Interim Inspection Report

Glasgow Royal Infirmary
0037

Date of Inspection: 7th July 2006
Date of Licence Committee: 4th September 2006

TRIM: 06/5619

CENTRE DETAILS

Centre Address	Glasgow Royal Infirmary Assisted conception Services Unit Walton Building 84 Castle Street Glasgow Scotland G4 0SF
Telephone Number	0141-211-4428
Type of Inspection	Interim Announced Inspection
Person Responsible	Mr Robin Yates
Nominal Licensee	Helen Lyall
Licence Number	L0037-11-C
Inspector(s)	Tony Knox (Lead Inspector) Dr Neelam Sood Elliot Lawrence
Fee Paid	The finance department at the HFEA reported regular and timely receipt of payment for treatment fees.
Licence expiry date	December 31st 2008

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About the Inspection:
This inspection visit was carried out on 7th July 2006 and lasted for 7 hours. The report covers the pre-inspection analysis, the visit and information received between July 2005 and June 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 makes 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 centre was first licensed in to carry out treatments in 1992, and has a good history of regulatory compliance.

The centre mainly treats NHS patients from the West of Scotland, having contracts with five of the surrounding health authorities. Patients are mainly referred to the centre by their GP, with some being referred through the university services. Treatment services are also provided to local asylum seekers and refugees, for whom they have access to interpreters if required. The PR stated that the estimated split between private and NHS funded patients is around 90% NHS funded and 10% private, and there is approximately an eight month waiting list to commence treatment.

The centre is very busy and open seven days a week: - Monday to Friday 8am to 5pm, Saturday 8am – 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 currently split between two sites located within the Glasgow Royal Infirmary. Consultations, scans and administration services are located within the Walton building whilst the laboratory, treatment rooms, men's production room, waiting room, quiet room, four bedded recovery area and operating theatre are located within the Queen Elizabeth building.

Some preliminary consideration has been given by hospital management to provide space for the unit to be relocated to a single site. It was stated by the PR that this was as yet only at discussion stage and no business plan has been produced.

Activities of the Centre

Licensed treatment cycles	**IVF** **ICSI** **Egg donation**	**345** **457** **10**
Donor Insemination		**11**
Unlicensed Treatments	**IUI** **Ovulation Induction** **Surrogacy**	
Research		**Applying for licence**
Storage		**Yes**

Summary for Licence Committee

- The inspectors recommend a three year extension to the licence with no additional conditions.
- Request was received from Maybeth Jamieson (senior scientist) to remove her name from the ICSI practitioners list as she no longer performs this function within the unit.

Risk Assessment

- The centre had a 32% risk score when first conducted. A review of the risk score in July 2006 showed that the risk score had reduced to 21% following work conducted within the centre directly linked to the previous report.

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
• Maintenance contracts were not in place to cover the incubators within the laboratory.	• Funding should be sought to ensure appropriate maintenance contracts are in place to cover this critical equipment	• 3 months
• There are no documented nursing policies or procedures.	• Nursing policies and procedures to be documented and version controlled.	• 6 months
• Not all of the policies provided at the centre were version controlled.	• Policies and procedures in use at the centre should be version controlled.	• 6 months
• The centres' computer records should accurately reflect the patients' notes records of samples in storage.	• A protocol to be devised within the laboratory to ensure that the computerised records for samples in storage are amended whenever a sample is removed.	• With immediate effect.
• During the freezing process within the laboratory, two separate patients' samples were held within the hood.	• Only one patients' sample should be processed within hood at any one time. Working process to be amended and protocols amended to reflect this change.	• With immediate effect.
• Daily equipment check log within the laboratory showed missing data.	• Daily checks to be performed in accordance with the centres SOP's.	• With immediate effect.

Recommendations	Time scale
Interpreters used at the centre for non-English speaking patients should sign a confidentiality declaration.	As soon as possible.
A patient satisfaction questionnaire to be devised and audited by the centre.	As soon as possible
Air quality within the laboratory and operating theatre to be re-tested to ensure compliance with the EUTD standards for air quality.	Prior to making any application under the EUTD.
Emergency equipment to be checked regularly, contain in-date equipment and have documented logs to show that the equipment has been checked.	With immediate effect.
Investigate ways of improving waiting room conditions for patients attending during the busiest times of the centre's operations.	As soon as possible.

