Interim Inspection Report

Centre for Assisted Reproduction, Gateshead
0170

Date of Inspection: 25 September 2007
Date of Licence Committee: 17 December 2007

Centre Details

Centre Address	Gateshead Health NHS Foundation Trust Queen Elizabeth Hospital, Sheriff Hill Gateshead Tyne & Wear NE9 6SX
Telephone Number	0191 445 2768
Type of Inspection	Interim
Person Responsible	Ian Aird
Nominal Licensee	Gateshead Health NHS Trust: Ian Renwick
Licence Number	L0170/9/a
Inspector(s)	Debra Bloor Tony Knox Stephanie Sullivan
Licence expiry date	31 January 2009

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About the Inspection:

This inspection visit was carried out on 25 September 2007 and lasted for 9 hours. The report covers the pre-inspection analysis, the visit and information received between 27 September 2005 and 25 September 2007.

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

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

At the visit the inspection team assesses the effectiveness of the centre through five topics. These are:
How well the centre is organised
The quality of the service for patients and donors
The premises and equipment
Information provided to patients and to the HFEA
The clinical and laboratory processes and competence of staff.

An evaluation is given at the end of each topic and for the overall effectiveness of the centre:
No Improvements Required – given to centres where there are no Code of Practice, legal requirements, recommendations or conditions that need to be imposed.
Some Improvements Required – given to centres that are generally satisfactory but with areas that need attention. Recommendations will usually be made to help Persons Responsible to improve the service.
Significant Improvements Required – given to centres that have considerable scope for improvement and have unacceptable outcomes in at least one area, causing concern sufficient to necessitate an immediate action plan or conditions put on the Licence.

The report includes a response form for the Person Responsible to complete following the inspection.

The HFEA welcomes comments from patients and donors, past and present, on the quality of the service received. A questionnaire for patients can be found on the HFEA website www.hfea.gov.uk .

Brief Description of the Centre and Person Responsible

The centre is part of the Gateshead Health NHS Foundation Trust and has provided licensed treatments since 1996. The unit offers self funded and NHS funded treatments to patients from the local geographical area. The centre was last inspected in September 2005 and was granted an interim inspection "holiday" in 2006. The centre provided approximately 281 licensed treatment cycles in the time period between April 2006 and March 2007.

The person responsible has been in post since 1998. He is experienced and suitably qualified and is included on the specialist register of the Royal College of Obstetrics and Gynaecology.

Activities of the Centre

	April 2004 – March 2005	April 2005 – March 2006	April 2006 - March 2007
IVF	147	127	158
FET after IVF	19	31	20
ICSI	44	67	77
FET after ICSI	11	5	13
Unknown		4	1
IVF with egg donation			5
Donor Insemination	31	13	7
Unlicensed treatments	intra uterine insemination, ovulation induction		
Research	No		
Storage	✓		

Summary for Licence Committee

The Centre for Assisted Conception, Gateshead is a moderately small unit providing approximately 250 licensed treatment cycles per year.

The unit has appropriate premises, suitably qualified and experienced staff and adopts appropriate clinical and laboratory procedures. Patients report satisfaction with the treatment that they receive. The centre has been responsive to recommendations made in the previous report and has been proactive in the development and implementation of a quality management system.

Improvements should be considered relating to the following aspects of the centre's practice:

- Screening of gamete donors;
- The control of air quality in the environment in which gametes are processed;
- The validation of processes and procedures;
- Safety of laboratory equipment;
- The documentation of training and assessment of competency;
- The continuing monitoring and review of witnessing practices.

At the time of the renewal inspection in 2005 it was noted that the premises were small and that the unit was operating at maximum capacity. Since that time, the Gateshead Health NHS Foundation Trust has agreed to fund the development of new premises to allow the service to be expanded. The inspection team support the continuation of the centre's licence.

Risk Assessment

Risk Assessment: 5%, low risk

Overall judgement of the effectiveness of the centre

No Improvements required	Some Improvement required	Significant Improvement required
	✓	

Evaluations from the inspection

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

Breaches of the Act or Code of Practice

Breach	Action required	Time scale
Treatment was provided without consideration of the welfare of the child. This is a breach of the Human Fertilisation and Embryology Act 1990, s.13 (5) (as amended).	An assessment should be completed before any further treatment is provided.	N/A
Sperm samples are processed in the laboratory where air quality has been assessed as being grade C/D. This is a breach of standard licence condition	It is acknowledged that the centre expects to move to new premises in the next 18 months and that it is expected that processing in the new premises will be	Further monitoring of air quality to be undertaken by 25 January 2007.

