Interim Inspection Report

Edinburgh Assisted Conception Unit
0201

Date of Inspection: 6th December 2006

Date of Licence Committee: 14th February 2007

CENTRE DETAILS

Centre Address	Edinburgh Fertility & Reproductive Endocrine Centre, Royal Infirmary of Edinburgh, 51 Little France Crescent, Edinburgh EH16 4SA
Telephone Number	0131 242 2446
Type of Inspection	Interim
Person Responsible	Dr K J Thong
Nominal Licensee	D Ms Sandra Mair
Licence Number	L0201/4/b
Inspector(s)	Elliot Lawrence Janet Kirkland Brian Woodward
Fee Paid - date	Not applicable
Licence expiry date	28th February 2009

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About the Inspection:
This inspection visit was carried out on the 6th December 2006 and lasted for 7 hours. The report covers the pre-inspection analysis, the visit and information received between July 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 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 Edinburgh Assisted Conception Programme has been licensed since 1992 and offers a range of fertility treatment services to NHS and self-funding patients.

The unit is located on the ground floor of the Edinburgh Royal Infirmary Hospital. The premises include a large waiting area, an overflow waiting area and a sub-waiting area for known donors. There are two sperm production rooms, four consulting rooms (two extra if needed), three scanning rooms, two cryostore, two theatres adjoined by the laboratory, semen analysis and preparation rooms, a recovery area for six patients and a research room for scientific staff.

The centre operates Monday to Saturday. Oocyte retrievals are performed Monday to Friday, Saturdays if required. Embryo Transfers are performed Monday to Saturday. The opening hours of the centre are typically 08:00 - 17:00; 09:00 – 13:00 on weekends.

The Person Responsible, a Consultant Subspecialist in Reproductive Medicine/consultant obstetrician and gynaecologist, has held the post of PR since 1998.

Activities of the Centre

Licensed treatment cycles	669 *	IVF IVF with donor eggs/donor sperm ICSI ICSI with donor eggs/sperm
Donor Insemination cycles	80 *	ICI with donor sperm
Unlicensed Treatments	✓	Intra-uterine insemination **(natural cycle and stimulated)** Ovulation induction with Gonadotophins Surrogacy Tubal surgery
Research	×	
Storage	✓	Storage of sperm (patient and donor) Storage of testicular tissue Storage of embryos

*HFEA statistics from December 2005 - December 2006

Summary for Licence Committee

Some improvements are required but the Inspectorate were satisfied with the key areas of service provided by the centre and recommend continuation of the centre's licence without additional conditions.

Risk Assessment

The current risk assessment for the centre based on the risk matrix is 5%, which is designated as low risk.

Overall judgement of the effectiveness of the centre

No Improvements required	Some Improvement required	Significant Improvement required
	X	

Evaluations from the inspection

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

Breaches of the Act or Code of Practice

Breach	Action required	Time scale
None		

Non-Compliance

Area for improvement	Action required	Time scale
Information about the complaints procedure should be clearly displayed at all times in the waiting area.	Ensure complaints information is clearly visible in the waiting room at all time	Immediately
The organisational chart should be updated to reflect that there are two separate teams of doctors and nurses involved in licensed treatments (IVF and DI / ICI respectively).	Update organisational chart	3 month

Recommendations	Time scale
Communication between the two nursing teams should be improved.	On going
Recommend harmonization of ACU and RML polices regarding storage of viral positive samples.	On going

Proposed licence variations

N/A
N/A

Changes/ improvements since last inspection

Recommendation from last inspection	Action taken
Review ICI procedure due to pregnancy rate of approximately 2%	ICI procedure has been changed to include post thaw analysis of sperm and to time insemination to coincide with LH surge. This led to an ongoing pregnancy rate of 8.2%
The waiting time for commencement of treatment after the initial consultation for self-funding patients is around 10 months and for NHS patients 18 months. The centre is actively seeking ways of reducing the waiting times	The waiting time to commence treatment has reduced to 6 months for self-funded patients.
Historical divisions of work within the nursing department remain despite efforts to combine the management of the department. We recommended that the centre consider ways of developing a team ethos that would assist the nursing team in moving forward as one cohesive group	Senior Nursing Manager has organised a team building event for the nursing staff. A further meeting is planned at which the roles and responsibilities of the nursing staff will be clarified. The management structure of the RML is currently being reviewed.

