Licence Renewal Inspection Report for Treatment and Storage Centres

Bourn Hall Clinic
0100

Date of Inspection: 20 July 2006
Date of Licence Committee: 22 November 2006

TRIM: 06/3144

CENTRE DETAILS

Centre Address	Bourn Hall Bourn Cambridge Cambridgeshire CB3 7TR
Telephone Number	01954 719111
Type of Inspection	Renewal
Person Responsible	Mike Macnamee
Nominal Licensee	Peter Brinsden
Licence Number	L0100/11/b
Inspector(s)	Dr Vicki Lamb
	Dr Neelam Sood
	Ms Jennifer Davenport
Fee Paid - date	Not yet due
Licence expiry date	30 March 2007

Index

About the Inspection:
This inspection visit was carried out on 20 July 2006 and lasted for 7 hours. The report covers the pre-inspection analysis, the visit and information received between September 2005 and July 2006.

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

The report summarises the findings of the 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

Centre 0100 was first licensed in 1991. It currently provides donor insemination, IVF, ICSI, egg sharing, IUI and freezing facilities. This is a large, active centre providing approximately 1100 treatment cycles in the last year.
The premises are based within a converted hall and purpose-built unit. The building is very extensive and provides an adequate, clean, private, well maintained and functional environment for patients, administrative staff, clinical and laboratory processes.
Sufficient numbers of appropriately qualified and competent staff are employed at the centre. There is an organisational structure in place which defines accountability, responsibility and reporting relationships. The centre is ISO 9001 accredited.
The person responsible is appropriately qualified to discharge his duties as outlined in section 17 of the HF&E Act. It was apparent that he was familiar with, clinical, nursing, laboratory, administrative and managerial aspects of the service. He is well supported by staff and an established management team.

Activities of the Centre

Licensed treatment cycles	IVF ICSI Egg donation Egg recipient	510 527 23 21
Donor Insemination		17
Unlicensed treatments	IUI	
Research	Yes	
Storage	Yes	

Summary for Licence Committee

The inspectors recommend the renewal of the centre's licence for five years.

The centre has a good history of compliance. One breach was identified during the inspection and the centre is currently working to address this. Since the inspection the PR has reported that this issue has been rectified.

Patient and staff satisfaction was seen to be good during the inspection and on analysis of the HFEA patient satisfaction surveys.

Risk Assessment

The centre has a risk score of 21%.

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
One sperm sample was being stored out of consent.	Consent for further storage must be obtained or the samples must be disposed of. The timing of billing should be changed, or some other effective mechanism put in place, in order to avoid this situation occurring.	Complied with since inspection Complied with since inspection

Non-Compliance

Area for improvement	Action required	Time scale
None		

Recommendations	Time scale
The security guards should be included on the centre's licence.	Complied with since inspection.

Proposed licence variations

None

Changes/ improvements since last inspection

The centre underwent a successful management buy out in December 2005, regaining independence from the previous parent company.

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 findings from inspection
Evidence is drawn from:

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

Areas of firm compliance
The Person Responsible (PR) and a number of staff commented that the organisational structure and operational procedures of the centre are appropriate for the licensed activities provided. The organisational structure is documented, known and available to all staff. It includes responsibilities, accountability and reporting relationships. The PR is appropriately qualified as documented in his CV, and demonstrated at interview, to meet the specified PR requirements and discharge his duties outlined in section 17 of the HF&E Act. He was aware of Chair's letters. In discussion the PR stated that HFEA alerts are circulated to all staff via email or in meetings. Staff stated that meetings occur every two weeks to discuss clinical concerns. Minutes of the meetings were seen during the inspection visit. The counsellor and other staff confirmed that updates on changes affecting all staff at the centre are emailed and sent to all members of staff. One of the consultants has been designated the centres quality manger. She was very involved in the ISO accreditation scheme, is currently updating and reviewing the centres quality manual and is implementing a document control policy across the entire service. The incident folder was reviewed by the inspection team. There were no incidents reported to the HFEA in the last year and no incidents in the incident folder which should have been reported. In discussion the PR explained that a Business Continuation Group exists within the centre. This group has developed plans of action in the event of an interruption to operations and formal arrangements are to be developed with another centre. There is also a Health and Safety Committee within the centre which operates site-wide. There is a risk management and a clinical effectiveness team at the centre. Each team meets at least quarterly to discuss areas for development. It was reported that inspections of the centre's transport clinics are undertaken at least every 2 years, and a clinical audit of the centre takes place every 6 months.

