



Renewal Inspection Report

**Glasgow Royal Infirmary
0037**

**Date of Inspection: 14 May 2008
Date of Licence Committee: 1 September 2008**

CENTRE DETAILS

Centre Name	Glasgow Royal Infirmary
Centre Number	0037
Licence Number	L0037/12/b
Centre Address	Assisted Conception Services Unit Walton Building 84 Castle Street Glasgow G4 0SF
Telephone Number	0141 211 4428
Type of Inspection	Renewal
Person Responsible	Dr Robin Yates
Nominal Licensee	Dr Helen Lyall
Inspector(s)	Dr Vicki Lamb
	Dr Chris O'Toole
	Mr Robert Sawers
Fee Paid – up-to-date	Not yet invoiced
Licence expiry date	31 December 2008
NHS/Private/Both	NHS

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About the Inspection:

This inspection visit was carried out on 14 May 2008 and lasted for 7.5 hours. The report covers the pre-inspection analysis, the visit and information received between 31 May 2007 and 14 May 2008.

The purpose of the inspection is to ensure that centres are providing a quality service for patients in compliance with the HF&E Act 1990, Code of Practice and to ensure that centres are working towards compliance with the EU Tissue and Cells Directive 2004/23/EC. Inspections are always carried out when a licence is due for renewal although other visits can be made in between.

The report summarises the findings of the licence renewal inspection highlighting areas of good practice, as well as areas where further improvement is required to improve patient services and meet regulatory requirements. It is primarily written for the Licence Committee who make the decision about the centre's licence renewal application. The report is also available to patients and the public following the Licence Committee meeting.

At the visit the inspection team assesses the effectiveness of the centre through five topics. These are:

How well the centre is organised

The quality of the service for patients and donors

The premises and equipment

Information provided to patients and to the HFEA

The clinical and laboratory processes and competence of staff.

An evaluation is given at the end of each topic and for the overall effectiveness of the centre:

No Improvements Required – given to centres where there are no Code of Practice, legal requirements 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.

NB: Where there are very minor issues to be addressed these are noted in the “minor issues to be addressed” section for each topic, and this will facilitate the evaluation of ‘no improvements required’. Where recommendations are made the HFEA will provide details of what needs to be addressed but not how they should be carried out as this is the responsibility of the Person Responsible.

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 centre was first licensed to carry out treatments in 1992, and has a good history of regulatory compliance.

The centre is very busy and open seven days a week: - Monday to Friday 8am to 5pm, Saturday 8am to 2pm and Sunday 8am to 11am. Egg collections are not conducted on either Saturday or Sunday and embryo transfers are not conducted on Sundays.

The centre is split between two sites within the Glasgow Royal Infirmary. Consultations, scans and administration services are located within the Walton Building whilst the laboratory, treatment room, men's production room, waiting room, quiet room, four bedded recovery area, operating theatre and cryostores are located within the Queen Elizabeth Building.

There have been no further developments as yet with regards to locating the unit within a single site at the Glasgow Royal Infirmary although discussions regarding this are still being held.

The centre has no additional conditions on its licence.

Activities of the Centre

Licensed treatment cycles	1066
Donor Insemination	0
Unlicensed treatments	Ovulation induction
Research	✓
Storage	✓

Summary for Licence Committee

The centre appears well organised and the staff showed evidence of good working relationships.

A number of regulatory issues were identified in the course of the inspection and these are summarised below:

- Average payment times are outside the 28 day limit.
- One issue in patient records relating to consent.
- One issue in patient records relating to screening.
- Validation of processes has not been done although work is ongoing with this.
- Competencies are not in place for embryologists.

- National success rates were not displayed alongside the centre's success rates.

Two recommendations have also been made by the inspection team relating to inaccuracies in the patient information.

The executive recommend renewal of the licence for a period of five years.

Risk Assessment

In May 2008, the centre's risk score (HFEA risk tool v3) was calculated as 16%. This is considered a low risk rating.