A.10.19	carried out in an environment that is compliant with requirements. In the interim, the PR should consider more frequent monitoring of the air quality in the laboratory and assess what, if any, measures can be taken to ensure that gametes are processed in air of grade C quality or above.	
Validation of key processes and procedures has not yet been fully established. This is a breach of S 7.8.3 of the COP and standard licence condition A.11.11.	It is recommended that a plan for validation is drawn up. The plan should take into account the particular needs of the unit and prioritise the validation of those processes considered to be most likely to impact on quality of the service.	Progress to be monitored in the course of the next inspection.

Non-Compliance

Area for improvement	Action required	Time scale
Egg donors have not been screened for *Neisseria gonorrhoea* or *Chlamydia trachomatis* as recommended in BFS guidelines.	The PR should review the standard operating procedures for screening of prospective donors after consideration of the BFS guidelines. The PR should also ensure that staff are aware of screening requirements and that all relevant screening tests are carried out on prospective egg donors. Alternatively, the rationale for non compliance with the guidelines should be documented. If screening procedures are changed, patient information should be updated to include all of the screening tests carried out.	Screening to be implemented immediately or rationale for non compliance with the guidelines to be documented.
Patients are not routinely provided with a copy of their written consent.	The PR should review procedures and ensure that patients are provided with a copy of their written consent or that a patient's refusal to accept a copy of their consent is documented. Alternatively, the rationale for non compliance with the	Immediate

	guidelines should be documented.	

Recommendations

	Time scale
The centre is relatively small and may be vulnerable to unexpected staff absence as a result. It is recommended that contingency plans for the provision of services, particularly embryology services, are developed and documented and that staff are made aware of the procedures that should be followed in the case of unplanned staff absence.	To be completed by 25 January 2007
Key pieces of laboratory equipment did not appear to have been subject to annual portable appliance testing (PAT) and it was observed that biological samples are processed in a centrifuge in open buckets. The centre should seek the advice of local health and safety representatives on the safety of laboratory equipment.	At the earliest opportunity.
Evidence of participation in inter laboratory comparison of sperm analysis performance through the National External Quality Assessment Service was provided in the course of the inspection. It was noted that the assessment of sperm number appeared consistently below average and it was recommended that the embryology team develop a procedure for reviewing and responding to the results of inter laboratory comparisons.	At the centre's discretion
Nursing staff have not documented their training in insemination and administration and management of conscious sedation or had the assessment of their competency in these tasks formally documented. The administration and management of conscious sedation should be reviewed by an appropriate specialist from the Trust in line with professional body guidelines. It is also recommended that a system for assessing competency and for documenting the assessment is developed and implemented.	At the centre's discretion.
The SOP for witnessing does not: • specify that identifiers (either marked on dishes or stated by patients) should be cross referenced against source material: • specify that disposal should be witnessed: • explain the requirement for an active identity check. The witnessing SOP should be further reviewed in consideration of these omissions.	To be completed by 25 January 2007

Proposed licence variations

No variations requested.

Changes/ improvements since last inspection

Recommendations from 2005 interim report	Action taken
The main pressure on the centre is the size of the premises in relation to its layout and the number of patients treated. Before workload is increased, the centre should develop an action plan detailing how additional patients can be accommodated. The plan should include information on how resources are to be provided and a review of staffing levels. This plan should be submitted to the HFEA before additional treatment cycles are provided.	The centre's activity was monitored in 2006 and it was noted that there had been no significant increase in the provision of licensed treatment cycles (a total of 252 IVF and DI cycles were provided in 04/05 period compared to 247 cycles in 05/06). The centre provided 281 cycles in 06/07 (an estimated 11% increase compared to 04/05). In June 2007, the person responsible submitted a report to the HFEA that documented the actions taken by the centre to secure the expansion of the facilities. The Trust has agreed to fund the expansion of the unit, including the development of new premises, to accommodate an estimated 400 treatment cycles. At the time of the interim inspection in 2007, suitable premises had been identified and unit staff were involved in negotiation to establish the specification for the refurbishment of the premises.
Not all patients have been routinely provided with a signed copy of 00(6) or 00(7) consent forms. The centre agreed to adapt the procedure to ensure that all patients are provided with a copy of their consent form.	Procedure not amended to ensure patients provided with a copy of their consent.
Patient information does not fully comply with all of the requirements of the COP. A small number of omissions were discussed and the centre should submit revised information to the HFEA at the time of the next inspection.	The person responsible confirmed that the changes had been made as requested and this was confirmed by review of a sample of the patient information provided in the course of the inspection.
Recommendations made by the Licence Committee considering the 2005 interim report	**Action taken**
In relation to the practice of obtaining consent to storage only after it becomes evident that there will be material to store, the Licence Committee asked that the centre reconsider this policy.	In the course of the 2007 interim inspection it was reported that consent to storage is now obtained at the beginning of treatment.