Areas for improvement
The security guards are not included on the centre's licence. This has been addressed since the inspection.
Executive recommendations for Licence Committee
None
Areas not covered on this inspection
All areas covered

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:

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

Live Birth Rates
The IVF/ICSI and FET success rates for all age groups are higher than the national average. The DI success rates do not differ significantly from the national average.
Areas of firm compliance
The patient information provided to the inspection team included information on success rates. The team considered the information provided to be satisfactory. The inspection team was informed that success rates for the centre are reviewed on a regular basis and presented to the management team quarterly. Individual performance for each staff member is also reviewed. Welfare of the Child issues are discussed at multi-disciplinary team meetings when appropriate, and it was reported to the inspection team that the 10 cases referred to the Ethics Committee in the last year were mainly due to requests for surrogacy treatment. During a tour of the premises it was seen that patient records are stored in a locked room, the lobby to which is accessed using a swipe card. Documentation provided to the inspection team states that women under 40 will have no more than 2 embryos transferred in each cycle. Four patients were interviewed and all were very happy with the service they had received. The men's rooms were seen by the team and were considered to be comfortable, quiet and discreet. The complaint log was reviewed on the day of the inspection. All of the 14 complaints received in the last year had been resolved. Responses to the HFEA patient questionnaire revealed that patients at this centre are more satisfied than average with all aspects of the centre and their treatment. An audit of counselling services was provided to the inspection team. A total of 575 sessions were provided between January 2005 and May 2006. The counsellor stated that patients can often be seen the next day. She attends multi-disciplinary team meetings and training courses. The counselling notes are kept separately from the main patient notes. The counsellor commented that she very much feels part of the team and is updated on changes within the centre, included in clinical discussions where relevant and enjoys the working environment of the centre.

The centre does not recruit sperm donors. They are currently looking into the possibility of importing sperm from abroad and will submit applications for Special Directions at the appropriate time. The centre have recently instigated a sperm sharing programme and there has been some positive responses to this from patients. An open day is held monthly on a Saturday afternoon where patients can attend to visit the centre, meet the staff and learn more about the treatments. New confidentiality protocols are being developed, and the team were informed that all staff sign a confidentiality agreement on commencement of employment. The PR is the Child Protection Officer.
Areas for improvement
None
Executive recommendations for Licence Committee
None
Areas not covered on this inspection
All areas covered

Evaluation
No improvements required

3. Premises and Equipment

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

Summary of findings from inspection:

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

Areas of firm compliance
The centre occupies extensive premises within a converted hall and also purpose-built buildings. There are several patient waiting rooms, facilities to ensure patient privacy and dignity and suitable equipment and space for the work carried out. A security guard patrols the premises throughout the night. The laboratory facilities have swipe card access and are also locked at night. The Head of Science reported that the background air quality in the laboratory is grade C and that in the flow hoods is grade A when at rest. All the storage dewars were seen to be locked and alarmed, and there is a spare dewar available in case of emergency. The dewar top up record was seen. The Scientific Inspector was told that dewars are replaced after 10 years use. Two low oxygen alarms are located in the laboratory. The method for testing these was demonstrated to the Head of Science during the inspection. The Head of Science informed the team that there is an emergency generator for back-up power supply, which is tested once a month. Records of quality control checks for the laboratory equipment were seen. They were performed regularly and the measurements were within acceptable parameters. The life support trolley was seen during a tour of the premises and it had been recently checked. In discussions the inspection team was informed that medical and nursing staff attend basic life support training every year, and advanced life support training every three years.
Areas for improvement
The final position of the low oxygen alarms is yet to be decided. Aspects for consideration were discussed during the inspection. The final position of the low oxygen alarms has been decided since the inspection. Information regarding this and protocols for testing and responding to the alarms have been submitted to the executive.
Executive recommendations for Licence Committee
None
Areas not covered on this inspection
All areas covered

Evaluation
Some improvements required

4. Information

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

Summary of findings from inspection:

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

Outcome of audit of records
23 patient records were reviewed at the inspection. These were found to be in good order with evidence of Welfare of the Child assessment and HFEA consents to use and storage.
Areas of firm compliance
The HFEA licence was seen displayed in the reception area. Registry at HFEA reported no issues of late reporting. The storage location of patient records was seen during the inspection and considered to be adequate. It was reported that all notes are returned to this room at the end of each day. It was explained to the inspection team that there is a bar coding system to aid in tracking the location of notes. The information for patients and protocols that were provided to the inspection team was considered to be adequate. Patients' notes were seen on the day of the inspection, with evidence of witnessing within them.
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
- Recruitment and retention of staff
- Staff competence, qualifications, training and CPD

Full time equivalent staff

GMC registered doctors	7
NMC registered nurses	13 plus 4 auxillary nurses
HPC registered scientists	3
Scientists working towards registration	4
Support staff (receptionists, record managers, quality and risk managers etc)	9