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, Standard Licence Conditions or Code of Practice: The table below sets out matters which the Inspection Team considers may constitute breaches of the Act, Standard Licence Conditions and/or the Code of Practice, and their recommended improvement actions and timescales. The weight to be attached to any breach of the Act, Standard Licence Conditions or Code of Practice is a matter for the Licence Committee:-

Breach	Action required	Time scale
The centre takes an average of 48 days to pay treatment fees. The HFEA payment terms are 28 days. Payment outside these terms is a breach of standard licence condition A13.3 which states that in consideration of the grant of the licence (or its variation to designate the individual named in this licence as Person Responsible), the Person Responsible agrees that s/he	The PR should put in place procedures to ensure that fees due to the HFEA are paid within the 28 day limit.	To be reviewed at the next inspection

<p>will pay to the Authority any additional fee, as defined in section 16(6) of the Act, within 28 days of the date of the notice of such additional fee.</p>		
<p>One set of records showed that the patient had had three embryos transferred but she had only consented to have two transferred. This is a breach of standard S.7.5.4(c).</p>	<p>Procedures should be put in place to ensure that appropriate consent to the number of embryos transferred is obtained including when the patient changes her mind during treatment.</p>	<p>Immediately</p>
<p>In one set of records the woman had consented to stored embryos being used by her husband in the event of her death. This would effectively mean that the female partner would become a donor, but there was no evidence of screening being undertaken to allow this. This is a breach of standard S.7.6.7.</p>	<p>Procedures should be put in place to ensure that women who wish their male partners to use stored embryos after their death are screened and provided with information on being donors.</p>	<p>Immediately</p>
<p>The processes used in carrying out licensable activities have not been validated. This is a breach of standard S.7.8.3.</p>	<p>The centre is in the process of validating these procedures.</p>	<p>By next inspection</p>
<p>Competency assessments have not been done for embryologists. This is a breach of S.6.2.9.</p>	<p>Competencies should be put in place for embryologists.</p>	<p>By next inspection</p>

Non-Compliance

Area for improvement	Action required	Time scale
Success rates for the centre were displayed in the waiting room but no national statistics were given for comparison. This is non-compliance with G.5.3.1(e) in the Code of Practice.	National statistics should be displayed alongside the centre's own results.	By 31 October 2008

Recommendations	Time scale
Patient information stated that there was no limit on the length of time eggs can be stored for. This should be amended to reflect the storage period permitted for gametes.	By 31 October 2008
Patient information stated that by law the maximum number of embryos that could be replaced was 2. This should be amended to reflect the current guidance in the Code of Practice.	By 31 October 2008

Proposed licence variations by last LC

None

Changes/ improvements since last inspection

Recommendations	Action Taken
Policy for witnessing within the laboratory does not reflect changes in practice introduced since the previous inspection.	Protocols have been updated
Male patients undergoing PESA operations have their consent forms filed within the hospital urology notes. It was recommended that these consent forms should be filed within the lab files so that they may be accessed easily for purposes of auditing stored samples against consent.	This is now done
Patients (female) who consent to their male partners using their embryos in the event of their death should be provided with additional	During the inspection it became apparent that this situation has not been resolved.

patient information pertaining to additional screening and registration as a donor requirements. This information should also include counselling details to discuss the implications of this option.	
Women who attend for treatment and sign consent for their partners to use their embryos in the event of their death are not currently screened or registered as donors. Women who sign consent to allow their partners to use their embryos in the event of their death should be screened and registered as donors.	During the inspection it became apparent that this situation has not been resolved.
Recommendation was made to develop a protection of children policy for the unit.	A policy has been developed
All administration staff to be provided with an annual appraisal and personal development plan (PDP).	This is now in place
A service contract should be organised for the low oxygen alarm within the laboratory.	This is now in place.
A formal documented service level agreement does not currently exist for contingency services. A service level agreement for contingency services to be formally documented.	This is now in place.
Blood samples are currently tested within the university laboratories which do not meet with the requirements of being CPA accredited or accredited to an equivalent standard. All blood tests will however need to be conducted in a laboratory which meets CPA or equivalent standards from the 5 th July 2007.	Blood samples are now tested in a CPA accredited laboratory.

