Interim Inspection Report

Andrology, Hammersmith Hospital
0080

Date of Inspection: 3 October 2007
Date of Licence Committee: 17 December 2007

CENTRE DETAILS

Centre Address	South Corridor, Area C/FR30, Hammersmith Hospital, Du Cane Road, London, W12 0HS
Telephone Number	0208 383 3589
Type of Inspection	Interim
Person Responsible	Kevin Lindsay
Nominal Licensee	Richard Chapman
Licence Number	L0080
Inspector(s)	Debra Bloor Neelam Sood
Licence expiry date	29 February 2009

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About the Inspection:

This inspection visit was carried out on 3 October and lasted for 7 hours. The report covers the pre-inspection analysis, the visit and information received between 3 April 2007 and 3 October 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 interim 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 Andrology unit at the Hammersmith hospital provides storage of sperm for patients who are undergoing treatment that may impair their fertility. The unit also occasionally provides the same service to patients seeking short term storage of sperm when undergoing fertility treatment. The laboratory is also contracted to carry out diagnostic sperm testing and expects to enter into an agreement to carry out sperm processing for an IUI centre in the next year.

The unit is part of the Imperial College Healthcare NHS Trust.

The person responsible (PR) has been in post since 1995. He is suitably qualified and experienced to carry out the role of PR.

Activities of the Centre

The centre is licensed for processing of gametes, storage of sperm and the procurement and distribution of gametes.

Summary for Licence Committee

The Andrology Unit at the Hammersmith Hospital is a small unit providing a service to patients wishing to store sperm before undergoing treatment that may impair their fertility. The unit stores an estimated 29,000 semen samples.

The unit has appropriate premises, suitably qualified and experienced staff and adopts appropriate laboratory procedures.

Improvements should be considered relating to the following:

- Provision of an out of hours service for responding to damage or failure to storage vessels;
- The monitoring and control of air quality in the laboratory;
- Witnessing protocols;
- Protocols and procedures for the transfer of gametes to other premises;
- The formalisation of contingency plans to accommodate fluctuations in workload and staffing levels;
- Continuing development and implementation of quality management procedures;
- Continuing development of third party agreements.

The centre has been responsive to recommendations made in the previous report and has been proactive in the development and implementation of a quality management system. The inspection team support the continuation of the centre's licence.

Risk Assessment

The centre's risk score is 20% which is considered low risk.

Overall judgement of the effectiveness of the centre

No Improvements required	Some Improvement require	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
This system for responding to a dewar or low oxygen level alarm out of hours is informal and results in a heavy dependency on the availability of the PR. It is a requirement of standard S 6.3.8 of the COP that the storage facilities for gametes and embryos shall have emergency procedures to deal with damage to storage vessels and/or failure of storage conditions.	It is recommended that the PR carries out an assessment of the risks associated with the current emergency systems and that the assessment is submitted for consideration by the Trust in line with the unit's clinical governance procedures.	Assessment to be completed and submitted to the Trust by 3 January 2008.
Quality indicators and monitoring of performance against the indicators has yet to be fully established. This is a breach of standards S 4.2.9	Quality indicators should be established and monitoring of performance against the indicators should be carried out in accordance with the	Indicators to be established by 3 January 2008. Monitoring of performance against the quality indicators

and S 9.5.2 of the 7th Code of Practice (COP).	requirements of the standards.	to be reviewed in the course of future inspections.
The validation of processes and procedures (as required by S 7.8.3 of the COP) has yet to be carried out.	It is recommended that the centre draws up a plan for validation and that the plan identifies which of the centres processes are likely to have the greatest impact on quality and that the validation of these processes is prioritised.	Progress towards the establishment and implementation of a validation plan to be monitored in the course of future inspections.
The establishment of agreements with all of third parties providing goods and services to the centre has yet to be completed. This is a breach of S 4.2.10 of the COP.	It is acknowledged that the centre has made significant effort to establish agreements but that the process has been hindered by poor response from some third parties. In the course of the inspection, the PR confirmed that the centre would continue its efforts to establish the agreements.	Progress towards the establishment of agreements with all of third parties to be monitored in the course of future inspections.
Background air quality in the laboratory has not been monitored The PR reported that background air quality will be monitored when the relocation of dewars is complete. This is a breach of standard licence condition A.10.19.	The PR should assess whether there are any risks of continuing to process sperm in a laboratory in which the background air quality has not been monitored and may not be complaint with requirements. The risk assessment should be submitted for consideration by the Trust in line with the unit's clinical governance procedures.	Risk assessment to be carried out by 3 January 2008. Progress in monitoring air quality and achieving grade D background air quality to be monitored in the course of future inspections.