Additional licence conditions and actions taken by centre since last inspection

C	**N/A**
A	**Complied Y/N**
C	**N/A**
A	**Complied Y/N**
C	**N/A**
A	**Complied Y/N**

Report of Inspection findings

1. **Organisation**

Desired Outcome: The centre is well-organised and managed and complies with the requirements of the HFE Act.

Summary of findings from inspection
Evidence is drawn from:

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

Areas of firm compliance
The management and co-ordination of resources is overseen by the PR, as shown on the organisational chart from the Quality Manual. The Quality Management system is certificated to ISO 9001:2000. The Assisted Conception Programme (ACP) Staff interviewed were clear about their own roles and responsibilities. The doctors and nursing staff are divided into two teams dealing with IVF and DI / ICI respectively. IVF/DI and embryology has a different management structure to andrology (RML). The move to the new Royal Infirmary brought together three services: IVF (and embryology), donor insemination and andrology in the Reproductive Medicine Laboratory (RML). The RML management structure is currently being reviewed to allowed better communication with the ACP. The ACP and RML are part of the Edinburgh Fertility and Reproductive Endocrine Centre (EFREC). Monthly operational meetings are held between the managers of each department to review the clinic activities and discuss issues. . Relevant action points are fedback to the staff at the weekly departmental meetings. Weekly multi-disciplinary team meetings are held by the PR. All members of staff are expected to attend. The weekly meetings cover patient treatments, discussion of difficult cases, HFEA communications, incidents, complaints, training, quality and governance issues. Discussions at the bimonthly meetings include complex cases. Meetings are minuted and evidence of this was seen during the inspection. Meeting minutes are distributed to all staff via email and a paper copy is available from the secretary on request. Staff interviewed during the inspection were aware of the HFEA incident alert system. The PR receives the alerts via email from the HFEA and circulates these to all staff. Alerts are discussed at the multi-disciplinary team meetings and relevant departmental meetings.

Risk is managed through the DATIX risk management system. A clinical co-ordinator oversees the development of risk registers and clinical incidents. The PR stated risk assessments are in place for all laboratory areas. Other risk assessments are undertaken as required. Recent risk assessments include the use of a freezing machine and embryo thawing, evidenced during the inspection.

A back up generator is in place which ensures continued supply to certain pieces of essential equipment in the event of a break in the main electricity supply.

The centre is an integrated part of the Women and Neonatal Services Clinical Governance structure.

Payment of treatment fees is timely and the Centre is not listed on the HFEA debtors list.

Areas for improvement
The organisational chart does not reflect that there are two separate teams of doctors and nurses involved in licensed treatments (IVF and DI / ICI respectively). Communication between the two nursing teams. Several nurses of the IVF team thought IUI was being performed instead of ICI.
Executive recommendations for Licence Committee
None
Areas not covered on this inspection
Business planning
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
Treatment results are audited monthly and information which is sent to patients updated annually.
Areas of firm compliance
A protocol for 'welfare of the child' (WoC) assessments was provided with the pre inspection paperwork. The form provided by the HFEA is being used for patients to complete. If there are concerns, the patient(s) are referred to another consultant in another speciality for assessment. 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 and consent to disclosure. A dedicated server ensuring that patients/donors computerised data is only accessible to staff on the licence. Paper notes are kept in a locked, dedicated storage room. Notes which are in use are kept in lockable cabinets. Counselling notes are stored in a separate locked cabinet to which only the counsellor has access. Non-current records are stored in the Hospital medical records depot. These records are only accessible to staff on the HFEA Licence. Patients are 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 trust's complaint's officer is on display in the centre waiting room, but is obscured by a filing tray on the reception desk. The complaint's log for the last year was reviewed; there were two complaints of which one has been resolved. All complaints are handled through the Trust's complaints procedure.