Proposed licence variations

None required.

Changes/ improvements since last inspection on 14/6/05

Recommendation	Action taken
600 inherited Oncology samples had not been split at the last inspection as per CH(04)03.	Full audit of the inherited samples was completed in April 2006 and samples split in accordance with the requirements of Chairs Letter CH(04)03.
Patient information to be updated regarding CMV screening, 'Welfare of the Child', parental responsibility, donor anonymity and opening the register.	All patient information had been updated as seen in information provided pre-inspection.
Dewars had not been connected to an autodial system at the last inspection	All dewars are now connected to an autodial system.
Protocol for re-freezing embryos was not in place at the last inspection.	Protocol for re-freezing embryos was produced and submitted to HFEA.

Additional licence conditions and actions taken by centre since last inspection

C	
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 PR demonstrated awareness of his responsibilities under the HFE Act, Code of Practice 6th Edition and other relevant legislation. He was aware of the new Standards document issued by the HFEA and the requirements of the EU Tissue Directives. • Despite being in two separate locations within the main hospital, the centre appears well organised and appropriately staffed for the numbers of cycles performed annually. • Staff interviewed stated they felt well supported both for CPD and in their roles. • The centre is part of the obstetrics and gynaecology directorate which meets monthly. Senior staff from the centre attend these meetings where clinical governance issues are discussed. The meetings are minuted and were evidenced during the course of the inspection. Feedback from these meetings is presented to staff at the centre during their regular monthly multidisciplinary meetings. These are also minuted and were evidenced. • A minuted clinical risk management meeting is held monthly which was evidenced during the inspection. Issues such as incidents, HFEA alerts and complaints are discussed at these meetings and action points are agreed. • All staff were aware of both the incident reporting and complaints procedures. • The finance department at the HFEA reported regular and timely receipt of payment for treatment fees. • Negotiations are currently in place with the Trust to employ an Andrology technician for the unit. It was noted that this would enable routine sperm tests to be conducted by this person and thereby reduce the workload for the remaining embryologists.
Areas for improvement
• The PR stated that the current PGD practitioner has recently tendered his resignation although has agreed to continue working within the unit one day per week until a replacement has been recruited. The PR stated that this was not ideal and would be remedied as soon as possible. In the interim, the levels of work required for PGD will be monitored by the centre, and workload adjusted accordingly.

Executive recommendations for Licence Committee
None
Areas not covered on this inspection
None

Evaluation
The centre is well organised and managed.

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
Data provided by the HFEA pre-inspection show that IVF, ICSI, FET in all age ranges and DI treatments in patients up to the age of 39 were all above the national average success rates. DI treatment for the age range of 40 – 42 was below the national average. OHSS rates shows are 2.54% which is above the national average. Data provided by the centre pre-inspection show 44 sets of twins were born out of 188 live births (23.4%) with 5 out of 11 reported live births from DI treatment (45.4%) were twins. There were no recorded three embryo transfers conducted and 69 cases of elective single embryo transfer during this period.
Areas of firm compliance
• The centre promotes single embryo transfer procedures. • Welfare of the child arrangements were in place, patient information reflects current requirements, and findings were seen to be adequately recorded in the patients' notes. Any potentially difficult cases can be referred to the centres ethics committee of which 24 referrals had been made since the time of the last inspection report. Ethics meetings are minuted and evidence of these minutes was seen during the course of this inspection. • All staff interviewed were aware of the confidentiality requirements, all patients' notes were seen to be stored in suitably secure storage with restricted access. • A translator is provided for non-English speaking patients. Wherever possible, the same translator is used for all stages of the patients' treatment and counselling. • The PR explained that treatment choice for patients can depend upon funding and eligibility criteria set by the health authorities. He stated that patients are made aware of the choices available to them during consultation, and they are actively involved in their treatment plans. • The complaints procedure was considered suitable for purpose by the inspectors. Notices were on display in the patients waiting areas showing how patients can access this

service. It was noted that since the last inspection, three complaints had been received. All complainants had been responded to within the stated timeframe within the complaints policy. Two of the complaints had been satisfactorily resolved with one complaint ongoing. This was being dealt with by the PR.

