Interim Inspection Report

Centre Name	Assisted Conception Unit UCH
Centre Number	0044
Licence Number	L0044-13-a
Centre Address	The New Wing, Eastman Dental Hospital, 256 Gray's Inn Road, London WC1X 8LD
Inspection date	11th April 2006
Licence Committee Date	27th July 2006
Inspector(s)	Dr E. Lawrence
	Mr T. knox
	Mr P. Qureshi
With Notice Short Notice Unannounced	With Notice
Person Responsible	Mr Paul Serhal
Nominal Licensee	Dr Joyce Harper
Licence expiry date	31st March 2008

About the Inspection

The focus of this interim inspection has been drawn from issues arising from the last inspection or information received. 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, sixth edition Code of Practice, and also to advise centres to work towards compliance with the EU Tissue and Cells Directive 2004/23/EC where relevant.

The report is used to summarise the findings of the interim inspection highlighting areas of good practice, as well as 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 continuation of the centre's licence. The report is also available to patients and the public following the Licence Committee meeting.

Inspection teams are drawn from a team of in-house inspectors and generally comprise a scientist, a clinician or nurse and a generalist. Prior to the inspection, the Person Responsible (PR) completes a pre-inspection questionnaire to provide the HFEA with details of any changes since the last inspection and factual information. Patient questionnaires are sent to the centre for distribution to patients so they can tell directly how good they consider the service is. There is also a self-assessment document for the PR to complete so that they and their staff may identify areas needing improvement. Persons Responsible are required to send the HFEA information on all treatments carried out and this information is gathered through an electronic system. All this information is analysed by the lead inspector prior to the visit taking place.

At the visit the inspection team assess 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.

Evaluations are given to each topic and the overall effectiveness of the centre:
No Improvements Required – given to centres where there are no Code of Practice, legal requirements, recommendations or new 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 PRs 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.
There will be an overall judgement made at the end of the five sections.

The HFEA welcomes comments from patients and donors, past and present, on the quality of the service received.

This inspection visit was carried out on 11th April 2006 and lasted for 7 hours. The report covers the pre-inspection analysis, the visit and information received between June 04 and February 06.

Brief Description of the Centre

1. The Assisted Conception Unit was first established as an HFEA licensed clinic in 1990. The majority of patients are self-funded. Patients attending the unit for pre-implantation genetic diagnosis or screening (PGD or PGS) are referred and funded by the NHS. The majority of the patients seen at the centre are from London and the surrounding area.

2. In November 2005 the centre moved to its new premises in the Eastman Dental Hospital. Fertility treatments are provided between 0900 and 1700 five days a week and if necessary patients are also seen at weekends. At least one member of staff from each of the clinical, embryology, nursing and administrative teams work at the weekend.

Activities of the centre

	06/04 – 05/05	06/05 – 02/06
Licensed treatment cycles	400	284
Donor Insemination	66	47
Unlicensed treatments	AIH, IUI, GIFT, MESA & Surrogacy	AIH, IUI, GIFT, MESA & Surrogacy
Research	Yes	Yes
Storage	Yes	Yes

This inspection covered the following issues arising from the last inspection Licence Committee 12th January 2005

1. The Committee noted that the centre has not yet changed its patient information to reflect the changes brought about by the Adoption and Children Act 2002 whereby an unmarried father will have parental responsibility for his child if he is registered as the father on the birth certificate. It therefore agreed that the centre should be required to ensure that this is addressed as soon as possible.

2. In the light of the concern expressed in the report, the Committee agreed that the centre should monitor the three embryo transfers which it carries out.

3. The Committee agreed that it is important that the centre continue to monitor workload pressures.

4. The Committee decided to make the following recommendation:
   - The centre must take action as soon as possible to comply with section 33 (5)of the Human Fertilisation and Embryology Act 1990, which requires that the centre ensures that all patients sign a consent to disclosure form to allow the centre to contact their GP.

Improvements since the last inspection

All recommendations of the Licence Committee held on the 12th January 2005 have been implemented.

Summary for Licence Committee

The inspection team recommends the continuation of the centre's licence.

Breaches of the Act or Code of Practice

Breach	Action required	Time Scale
None		

Non-Compliance

Area for improvement	Action required	Time scale
None		

Recommendations

- The PR should ensure that minutes are generated for scheduled meetings and include the date of the meeting and a list of the names of attendees.
- It is recommended that an agenda should be produced in advance of the MTDM and sent to the independent counsellor for review/comment.
- Minutes of meetings should be circulated to all relevant staff.

- The counsellor undertakes the counselling at her home and has little direct contact with the unit. It is recommended that an agenda should be produced in advance of the MTDM and sent to the independent counsellor for review/comment.
- Minutes of meetings should be sent to the counsellor.

- Some discrepancies were found in the patient information and should be revised and updated versions submitted to the HFEA.

Proposed licence variations

None

The effectiveness of the provision

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:

- 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 unit was assessed as organised. The evidence included accurate record keeping, with clear lines of communication and daily routine. A list of attending patients is printed off daily and doubles as a fire evacuation list. There are daily meetings where the treatment plans of patients are discussed; outcomes are documented in the patient's notes. A whiteboard in the corridor contained details of the cardiac arrest team. The staff confirmed that the systems are known and work in practice. Risks and the way in which they are managed are identified and recorded by staff at their meetings. These include, for example, PGD/PDS, the laboratory, theatre, outcome data, training and communication. Staff interviewed were aware of the process involved in reporting incidents and were familiar with Alerts issued by the HFEA.
Areas for improvement
• The complaints procedure was not displayed in the reception area. This was rectified during the inspection. • The PR should ensure that minutes are generated for scheduled meetings and include the date of the meeting and a list of the names of attendees. • It is recommended that an agenda should be produced in advance of the MTDM and sent to the independent counsellor for review/comment. • Minutes of meetings should be circulated to all relevant staff.
Executive recommendations for Licence Committee
To note recommendations regarding minutes to meetings.
Standard of organisation within the centre
Some improvement required

Areas not covered on this inspection
➢ Business planning ➢ Payment of treatment fees

Data analysis/success rates

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
Reviews/audits of practice and treatment outcomes are undertaken annually.
Areas of firm compliance
An open evening occurs on the first Wednesday of each month for prospective patients. Staff members from the different disciplines give short talks and answer any questions. During the inspection one patient was interviewed. The patient stated: • All the information received written and orall was clear and concise. • The staff are professional and sympathetic and ensure patients are looked after. • Welfare of the Child (WoC) requirements and completing consent forms was explained thoroughly which made the process in her mind simple. • Dignity had been respected at all times through the treatment process including providing a chaperone as required. • An emergency mobile telephone number had been given to her for use out of hours which she stated she had not required. • Saw the independent counsellor for one session. She stated that she was pleased with the service provided and stated that she was "very human" • The patient noted that on several occasions her appointment times had been delayed on the day, but added that this was the only thing which could be improved. An audit of counselling for 2005 was supplied at the time of the inspection. The report was as follows: • Implications: 63 sessions • Support/therapeutic: 37 sessions • Psychological assessment: 1 session • WoC assessment: 3 sessions

• Disagreement: 1 session • 95 of the 105 patients to see the counsellor were new referrals • The counsellor is supervised once every fortnight. • Waiting time to see the counsellor is 1 -3 days.
Areas of improvement
• The counsellor undertakes the counselling at her home and has little direct contact with the unit. It is recommended that an agenda should be produced in advance of the MTDM and sent to the independent counsellor for review/comment. • Minutes of meetings should be sent to the counsellor.
Executive recommendations for Licence Committee
To note recommendation regarding agenda and minutes of MDTMs.
Standard of Quality within Centre
Some improvement required
Areas not covered on this inspection
None

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
- Safe storage and disposal of embryos and gametes
- Safe equipment, servicing and maintenance
- Prevention of incidents/ accidents

Areas of firm compliance
• The unit has recently moved to the Eastman Dental Hospital and has been signed off by the HFEA and HCC as being fit for purpose. Security is maintained through locks on the doors of all appropriate rooms. • Equipment critical to service provision is monitored/checked daily. Evidenced through the records for the resuscitation trolley, incubators. • All dewars are alarmed and linked to an autodialler. There is a protocol for responding to the alarm and this was seen by the scientific inspector. • A low level oxygen alarm was seen in the laboratory.
Areas for improvement
None
Executive recommendations for Licence Committee
None
Standard of premises and equipment
No improvement required
Areas not covered on this inspection
None

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
- Protocols
- Record keeping (including consents)

Outcome of audit of records

Outcome of audit of records
The inspection team reviewed 10 sets of patient records chosen at random. They included one egg donor and recipient, one IUI and seven IVF/ICSI patients. No discrepancies were found.
Areas of firm compliance
• Patient notes were seen to be held within a purpose build room which is manned during the day and secured during out of office hours. • Patient notes showed there was an effective process for assessing the welfare of any children resulting from, or affected by the outcome of assisted conception treatment. There was also evidence of posthumous consent. • The Registry is satisfied with the information provided by the centre and mandatory forms are returned within the established time scales.
Areas for improvement
Some discrepancies were found in the patient information submitted for this inspection. • The ACU egg sharing programme sheet indicates that egg donors could remain anonymous. The PR stated that this sheet has been updated and would submit a copy to the HFEA. • On the outcomes data sheet it is not clear what is meant by pregnancy rate. The PR agreed to clarify this on the data sheet and submit a copy to the HFEA. • The information sheet on OHSS should be updated to include the possibility of death.
Executive recommendations for Licence Committee
To note recommendations regarding updating patient information
Standard of information within the centre
Some improvement required
Areas not covered on this inspection
No protocols were reviewed as they have not changed since the last year.

5. Laboratory and Clinical Practice

Desired outcome: Staff are competent and recruited in sufficient numbers to ensure safe practice in the laboratory and clinically

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

RCOG registered doctors	3
Trainee doctors	1
NMC registered nurses	9
Trainee nurses	1
HPC registered scientists	4
Trainee scientists	1
Support staff (receptionists, record managers, quality and risk managers etc)	9

Highlighted areas of firm compliance
• The most recent audit of stored material was submiited to the HFEA in March 2006. • No discrepancies were observed during a spot check tracking one sperm sample and one embryo from the laboratory record to the dewar and vice versa. • Witnessing arrangement are in place. The witnessing records for recent examples of patients were observed by the scientific inspector. • Samples are stored for oncology patients but are not split.
Areas for improvement
Oncology samples are not split as required by the Chair's Letter CH04(03). Since the inspection the laboratory manager has informed the inspector that all oncology samples have been split.
Executive recommendations for Licence Committee
None
The centres provision and quality of (and for) staff
• New members of staff undergo a comprehensive induction program. Each process to be undertaken is listed on an induction sheet, which is signed by their supervisor when the training is complete. The induction sheet was evidenced for a new member of staff.

- Members of staff are supported in their CPD. Funds are provided by the centre or through applying to drug companies. Examination of staff training records showed they have attended courses such as ALS, venepuncture training and the 2006 ACE conference. Mandatory training programs have included infection control, BLS, manual handling and fire procedures. Since moving to the new premises infection control and BLS training has been run.
- There was evidence of an enhanced CRB check within the personnel records examined.
- The members of staff involved were aware of the appraisal process which is held annually by the PR.

Executive recommendations for Licence Committee
None
Standard of laboratory and clinical practice
No improvement required
Areas not covered in this inspection
➢ Clinical practice ➢ PGD/ PGS

Breaches of the Code of Practice or Act

Compliance with additional conditions and requests

Conditions

None

Actions requested in previous report

Action	Timeframe	Centre's action
None		

The inspection team

List the inspectors identifying the lead inspector and support inspectors.

Dr E. Lawrence	Chair, Inspector, HFEA
Mr T. Knox	Inspector, HFEA
Mr P. Qureshi	Inspector HFEA

Report compiled by:

Name: Dr E. Lawrence

Designation: Inspector

Date: 1st May 2006

Appendix A: Centre Staff interviewed

The inspection team interviewed the PR, Mr Paul Serhal, and nine other members of staff.

Appendix B: Licence history for previous 3 years

2006
Interim Inspection 11th April 2006

2005
Post-change of Premises Inspection 12th December 2006

Licence Committee 12st October 2005-Change of Premises
The Committee agreed to the change of premises.

