of a log signed by the member of staff checking the trolley. If required, any patient requiring emergency medical attention over and above that which can be provided at the centre can be transferred to one of the local hospitals for which the PR has admittance rights.
- The PR explained that 15 incubators are used within the laboratory for the incubation of embryos. He explained that embryos created are split between two incubators. This provides additional safeguards against any one of the incubators failing.
- Systems are in place within the laboratory to capture all relevant traceability data.
- The PR reported that staff qualifications and affiliations with relevant professional bodies are obtained prior to a contract of employment being awarded, and that registration details are then checked annually to ensure registration has not expired. The Quality Manager confirmed that criminal record bureau checks are also performed on each member of staff prior to commencement.
- Staff interviewed stated that they felt well supported in their roles both by their working colleagues and by the management of the unit.
- All staff interviewed stated that they were well supported in their training needs and continuous professional development. Evidence was seen that an effective induction programme is in place for all new starters (induction checklist evidenced), and training logs are maintained centrally for all staff containing details of all mandatory training provided and all in house training programs provided for staff, also evidenced.
- Assessments of staff competence are conducted and documented within the personnel folders for the staff. Evidence was provided where the PR had assessed a newly appointed embryologist as being competent.
- All staff receive an annual appraisal. These are documented and kept within each staff members personnel file.
- Both the Quality Manager and the PR noted that a staff audit program is in place. It was explained that staff from other disciplines within the unit audit each others practice against written protocols.
- The laboratory subscribes to the NEQAS scheme.

Areas for improvement

- During the inspection, it was noted that a three-embryo transfer had been performed on a woman under the age of 40 years. It was explained that a clinical decision had been made based on the patients' "difficult" history including several unsuccessful attempts using IVF in another unit.
- Witnessing protocols do not currently reflect actual practice. It was noted that although all appropriate witnessing steps were conducted, the policy did not reflect this. It was agreed with the senior embryologist, external consultant and the PR that the policy would be reviewed within the near future, at the same time as conducting a full risk assessment on witnessing practices within the centre.
- At the time of the inspection, no licensed embryo practitioners' report for the period of 2006 had been forwarded to the HFEA in relation to PGD. This was raised with the PR during the inspection who provided assurances that this data would be submitted within the near future. In addition, there had been no report forwarded to the HFEA regarding the number of PGD cases that had been performed during the current year. The PR again

gave assurances that this information would be forwarded within the near future. During the feedback session at the end of the inspection, the logs containing information related to PGD cases performed at the centre were made available, however these were not inspected at that time. This information to be submitted as per the requirements set out in Chairs Letter CH(06)03 to the HFEA within one month.

- Nine scientists were reported by the PR as not being HPC registered. Evidence should be made available during future inspections at the centre to show progress being made by staff to meet with HPC registration requirements.

Areas for consideration
During the course of the inspection, it was noted that the centre store gametes and embryos together within the same dewar. Recommendation is made to assess the potential risks associated with this practice and the possibility of cross-contamination.
Executive recommendations for Licence Committee
Emphasise the requirement to present appropriate documentation regarding PGD as highlighted in CH(06)03.
Areas not covered on this inspection
Validation of equipment and processes.

Evaluation
Some improvement required.

Report compiled by:

Name TONY KNOX

Designation HFEA Inspector

Date 23rd November 2007

Appendix A: Centre Staff interviewed

Mr. Mohamed Taranissi (PR)
Four other centre staff.

Appendix B: Licence history for previous 3 years

Centre was first Licensed in 1995

Licence	Type	Active From	Expires
L0157/19/a *	Treatment and Storage	29/09/2007	17/01/2008
L0157/18/a	Treatment and Storage	10/08/2007	28/09/2007
L0157/17/a	Treatment and Storage	19/07/2007	09/08/2007
L0157/16/a	Treatment and Storage	14/07/2007	19/07/2007
L0157/15/a	Treatment and Storage	05/07/2007	13/07/2007
L0157/14/a	Treatment and Storage	01/07/2007	04/07/2007
L0157/13/b	Treatment and Storage	01/07/2006	30/06/2007
L0157/13/a	Treatment with Storage	01/04/2006	30/06/2007
L0157/12/b	Treatment with Storage	01/09/2005	30/06/2007
L0157/12/a	Treatment with Storage	01/09/2005	30/06/2007
L0157/11/c L0157/11/b L0157/11/a	Treatment with Storage	01/07/2004	30/06/2007

* This Licence was last considered on 13th July 2007. Findings and decisions from that Licence Committee can be found in the minutes dated 13th July 2007 on the HFEA website. The decision is currently subject to appeal.

Appendix C:

RESPONSE OF PERSON RESPONSIBLE TO THE INSPECTION REPORT

Centre Number……

Name of PR……..

Date of Inspection……..

Date of Response……

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

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

Signed……

Name…….

Date……

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

TRIM: