Interim Inspection Report

Nottingham University Research and Treatment Unit in Reproduction (NURTURE)
0076

Date of Inspection: 8 November 2007
Date of Licence Committee: 28 January 2008

TRIM: 06/5619

CENTRE DETAILS

Centre Address	'B' Floor, East Block, University Hospital Nottingham, NG7 2UH United Kingdom
Telephone Number	0115 8230700
Type of Inspection	Interim
Person Responsible	James Hopkisson
Nominal Licensee	Ian Johnson
Licence Number	L0076/13/a
Inspector(s)	Debra Bloor Janet Kirkland
Licence expiry date	31 May 2011

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About the Inspection:

This inspection visit was carried out on 8 November 2007 and lasted for 8 hours. The report covers the pre-inspection analysis, the visit and information received between 2 November 2006 and 8 November 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 provides self funded and NHS funded treatments to patients from the local area. NURTURE is owned by the University of Nottingham and is housed in the Queens Medical Centre at the University Hospital, Nottingham. The centre registered with the Healthcare Commission in 2005.

In the time period from July 2006 to June 2007 NURTURE provided 386 cycles of IVF, ICSI and FET treatments for 321 patients. The centre also carried out 26 cycles of treatment involving IVF with egg sharing or egg donation. No DI treatments were provided. This represents a 13% increase from the previous year when 364 cycles of IVF,ICSI and FET were provided. Over the same time period the centre reported a 20% twin pregnancy rate with no higher order pregnancies.

The Person Responsible (PR) has been in post since September 2003 and is appropriately qualified and experienced for the role.

Activities of the centre from 1 July 2006 to 30 June 2007

Licensed treatment cycles	386 (IVF, ICSI and FET) 22 (IVF with egg sharing) 4 (IVF with donated eggs)
Unlicensed treatments	Intrauterine insemination (IUI), timed intercourse, ovulation induction, infertility investigations
Research	✓
Storage	✓

Summary for Licence Committee

NURTURE is a moderately large unit providing approximately 400 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 proactive in the development and implementation of a quality management system and this is reflected in the centre's outcomes which continue to show an upward trend.

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

- The establishment of documentation relating to the re-provision of services in an emergency situation;
- The provision of mandatory health and safety and life support training to staff;
- Screening of gamete donors;
- The documentation of training and assessment of competency;

The inspection team supports the continuation of the centre's licence. The weight to be attached to breaches and areas of non-compliance highlighted in this report is a matter for the Licence Committee.

Risk assessment

20%, green, 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 – in the opinion of the inspection team the following issues constitute breaches:

Breach	Action required	Time scale
For the year up to October 2007, the average time taken to pay HFEA invoices was 48 days. Licence condition A.16.3 states that In consideration of the grant of the licence, the Person Responsible agrees that 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.	The Person Responsible should review the arrangements for payment of invoices.	At the centre's discretion. Progress to be monitored at the time of the next inspection.

The centre does not have written policies and procedures for the re-provision of services in an emergency situation: this is a requirement of standard licence condition A.10.23.	The centre should develop written procedures in compliance with the requirements of this condition.	To be completed by 8 March 2008.
Not all members of the unit's staff completed mandatory health and safety and life support training in the last year. COP standard S.6.2.7 states that personnel shall be provided with appropriate initial/basic training which is updated as required when procedures change or scientific knowledge develops. Adequate opportunities shall be given for relevant professional development.	The PR agreed to ensure that all staff participate in the required training at the next available opportunity. It was considered likely that training could be completed by March 2008. The PR should advise the HFEA when all staff have been brought up to date with training.	Training to be completed by 8 March 2008 and the HFEA to be advised when all staff have received training.

Non-Compliance – in the opinion of the inspection team the following practices were non compliant

Area for improvement	Action required	Time scale
Egg donors have not been screened 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, the provision of patient information should be reviewed.	Screening to be implemented immediately or rationale for non compliance with the guidelines to be documented.
The centre carried out five three embryo transfers in patients aged less than 40 years in the time since the last inspection. G.8.5.1 (a) of the COP states that where a woman is to receive treatment using her own eggs, or embryos created using her own eggs, whether fresh or previously cryopreserved where the woman is aged under 40 at the time of transfer the centre should not transfer more than two eggs or two embryos in any treatment cycle, regardless of the procedure used.	No action required: the rationale for non compliance with these guidelines is recorded in the three embryo transfer log.	

