



New Premises Site Visit Report

Name of Applicant	Professor Brian Lieberman (Person Responsible)
Address of Proposed Premises	The Bridgewater Hospital 120 Princess Road Manchester M15 5AT
Has the applicant been licensed before	Yes
If yes: Centre Number and Address of previous premises	0033 BUPA Hospital Russell Road Whalley Range Manchester M16 2AJ
Inspector(s)	Dr Vicki Lamb
	Mr Tony Knox
Date of visit	26 April 2006
Date of any previous visits to these premises	19 January 2006 (Renewal inspection visit. The administration offices had moved to this site but no licensed treatment was occurring here at that time.)

About the Site Visit

The purpose of the site visit report is to confirm to the PR the findings of the inspection highlighting areas of firm compliance and good practice, as well as areas where further improvement is required. The report may be shared with other regulators on a need to know basis, such as the HC and HTA.

Brief Description of the Centre

Manchester Fertility Services has been providing fertility treatment and storage of gametes and embryos since 1986.

A renewal inspection was undertaken on 19 January 2006 and the centre's licence was renewed for a period of three years. There are no conditions or recommendations on the current licence.

This is a fee-paying unit that does not have an NHS contract with any PCT.

Most patients attending for treatment live in the local area and are referred by their GP. The centre treats a small number of overseas patients. There are no patient selection criteria.

The centre is currently based on two sites; the administration offices and consulting rooms are at The Bridgewater Hospital, which is a newly built site, and the laboratories and theatre (where licensed treatment is undertaken) are at the BUPA Hospital. The centre intends to move all activity to The Bridgewater Hospital.

Summing up meeting notes

The room intended for the storage of patient records is already full and arrangements need to be made to make further storage space available.

Alternative office space should be found for the Managing Director of the hospital.

Patients from the main hospital should not be using the rooms within the centre.

Fire doors must not be propped open.

Signage to the fire exit in the secretaries' office must be improved.

The lift control room door should be kept locked and the stores removed from that room.

The Principal Embryologist agreed to look into the provision of a suitable transporter for sperm samples.

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 of:

- Organisation of the centre
- Resource management
- Risk management
- Contingency arrangements
- Clinical governance

Summary of Findings
<p>The hierarchical organisation and staffing structure of the centre will remain the same following the change of premises, and this was considered satisfactory at the last inspection. A draft timeline has been put in place for the move and this was shared with the inspection team. Staff are intending to have a six week period between the building work being completed and patients receiving treatment. A small number of patients will receive treatment when the new premises are first opened. This will enable the patients to be transferred to centre 0067 for treatment if there are any unexpected problems with the new premises. Centres 0033 and 0067 have an existing close working relationship; Professor Lieberman is Person Responsible at both centres.</p> <p>A risk assessment for the relocation of the nitrogen storage vessels containing sperm and embryos has been performed by the centre staff and was provided to the team.</p> <p>The clinical governance of the centre will come under that of the Bridgewater Hospital as a whole. The new hospital is registered with the Healthcare Commission. An inspection team from the Healthcare Commission have visited the centre and the Bridgewater Hospital and discussion with that Inspector revealed that they have no concerns.</p>
Areas for improvement
None
Executive recommendations for Licence Committee
None
Standard of organisation
(a) The applicant meets the requirements for organisation

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:

- Confidentiality (including safe storage of patients' records)
- Privacy and dignity of patients
- Counselling facilities and services