Additional licence conditions and actions taken by centre since last inspection

None

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:

1. Leadership and management
2. Organisation of the centre
3. Resource management
4. Risk management
5. Incident management
6. Contingency arrangements
7. Business planning
8. Clinical governance
9. Payment of treatment fees

Areas of firm compliance
<p>The PR has completed the PR entry programme to the satisfaction of the executive.</p> <p>An organisation chart was provided to the inspection team showing clear lines of responsibility.</p> <p>The centre has a procedure for reporting and investigating incidents. Centre staff are aware of HFEA incident reporting requirements and incidents have been reported appropriately.</p> <p>A contingency agreement in case of unexpected interruption of services is in place.</p> <p>The inspection team were informed that the centre is due to have several computers installed shortly. This will enable many more staff to have access to a computer which in turn should enable easier dissemination of information and access to the quality management system.</p> <p>The whole team appeared to be well organised with a good working relationship.</p>
Areas for improvement
<p>The centre takes an average of 48 days to pay treatment fees. The HFEA payment terms are 28 days. Payment outside these terms is a breach of standard licence condition A13.3 which states that in consideration of the grant of the licence (or its variation to designate the individual named in this licence as Person Responsible), the Person Responsible agrees that s/he will pay to the Authority any additional fee, as defined in section 16(6) of the Act, within 28 days of the date of the notice of such additional fee.</p>
Areas for consideration
None
Executive recommendations for Licence Committee

The PR should put in place procedures to ensure that fees due to the HFEA are paid within the 28 day limit.

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:

1. Quality Management System
2. Quality Policy
3. Quality Manual
4. Quality objectives and plans
5. Quality Management review/evaluation
6. Monitoring and resolution of complaints
7. Staff suggestions
8. Document control
9. Live Birth Rates

Live Birth Rates
Pre-validation and pre-quality assured calculations on the HFEA held register data (31 March 2003-1 st April 2006) show: ¹ <ul style="list-style-type: none">• ICSI/IVF success rates are in line with the national average with the exception of age bands <35 and 35-37 where they are shown to be significantly higher than the national average.• Frozen embryo transfer success rates are in line with the national average with the exception of age bands <35 and 35-37 where they are shown to be significantly higher than the national average.• Donor insemination success rates are in line with the national average with the exception of age band 40-42 which is significantly lower than the national average.
Areas of firm compliance
There is a Quality Manager in post whose sole role is to maintain the quality management system. There is a programme of audits scheduled for 2008 and this was seen by the inspection team. The centre has a number of key performance indicators, for example on the number of cycles in which all embryos are frozen, the number of oocytes collected per cycle and the number of cancelled cycles. These are used to ensure continued good practice. All the third party agreements seen by the inspection team were fully completed. The complaints policy was seen along with the log of complaints. Many of the complaints were about issues outside the centre's control.

¹ This data is supplied to the HFEA by individual clinics who are responsible for its accuracy and for verifying it. The data published by the HFEA on our website is a snapshot of the state of the Register at a particular time. The data in the Register may be subject to change as errors are notified to us by clinics, or picked up through our quality management systems.

Authorised documents in the quality management system are held on a shared computer drive to allow access by all centre staff.
Areas for improvement
None
Areas for consideration
None
Executive recommendations for Licence Committee
None
Areas not covered on this inspection
None
Evaluation
No improvement required

3. Premises and Equipment

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

Summary of findings from inspection:

1. General Suitable premises
2. Clinical facilities
3. Counselling facilities
4. Laboratory facilities
5. Air quality
6. Storage facilities for gametes and embryos
7. Staff facilities
8. Management of equipment and materials
9. Control of records
10. Risk assessments