Additional licence conditions and actions taken by centre since last inspection

The previous licence was issued without any additional conditions.

Report of Inspection findings

1. Organisation

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

Summary of findings from inspection
Evidence is drawn from:

- Leadership and management
- Organisation of the centre
- Risk management
- Incident management
- Complaint handling
- Contingency arrangements
- Business planning
- Payment of treatment fees

Areas of firm compliance
The Person Responsible (PR) has completed the HFEA PR entry programme. The responses submitted to the HFEA were considered consistent with suggested responses. The centre has implemented quality management procedures and appointed a quality manager. Some performance targets have been established and work continues to complete the process. Evidence of monitoring of clinical, laboratory and counselling practices was provided in the course of the inspection. The centre has made progress in establishing 3rd party agreements with suppliers: it was reported that 19 of the 47 suppliers approached had responded to requests for the establishment of agreements. The centre's standing operating procedure for the management and reporting of incidents and the incident log were reviewed in the course of the inspection. The centre appears to have a reporting culture. The centre has an appropriate complaints policy and procedures for making a complaint are publicised on the notice board in the patient's waiting area. The complaints log was reviewed in the course of the inspection. The centre has been proactive in developing a system for recording and responding to patient comments and appeared concerned to ensure that patients feel able to express concerns and that these are dealt with promptly and effectively. Historically, the main pressure on the centre has been the size of the premises in relation to its layout and the number of patients treated. A business plan for the development of new facilities to accommodate an estimated 400 treatment cycles has been agreed with the Trust and suitable premises have been identified. The centre's staff are currently engaged in discussions with the local estate management to finalise the specifications of the new building.

Treatment fees have been paid to the HFEA within prescribed timeframes.

The centre's documentation shows evidence of version control and review.

Areas for improvement
The centre is relatively small and is vulnerable to unexpected staff absence as a result. It is recommended that contingency plans for the provision of services, particularly embryology services are developed and documented and that staff are made aware of the procedures that should be followed in the case of unplanned staff absence. The centre has been proactive in developing quality management procedures but validation of key processes and procedures has not yet been undertaken. It is recommended that a plan for validation is developed in line with the requirements of S 7.8.3 of the COP. The plan should take into account the particular needs of the unit and prioritise the validation of those processes considered to be most likely to impact on quality of the service.
Executive recommendations for Licence Committee
Contingency arrangements and plans for the validation of key processes and procedures should be monitored in the course of the next inspection.
Areas not covered on this inspection
Resource management Clinical governance

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)
- Patient feedback and satisfaction
- Counselling facilities and services
- Donor selection
- Protection of children arrangements (for patients under 18yrs)

Live Birth Rates

In the time period from 1 April 2005 to 31 March 2006 the centre provided 234 cycles of IVF, ICSI and frozen embryo transfer treatment for 178 patients and 13 cycles of DI for 8 patients. In the time period from 1 April 2006 to 31 March 2007 the centre provided 269 cycles of IVF, ICSI and frozen embryo transfer treatment for 213 patients and 7 cycles of DI for 6 patients. This represents an approximate 11% increase in workload in 2006/7 when compared to 2004/5. In 2006/7, for the first time, the centre provided 5 cycles of altruistic egg donation for 4 patients.

Over the same time periods the centre reported a 15% twin pregnancy rate with 1 higher order pregnancy and a 20% twin pregnancy rate with no higher order pregnancies.

Clinical pregnancy rates for the time period from April 2006 to March 2007 and live birth rates for the preceding 2 years are as follows.

	IVF	FET after IVF	ICSI	FET after ICSI	DI
Clinical pregnancy rate per treatment cycle: 01/04/06 to 31/03/07	25%	10% (2/20)	34%	39% (5/13)	43%
Live birth rate per treatment cycle: 01/04/05 to 31/03/06	26%	23%	36%	40%	8%
Live birth rate per treatment cycle: 01/04/04 to 31/03/05	21%	21%	34%	18%	6%

These data have not been verified by the clinic and may be subject to change.