Summary of Findings
<p>The services offered to patients will not change as a result of the change of premises. The inspection team toured the premises. Building work was still underway and the proposed new premises were unfinished at the time of the visit. All access to the centre will be controlled with an intercom system, proximity cards or keypad locks. Areas such as the laboratory and records store will have additional proximity card systems or keypad locks. Evidence of this was seen on the tour. The centre will have it's own dedicated entrance and reception area, separate from that of the main hospital, which will provide additional confidentiality for patients. This entrance is in use at present. Consulting rooms in the new premises are already in use and were considered adequate at the last inspection. The team was shown the recovery area which will be used for both fertility patients and patients attending the main hospital. There are some private rooms and curtained bays for extra privacy as well as an open recovery area.</p> <p>Centre staff informed the team that the Managing Director of the hospital would have an office within the centre. The team considered that this would be inappropriate and would increase the potential of a breach of patient confidentiality, particularly due to the number of staff and visitors, who would not be on the centre's licence, requiring access to the Managing Director. The team was also informed that one of the rooms within the centre will be used by patients from the main hospital. The inspection team considered that to be inappropriate for similar reasons.</p> <p>The team were shown the room in which it was intended to store patient records. This room had a key pad lock for security. The team considered that the room was rather small for it's intended purpose, and suggested an alternative location for storage of patient records (see section 3).</p> <p>There is a counselling room within the unit which is situated in a quiet area adjacent to offices.</p>
Highlighted areas of firm compliance
<p>Access to the centre and to specific areas within the centre will be controlled via an intercom system, proximity cards or keypad locks.</p> <p>The centre has a dedicated entrance and reception.</p>
Areas for improvement
<p>The room intended for the storage of patient records is already full and an alternative should be found.</p> <p>Alternative office space should be found for the Managing Director of the hospital.</p> <p>Patients from the main hospital should not be using rooms within the centre.</p>
Executive recommendations for Licence Committee
<p>The Managing Director of the hospital should not have an office within the centre due to a risk</p>

of a breach of patient confidentiality.

Patients from the main hospital should not be using the rooms within the centre for similar reasons.

The quality of service provided

(b) Actions need to be taken before the applicant meets the requirements for **quality**

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

Summary of Findings

Floor plans have been submitted to the inspection team outlining the areas the centre will be occupying. The team toured the proposed new premises, which were not yet completed, and considered them to be generally suitable for the volume of patients and treatments offered. The embryology laboratory is being built to meet the requirements of the European Union Tissues and Cells Directive (EUTD) and clean room standards. There is a double change area with an airlock. The centre staff confirmed that in an emergency the doors creating the airlock will release, and the team also observed an emergency break-glass button. There is a theatre adjacent to the embryology laboratory which will be used for egg collections and embryo transfers. Both the theatre and embryology laboratory were spacious with adequate facilities. There will be a separate andrology laboratory for performing routine semen analyses and two sperm production rooms. Preparation of sperm for treatment will take place in the embryology laboratory. The team queried how the sperm sample would be conveyed from the production room to the embryology laboratory, and then to a treatment room in the case of IUI samples. The Principal Embryologist suggested that there would need to be a 'runner' who could transport the samples and perform other miscellaneous tasks for the embryologists while they were in the embryology laboratory. She also acknowledged that a suitable transporter for the sperm would need to be acquired.

The cryostore will be located next to the embryology laboratory with liquid nitrogen being piped from storage tanks situated in secure stores on the outside of the building. There will be a low oxygen monitor and the alarm light for this was seen outside the cryostore room.

The Principal Embryologist informed the team that the dewars will be fitted with alarms.

Much of the equipment for the new premises will be newly purchased. The staff provided the team with a list of equipment that will be transported from the old premises and what will be disposed of. Professional movers who specialise in laboratory and office relocations have been appointed.

A large number of offices, treatment and consulting rooms will be available within the centre which the team felt would enhance the working environment for staff and the patients' experience.

The staff informed the team that one of the rooms within the centre will be used by patients from the main hospital. The inspection team considered that to be inappropriate (see section 2). It was suggested that this room could be used for storage of patient records.

During the tour of the premises it was noted that a fire door was propped open, there was inadequate signage to a fire exit and the lift control room door was unlocked with stores in that room restricting access to a fire extinguisher. The staff were informed that these issues should be addressed immediately.

Highlighted areas of firm compliance

The embryology laboratory is being built to clean room standards.

There will be a low oxygen monitor and the nitrogen dewars will be alarmed.
Areas for improvement
Fire doors must not be propped open. Signage to the fire exit in the secretaries' office must be improved. The lift control room door should be kept locked and the stores removed from that room.
Executive recommendations for Licence Committee
The health and safety issues identified should be addressed immediately.
The standard of the premises and equipment
(b) Actions need to be taken before the applicant meets the requirements for premises

4. Information

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

Summary of findings from inspection:

- Information to patients and donors
- Protocols

Summary of Findings
Centre staff supplied the team with letters informing suppliers and patients with samples in storage of the centre's change of address. The inspection team was informed that patients receiving treatment currently are aware of the location of the new premises as consultations are already taking place there. Staff have identified that some protocols require revision or deletion due to the relocation. This is currently being undertaken.
Outcome of audit of records
Not done at this inspection
Highlighted areas of firm compliance
Patients with samples in storage have been informed of the centre's new address.
Areas for improvement
None
Executive recommendations for Licence Committee
Revised protocols to be submitted within three months of centre opening.
The standard of information provided
(a) The applicant meets the requirements for information

