Licence Renewal Inspection Report for Treatment and Storage Centres

Assisted Conception Unit
0119

Date of Inspection: 19th October 2006
Date of Licence Committee: 14th February 2007

TRIM: 06/3144

CENTRE DETAILS

Centre Address	Assisted Conception Unit, Birmingham Women's Hospital, Edgbaston Birmingham, B15 2TG
Telephone Number	0121 623 6916
Type of Inspection	Licence Renewal
Person Responsible	Sue Avery
Nominal Licensee	Julie Burgess
Licence Number	L0119/13/c
Inspector(s)	Elliot Lawrence
	Neelam Sood
	Bryan Woodward
Fee Paid - date	Not due yet
Licence expiry date	30/11/2007

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About the Inspection:
This inspection visit was carried out on 19th October 2006 and lasted for 8 hours. The report covers the pre-inspection analysis, the visit and information received between November 2005 and October 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

The Assisted Conception Unit at the Birmingham Women's Hospital has been licensed by the HFEA since 1992. Treatment is provided to patients funded by the local PCTs and self funded patients who fall outside the eligibility criteria or who want to progress to treatment faster than current NHS waiting lists allows.

The centre is licensed to carry out DI, IVF and ICSI with donor gametes; and chemical assisted hatching. In 2005 the centre performed approximately 800 licensed treatment cycles. The service is centered on the nursing staff with patients being prepared for treatment in the outpatients' department.

The unit has a good history of regulatory compliance and the current licence has no additional conditions.

The Person Responsible (PR) is Sue Avery who has held the position since August 2004.

Activities of the Centre

Licensed treatment cycles	**IVF** **ICSI** **FET** **Egg sharing** **Egg donation**	
Donor Insemination	**Yes**	
Unlicensed Treatments	**IUI, Ovulation Induction**	
Research	**Yes**	
Storage	**Yes**	

Summary for Licence Committee

The inspectorate were satisfied that the centre is well organised. Four breaches were noted during the inspection and a number of recommendations have been made:

- Emergency contingency plans to be documented and formalised.
- Ensure storage tanks are secured and alarmed at all times when in use.
- The centre was reminded to ensure that all witnessing steps stated in the Direction D.2004/4 are contemporaneously witnessed and signed.
- Update witnessing protocol to include disposal of embryos and gametes as required by Direction D2004/4.
- It is recommended that a risk assessment is performed on the witnessing steps that occur in the GMP laboratory.

Risk Assessment

Last calculated risk score was 5%, which falls within the low risk category.

Overall judgement of the effectiveness of the centre

No Improvements required	Some Improvement required	Significant Improvement required
	✓	

Evaluations from the inspection

Topic	No Improvements required	Some Improvement required	Significant Improvement required
1. Organisation		✓	
2. Quality of the service	✓		
3. Premises and Equipment	✓		
4. Information		✓	
5. Laboratory and clinical processes		✓	

Breaches of the Act or Code of Practice

Breach	Action required	Time scale
In four files not all of the double witnessing steps were signed by two persons. The centre was reminded to ensure that all witnessing steps stated in the Direction D.2004/4 are contemporaneously witnessed and signed.	Ensure that all witnessing steps are contemporaneously witnessed and signed.	**Immediately**

Non-Compliance

Area for improvement	Action required	Time scale
Ensure storage tanks are secured and alarmed at all times when in use.	Secure individual dewars and store samples in alarmed dewars	All remedial actions taken during the inspection

Recommendations	Time scale
Ensure emergency contingency plans to be documented and formalised.	**One month**
Update witnessing protocol to include disposal of embryos and gametes.	**One month**
Perform a risk assessment on the witnessing steps that occur in the GMP laboratory.	**One month**

Proposed licence variations

None

Changes/ improvements since last inspection

Recommendation	Action taken
Compliance with the EU Tissue Directive 2004/23/EC coming into legislation in 2007.	The Laboratory has been upgraded to meet the requirements. The theatre is in the process of being upgraded.
OHSS protocol should revised to take in consideration the issues raised by HFEA Alert 17.	OHSS protocol updated and submitted to HFEA inline with the Licence Committee's recommendations.

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
- Clinical governance

Areas of firm compliance
The centre was found to be well organised, with clear reporting lines for staff. An organisation chart was provided to the inspection team. All paperwork requested on the day of inspection was produced promptly, reflecting good and effective organisation within the centre. There are a number of regular meetings within the centre. An operations meeting is conducted weekly and monthly so part time staff can attended. The meeting covers issues such as NHS contracts, budget, reports from each discipline, discussion of new protocols, staffing issues and HFEA communications. A seminar based multi disciplinary meeting is held once a monthly which all staff are encouraged to attend. There is also a weekly clinical meeting to discuss current cases. There is an established risk management and clinical governance structure through the Trust. The PR sits on the hospital clinical governance board, which meets on a monthly basis. All incidents reported (clinical and non-clinical) and complaints received by the hospital are discussed and reviewed. The inspection team viewed the incident reporting policy and incident reporting books. Minutes for all meetings are circulated by email. Hard copies are kept in the staff room in order that they are available to all staff at any time. The folders were reviewed by the inspection team. There is a good system for ensuring that all staff are aware of HFEA Alerts and Chair's letters. Evidenced from meeting minutes and interviewing staff. A folder contains the details of the HFEA Alerts, the recommendation(s) and if the unit needs to take any actions. An action completion date is also given. Examined during the inspection. We were also provided with a complete set of hospital risk management policies and procedures. All staff interviewed were aware of the incident reporting procedure.