Analysis of HFEA held register data for the time period 31 March 2002 to 1 April 2005 and comparison with national statistics showed that the centres success rates were in line with national averages with the following exceptions:

- live birth rates following IVF and ICSI in patients aged under 35 were significantly higher than the national average;
- frozen embryo transfer success rates in patients aged between 40 and 42 years were significantly lower than the national average;

- donor insemination success rates in patients aged between 40 and 42 years were significantly lower than the national average.

Areas of firm compliance

Evidence of the completion of welfare of the child assessments was seen in the course of a review of patient records. The counselling audit recorded that in the year from October 2006 to September 2007, eight counselling sessions were provided for the purpose of carrying out a welfare of the child assessment.

Patient records are stored in secure filing cabinets in an office within the centre's premises and in the counselling room. The rooms are locked when unoccupied and access to the office is controlled by key pad entry system and bell.

The HFEA has received feedback from a total of 75 patients who have received treatment at the centre. Responses to multiple choice questions were positive with 70 patients having compliments about the treatment they received and only 3 having any complaints. Eighteen patients (25%) commented that counselling services were inaccessible but nationally, 32% of patients providing feedback to the HFEA make this comment. Written feedback was positive about the accessibility of counselling and all patient information sampled provided information on the service and the name and contact details for the counsellor. In consideration of this, the inspection team were satisfied that the service is accessible to patients.

The centre has access to approximately 15 hours of counselling time per week (the centre treats approximately 5 patients per week). Patients can be referred to the service by any of the centre's staff or by the patient themselves through self referral or through an external agency (GP or community heath worker for example). There is no waiting list for referrals but appointments are made up to four weeks in advance. The counsellor reported that she has started to gather feedback on the service from patients using a questionnaire. Counselling records are stored separately and securely.

The only repeated negative text responses related to the cramped nature of the unit and the inadequacy of the waiting area, all of which were commented on in last report and should be resolved when the expansion plans for the unit are implemented.

The centre has been proactive in implementing a system for logging patient comments and responding to verbal feedback.

Areas for improvement

The centre provided treatment with altruistically donated eggs for the first time in 2006/7. The records of two egg donors were reviewed and it was noted that screening had been undertaken in line with British Fertility Society (BFS) guidelines[1,2] with the following exceptions: no evidence of screening for *Neisseria gonorrhoea* or *Chlamydia trachomatis* was seen in the patient records. The centre's standard operating procedure (SOP) for screening of prospective donors was also reviewed and it was noted that the guidelines on screening for

[1] BFS Recommendations on Good Practice for the Screening of Egg and Embryo Donors, Human Fertility 2000, **3**, 162-165.
[2] G 4.9.1 of the 7th COP states that in addition to the requirements set out in Appendix A, donors of gametes and embryos should be screened in accordance with current professional guidance produced by the relevant professional bodies.

gonorrhoea and Chlamydia are not documented in the SOP. Subsequent to the inspection, the PR submitted a revised SOP to the HFEA which references all of the screening tests recommended in the BFS guidelines.

The PR should ensure that staff are aware of the revised procedures. The SOP should also be reviewed to ensure that clear guidance is provided to staff on the circumstances under which additional screening tests should be carried out in patients from relevant ethnic groups (see A.7.2 of the 7th Code of Practice – COP).

The counsellor has a role in carrying out welfare of the child assessments and in counselling gamete donors and the recipients of donated gametes. The PR and counsellor should consider how the needs of patients could be accommodated if the counsellor or a patient experienced or perceived a conflict within these roles.

Executive recommendations for Licence Committee
Screening in line with the BFS guidelines should be implemented immediately or the rationale for non compliance with the guidelines should be documented. Compliance with the recommendation to be monitored in the course of the next inspection.

Areas not covered on this inspection
Privacy and dignity of patients: no comments were made in respect of privacy or dignity in feedback to the HFEA. On the day of the inspection, none of the patients receiving treatment wished to meet with members of the inspection team.