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:

Summary of Findings
This was not covered during the inspection. It was covered during the previous inspection and found to be adequate.
Highlighted areas of firm compliance
Areas for improvement
Executive recommendations for Licence Committee
None
The provision and quality of staff

Topic 1

- (a) The applicant meets the requirements for **organisation**
- (b) The following actions need to be taken by the date shown before the applicant meets the requirements for **organisation**

Action needed:	To be completed by:
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The following conditions apply:

- (c) The applicant does not yet meet the requirements for **organisation** for the following reasons:

Topic 2

- (a) The applicant meets the requirements for **quality**
- (b) The following actions need to be taken by the date shown before the applicant meets the requirements for **quality**

Action needed:	To be completed by:
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- Alternative office accommodation should be found for the Managing Director of the hospital.
- Patients from the main hospital should not be using the rooms within the centre

To be completed by:

- The date the centre opens
- The date the centre opens

The following conditions apply:

- (c) The applicant does not yet meet the requirements for **quality** for the following reasons:

Topic 3

- (a) The applicant meets the requirements for **premises**
- (b) The following actions need to be taken by the date shown before the applicant meets the requirements for **premises**

Action needed:	To be completed by:
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- Fire doors must not be propped open.
- Signage to the fire exit must be improved.
- The lift control room door should be kept locked and the stores removed from that room.

To be completed by:

- Immediately
- Immediately
- Immediately

The following conditions apply:

- (c) The applicant does not yet meet the requirements for **premises** for the following reasons:

Topic 4

- (a) The applicant meets the requirements for **information**
- (b) The following actions need to be taken by the date shown before the applicant meets the requirements for **information**

Action needed:

To be completed by:

The following conditions apply:

- (c) The applicant does not yet meet the requirements for **information** for the following reasons:

Topic 5

- (a) The applicant meets the requirements for **laboratory and clinical practices**
- (b) The following actions need to be taken by the date shown before the applicant meets the requirements for **laboratory and clinical practices**

Action needed:

To be completed by:

The following conditions apply:

- (c) The applicant does not yet meet the requirements for **laboratory and clinical practices** for the following reasons

Next Action

The centre will stop providing treatment and move to the Bridgewater Hospital at the beginning of June. A post-move visit is scheduled for 14 June 2006. The centre hope to commence treatments as soon as possible after that date.

Summary of findings for Licence Committee

(If final visit before Application considered by LC)

The inspection team recommends that the centre is licensed for storage and treatment at both premises for a period of three months, subject to the following:

- The Managing Director of the hospital should not have an office within the centre due to a risk of a breach of patient confidentiality and patients from the main hospital should not be using the rooms within the centre for similar reasons. This should be addressed before the centre opens.
- Fire doors must not be propped open, signage to the fire exit must be improved and the lift control room door should be kept locked and the stores removed from that room. These should be addressed immediately.
- Centre to submit revised protocols within three months of centre opening.

A post-move inspection is scheduled for 14 June 2006.

The PR has requested that chemical assisted hatching be removed from the Centre's treatment licence.

Appendix A: The inspection team and staff interviewed

The inspection team

Dr Vicki Lamb	Chair, Inspector, HFEA
Mr Tony Knox	Inspector, HFEA

Report compiled by Dr Vicki Lamb

Designation: Inspector

Date: 4 May 2006

RESPONSE OF PERSON RESPONSIBLE TO INSPECTION REPORT

Centre Number: 0033

Name of PR: Professor Brian Lieberman

Date of Inspection: 26 April 2006

Date of Response: 11 May 2006

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

- Alternative office accommodation will be found for the MD of the hospital
- Patients from the main hospital will not be using the rooms within the centre
- All staff are aware that fire doors must not be propped open
- The Facilities Manager of the hospital has been made aware that signage to the fire exit in the secretaries office must be improved
- The stores have been removed from the lift control room and this door is now locked
- We intend to identify additional space for notes storage but do not foresee that this will be a long term problem as our notes are going on line

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

Signed.....

Name: Professor Brian Lieberman

Date: 11 May 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).

There will be two semen production rooms and not three as stated on page 5