Areas of firm compliance
<p>The air quality in the laboratory meets the requirements of the HFEA. Evidence of the air quality in the laboratory and hoods were seen on the day of the inspection. Air quality is checked on every three months.</p> <p>The centre have conducted a number of risk assessments since the last inspection. The inspection team were informed that following a recent incident all the risk assessments have been reviewed.</p> <p>The cryostore is fitted with a low level extractor which operates all the time to ensure movement of air within this room.</p> <p>All storage dewars were seen to be alarmed and the inspection team were informed that there is a recompensed on-call rota. Low oxygen monitors were also seen to be in place.</p> <p>The inspection team were informed that all critical equipment is connected to the hospital generator.</p>
Areas for improvement
<p>The physical facilities could be improved. Although there are two scan machines available there is only one scan room available. The inspection team felt that effort should be made to find a second scan room to enable the equipment to be used to best effect and avoid waste of resources.</p>
Areas for consideration
None
Executive recommendations for Licence Committee
None
Areas not covered on this inspection
None

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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:

1. General Information
2. Meetings and communication
3. HFEA Alerts
4. Welfare of child
5. Confidentiality and access to health records
6. Traceability and coding
7. Coding/ identification of samples
8. Information for service users/consents
9. Donor information
10. Donor registration
11. Surrogacy
12. Procurement and distribution of receipt of gametes and embryos
13. Home procurement report documentation
14. Packaging & distribution
15. Labelling of packages containing procured gametes
16. Transportation, labelling of shipping container and recall
17. Receipt of gametes

Areas of firm compliance
<p>The centre has used the HFEA's audit tool for checking compliance with HFEA alert 21: Transport hazards of gametes / embryos nationally and internationally. This audit tool was also used on the day of the inspection to check the centre's compliance. Protocols and records were checked and these were found to be compliant.</p> <p>Records of meetings held were seen. These include: ACS management group, clinical, embryology, quality, nursing, administration and research. The minutes of these are kept on a shared computer drive accessible to centre staff.</p> <p>The treatment licence and information on how to make a complaint was displayed in both areas of the centre.</p> <p>Counselling records are stored securely in locked cabinets.</p> <p>The identity of individuals undergoing treatment is verified by mean of photographic ID.</p> <p>Batch records and traceability records for critical items were seen and an SOP for this was provided to the team</p> <p>One couple undergoing treatment were interviewed on the day of the inspection. They were happy with the treatment they had received and had been fully informed about the drugs to be taken, how to contact the counsellor and who to contact in an emergency.</p>
Areas for improvement
<p>Success rates for the centre were displayed in the waiting room but no national statistics were</p>

<p>given for comparison. This is non-compliance with G.5.3.1(e) in the Code of Practice.</p> <p>Two issues relating to patient information were discussed:</p> <ul style="list-style-type: none"> • The information stated that there was no limit on the length of time eggs can be stored for. This should be amended to reflect the storage period permitted for gametes. • The information stated that by law the maximum number of embryos that could be replaced was 2. This should be amended to reflect the current guidance in the Code of Practice.
<p>Areas for consideration</p> <p>Although an information leaflet on OHSS was available to inform other doctors what to do in case of a patient presenting with this condition, the clinical inspector felt that this leaflet could be improved. As many of the leaflets are being updated special attention should be paid to the content of this leaflet.</p>
<p>Executive recommendations for Licence Committee</p> <p>The PR should ensure that national statistics are displayed alongside the centre's own results.</p> <p>Patient information should be amended as detailed above.</p>
<p>Areas not covered on this inspection</p> <p>None</p>
<p>Evaluation</p> <p>Some improvement required</p>

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:

1. Laboratory processes
2. Selection and Validation of laboratory procedures
3. Laboratory's documented procedures
4. Storage of gametes and embryos
5. Counselling
6. Witnessing

Full time equivalent staff

GMC registered doctors	5
NMC registered nurses	7.9
HPC registered scientists	5
Scientists working towards registration	0
Support staff (receptionists, record managers, quality and risk managers etc)	9
Counsellors	1

Summary of laboratory audit / Audit of records

The centre has carried out an audit of all stored gametes and embryos. All samples of gametes and embryos were accounted for. Four administrative errors were identified but in all cases the patient's embryology notes were correct. These errors have been corrected. Evidence of a rolling audit, due to begin in June 2008, was seen on the day of the inspection.

One set of records showed that the patient had had three embryos transferred but the consent form indicated that she had only consented to have two transferred. Further examination of this set of records showed that a discussion occurred between the patient and centre staff some time after the consent form was signed and the patient had changed her mind and wished to have three embryos transferred. However the consent form was not changed to reflect this change of plan.