Evaluation
Some improvement required

3. Premises and Equipment

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

Summary of findings from inspection:

- Suitable premises
- Storage facilities for embryos and gametes
- Safe equipment, servicing and maintenance

Areas of firm compliance
On the day of the inspection the premise and facilities appeared well maintained and suitable for purpose. Gametes and embryos are stored in the laboratory. Access the laboratory is keypad controlled and is limited to licensed personnel only. Cryopreservation dewars are fitted with low nitrogen level alarms and the laboratory is fitted with a low oxygen level alarm Evidence of the maintenance of laboratory equipment was provided in the course of the inspection. Most manipulation of gametes and embryos is carried out within a class 2 hood. Air quality within the hood and in the laboratory is monitored every six months by a contractor. In June 2007 the quality of the air in the flow hood was measured as grade A while in the laboratory the air quality was assessed by microbiological methods as grade C and by measurement of particle counts as grade D. Procedures have been implemented to ensure the traceability of all materials that come into contact with gametes and embryos. The procedures were demonstrated in the course of the inspection and appeared robust. There is resuscitation equipment in the unit. Resuscitation equipment in the fertility clinic is checked weekly as recommended by the Trust Resuscitation Officer in a report dated May 2007.
Areas for improvement
Key pieces of laboratory equipment did not appear to have been subject to annual portable appliance testing and it was observed that biological samples are processed in a centrifuge in open buckets. The centre should seek the advice of local health and safety representatives on the safety of laboratory equipment. Sperm samples are processed in the laboratory where air quality has been assessed as being grade C/D. Guidelines G 9.4.3 of the COP state that wherever practical, the centre should carry out procedures involving the processing of gametes or embryos in an environment with air quality of at least Grade C in the critical work area. The PR should consider more frequent monitoring of the air quality in the laboratory and assess what, if any, measures can be taken to ensure that gametes are processed in air of grade C or above. It is noted that the centre is

at an advanced stage of planning relocation to new premises that will be able to accommodate the equipment necessary to allow processing in a more controlled environment.
Executive recommendations for Licence Committee
Progress in responding to recommendations to be monitored at the next inspection.
Areas not covered on this inspection
Prevention of incidents/ accidents

Evaluation
Some improvement required

4. Information

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

Summary of findings from inspection:

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

Outcome of audit of records
A sample of five sets of patient records was audited in the course of the inspection. Consents were present, correctly completed and compatible with treatment in all five sets of records with the following exceptions: • In one set of records, there was no evidence that a welfare of the child assessment had been completed. The assessment should be completed before any further treatment is provided. • In three sets of records both copies of the 00(6) and 00(7) consent forms were present in the patient notes suggesting that patients had not been provided with copies of their consents. Failure to carry out a welfare of the child assessment is a breach of standard S 7.1.2 of the COP.[3] Failure to provide patients with a copy of their consent to storage of gametes and/or embryos is a breach of COP guidelines. [4]
Areas of firm compliance
Documents reviewed in the course of the inspection were version controlled and showed evidence of revision. All of the documents requested by the inspection team were provided promptly suggesting good organisation and management of information. Information is provided to the HFEA register within recommended timeframes. At the time of the renewal inspection in 2005, a number of recommendations were made relating to patient information. All of the recommendations had been adopted in a sample of the centres patient information reviewed in the course of the inspection.
Areas for improvement
The 2005 renewal inspection report noted that the patients were not routinely provided with copies of their consent forms. Previously, the centre sought consent to storage only after it was known that there were suitable embryos available for cryopreservation but in the time since the renewal inspection, this practice has been changed and consent to storage is now

[3] S 7.1.2 of the 7th COP states that the Centre shall ensure that all assisted conception processes are conducted in a manner that takes into account the welfare of any child that may be born as a result of treatment services.
[4] G 6.6.3 of the 7th COP states that the centre should give a copy of the written record of consent to each person who gives consent to the storage of gametes or embryos.

obtained at the beginning of treatment.

However, also in the time since the renewal inspection, the HFEA has introduced new consent forms that are no longer provided with a carbonated second copy and forms now have to be duplicated before patients can be provided with a copy of their consent. In the course of discussing the failure to supply copies of "old style" consents to patients it became apparent that lack of access to a copier has also prevented copies of "new style" forms being provided to patients. Subsequent to the interim inspection the PR confirmed that procedures had been reviewed to ensure that patients are provided with a copy of their consent.

Following the review of donor screening procedures, information for patients receiving treatment with donor gametes or for patients donating gametes should be reviewed to ensure that the information references all of the screening tests carried out.

Executive recommendations for Licence Committee
None

Areas not covered on this inspection
Record keeping Protocols

Evaluation
Some improvement required.