There have been 31 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. The patient was satisfied with the treatment provided. The unit staff were complimented for their support, providing clear information and answering all questions asked. Privacy and dignity were protected at all times. The patient stated they were made aware of the counselling service provided.

Counselling is provided without charge and is routinely offered to all patients at their initial consultation. This was confirmed through staff and patient interviews. Counselling is mandatory for all donors and patients using donated gametes or embryos in their treatment. The unit has a main and relief counsellor (in case of emergency). The main counsellor stated that all counsellors are registered with the British Infertility Counselling Association and receive 1 hour supervision each month. A counselling audit for 2005 was provided with the pre-inspection paperwork. The report indicates 373 patients attended counselling sessions of which 157 were new referrals.

Areas for improvement
Information about the complaints procedure should be clearly displayed at all times in the waiting area.

Executive recommendations for Licence Committee
None

Areas not covered on this inspection
Protection of children arrangements (for patients under 18yrs) Donor selection Egg sharing and surrogacy

Evaluation
Some improvements required

3. Premises and Equipment

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

Summary of findings from inspection:

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

Areas of firm compliance
The premises have not changed since the last inspection and were found to be fit for purpose. In order to meet the requirements of the EUTD, a class 2 biohazard cabinet has been order for egg collections. The consultant embryologist stated the other flow hoods provide grade A air, in a background of grade C. The embryo cryostore is in the ACU, whilst the sperm cryostore is in the RML. These rooms are next door to each other. Access to the cryostores is restricted by digital locks. All dewars are locked and fitted with alarms linked to an auto dial out system. During the week the RML biomedical scientists are on call for the alarms. The embryologists cover the weekends. Low oxygen alarms are present in both cryostores. The procedure for responding to the alarms was evidenced during the inspection. A back-up dewar for storage of sperm and embryos it available in cases of an emergency. Key pieces of laboratory equipment were seen to be serviced regularly. Daily monitoring of temperatures of incubators, hot blocks and heated stages was evidenced from the log book.
Areas for improvement
None
Executive recommendations for Licence Committee
None
Areas not covered on this inspection
None
Evaluation
No improvements required

4. Information

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

Summary of findings from inspection:

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

Outcome of audit of records
Fifteen patient records were selected at random on the day of the inspection. The records were found to be well organised and complete. Evidence of appropriate consents and 'Welfare of the Child Assessments' were found in all files. No discrepancies were found. The last operational audit occurred in March 2004. It was not selected for a visit in 2006 as it was considered to be medium risk by the Audit team.
Areas of firm compliance
Documents within the centre are document controlled and comply with ISO 9001:2000. The document control officer oversees the issue, change, review and destruction of documents and communicates these to the staff. This was evidenced from the spreadsheet of the controlled documents. All protocols and patient information requested were submitted with the pre inspection paperwork. These were reviewed and found to be satisfactory. Patients interviewed and patient questionnaires reflected their satisfaction with provision of information. The HFEA registry reported no concerns or issues with the centre's returns.
Areas for improvement
None
Executive recommendations for Licence Committee
None
Areas not covered on this inspection
None
Evaluation
No 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	21
NMC registered nurses	8
HPC registered scientists	3
Scientists working towards registration	2
Support staff (receptionists, record managers, quality and risk managers etc)	2 Clinical Support Workers 1 Biomedical Scientist 3 Secretaries 2 Medical Clerks

Summary of laboratory audit
The ACU carried out an audit of stored embryos between June – July 2006. The report shows seven discrepancies were found and corrected. The RML performed an audit of the semen samples December 2006. Some discrepancies were found in the database record and were resolved.
Summary of spot check of stored material
Two embryos were tracked from the records to the tank(s), no discrepancies were noted. Two sperm samples were tracked from the records to the tank(s), no discrepancies were noted
Areas of firm compliance
All patients are screened and assessed in accordance with the centres' clinical protocols, evidenced in the patients' notes. The patient information for IVF and DI provided, details the screening tests required for patients and donors. All patients are screened for HIV, Hep B and Hep C. The ACU and RML operate different policies regarding viral positive patients: the ACU uses a separate dewar for embryos; the RML does not for sperm (including testicular samples retrieved by the ACU).