The centre is in the process of implementing ISO9001:2000
Areas for improvement
• Contingency plans to be documented and formalised.
Executive recommendations for Licence Committee
None
Areas not covered on this inspection
➢ Business planning ➢ Payment of treatment fees
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
The Centre's success rates are clearly displayed in the patient's waiting room.
Areas of firm compliance
A protocol for 'welfare of the child' (WoC) assessments was provided to the inspection team. This was found to be satisfactory. The form provided by the HFEA is being used for patients to complete. If the staff have concerns regarding a patient, they ask patient permission to contact their GP. There is access to an ethics committee in the event concerns being raised that cannot be resolved. All patient records reviewed had evidence of WoC assessments. Current patient records are securely stored within a room which can only be entered via key pad access. Older records are store in secure off-site storage. The choice of treatment is first discussed at the treatment information evening. Patients are then talked through the range of treatment options appropriate to themselves during their initial consultation with the consultant. This was confirmed through interview with nursing staff and patients. The complaint's policy and name of the complaint's manager, is clearly displayed in the centre waiting room. The complaint's log for the last year was reviewed; there were eight complaints of which six have been resolved. All complaints are handled through the Trust's complaints procedure. The centre does have its own patient feedback system, but has had minimal feedback. There have been six HFEA patient questionnaires returned since the last inspection. A summary of the feedback was provided to the PR. The vast majority of comments were positive. All patients commented that they had received sufficient written and verbal information and were given the opportunity to ask questions. Most patients stated they were made aware of the availability of counselling which was easily accessible.

Two patients were interviewed on the day of inspection; all were satisfied with their experience and treatment at the centre. They complimented the level of personal interaction and the level of information provided.

There is one independent counsellors employed by the centre. The counsellor is registered with British Infertility Counselling Association and receives monthly supervision. The counsellor reported that she had undertaken appropriate CPD within the last year.

Counselling is free of charge and is routinely offered to all patients at their initial consultation. This was confirmed through staff and patient interviews. The counselling information is included in patient information packs, which states the counsellor's name and contact number. Patients normally self refer, or are referred by a member of the clinical or nursing staff. Counselling is considered mandatory for those receiving or donating gametes. A counselling audit for the period April 2005 to March 2006 was provided. This showed that 122 patients had received counselling.

The counsellor's confidential notes are kept in locked filing cabinets in the counsellors offices.

New documentation on donor selection and egg sharing agreements were provided on the day of inspection. These had been reviewed in line with the recent SEED guidance.

Areas for improvement
None
Executive recommendations for Licence Committee
None
Areas not covered on this inspection
None
Evaluation
No 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 centre is located on the second floor of the hospital. A patient waiting area is sited next to the reception area, which leads to three consulting rooms and a coded-locked patient records store. Through a set of coded-locked doors are the theatre, recovery room and two laboratories and cryostore. The main laboratory has been refitted to meet current good manufacturing practice. The cryostore can only be accessed through a locked door with swipe card. The cryostore contains a low level oxygen alarm. The oxygen alarm and dewar alarms are linked to an autodial out system which is checked weekly on a Friday. The record of testing was examined and up to date. The autodialer phones a pager which is carried by the person on call. During the inspection it was found that two dewar were not secure and two dewars were not alarmed. The two unlocked dewars were padlocked during the inspection. All samples were moved to alarmed dewars during the inspection. All long term storage samples have been split between two dewars and was confirmed by examining the database of stored samples. Cabinets, incubators, fridges and other essential pieces of equipment had documented evidence of regular servicing/maintenance. The centre's treatment room contains resuscitation equipment and anaphylaxis kit. All clinical staff receive annual advanced life support training. Evidenced from records of mandatory training. The inspection team found the male production room to be satisfactory but thought it would benefit from some decoration. There are two comfortable, discreet rooms available for patients providing sperm samples. Patients are presented with a form which identifies them and must be signed before the handover of the sample pot. Receipt of the sample is similarly witnessed. Home production is discouraged but if it does occur the patient signs a form confirming that this was done at his request. We were informed the hospital has a back up generator for use in an emergency.