In one set of records the woman had consented to stored embryos being used by her husband in the event of her death but there was no evidence of screening being undertaken to allow this.

Summary of spot check of stored material

A spot check of stored material was carried out on the day of the inspection. The records of two patients with embryos in storage were selected and the location of the stored material was traced from these records to the storage dewars. No anomalies were found. The locations of the embryos of one patient and gametes from another patient were recorded and these were traced back to the relevant patients' records. Again no anomalies were found.

Areas of firm compliance

The laboratories where licensable activities are carried out and where the dewars containing stored gametes and embryos are secure and only accessible to personnel named on the centre's licence.

All dewars are alarmed and the laboratory has a low level O₂ alarm. All alarms are linked to a 24 hour monitoring system.

All equipment used in the process of carrying out licensable activities is serviced and maintained on a regular basis. The centre carries out daily checks on the temperature and CO₂ levels of all incubators. Evidence of service contacts, maintenance records and daily testing were seen on the day of the inspection.

The centre has records ensuring that all the equipment and consumables used in carrying out licensable activities is traceable and has been validated.

All procedures used in the process of carrying out licensable activities are witnessed in accordance with HFEA guidance. The centre carried out an audit of its witnessing system on 26 March 2008. Evidence of this was seen on the day of the inspection. A spot check of the centre's witnessing was carried out on the day of the inspection. Records of five patients were audited and evidence that all key steps used in the provision of licensable treatment had been appropriately witnessed was seen. The witnessing procedures appeared to be robust.

All patients undergoing current treatment are screened in accordance with HFEA guidelines.

The centre has five qualified embryologists. All embryologists have a programme to ensure continued professional development. The records of the continued professional development for one of the embryologists were examined on the day of the inspection. The competences of the embryologists to carrying out licensable activities e.g. ICSI is monitored.

The centre, in conjunction with the regional genetics laboratory, has a PGD programme. In the last year the centre has carried out 16 cycles of PGD for 13 patients. All tests carried out were for conditions listed on the centre's licence.

The counsellor is BICA accredited and her certificate was seen on the day of the inspection.

Records demonstrated that all the three embryo transfers that had been performed were in women over the age of 40.

The centre participates in the NEQAS scheme for semen analysis.

Evidence of registration, induction, training and job descriptions were seen for a selection of staff. The doctor interviewed confirmed that his competencies were recorded and signed off. Competencies were seen for nursing and medical staff and comprehensive training records were also seen.

Areas for improvement

One set of records showed that the patient had had three embryos transferred but she had only consented to have two transferred. This is a breach of standard S.7.5.4(c) and non-compliance with G.8.2.2.

In one set of records the woman had consented to stored embryos being used by her husband in the event of her death. This would effectively mean that the female partner would become a donor, but there was no evidence of screening being undertaken to allow this. This is a breach of standard S.7.6.7 and non-compliance with G.4.9.1.

The processes used in carrying out licensable activities have not been validated. The centre is in the process of developing procedures for validating these processes. According to standard S.7.8.3 all laboratory procedures should be validated.

Competencies should be put in place for embryologists to ensure compliance with S.6.2.9.

Areas for consideration

The figures provided by the counsellor showed that 563 sessions of counselling were given between 1 April 2007 and 31 March 2008. The counsellor feels that she needs to be contracted for more hours in order to meet the demands of the counselling service.

Executive recommendations for Licence Committee

Procedures should be put in place to ensure that appropriate consent for the number of embryos transferred is obtained.

If a woman wants her male partner to their stored embryos in the event of her death she should be given information on being a donor and screened appropriately.

Validation of processes should be carried out.

Competencies should be put in place for embryologists.

Areas not covered on this inspection

None

Evaluation

Some improvement required

Report compiled by:

Name.....Vicki Lamb.....

Designation.....Inspector.....

Date...6 June 2008.....