Non-Compliance

Area for improvement	Action required	Time scale
Procedures for witnessing and for the transfer of cryopreserved material are not fully compliant with guidelines G 13.1 and G 13.2 of the COP and the recommendations of Alert 21.	The PR should review the protocols for witnessing and transfer of cryopreserved material to ensure that the requirements of the relevant guidelines are reflected in the protocols and that the protocols reflect laboratory practice. If protocols are revised as a result of the review, staff should be made aware of the changes and compliance with revised procedures should be monitored.	Procedures to be reviewed by 3 January 2008 Implementation of procedures to be monitored in the course of future inspections.

Recommendations	Time scale
A documented procedure for prioritising workload and/or restricting workload to accommodate fluctuations in staffing and/or workload should be established	To be monitored in the course of future inspections.

Proposed licence variations

None requested

Changes/ improvements since last inspection

Recommendations made in interim report of 6 October 2006	Action taken
Storage of samples for patients receiving treatment that may impair their fertility (oncology samples) should be split in accordance with Chair's letter CH(04)03.	Completed as recommended. Evidence of the storage of samples in two locations was seen on review of a sample of patient records in October 2007.
Dewars should be fitted with low nitrogen or high temperature alarms in accordance with Chair's letter CH(04)	Completed as recommended.
A risk assessment to be performed of the safety of samples in store in tanks which are not alarmed.	Completed as recommended.
A procedure to be put in place to maximise the safety of the samples until the necessary building work and installation of new tanks and autodial alarm facility has been completed.	Measures were in place (and continue to be in place) to assess the nitrogen use of storage dewars. These measures would indicate any imminent failure of storage dewars and allow preventative action to be taken in advance of a catastrophic failure.
The Person Responsible to discuss with the Trust the urgency for the new tanks to be installed and alarmed.	Installation of new tanks was completed at the time of the unannounced inspection in April 2007.
A protocol to be followed in the event of the activation of the low level oxygen alarm to be produced and brought to the attention of all staff.	Protocol developed and submitted to HFEA. Staff awareness of the procedures was not reviewed in the course of the interim inspection.
Tanks to be placed in a suitable position away from the risk of excessive condensation	Tanks not observed to be at risk of exposure to excessive condensation in course of interim inspection.
Tanks to be placed in a suitable position to allow adequate ventilation of the room	At the time of the 2007 interim inspection, the cryostore facilities were ventilated by a manually operated extraction fan and an automatic ventilation system linked to the low oxygen level alarm.

Recommendations made in the report of the unannounced inspection carried out on 3 April 2007	Action taken
Completion of the alarm system installation to include; • fitting of low-level nitrogen alarms to each dewar • an alarm management system with auto-dialler • fitting of a low oxygen monitor with external warning system	Installation of low nitrogen level or high temperature level alarms to all storage dewars, and connection to an auto dial system was observed in the course of the 2007 interim inspection. Low oxygen monitor and external warning system observed to be in place at the time of the 2007 interim inspection.
The premises housing the cryo-dewars to be fully risk assessed for health and safety reasons and passed fit for purpose and the report forwarded to the HFEA. This will be referred to the Health and Safety Executive by the HFEA.	Assessment reported to have been completed as requested.
The Person Responsible to ensure safety measures are in place in the absence of a low oxygen monitor with external warning system.	Low oxygen monitor and external warning system observed to be in place at the time of the 2007 interim inspection.
Air quality monitoring to be undertaken in the facility to establish both; • background air quality.; • air quality within the working environment where gametes are to be handled/processed	Gametes are processed in a class II hood. It was reported that air quality within the hood is monitored by a third party every six months. The PR reported that as there continues to be movement of equipment within the laboratory pending the completion of improvements to the cryostore he has been advised not to monitor the background air quality. The PR confirmed that the monitoring would be undertaken when the refurbishment of the cryostore is complete.

Additional licence conditions and actions taken by centre since last inspection

C	The centre must ensure that all storage dewars are fitted with low nitrogen level alarms fitted to an autodialler system by 1 March 2007.
A	The centre was not able to complete the installation of alarms within the prescribed timeframe. The installation of alarms was completed by July 2007.