Recommendations

Recommendation	Time scale
Validation of key laboratory processes is documented in the form of student project reports (theses). The director of embryology should consider whether the information contained in the reports should be represented in a more formal way to satisfy the requirements of the quality management system.	At the discretion of the centre.

Thirty one of the 105 patients providing feedback to the HFEA since the last inspection (28%) said that counselling services were inaccessible. Nationally 32% of patients make this statement.	The PR should consider reviewing how the service is accessed.

Proposed licence variations

No variations requested

Changes/ improvements since last inspection

Recommendation	Action taken
At the time of the inspection, the centre had embryos in store for which there was no valid consent to storage (storage expired 25 June 2006). The HFEA was kept fully informed of the issue and the centre reported that they would continue their efforts to resolve the situation as soon as possible. It was recommended that the HFEA be advised when the issue was resolved	The embryos were exported on 27 April 2007 under the auspices of special directions issued by the HFEA. The export was reported to the HFEA as recommended.
The PR should consider formalising contingency arrangements.	In relation to this recommendation the PR reported that when he is absent the responsibility for the unit on a day to day basis falls to the director of embryology. This is documented in the Quality Manual. The process of reporting incidents in the PRs absence is also covered in the Adverse Incident SOP. Both senior clinicians endeavour not to be out of the UK at the same time. A chart of absences of key staff is kept to help coordinate this. As yet the centre does not have an agreement with another unit to take over treatments and storage in the event of a total systems failure. In the course of the interim inspection it was noted that following planned recruitment to the clinical team in the next year it will be possible to cover unexpected staff absence from the existing staff pool.
The centre should consider assessing all activities which give rise to risk	Not reviewed in the course of the interim inspection.

prospectively.	
Within three months the centre should assess whether there is any risk associated with the checking systems currently in place for resuscitation equipment.	It was reported that a risk assessment was carried out within the prescribed timeframe and that a revised checking procedure was implemented following the assessment.
Within three months the PR should develop a system for monitoring the content of patient information and for implementing changes as required.	Within three months the PR reported that following ISO accreditation all leaflets, letters and templates are centrally controlled. If there is a requirement to alter any of the documentation there is an SOP that documents the procedure to be followed and ensures the destruction of out of date paper copies.
Within three months the centre should develop a training programme to ensure that all staff participate in mandatory training and BLS training (where appropriate) in the next year.	Within the prescribed timeframe, the PR reported that records are kept within the department of all of the mandatory training that is required. It was also reported that a member of the embryology team represents the unit on the local safety committee and ensures all mandatory training, including basic life support (BLS), is up to date. In the course of the interim inspection it was reported that not all members of the team had received mandatory health and safety training in the last year as recommended.

Additional licence conditions and actions taken by centre since last inspection

The current 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
- Incident management
- Contingency arrangements
- Clinical governance
- 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 effective quality management procedures and has appointed a quality manager. Quality performance targets have been established and evidence of monitoring of clinical and laboratory practices was provided in the course of the inspection. The centre's documentation shows evidence of version control and review. The centre has been proactive in developing quality management procedure and validation is estimated to have been carried out for approximately 50% of the key laboratory processes and procedures. The centre has made progress in establishing 3rd party agreements with suppliers: 10 agreements were in place at the time of the inspection and it was reported that this represents all of the agreements that are required. The content in a sample of agreements that was reviewed in the course of the inspection was in line with HFEA recommendations. The centre appears to have a reporting culture in relation to incidents: incidents have been reported within prescribed timeframes and have been investigated and resolved effectively. Staff interviewed in the course of the inspection were aware of recent HFEA alerts. Evidence of the review of procedures in response to Alert 21 was seen in the course of the inspection and evidence of discussion of Alerts was seen in the minutes of multidisciplinary team meetings. Historically, there have been concerns about the effectiveness of the centre's governance procedures. These concerns arose because the unit feeds into an academic governance structure (The University of Nottingham) rather than a clinical governance structure. This was discussed in the course of the inspection and it was reported that governance issues raised by the unit are responded to satisfactorily and it is considered that the unit does have an effective governance procedure in place. Evidence of this was seen in the course of the

review of the most recent health and safety inspection report. The inspection had identified a need for improved flooring in the cryostore and after consideration of the report funds have been allocated for the necessary improvements.