- Counselling services are provided for all patients. Notices were evidenced in public areas detailing how these services could be accessed. The counsellor stated that counselling notes are kept within a locked storage cabinet within her office to which only she has access to. The counsellor is appropriately qualified and registered with BICA, and she receives one and a half hours of professional supervision monthly. Counselling services are provided free of charge. She stated that she also attends regular multidisciplinary meetings within the unit and although remains independent, feels included as a member of the team. Information provided in the pre-inspection questionnaire notes that there is currently a two week waiting list for counselling services.
- The centre subscribes to the main hospital's policies on equality, anti-discrimination and child protection policies.
- Patients are required to provide photographic identification (passport or driving licence), as proof of their identity before entering into a treatment program.
- The patients interviewed were generally happy (see below) with the treatment and service provision, and with the overall professionalism of the staff.

Areas for improvement

- Additional focus should be given by the centre to reducing their multiple birth rates. The PR stated that they would continue to audit their results.
- It was recommended that all interpreters used within the centre should, in addition to receiving verbal instruction regarding confidentiality, sign a confidentiality declaration.
- Although a "Suggestion Box" is provided within the waiting room for patients' feedback, comments made had not been analysed. It was recommended a system is implemented for patients' feedback to include the effectiveness of the counselling services.
- At the time of the inspection it was noted that a number of patients waiting to be seen had to wait in the corridor outside of the main waiting room due to insufficient space. Patients interviewed during the inspection raised this as an area of concern. In discussion with the PR, he stated that this problem occurs for a short period of time only in the morning when all patients are attending the centre either for consultation or monitoring. It was noted by the inspectors that this problem was resolved within an hour. The PR stated that alternatives had been considered for moving the waiting room to another location; however this was not possible due to space constraints within the centre.

Executive recommendations for Licence Committee

None

Areas not covered on this inspection

Donor selection was not covered as this service is no longer provided.
Egg sharing is not provided at the centre and there have been no recent surrogacy cases.

Evaluation

The overall standards provided at the unit for patients are good. Additional focus should be given however to reducing the multiple birth rates.

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 amount of space within the laboratory was raised as a matter of concern in the previous inspection. As a consequence to this, all of the storage dewars were moved to a separate storage holding facility thereby increasing the available space within the laboratory. • All dewars within the cryostore were independently alarmed, locked and connected to an autodial facility. • Emergency backup power is supplied to the centre via a backup generator. • All oncology samples within the centre had been split in accordance with the requirements of Chair Letter CH(04)03. • All critical equipment was noted as being checked and maintained with the exception of the centre incubators. • Double witnessing was evidenced as being conducted in compliance with Chair's Letter CH(04)02.
Areas for improvement
• The new dewar storage facility provides little to no extraction ventilation and as a consequence, the door to this area is normally left open. During the inspection, it was noted that just outside of the storage area are a set of double doors leading into the main part of the hospital. These were also open at the time of inspection, although staff working within the unit reported that these are normally locked. This does not comply with HFEA Code of Practice 2.22. It was recommended that, due to the number of storage dewars within the area and the amount of liquid nitrogen stored, additional ventilation should be provided for this area, the double doors leading into the main hospital should remain locked and the door to the cryostore should as a minimum be kept locked when staff are not working within it. • It was noted by the PR that air testing within the laboratory and operating theatres had been performed using settle plates. Results from these tests showed that the air quality provides a background "C" classification which meets the requirements of the EU Tissue Directives. Both the PR and the Senior Embryologist however were not confident of these results and stated that they would arrange for these tests to be repeated. • Emergency crash trolley within the Walton building contained out of date stock and was not regularly checked. A recommendation was made to re-equip the crash trolley and maintain a log to show that the equipment was checked on a regular basis. • Senior staff within the operating theatre of the Queen Elizabeth building stated that their emergency trolley was checked daily. However, there was no log to evidence this. It was recommended that a log be created to document the daily checking of the emergency

equipment within this area.