The double witnessing 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.

New staff attend a formal 5 day hospital trust induction programme which includes manual handling, resuscitation and health and safety. The unit induction programme for staff involves an induction pack and mentoring, evidenced for the nurses and embryologists via training records.

The unit clinical induction covers NICE guidelines, Code of Practice and introduction to journals and books available for CPD. New members of the nursing team have a mentor for up to six months and an appraisal after three. Evidence by interviewing members of the nursing team.

All staff interviewed expressed satisfaction with the provision for Continuing Professional Development (CPD). Documented evidence of CPD for members of the embryology and nursing team was provided during the inspection. The embryologists are registered for the Association of Clinical Embryologists CPD scheme. This has involved attending clinical meetings, journal research and external meetings such as ESHRE. Two members of the team are in the process of applying for registration with the Health Professions Council.

Examples of nurses CPD provided this year are: study days on counselling and Chlamydia.

Recruitment of new staff follows the recruitment policy of the Trust HR Dept. The PR has an input into this and requests the skills and qualifications required. Staff qualifications are checked via original certificates during interview by the HR department. Professional qualifications are verified electronically with the NMC, GMC or HPC prior to appointment by HR.

Retention of staff does not appear to be a concern for the PR; many members of staff have worked at the centre for a number of years and a number of those interviewed expressed their satisfaction with the stability of the team.

Areas for improvement

Recommend harmonization of ACU and RML polices regarding storage of viral positive samples.

Executive recommendations for Licence Committee

None

Areas not covered on this inspection

PGD/ PGS
Recruitment practices: Registration numbers for staff not checked

Evaluation

Some improvement required

Report compiled by:

Name: Elliot Lawrence

Designation: Inspector

Date: 11th December 2006

Appendix A: Centre Staff interviewed

Dr K J Thong, PR, and seven other members of the centre's staff met with members of the inspection team.

Appendix B: Licence history for previous 3 years

Licensing History

Centre: Edinburgh Assisted Conception Unit

Number: 0201

Licence	Status	Type	Active From	Expiry Date
L0201/4/b	Active	Treatment with Storage	01/05/2006	28/02/2009
L0201/4/a	Replaced by New Version	Treatment with Storage	01/03/2006	28/02/2009
L0201/3/a	Expired	Treatment with Storage	03/10/2005	28/02/2006
L0201/1/b	Expired	Treatment with Storage	22/02/2002	28/02/2003
L0201/2/a	Replaced by New Version	Treatment with Storage	01/03/2003	28/02/2006
L0201/1/a	Replaced by New Version	Storage Only	22/02/2002	28/02/2003

Appendix C:

RESPONSE OF PERSON RESPONSIBLE TO THE INSPECTION REPORT

Centre Number……

Name of PR……..

Date of Inspection……..

Date of Response……

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

1. Information about the Complaints Procedure

This was displayed in the waiting area and was not clearly visible on the day of the inspection. We have displayed this information clearly in our waiting area.

2. Page 7

I shall raise your concerns regarding communication between the two nursing teams. Senior management will address your concerns.

3. Storage of non-infective material

The concerns raised on the inspection are about the inconsistent policy regard storage of “infectious” material. We would like to point out that we do not store infectious material in the unit, but we do store non-infectious material (eg Hepatitis B core positive). We hope over the next year to harmonise our protocols for storing this material, so that sperm and embryos are stored under the same conditions.

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).

4. The Organisational Chart

There are two teams of nursing staff involved in IVF and DI treatment. However, in my opinion, we carry out our treatments competently and with compassion and this was reflected in our in-house survey and HFEA questionnaire survey.