5. Laboratory and Clinical Practice

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

Summary of findings from inspection:

- Procedures in practice
- Laboratory processes and practice
- Clinical practice
- Staff competence, qualifications, training and CPD

Full time equivalent staff

GMC registered doctors	3
NMC registered nurses	3 (with 1 additional experienced member of staff available when required)
Nursing assistants	1
HPC registered scientists	3 (approximately 2 WTE)
Counsellor	1 (approximately 15 hours per week allocated to IVF patients)
Support staff (receptionists, record managers, quality and risk managers etc)	1

Areas of firm compliance
Laboratory activity was observed at the time of egg collection and witnessing procedures appeared satisfactory. A member of the embryology team was able to provide evidence of participation in Association of Clinical Embryologists continued professional development (CPD) training programme. A member of the nursing team reported receiving induction training on joining the unit and provided evidence of participation in training on acting as a witness. Evidence of participation in mandatory health and safety training and basic and intermediate life support training for relevant staff was provided in the course of the inspection. The centre carried out a comprehensive review of witnessing practices in the time covered by this report. The documentation of witnessing was reviewed in the records of five patients in the course of the inspection. Witnessing at all relevant stages was documented with the exception of the witnessing at the time of disposal however, it was noted that in a later record, this procedure was witnessed as required, indicating that the audit of witnessing practice carried out by the centre had been robust in identifying areas for improvement. The centre maintains a centralised log of signatures of those staff trained in witnessing. The centre did not perform any three embryo transfers in patients less than 40 years of age in the time covered by this report. Evidence of participation in inter laboratory comparison of sperm analysis performance

through the National External Quality Assessment Service was provided in the course of the inspection.

Areas for improvement

When reviewing the outcome of NEQAS assessments it was noted that the assessment of sperm number appeared consistently below average. Subsequent to the inspection it was reported that action had been taken in relation to this observation. It is recommended that the embryology team develop a documented procedure for reviewing and responding to the results of inter laboratory comparisons.

Members of the nursing team occasionally perform inseminations and also administer sedation for egg collection. At the time of the interim inspection it was reported that staff had not documented their training in these procedures or had the assessment of their competency in these tasks formally documented. The PR reported that the procedures for the administration and management of conscious sedation are under review and that a member of the nursing team is a member of the Trust safe sedation working group. It is recommended that the administration and management of conscious sedation is reviewed by an appropriate specialist from the Trust in line with professional body guidelines.[5]

Subsequent to the inspection the PR reported that the centre plans to implement guidelines of the Royal College of Nursing in respect to the documentation and assessment of competency.

The standard operating procedure for witnessing was reviewed in the course of the inspection. Although the SOP does document the witnessing requirements at each of the required stages, the procedure does not specify that identifiers (either marked on dishes or stated by patients) should be cross referenced against source material such as patient records or laboratory sheets. The procedure does not specify that disposal should be witnessed or explain the requirement for an active identity check although this is specified in separate witnessing guidelines. It is recommended that the witnessing SOP is further reviewed to bring all of the relevant information together.

Executive recommendations for Licence Committee

Compliance with recommendations to be reviewed at the time of the next inspection.

Areas not covered on this inspection

It is usual practice to review the centre's system for identifying samples approaching the expiry of the consented storage period and to carry out a spot check audit of cryopreserved material. However, on the day of the inspection one member of the embryology team was ill and the remaining embryologist was called away from the unit in the late afternoon because of unexpected family illness. As a result these systems were not reviewed.

[5] U.K. ACADEMY OF MEDICAL ROYAL COLLEGES AND THEIR FACULTIES, Implementing and ensuring Safe Sedation Practice for healthcare procedures in adults, Report of an Intercollegiate Working Party chaired by the Royal College of Anaesthetists. These guidelines recommend that each hospital should nominate two consultants, one an anaesthetist and the other a user of sedation, to collaborate in the local implementation of guidelines.

Recruitment and retention of staff

Evaluation
Some improvement required.

Report compiled by:

Name…Debra Bloor……

Designation…Inspector……

Date……11 October 2007……

Appendix A: Centre staff interviewed

The inspection team met with the PR, Mr Ian Aird and five other members of the unit's staff.