- The log showing the daily environmental checks within the laboratory had not been completed in accordance with the laboratory standard operating procedures for every occasion.
- Incubators within the laboratory were not covered by maintenance contract. Funding should be sought from the Trust to ensure these critical pieces of equipment are adequately covered.
- There is process/procedure for documenting training on new equipment. It was recommended that a system be introduced for staff to become accustomed to using new equipment before introducing the equipment into full use within the unit. It was explained that by doing this, potential incidents could be avoided due to unfamiliarity with the equipment.

Executive recommendations for Licence Committee
• Conditions within the cryostore to be improved as noted above. • Air quality within the operating theatre and embryology laboratory to be re-tested and certificated to ensure compliance with EUT Directives.
Areas not covered on this inspection
None

Evaluation
Some improvements are required to promote safety and security of staff and equipment as given above. The PR and senior members of staff interviewed during the course of the inspection are aware of these requirements and are actively working towards improvement.

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
19 x sets of patients' notes were obtained for the purposes of auditing during the inspection. The treatments provided included standard IVF, IVF with ICSI, egg donors and recipients, donor IUI and FET treatment cycles. No errors were detected in any of the records audited by the inspectors. All consents had been completed correctly and there was evidence in all notes reviewed that a "welfare of the child" assessment had been performed. The last operational audit performed by the HFEA was conducted between 29th and 30th April 2004. This was detailed in the last inspection report and therefore not included in this report.
Areas of firm compliance
• All patients records audited during the course of the inspection were complete. • All patient information provided reflects current legislation and is up to date. • Patients interviewed stated that the information provided to them was complete and understandable.
Areas for improvement
• There were no documented nursing policies/procedures. • Not all of the protocols that had been created at the centre were version controlled. The PR stated that a process is in place to commence further reviews and changes. • Registry department at the HFEA noted that whilst there had been an improvement in the timely submission of treatment data from the centre, a 23% late response rate since the last inspection show that some further improvements are still necessary. The PR stated that he was currently looking at ways of improving this.
Executive recommendations for Licence Committee
None
Areas not covered on this inspection
None

Evaluation
Information provided for patients is up to date, understandable and complete. Staff are currently working towards the provision of documented policies and procedures which are version controlled to meet with the requirements of the EUT Directives.

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	5
NMC registered nurses	11 qualified nurses grades E to G (7.45 full time equivalent) Plus 2 nursing assistants (1.8 whole time equivalent)
HPC registered scientists	5
Scientists working towards registration	0
Support staff (receptionists, record managers, quality and risk managers etc)	6

Summary of laboratory audit
Prior to the inspection in August 2005, the centre inherited 600 oncology samples from the university department. A pre-transfer audit had been conducted on these samples showing a number of discrepancies in samples location and consents. In addition, none of the samples had been split. In April 2006, the centre closed for a period of two weeks and a full audit was conducted on these samples. All samples have now been split in accordance with Chair's Letter CH(04)03, and their location accurately recorded. A location map for each dewar has also been created and all future audits on these dewars will be conducted against these records. Audit of embryo dewars was conducted in 2005. A number of errors were recorded primarily due to the computerised record not being updated when a sample was thawed. Verification of thawing was recorded within the patients' notes. All of these errors were corrected at the time of the audit.
Summary of spot check of stored material
An audit of embryos, one from records to dewar and one from dewar to records was conducted by the scientific inspector. No discrepancies were found. An audit of sperm, one from records to dewar and one from dewar to records was conducted by the scientific inspector. One discrepancy was found. Four straws of sperm were physically in the dewar location although documentation stated that there should have been

five straws. The laboratory records were traced which showed that one straw had been used on 16th June 2006 in an ICSI procedure but the records had not been updated to reflect this. Centre staff updated the records accordingly during the course of the inspection.