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
- Risk management
- Incident management
- Contingency arrangements

Areas of firm compliance
The person responsible (PR) has completed the HFEA PR entry programme. The responses provided were considered to be in accordance with suggested responses. A member of the team has been designated as the quality manager and the unit has developed and implemented a quality management system. Progress has been made in the establishment of third party agreements: a proposed agreement was reviewed and was considered compliant with HFEA guidelines. The PR reported that not all suppliers have responded to requests for the establishment of an agreement but confirmed that efforts to complete the process would continue. The centre participates in inter laboratory comparison of performance in the assessment of sperm motility and morphology assessment as mediated through the national external quality assessment service (NEQAS). A document has been developed to record relevant data on products and materials coming into contact with gametes and embryos. A member of the inspection team saw evidence that a range of internal audits has been undertaken within the time since the last interim inspection. The unit holds quarterly and weekly departmental meetings and minutes of these meetings were reviewed in the course of the inspection. Evidence of discussion of the following was observed in the minutes of team meetings: • HFEA alerts; • incidents; • educational discussions and staff suggestions; • continuous professional development training. The unit has a policy for the reporting of adverse incidents and the incidents log was reviewed in the course of the interim inspection.

The laboratory has attained clinical pathology accreditation.

Areas for improvement
The quality manager has yet to establish quality indicators and it is recommended that this is completed and monitoring of performance against the indicators is carried out in accordance with the requirements of standards S 4.2.9 and S 9.5.2 of the 7th Code of Practice (COP). The validation of processes and procedures (as required by S 7.8.3 of the COP) has yet to be carried out. It is recommended that the centre draws up a plan for validation and that the plan identifies which of the centres processes are likely to have the greatest impact on quality and that the validation of these processes is prioritised. The PR reported that the nature of the service (which offers an open access clinic to patients) and staff involvement in the provision of an out of hours service can cause fluctuation in both workload and staffing levels. It was reported that there are informal arrangements for managing such fluctuations but it was recommended that the arrangements are formalised in the form of a documented procedure for prioritising workload and/or restricting workload as required.

Executive recommendations for Licence Committee
Progress in establishment of quality indicators an in validation to be monitored in the course of the next inspection.

Areas not covered on this inspection
Business planning Clinical governance Resource management

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:

- Confidentiality (including safe storage of patients' records)
- Privacy and dignity of patients
- Complaint handling
- Patient feedback and satisfaction
- Protection of children arrangements (for patients under 18yrs)

Areas of firm compliance
Records are stored securely and it was reported that computer systems are local and therefore inaccessible to non licensed personnel. Sperm production facilities appeared private and appropriate for purpose. No feedback has been received by the HFEA in relation the services provided by the unit but evidence was seen that the centre intends to gather patient feedback within the next year. Contact details for the PR are on display in the patient area for those patients wishing to make a complaint. The centres complaints policy was reviewed in the course of the inspection and review of the complaints log highlighted no issues of concern. It as reported that the assessment of "Gillick" competence of minors attending the clinic is usually carried out by the PR or a senior colleague: all individuals assessing the ability to provide informed consent are reported to be confident in the requirements of their role.
Areas for improvement
None
Executive recommendations for Licence Committee
None
Areas not covered on this inspection
Counselling facilities and services

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

Areas of firm compliance
The records for key pieces of laboratory equipment showed evidence of appropriate maintenance. Cryopreservation dewars are housed in a room adjacent to the laboratory and at the time of the inspection, two large new dewars were being stored in the laboratory. At the time of the inspection, the centre was in the process of rationalising storage of cryopreserved material and it is anticipated that all dewars will soon be housed within the cryostore. Dewars are fitted with low nitrogen or temperature alarms and the alarms are connected to an auto dial system. The cryostore is fitted with a low oxygen level alarm which is connected to a remote display that would alert staff to low oxygen levels before entering the laboratory. Evidence was seen in a set of patient records and in the storage index that samples stored for a patient who has undergone treatment that may have impaired his fertility are stored within separate dewars. Sperm samples are handled and processed in a class II hood. Air quality within the hood is monitored under contract biannually and was reported to be complaint with requirements for processing of gametes.
Areas for improvement
The centre is in the process of rationalising the cryostore and relocating and installing new equipment. As a result of this, background air quality in the laboratory has not been monitored as it is anticipated that measurements could be affected by the movement of equipment. This is a breach of standard licence condition A.10.19. The PR reported that background air quality will be monitored when the relocation of dewars is complete. The PR should assess whether there are any risks of continuing to process sperm in a laboratory in which the background air quality has not been monitored and may not be complaint with requirements. The PR carries a bleep that would alert him to a dewar or low oxygen level alarm. If the PR is not available to carry the bleep then the responsibility is occasionally delegated to another senior member of staff. If there is no response to an alarm then members of the hospitals security staff have contact details for members of the laboratory team. This system is informal and results in a heavy dependency on the availability of the PR out of hours. It is a requirement of standard S 6.3.8 of the COP that the storage facilities for gametes and embryos shall have emergency procedures to deal with damage to storage vessels and/or failure of storage conditions. Guidelines at G 9.3.1 of the COP state that there should