Areas for improvement

For the year up to October 2007, the average time taken to pay HFEA invoices is 48 days. This is considered “average” when compared to other centres. Licence condition A.16.3 states that in consideration of the grant of the licence, the Person Responsible agrees that 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. The PR should review the arrangements for the payment of invoices.

Validation of key laboratory processes is documented in the form of student reports. The director of embryology should consider whether the information contained in the reports should be represented in a more formal way to satisfy the requirements of the quality management system.

The centre expects to have sufficient staff to ensure that unexpected staff absences can be covered from the existing staff pool however, the centre does not have written policies and procedures for the re-provision of services in an emergency situation: this is a requirement of standard licence condition A.10.23. The centre should develop written procedures in compliance with the requirements of this condition.

In the course of the inspection it was noted that although staff were aware of incident reporting requirements there was a tendency for staff to assume that incidents related only to laboratory events. The PR should consider raising awareness of incident reporting requirements particularly in relation to administrative, clinical and nursing activities.

Executive recommendations for Licence Committee

Progress in relation to the payment of invoices and the establishment of written documentation for the re-provision of services in an emergency should be monitored at the time of the next inspection.

Areas not covered on this inspection

Business planning
Organisation of the centre
Resource management
Risk management

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)
- Privacy and dignity of patients
- Complaint handling
- Patient feedback and satisfaction
- Counselling facilities and services
- Donor selection
- Egg sharing and surrogacy

Live Birth Rates

In the time period from 1 July 2006 to 31 June 2007 the centre provided 386 cycles of IVF, ICSI and FET treatment for 321 patients. The centre also carried out 26 cycles of treatment involving IVF with egg sharing or egg donation. No DI treatments were provided. This represents a 13% increase from the previous year when 364 cycles of IVF,ICSI and FET were provided. Over the same time period the centre reported a 20% twin pregnancy rate with no higher order pregnancies.

Outcomes for the same time period are summarised in the table below:

	IVF	FET after IVF	ICSI	FET after ICSI	Egg share and egg donation cycles
Clinical pregnancy rate per treatment cycle[b] 01/07/06 to 31/06/07	40%	10% (3/29)	41%	33% (6/18)	54% (14/26)
Live birth rate per treatment cycle[c] 01/07/05 to 31/06/06	32%	29% (6/19)	32%	11% (2/21)	38% (10/26)

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

[b] Where fewer than 50 cycles have been provided the numbers in parentheses represent the clinical pregnancies expressed as a function of the number of treatment cycles provided.
[c] Where fewer than 50 cycles have been provided the numbers in parentheses represent the number of live births expressed as a function of the number of treatment cycles provided.

Although it should be noted that these data compare clinical pregnancy rates with live birth rates, they do suggest a continuing upward trend in outcomes.

Areas of firm compliance
Evidence of the completion of satisfactory welfare of the child assessments was seen in two sets of patient records. Patient records are stored in an area which is accessible to licensed personnel only. The records store is locked when the unit is closed. The store appeared well organised and it was possible to retrieve records quickly and efficiently. Counselling records are stored separately from clinical notes in a locked cabinet. The complaints log was reviewed in the course of the inspection. Complaints were logged and details of the responses provided and any actions taken as a result of the complaint were documented. The centre appeared to have an effective complaints procedure. Three patients met with members of the inspection team. All reported that their privacy and dignity had been respected in the course of their treatment and reported that they had been provided with information on the side effects of treatment, contacting the centre out of hours and the counselling service. The HFEA received feedback from 105 patients who received treatment at the centre in the time since the last inspection (approximately 30% of the patients treated in that time). Eighty six patients had compliments about the treatment they received while only 9 had any complaints. The responses were very positive and commended the professionalism and friendliness of staff. Counselling is provided by two suitably qualified and experienced staff. Gamete donors are seen by both counsellors separately: one counsellor assumes an assessment role and the other provides implications counselling. It was reported that there is funding for 7 hours of counselling time per week with two hours of this time allocated to administration. It was reported that there is no waiting list for counselling appointments and that patients are able to make an appointment to see a counsellor by contacting the unit's reception staff. Ninety three percent of patients providing feedback to the HFEA reported that they were made aware of the counselling service and patients interviewed on the day of the inspection also reported that they had been provided with information about the service. A member of the counselling team attends the monthly patient information evenings. A total of 247 counselling sessions were provided between January 2006 and August 2007. The unit treated an estimated 794 patients over the same time period and if it is assumed that the majority of patients attended only a single session then this represents a counselling uptake of approximately 30%. Procedures for the recruitment and assessment of egg donors and egg sharers were reviewed in the course of the inspection. Donors are asked to complete a medical history questionnaire and are screened for infectious diseases and genetic conditions when relevant.
Areas for improvement
Thirty one of the 105 patients providing feedback to the HFEA since the last inspection (28%) said that counselling services were inaccessible. Nationally 32% of patients make this statement. Evidence observed in the course of the inspection and feedback provided by

patients supports the conclusion that counselling services are well publicised and are used by patients however on the basis of the feedback relating to accessibility the PR might wish to review how the service is accessed.