Appendix B: Licence history for previous 3 years

The centre was first licensed in 1996

Licence's issued in last three years as follows:

Licence	Type	Active from	Active to
L0170/9/a	Treatment with Storage	05/07/07	31/01/2009
L0170/8/a/b	Treatment with Storage	01/02/2006	31/01/2009
L0170/7/a	Treatment with Storage	01/10/2005	31/01/2006
L0170/6/c	Treatment with Storage	16/06/2004	31/01/2006
L0170/6/b	Treatment with Storage	19/01/2004	31/01/2006

L0170/9/a, L0170/8/a/b, and L0170/7/a

No recommendations, no conditions

L0170/6/c and L0170/6/b

Recommendations

- The Committee were concerned to note that the patient information has not been modified in line with previous recommendations and wished this recommendation to be reiterated in full. It also suggested that the Risk Assessment Patient Information be subjected to a comprehension test by a lay person and modified where appropriate.
- You as the Person Responsible should continue to monitor the level of activity within your centre and ensure that the restricted space available does not put patients or staff at risk.
- Your Centre should ensure that all outcomes are completed on the IVF and ICSI embryo culture sheets and that your Centre fit low level nitrogen alarms to dewars and install a low level oxygen alarm in the laboratory
- The patient information should be amended as follows:
    - The OHSS patient information should be amended to highlight which symptoms are of concern; at what stage during treatment it is likely to occur; that OHSS can need hospital treatment and can be life threatening; and an emergency phone number

should be highlighted whenever OHSS is mentioned. This should be submitted to the HFEA.
    - The centre should include information regarding parental responsibility for unmarried couples.
    - In the patient information leaflet, section 5, the centre should highlight the alcohol limits are general and discuss alcohol consumption prior to, during and after treatment separately.
    - The centre should include information on storage of sperm for patients.
    - The centre should consider proofreading all the literature as numerous mistakes were noted by the inspection team; this should include updating all information, for example, current costs.
- The protocols should be updated and amended as follows:
    - The protocols should be updated to reflect current work practice including removing references to the use of pentoxyphylline.
    - All protocols should be dated or have version numbers so the centre is always using the most up to date version.
    - The centre should complete the update of protocols to include all the documented witnessing procedures.
    - A protocol for storage of patient's own sperm should be produced.

Conditions

- The Person Responsible must ensure that an additional dewar is purchased for the centre and donor sperm is stored separately from screened patient material.
- The Person Responsible must ensure that the following patient information is amended and submitted to the HFEA:
    - Sections where donor anonymity is discussed should include information about a child being born disabled as a result of a donor's failure to disclose defects may be able to sue the donor and the clinic for damages.
    - When donor anonymity is discussed, it must be clear that, as the law currently stands, no identifying information will be given to the recipient or any resulting child(ren).
    - The centre should clarify in the patient information and on the research consent form, the issue of consent and up to what point it can be withdrawn.

Appendix C: Response of person responsible to the inspection report

Centre Number……...0170……

Name of PR……Mr Ian Aird…….

Date of Inspection…….25th September 2007……..

Date of Response……..1st November 2007……

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

Breaches of the Act or Code of Practice

Breaches of the Act

1. Providing treatment without consideration of the Welfare of the Child

Action Taken:
A check list has been introduced that is completed for all patients prior to the commencement of treatment. This check list includes confirmation that a welfare of the child assessment has been carried out and that it is up to date and valid. This form is completed by a member of the nursing staff prior to the commencement of gonadotrophin therapy. A copy of this list has been included in the documentation returned with this response.

Time Scale
Already implemented

2. Sperm samples are processed in air quality graded as C/D.

Action Taken:
When the original assessment of air quality was carried out there was fault with the air conditioning unit supplying the lab. The subsequent air quality suffered as a result. This fault has been rectified and the external assessors have been contacted to recheck the air quality.

Time scale
Reassessment will be carried out before the specified date of 25th January 2007.

3. Validation of Key Processes

Action Plan :
Process mapping has identified the key processes most likely to impact on the quality of service. These processes will be prioritised. The Quality Manager and Person

Responsible are to attend workshops relating to quality management and validation of procedures. This knowledge will be disseminated to other members of staff and the necessary validation will be implemented

Time Scale:
Validation to be implemented prior to the next inspection.

Non Compliance with the Code of Practice

1. Screening of egg donors

Action taken
The standard operating procedure and patient information leaflet have been amended to include screening for *Neisseria gonorrhoea* and *Chlamydia trachomatis* in line with BFS recommendations. A pre treatment checklist is also completed to confirm that all screening tests have been completed and results reviewed. Revised documentation has been submitted to the HFEA.

Time scale:
Already implemented

2. Issuing copies of consent forms to patients

Action taken:
The pre treatment check list has been amended to include confirmation that copies of the consent forms have been given to the patients or that patients declined the offer of receiving a copy. Revised documentation has been submitted to the HFEA.