adequate staffing and funding to allow the implementation of formal emergency procedures including 'on-call'. It is recommended that the PR carries out an assessment of the risks associated with the current emergency systems and that the assessment is submitted for consideration by the Trust in line with the unit's clinical governance procedures.
Executive recommendations for Licence Committee
None
Areas not covered on this inspection
Prevention of incidents/ accidents

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:

- Consent
- Protocols

Outcome of audit of records
In a sample of patient records reviewed all consents were found to be present and complete and compatible with the treatment provided.
Areas of firm compliance
Documentation of witnessing in a small sample of patient records was reviewed and appeared compliant with requirements.
Areas for improvement
Laboratory protocols for witnessing and for transfer of cryopreserved material were reviewed in the course of the inspection. Following discussion it was agreed that the protocols do not reflect all of the requirements of the witnessing guidelines as described at G 13.1 and 13.2 of the COP or all of the recommendations relating to the transfer of material as outlined in Alert 21. It was observed that the transfer protocol may not reflect actual laboratory practice. The PR should review the protocols to ensure that the requirements of the relevant guidelines are reflected in the standard operating procedures (SOPs) and that the protocols reflect laboratory practice. If SOPs are revised as a result of the review, staff should be made aware of the changes and adherence to the procedures should be monitored.
Executive recommendations for Licence Committee
Witnessing protocols and practice should be reviewed in the course of the next inspection.
Areas not covered on this inspection
Record keeping Information management Information to patients and donors

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:

- Staff competence, qualifications, training and CPD

Staff

HPC registered scientists	6
Scientists working towards registration	1
Research scientists	2
Conscripted witnesses	2
Support staff (receptionists, record managers, quality and risk managers etc)	6
Independent counsellor	1

Summary of laboratory audit
Audit of cryopreserved material is carried out on a rolling basis. An estimated 2,600 samples (approximately 10% of the 29,000 samples estimated to be in store) have been audited since the last inspection. A number of discrepancies were observed but the majority of these were computer generated anomalies that were resolved rapidly. Two discrepancies remain unresolved: both of the samples were stored before the advent of witnessing. The discrepancies have been noted in patient files but if samples have fallen to the bottom of dewars it is not anticipated that the discrepancies will be resolved until the dewars are decommissioned.
Summary of spot check of stored material
Two samples were traced from laboratory record to cryopreservation dewar and from dewar to record. No discrepancies were observed.
Areas of firm compliance
The training records of two members of the unit's staff were reviewed and were considered to show evidence of appropriate continued professional development training. Six members of the laboratory team are Health Professions Council (HPC) registered biomedical scientists and one member of the team working in the unit at the time of the inspection was working towards HPC registration.
Areas for improvement
Standard S 7.8.12 of the COP states that storage centres shall carry out reviews of stored gametes and embryos at least once every two years. If, as seems likely, the centre will not be able audit the remaining 90% of the cryopreserved material in the next year, the PR should consider assessing whether there are any risks associated with failure to audit all cryopreserved material and any steps that can be taken to moderate risks.
Executive recommendations for Licence Committee

None

Areas not covered on this inspection
Safe handling systems Recruitment and retention of staff Assessment of patients Procedures in practice Laboratory processes and practice

Evaluation
Some improvement required

Report compiled by:

Name…Debra Bloor…….

Designation……Inspector…….

Date……16 October 2007……

Appendix A: Centre staff interviewed

The PR and two other members of the centre's staff were interviewed by the inspection team.

Appendix B: Licence history for previous three years

First Licensed 1992

2007

A Licence Committee considered the centre's application to vary the licence in compliance with the EUTD on 2 May 2007. The committee agreed to vary the centre's licence pursuant to the Human Fertilisation and Embryology Act 1990, as amended by the Human Fertilisation and Embryology (Quality and Safety) Regulations 2007, subject to prompt resolution of the outstanding areas of non-compliance

2006

Unannounced inspection 3 April 2007.
Report not presented to Licence Committee.