Areas for improvement
Ensure storage tanks are secured and alarmed if samples are present.
Executive recommendations for Licence Committee
None
Areas not covered on this inspection
None
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
On the day of inspection 15 patient records were selected at random. These were reviewed for evidence of consents, WoC assessments and witnessing. All files were found to contain appropriate completed and signed consents and WoC assessments. In four files not all of the double witnessing steps were signed by two persons. The centre was reminded to ensure that all witnessing steps stated in the Direction D.2004/4 are contemporaneously witnessed and signed.
Areas of firm compliance
All patient information was submitted with the pre inspection paperwork. This was found to be complete, clearly written in a patient friendly manner. All necessary detail was found within the information, the inspection team considered it to be of a good standard. Patients interviewed and patient questionnaires reflected their satisfaction with provision of information. All protocols requested were submitted with the pre inspection paperwork. These were reviewed and found to be appropriate and fit for purpose. All protocols were numbered and had review dates. The HFEA registry reported no concerns or issues with the centre's returns.
Areas for improvement
• Contemporaneous witnessing • Update witnessing protocol to include disposal of embryos and gametes as required by Direction D2004/4.
Executive recommendations for Licence Committee
None
Areas not covered on this inspection
None
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	5
NMC registered nurses	7
HPC registered scientists	4
Scientists working towards registration	3
Support staff (receptionists, record managers, quality and risk managers etc)	2 Counsellors 3 Healthcare Assistants 7 Admin and Clerical

Summary of laboratory audit
An audit summary dated 08/08/06 of the andrology tanks was submitted. The centre reported 11 minor consent and spelling related discrepancies between the tissue in storage and the index of tissue in the bank. An audit summary of the embryology tanks dated 06/05 – 08/05 was submitted. The centre reported no discrepancies. Auditing of the sperm and embryo tanks is on going.
Summary of spot check of stored material
One embryo and one sperm sample were checked from the tank to the notes, no discrepancies were found.
Areas of firm compliance
Patient information details the screening requirements for patients and donors, and the rationale behind this. Screened and unscreened samples are stored in separate dewars. The double witnessing sheet in the laboratory was observed and showed that the procedures on the day of the inspection had been signed off. The laboratory manager was able to find all paperwork requested. This indicated a well organised documentation system.

The use of a GMP laboratory means witnessing of procedures involves viewing hand handle dishes through the window in the laboratory door. It is recommended that this process is risk assessed.

The three embryo transfer policy clearly states that three embryos will not be transferred unless the woman has reached her 40th birthday and there are other appropriate circumstances. The three embryo transfer log showed that three embryo transfers had been performed on patients over forty.

The level and availability of CPD to staff was assessed as good. All staff interviewed reported that they were content with the availability and accessibility of CPD, training and development.

Examples of nurses CPD provided this year are: resuscitation, manual handling, fire safety, distance learning scanning course at Derby (2 nurses undertaking this course.)

It was reported that CPD for the embryologists occurs inline with the ACE scheme. This has involved attending clinical meetings, journal research and external meetings such as ESHRE. One members of the team has just finished ACE certificate and is in the process of registering.

Recruitment of new staff follows the rigorous recruitment policy of the Trust HR Dept. The PR has an input into this and requests the skills and qualifications required. She also sits on recruitment panels. The PR is confident that all references are followed up.

Areas for improvement
It is recommended that a risk assessment is performed on the witnessing steps that occur in the GMP laboratory and be submitted to the HFEA.
Executive recommendations for Licence Committee
None
Areas not covered on this inspection
None
Evaluation
Some improvement

Report compiled by:

Name:

Designation: Inspector

Date: 16th November 2006

Appendix A: Centre Staff interviewed

The PR, Dr Sue Avery and nine other members of the team.

Appendix B: Licence history for previous 3 years

Licence	Status	Type	Start date	Expiry date
R0119/13/c	Active	Treatment with Storage	01/05/2006	30/11/2007
R0119/13/b	Expired	Treatment with Storage	01/02/2006	30/11/2007
R0119/13/a	Expired	Treatment with Storage	01/09/2005	30/11/2007
R0119/12/a	Expired	Treatment with Storage	01/12/2004	30/11/2007
R0119/11/b	Expired	Treatment with Storage	24/11/2004	30/11/2004
R0119/11/a	Expired	Treatment with Storage	01/12/2003	30/11/2004

No conditions or recommendations on Licences.

Appendix C:

RESPONSE OF PERSON RESPONSIBLE TO THE INSPECTION REPORT

Centre Number……0119

Name of PR…… Sue Avery

Date of Inspection……19th Oct 06

Date of Response……..6th Dec 06

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

Since the inspection a risk assessment of witnessing in the GMP laboratory has been undertaken and submitted to the HFEA. The process involves the embryologists each being asked to read a series of names written on dishes through the glass panel. The risk assessment showed "None of the embryologists produced any mis-identification errors, neither did the administrator".

Since the inspection formalised a reciprocal agreement with the CRM at Walsgrave to take responsibility for each others patients/stored material in the event of disaster. A copy of the agreement has been sub,mitted to the HFEA.

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).

Witnessing for embryo disposal - the paperwork is attached. It is referred to in point 15 of the witnessing protocol. There is no separate sheet for this as the signatures are on the freeze sheet and in the notes. I am not sure why this was missed on the day.

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