Time Scale
Already implemented

Recommendations

1. Contingency plans for unexpected staff absence

Action Plan:
We are currently in consultation with other IVF units within the Northern Region to formulate contingency plans in case of unexpected staff absence or other unpredictable emergency situations that could affect IVF units.
Since the inspection was carried out a new embryologist has started work with us. This improves the laboratory staffing levels to 2.4 whole time equivalents spread across 3 embryologists. There are also 3 clinical staff, 3 trained nursing staff and also one midwife with IVF experience who can provide cover in emergencies and 1 health care assistant to cover the staffing needs of the unit.

Time scale
Unit currently fully staffed. Agreement with other units is likely to take between 6 and 12 months to finalise arrangements

2. Portable appliance testing (PAT) of laboratory equipment

Action Taken:
All relevant equipment within the laboratory has been tested since the inspection. We are currently investigating the cost implications of purchasing a new centrifuge.

Time Scale
All PAT testing completed. Replacement of centrifuge is planned to be carried out alongside purchase of other equipment that will be required with the move to the new unit. The move is currently planned within 18 months.

3. Inter-laboratory comparison of sperm analysis.

Action Taken:
Inter-laboratory comparison via NEQAS has identified that our laboratory consistently assesses sperm numbers as lower than other laboratories. Since this has been highlighted we have purchased a new Makler counting chamber. We will re analyse our results and compare with other laboratories to see if this makes a difference. It should be added that despite this apparent difference it does not skew our treatment choice towards ICSI.

Time Scale:
New counting chamber already in use. Further inter-laboratory comparison will take place over the next 6 months.

4. Training and documentation of competencies for nursing staff carrying out Insemination and sedation procedures.

Action taken:
We will be implementing the competencies as laid down by the Fertility Group of the Royal College of Nursing for each individual nurse practising within the unit both qualified and unqualified. This will be incorporated within personal development plans and in conjunction consultant supervision. Nursing staff are being enrolled on safe sedation courses organised by the Anaesthetic Department of Newcastle Hospitals

Time Scale:
Implementation of the nursing competencies is an ongoing process which is due to start within the next month.
The first 2 nurses are due to attend this course on the 8th November and there will be a rolling program for all staff administering sedation to attend for initial training and follow up thereafter.

5. Witnessing SOP

Action taken:
All recommendations have been incorporated into an updated SOP Revised documentation has been submitted to the HFEA.

Time scale:
Already implemented

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).

Date of Inspection on front of Draft report is 25th October 2007. Inspection took place on 25th September 2007.

Table on Page 13 quoting live birth rates contains 2 different sets of figures for 01/04/05 to 31/03/06

Full time equivalent staff (Page 20) quotes 4 NMC registered nurses, we currently have 3 full time NMC registered nurses and one midwife who covers during leave.

These inaccuracies have been corrected in the body of the text.

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.

Regulation Department
Human Fertilisation & Embryology Authority
21 Bloomsbury Street
London
WC1B 3HF

Licence Committee Meeting

17 December 2007
21 Bloomsbury Street London WC1B 3HF

MINUTES Item 6

Centre for Assisted Reproduction (0170)
Interim inspection

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

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 (38 pages)
- no papers were tabled.

1. The papers for this item were presented by Debra Bloor, HFEA Inspector. Dr Bloor informed the Committee that this centre is relatively small, conducting about 250 cycles per year to a mixture of self funding and NHS patients. The centre had been granted an inspection holiday in 2006 so had last been inspected in 2005. Dr Bloor informed the Committee that the interim inspection visit had taken place on 25 September, at the time of the inspection the risk score was at 5%

2. Dr Bloor summarised the main findings of the inspection report, focusing on the areas of improvement, which were relatively large in number and listed at pages 6 to 8 of the report. Dr Bloor emphasised that the Person Responsible had been very cooperative at the inspection and had been quick to respond to the areas for improvement.

3. The Committee noted the positive response to the inspection by the Person Responsible. They further noted that despite its small size the centre has a low risk score and good success rates.

4. The Committee noted the comment at page 15 of the inspection report that the counsellor has a role in carrying out welfare of the child assessments. The Committee expressed their concern about this situation and agreed that it amounts to a possible breach of G.7.1.1 of the Code of Practice, which states that: “The centre should ensure that provision of counselling is clearly distinguished from the clinical assessment of a person’s suitability for treatment.”

5. The Committee agreed that it was content for the centre’s licence to continue.

Signed…… … Date……..
Jennifer Hunt (Chair)