Summary of laboratory audit
A rolling audit of stored samples is performed during the course of each year. A summary of the 2005 audit was provided prior to the inspection. No discrepancies were reported.
Summary of spot check of stored material
A spot check of stored material was conducted during the course of the inspection. Two embryo samples were checked from the log book entry to their place within the dewars, and two embryo samples were checked from the dewars to the log book entries. No errors were found. Two sperm samples were checked from the log to the dewar location. No errors were recorded.
Areas of firm compliance
All patients are screened for HIV, Hepatitis B and C prior to treatment. Witnessing was observed in practice within the laboratory. Witnessing was performed each time a sperm sample was moved between tubes. A new protocol has been developed, which was shown to the Scientific Inspector, making witnessing procedures more clear. Evidence of communication between the clinical and laboratory staff was observed on the day of the inspection. All staff are recruited via the Human Resources department at Bourn Hall. The Head of the Medical Team explained the process, confirming that references are taken up and staff are initially employed for 12 months before being offered a permanent contract. An induction programme for new staff is in place. This takes place over the course of 3 months for medical staff and evidence of induction training was seen for one of the

embryologists.
The Head of the Medical Team confirmed that all the doctors have GMC registration.
Evidence of Health Professions Council registration was seen for two of the embryologists and one record of CPD was seen also.
Appraisals take place once a year with a mid-year review.
All staff interviewed stated that they had opportunities for CPD, in the form of both internal and external activities.

Areas for improvement
One sperm sample was being stored out of consent. It was explained that this had occurred due to the timing of billing patients for storage. The Scientific Inspector suggested that the timing of billing should be changed in order to avoid this situation occurring. The Head of Science is writing a new protocol for this and will provide it when it is completed. Since the inspection the PR has confirmed that consent for further storage has been obtained from the patient and the protocols for billing have been amended and submitted to the executive.
Executive recommendations for Licence Committee
None
Areas not covered on this inspection
PGD/PGS – not provided at this centre.

Evaluation
Some improvements required

Report compiled by:

Name: Dr Vicki Lamb

Designation: Inspector

Date: 11 August 2006

Appendix A: Centre Staff interviewed

Person Responsible – Dr M Macnamee

Eight other members of staff

Appendix B: Licence history for previous 3 years

2002

Licence Committee 17th July
The Committee agreed to continue the Centre's licence, to expire on the 31st April, 2004, with no conditions and no recommendations.

2003

Licence Committee 26 March 2003
Change of nominal licensee

Licence Committee 7 October 2003
ICSI practitioner inspection report

2004

Licence Committee 13 December 2004
After reviewing his Curriculum Vitae, the Committee agreed to recognise Mr Tony Knox as the Person Responsible. They also agreed to recognise Mr Peter Brinsden as Nominal Licensee. Licence continued with no conditions and no recommendations.

2005

Licence Committee 31 October 2005
Licence continued with no conditions.

Licence Committee 19 December 2005
Change of PR approved.

Appendix C:

RESPONSE OF PERSON RESPONSIBLE TO THE INSPECTION REPORT

Centre Number: 0100

Name of PR: Mike Macnamee

Date of Inspection: 20th July 2006

Date of Response: 18 August 2006

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

1. Breach sperm sample: Patient contacted and consent renewed for further storage. Protocol for billing revised to ensure future compliance.
2. Low O2 alarms: protocols in development and will be submitted by October.
3. Security Guards: Request for inclusion on licence August 2006.

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

Name: Mike Macnamee

Date: 18th August 2006

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).

Nil

Licence Committee Meeting

22 November 2006
21 Bloomsbury Street London WC1B 3HF

MINUTES Item 2

Bourn Hall Clinic (0100)
Licence renewal

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

In Attendance:
Trish Davies, Director of Regulation
Marion Witton, Head of Inspection
Claudia Lally, Committee Secretary

Legal Adviser:
Judith Maunder, Morgan Cole Solicitors

Observing:
Melanie Ash, Regulatory Administrator
Grace Cunningham, 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 (30 pages)
- no papers were tabled.

1. The papers for this item were presented by Vicki Lamb, HFEA Inspector. Dr Lamb informed the Committee that this centre had a good history of regulatory compliance. The inspection team had identified one breach of the Human Fertilisation and Embryology Act 1990, which was a sperm sample being stored after the expiry of the consent to storage. The centre has since addressed this event and the reasons for it. On the day of the inspection visit, the inspection team spoke to patients and to staff. The patients, in particular, said that they were very satisfied with the treatment they were receiving. The inspection had been very positive and the inspection team recommended the licence be renewed for a period of five years.

2. The Committee decided to renew the centre's licence for a period of five years with no additional conditions.

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