All doctors and nurses involved in licensed activity are on our HFEA licence. The organisational chart reflects the line management of doctors, nurses and embryological staff. It is almost impossible to have an organisational chart which denotes the duties of each individual. The donor insemination service is run by the nursing staff and if they have any problems or queries, seek the advice of a member of the medical team who are on the licence. The DI programme is fully funded by the NHS. There is only limited funding for IVF and in the self funding programme, the IVF staff are employed to undertake activity in the IVF programme. There is obviously cross cover between medical and nursing staff for the DI and IVF programme. I shall seek to advise Ms Sandra Mair, Director of Performance and Licensee, regarding the organisational chart. The structure of the clinic requires senior management input, and it would take more than a month to review our organisational structure.

5. Page 10, Relating to Areas for Improvement

It was stated that the organisational chart does not reflect that there are two separate teams of doctors and nurses involved in licensed treatments (IVF and DI/ICI respectively). Although there are nominally two separate teams carrying out licensed treatment for DI and IVF, there is considerable overlap in their duties and we are currently working towards amalgamating these teams into a single functional IVF/DI team. We feel to represent them separately on an organisational chart would be a retrograde step at this point and not necessary for the adequate functioning of all team members. If nurses currently predominantly employed in the area of IVF were not aware that EFREC is currently licensed to carry out ICI, this is probably because we do not use this particular abbreviation in our everyday practise. Several of the nurses interviewed were relatively new to the service and not yet completely familiar with relatively uncommon abbreviations used in different areas of practise. These new members of the nursing staff have provided an excellent service to our patients since they have been in post, but it has been difficult to rotate members of nursing staff through every different area of clinical practise at the present time. To avoid confusion, we feel it would be prudent for licensing teams to refrain from the use of relatively uncommon abbreviations (eg ICI) when interviewing staff during HFEA inspections.

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

Licence Committee Meeting

14 February 2007
21 Bloomsbury Street London WC1B 3HF

MINUTES Item 3

Edinburgh Assisted Conception Unit (0201)
Interim Inspection

Members:
Emily Jackson, Lay Member – Chair
Ruth Fasht, Lay Member
Maybeth Jameson, Consultant Embryologist, Glasgow Royal Infirmary

In Attendance:
Frances Clift, Legal Adviser
Chris O'Toole, Head of Research Regulation
Claudia Lally, Committee Secretary

Observing:
Sally Cheshire, Lay Member
Anna Carragher, Lay Member
William Ledger, Professor of Obstetrics and Gynaecology, University of Sheffield

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

The following papers were considered by the Committee:

- papers for Licence Committee (30 pages)
- no papers were tabled.

1. The papers for this item were presented by Elliot Lawrence, HFEA Inspector. Mr Lawrence informed the Committee that this centre is organised unusually with a separation of the provision of IVF and of treatment with donor gametes. This unusual division of services has a number of implications for the way in which the centre is run and in particular for the communication of information to centre staff, notwithstanding this point, however, the systems in place do seem able to overcome these potential difficulties.

2. The Committee noted Dr Lawrence's comments and also accepted the centre's reasons for not wanting to reorganise the centre along more conventional lines.

3. The Committee noted that the inspection report records the fact that the centre did not have its complaints procedure clearly displayed in the patient's waiting room, and that this is a breach of the Code of Practice part 13.4.

4. Dr Lawrence informed the Committee that the names of all the Trust's doctors and gynaecologists are recorded on the centre's licence. The Committee noted that this was highly unusual, and they agreed that it was concerning that this might result in a high volume of information about patient's treatment being passed to individuals who would, in more usual circumstances, require specific consent from the patients concerned in order to access the information. The Committee also expressed its concern that the large list of Doctors and Gynaecologists named on the centre's licence but who are not involved on a daily basis with the treatment of individuals might not be being kept up to date with regulatory requirements in the way that would normally be expected. The Committee asked the Executive to investigate these concerns and to report back to the Committee with their findings.

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

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