Appendix A: Centre Staff interviewed

PR and six members of staff

No conflicts of interest were declared

Appendix B: Licence history for previous 3 years

Licence	Status	Type	Valid from	Valid to
L0037/12/b	Active	Treatment with storage	28/08/2007	31/12/2008
L0037/12/a	Replaced by new version	Treatment with storage	05/07/2007	31/12/2008
L0037/11/d	Replaced by new version	Treatment with storage	01/10/2006	31/12/2008
L0037/11/c	Replaced by new version	Treatment with storage	01/04/2006	31/12/2008
L0037/11/b	Replaced by new version	Treatment with storage	01/01/2006	31/12/2008
L0037/11/a	Replaced by new version	Treatment with storage	01/01/2006	31/12/2008
L0037/10/a	Replaced by new version	Treatment with storage	01/09/2005	31/12/2005
L0037/9/d	Replaced by new version	Treatment with storage	09/02/2005	31/12/2005

Appendix C:

RESPONSE OF PERSON RESPONSIBLE TO THE INSPECTION REPORT

Centre Number...0037.....

Name of PR.....Dr R Yates.....

Date of Inspection.....14/05/08.....

Date of Response.....04/07/08.....

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

Signed.....by email.....

NameRobert W S Yates.....

Date..... 04/07/08

1. 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).

Nil

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

- 1. I will reinforce to the Finance Manager, Operations Manager and the General manager of the Directorate this requirement. I would also point out that on several occasions the actual bill was not received in the unit and thus could not be forwarded to the finance department.
- 2. We only did 3 3 embryo transfers last year. There are SOP's in place for 3 embryo transfers and this must have been missed on the day.
- 3 We have an SOP in place for this when screening the couple. We have also instigated a new procedure where all patients who have embryos frozen in a particular week will have their notes reviewed at our Friday meeting and lettered for screening if required.
- 4 Our quality manager has begun validation processes
- 5. Competency assessments will be carried out for embryologists in line with the KSF

Licence Committee Meeting

1 September 2008
21 Bloomsbury Street London WC1B 3HF

MINUTES Item 1

Glasgow Royal Infirmary (0037) Licence Renewal

Members of the Committee:

Walter Merricks, Lay Member – Chair
Sally Cheshire, Lay Member
David Archard, Lay Member
Jennifer Hunt, Senior Infertility
Counsellor, IVF Hammersmith

In Attendance:

Debra Bloor, Head of Inspection
Claudia Lally, Committee Secretary

Providing Legal Advice to the
Committee:
Graham Miles, Morgan Cole

Declarations 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 (31 pages)
- no papers were tabled.

1. The papers for this item were presented by Vicki Lamb, HFEA Inspector. Dr Lamb informed the Committee that this centre has been licensed since 1992 and has a good history of regulatory compliance. Dr Lamb reported that the renewal inspection visit took place on 14 May 2008 and found the centre to be well organised. However, a number of regulatory issues were identified at the visit, as summarised at pages 6 to 8 of the inspection report.
2. Dr Lamb listed the regulatory issues which were identified. These were as follows.
 - The centre takes an average of 48 days to pay treatment fees.
 - One set of patient records reviewed as part of the inspection showed that the patient had had three embryos transferred but had only consented to have two transferred.
 - In another set of patient records, the patient had consented to stored embryos being used by her husband in the event of her death. However, there was no evidence the necessary screening had taken place to allow for this possibility.

- The processes used in carrying out licensable activities had not been validated.
 - Competency assessments for Embryologists had not been carried out.
 - Success rates for the centre were displayed in the waiting room without national statistics being provided for comparison.
 - Patient information about storage of eggs did not reflect statutory storage periods.
 - Patient information about the number of embryos did not reflect current guidance in the HFEA Code of Practice.
3. Dr Lamb summarised the response to the inspection report received from the Person Responsible and appended at page 22 of the report. This response highlighted the follow up action being taken by the centre to address the concerns of the inspection team and indicated that all the matters raised at the inspection are in the process of being addressed. Dr Lamb recommended that the centre's licence be renewed for a period of five years.

The Committee's Decision

4. On the basis of the information before them, the Committee decided to renew the centre's licence for a period of five years.

Signed..... Date.....
Walter Merricks (Chair)