Areas of firm compliance

- Following a risk assessment performed on the available space within the laboratory, all storage dewars were re-located to an alternative storage area. The space within the laboratory was now considered suitable by the scientific inspector for the number of cycles performed within the centre.
- The main hospital policy for staff recruitment is followed. The PR stated that the staff have involvement in the process. Recommendation to the Trust has been made to employ a Quality Manager in line with the requirements of the EUTD. This is under consideration at the present time.
- Staff interviewed stated that they felt well supported within the unit both for the roles they perform and in their ongoing continuing professional development (CPD). All staff receive annual mandatory updates in basic life support. Induction programmes are in place for all new staff and the induction and any training attended is recorded for each member of staff. These records were evidenced during the inspection.
- The PR confirmed that all staff are appropriately qualified and registered with their respective professional bodies.

Areas for improvement

- A system for accurately updating the records of samples in storage must be developed for the laboratory. This is based primarily on the evidence noted within the audit for 2005 and on the error noted during the spot check of the laboratory samples on the day of inspection.
- It was noted by the scientific inspector that during the freezing process within the laboratory, two patients' samples were held within the same hood. This was raised with the senior embryologist noting that only one patients' sample should be held within the hood for processing. It was noted by the senior embryologist that only one sample is worked on at any one time but agreed that an alternative system would be employed. Protocols to be amended accordingly.
- Witnessing procedures for freezing at weekends is not conducted in compliance with Chair's letter CH(04)02. In the event a freeze occurs on a Saturday, this is witnessed on Monday.
-

Executive recommendations for Licence Committee

- A system to be devised to ensure that all laboratory processes are witnessed in accordance with Chair's letter CH(04)02. This was agreed with both the PR and the Senior Scientist.

Areas not covered on this inspection

For PGD see "Organisation" section of this report.

Evaluation
Improvements within the laboratory have been made since the last inspection which shows a commitment by the PR and staff to comply with all relevant Regulations. Some additional improvements are still required as documented above, which the PR and senior members of staff are aware of and are actively working towards.

Report compiled by:

Name……TONY KNOX

Designation……Lead Inspector

Date……1st August 2006

Appendix A: Centre Staff interviewed

Robin Yates (Person Responsible) and five members of staff

Appendix B: Licence history for previous 3 years

First licensed 31 July 1992.

2006

Interim inspection for treatment and storage 7th July 2006.
Research inspection to commence research project 7th July 2006.

Licence Committee 22nd March 2006

Application was presented for the centre to carry out PGD for Ornithine Transcarbamylase Deficiency. This is an X linked urea cycle defect which can lead to the accumulation of ammonia in the body, which can lead to irreversible brain damage, coma and death, even if promptly treated. This was approved. In addition, the centre applied to carry out PGD for Androgen Insensitivity Syndrome. This is a condition also known as testicular feminisation syndrome which is an X linked condition. This was also approved.

2005

Renewal Inspection 14 June 2005
Licence Committee 5th September 2005

LC agreed to continue licence for a period of three years. LC granted a six month extension to the centre to split 600 inherited oncology sperm samples. This was completed in April 2006.

2004

Licence Committee: 11 November 2004
Interim Inspection & variation of licence to add storage of eggs.

LC agreed to continuation of centre's licence with no additional conditions or recommendations. LC agreed to vary centre's licence to include storage of eggs

Interim Inspection 3 September 2004

Licence Committee 5th April 2004

The Committee agreed to grant the Variation to include pre-implantation genetic diagnosis (PGD) for the balanced reciprocal translocation: 46,XX,t(4;16)(q25;q12.1)mat.ish t(4;16)(D4S2930-,16qtel48+;D16Z3+,16qtel48-,D4S2930+) AP-04-0042 on the Centre's treatment licence.

2003

Licence committee 29th October 2003

The Centre's application to vary licence Annex 1 to add pre-implantation genetic diagnosis for X-linked Alport Syndrome (Variation Number 00319) was considered by licence committee who agreed that the variation was necessary or desirable for the purposes of providing treatment services.

Licence committee 14th August 2003

Licence committee added one additional recommendation to the centres licence, and no conditions.

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

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).

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