Interim inspection 6 October 2006 (postponed from 28th September).
The interim report was considered by a Licence Committee on 30 October 2006.
The Committee agreed to issue a notice of proposal to vary the centre's licence to add the following condition:

- The centre must ensure that all storage dewars are fitted with low nitrogen level alarms fitted to an autodialler system by 1 March 2007.

2005

Renewal inspection 27th October
The renewal report was considered by a Licence Committee on 19 January 2006
The Committee agreed to renew the centre's licence for a period of three years with one additional condition:

- The centre must complete the splitting of its oncology samples by the end of July this year, and submit a plan, by March 14th, setting out how this will be achieved.

2004

Interim inspection 9th November
Report considered by a Licence Committee 28 February 2006
The licence was continued without variation.

Appendix C: Response of person responsible to the inspection report

Centre Number……0080……

Name of PR……Dr K Lindsay……

Date of Inspection……3 October 2007……..

Date of Response……3 December 2007……

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

The IUI programme remains 'on hold' and will not resume until our partners at The West Middlesex Hospital obtain the appropriate licence.

The background 'air' quality D is being perused. However, successful sperm freezing for over 30 years and the use of Grade A air quality in the working environment presents a very low risk. Indeed to my knowledge there is no case reported where environmental contamination has been reported in such conditions. Nonetheless we intend to purchase a mobile air polisher so that we can begin testing the background air within the next 2-3 months and an air particle counter will be available before the end of the year.

We are reviewing our documents in response to the inspection, the restructuring of the organisation and a new CPA inspection due in April 2008. A main focus in the changes will be the contemporaneous nature of our witnessing process. Although, robust form changes are need to constantly remind staff that the time as well as date need to be recorded.

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

Signed

Name……Dr K Lindsay……

Date……3 December 2007……

2. Correction of factual inaccuracies

Please let us know of any factual corrections that you believe need to be made (NB we will make any alterations to the report where there are factual inaccuracies. Any other comments about the inspection report will be appended to the report).

The PR is Dr K Lindsay not Lindsey The department is fully CPA accredited however it has not sought ISO 9001 certification.

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 electronically to Debra.Bloor@HFEA.gov.uk
or in hard copy to

Debra Bloor
Human Fertilisation & Embryology Authority
21 Bloomsbury Street
London
WC1B 3HF

Licence Committee Meeting

17 December 2007
21 Bloomsbury Street London WC1B 3HF

MINUTES Item 5

Andrology Hammersmith (0080)
Interim Inspection

Members of the Committee:	In Attendance:
David Archard, Lay Member – Chair	Trish Davies, Director of Regulation / Deputy Chief Executive
Sally Cheshire, Lay Member	Janet Kirkland, Inspector
Hossam Abdalla, Director of Lister Fertility Centre	Claudia Lally, Committee Secretary
	Providing Legal Advice to the Committee: Sarah Ellson, Field Fisher Waterhouse Solicitors

Conflicts of Interest: Jennifer Hunt declared a conflict of interest in relation to this item and left the meeting. Other 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 (28 pages)
- no papers were tabled.

1. The papers for this item were presented by Debra Bloor, HFEA Inspector. Dr Bloor informed the Committee that this is a small unit in London which provides storage of sperm for patients who are undergoing treatment that may impair their fertility. The clinic also undertakes some diagnostic sperm testing. Dr Bloor drew the Committee's attention to the fact that the clinic currently has an estimated 29,000 samples in storage.

2. Dr Bloor summarised the main findings of the inspection visit, she reported that a finding of the previous inspection of the centre was that low nitrogen level alarms had not been fitted to the dewars; the fitting of alarms was made an additional licence condition. These alarms were finally fitted in July 2007. All samples are now stored in two locations, so the centre is currently fully compliant with the requirement of Chair's letter CH(04)03.

3. Dr Bloor drew the Committee's attention to the relatively large number of areas for improvement listed at pages 6-8 of the inspection report. She also stated that the Person Responsible had been cooperative with the inspection team and has responded positively to the recommendations made at the inspection visit.

4. The Committee endorsed the recommendations made in the report and agreed that they would expect to see compliance with these recommendations in line with the time frames specified. The Committee requested that compliance be monitored by the Executive.

5. The Committee agreed that the centre's licence should continue.

Signed…… … Date……..
David Archard (Chair)