Pre-change of Premises Inspection 16th September 2005

Licence Committee 12st January 2005– Renewal Inspection
The Committee noted there were no additional conditions on the centre's licence agreed to add three recommendations.

2004
Renewal Inspection 28th October 2004

Licence Committee 15th September 2004
The licence committee agreed to split off the responsibility for the research project R0113 to a new centre [0245 Human Genetics & Embryology Laboratories]. There was no physical change to the location of the project.

Licence Committee 13th May 2004
The committee agreed to vary the licence to include pre-implantation genetic diagnosis (PGD) for a complex translation. [AP-03-0068]

Licence Committee 22nd April 2004
The committee agreed to vary the licence to include pre-implantation genetic diagnosis (PGD) for three β thalassaemia mutations. [AP-04-0049]

Licence Committee 5th April 2004
The committee agreed to vary the licence to include pre-implantation genetic diagnosis (PGD) for four β thalassaemia mutations. [AP-04-0049]

Licence Committee 28th January
The committee agreed in principal to include PGD for a complex translocation [AP-03-0068] further clarification was sought. See Licence Committee 13/05/2004.

Licence Committee 21st January – Interim Inspection
The Committee noted there were no additional conditions on the centre's licence agreed to add two recommendations.

Appendix C:
RESPONSE OF PERSON RESPONSIBLE TO INSPECTION REPORT

Centre Number……**0044** ……

Name of PR……**MR PAUL SERHAL**……

Date of Inspection……**11 April 2006**……..

Date of Response……**22 May 2006**……

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

- Copy of the updated ACU egg sharing programme sheet attached.
- Clarification of pregnancy rates on outcomes data sheet - copy attached.
- Information sheet on OHSS has been updated to include "On rare occasions these may be life threatening" - copy attached.
- Since the inspection oncology samples have been split as required by the Chair's Letter CH04(03) and copy of the e-mail sent to HFEA from the laboratory manager confirming split is attached.

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

Signed…… ……

Name…….**Mr Paul Serhal**……

Date……...**22 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).

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 this section of the report to:

Dr Marion Witton
Head of Inspection, HFEA
21 Bloomsbury Street
London
WC1B 3HF
HF

TRIM: 06/3141

Licence Committee Meeting

27 July 2006
21 Bloomsbury Street London WC1B 3HF

MINUTES Item 4

Assisted Conception Unit UCH (0044)
Interim Inspection

Members:
Clare Brown, Lay Member – Chair
Ivor Brecker, Lay Member
David Barlow, Executive Dean of Medicine, University of Glasgow

Observing:
Ruth Fasht, HFEA Member

In Attendance:
Marion Whitton, Head of Inspection
Claudia Lally, Secretary to the Committee

Providing Legal Advice:
Sinead Glasgow, Legal Adviser to the HTA

Conflicts of Interest: members of the Committee declared no conflicts of interest in relation to this item.

The following papers were considered by the Committee:

- papers for Licence Committee (68 pages)
- no tabled papers.

1. The papers for this item were presented by Elliot Lawrence, HFEA Inspector. Dr Lawrence informed the Committee that the inspection team recommended that the counsellor is better informed of centre activities, as the counsellor works from home and currently has little direct contact with the unit. Dr Lawrence further informed the Committee that the recommendations by the inspection team have all been taken up by the centre.

2. The Committee noted the inspectors' comments at part four of the inspection report which state that improvement was required to the standard of the information provided by the centre. In particular, the Committee noted the patient information sheets at pages 61 and 62 of the committee papers. These sheets give pregnancy rates and clinical pregnancy rates for ICSI, IVF, Egg recipients and frozen thawed embryo transfers. The Committee agreed with concern that this information was misleading and that the centre must change these sheets to record live birth rates rather than clinical pregnancy rates. If pregnancy rates are to be published at all, these should just be per treatment carried out, and should not be broken down into the various treatments given, as the numbers that these

statistics are based on are too small to be statistically significant. The Committee agreed that the centre should update its information and submit a revised version in three months of receipt of these minutes.

3. The Committee noted that since the time of the inspection the laboratory manager has informed the Executive that all oncology samples have now been split in accordance with Chair's letter CH(04)03.

4. The Committee agreed that the centre's licence should continue with no additional conditions.

Signed…… … Date……..
Clare Brown (Chair)