The records of two egg donors were reviewed and it was noted that the screening carried out was not fully in line with British Fertility Society (BFS) guidelines[1,2]. The centre's standard operating procedure (SOP) for screening of prospective donors was also reviewed and it was noted that not all of the recommended screening was documented in the SOP. SOPs were revised immediately post inspection to reflect that in future screening will be carried out for all of the conditions recommended in guidelines and the genetic questionnaire was revised to reflect what genetic information is required to determine whether additional screening tests are required in compliance with A.7.2 of the7th Code of Practice (COP).

Information for patients seeking to donate gametes or have treatment with donated gametes was also revised immediately post inspection to provide information on all of the screening tests carried out.

Executive recommendations for Licence Committee
None

Areas not covered on this inspection
Choice of treatments Protection of children arrangements (for patients under 18yrs)

Evaluation
Some improvement required.

[1] [1] BFS Recommendations on Good Practice for the Screening of Egg and Embryo Donors, Human Fertility 2000, **3**, 162-165.

[2] [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.

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 premises and facilities appeared clean, well maintained and suitable. Gametes and embryos are stored in a designated cryostore that is accessible to licensed personnel only. Dewars are locked individually and are fitted with low nitrogen level alarms. The cryostore is fitted with a low oxygen level alarm. Evidence of the maintenance of laboratory equipment was seen in the course of the inspection. Manipulation of gametes and embryos is carried out within class 2 hoods. Air quality within the hoods and in the laboratory is monitored approximately every six months. Air quality in the hoods has been assessed as grade A and in the laboratories the background air quality has been assessed as grade D or above. This is compliant with the requirements of standard licence condition A.10.19. Procedures have been implemented to ensure the traceability of all materials that come into contact with gametes and embryos. Traceability was tracked in a set of patient records and the procedures appeared robust and in line with requirements. There is resuscitation equipment in the unit: the equipment had been checked on the day of the inspection.
Areas for improvement
In the course of the inspection it was noted that action was taken when an anomalous result was obtained in the course of air quality monitoring. The centre should review the time intervals between air quality monitoring and validate the frequency of testing. Written procedures should be developed that document what action should be taken if monitoring reveals that air quality falls below the expected standard.
Executive recommendations for Licence Committee
None
Areas not covered on this inspection
Prevention of incidents/ accidents

Evaluation
Minor 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
- Protocols

Outcome of audit of records
Consents were present, correctly completed and compatible with treatment in the two sets of patient records reviewed.
Areas of firm compliance
Protocols reviewed in the course of the inspection were comprehensive, were controlled and showed proposed review dates. All information requested by the inspection team was provided promptly in the course of the inspection. This suggests that staff are familiar with and have access to information and protocols. The centre has comprehensive SOPs for witnessing and for the transfer of cryopreserved material and these were reviewed in the course of the inspection. The standard operating procedure for witnessing documents the witnessing requirements at each of the required stages. It was also reported that there is a policy that documents the procedures to be followed when treating patients with the same or similar names.
Areas for improvement
A number of HFEA treatment forms remain outstanding having been returned to the centre because of errors. Where errors result because gamete donors are not registered it is recommended that the centre communicate with the suppliers of donated gametes to ensure that the donor codes being used are accurate and that the supplying centre has registered donors with the HFEA. If problems persist the PR should review the need for further training and or obtain advice on the completion of the HFEA forms. The SOP for witnessing is comprehensive but 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 although evidence that this is done was observed on the day of the inspection. Some minor modifications were recommended to ensure that the documents reflect practice and the requirements of the revised witnessing guidelines introduced in the 7th COP. The SOP for transfer of cryopreserved material did not detail all of the requirements outlined in Alert 21 and it was agreed that the SOP would be revised to reflect the requirements as follows: procedures in cases where labelling is degraded; labelling requirements on transfer

packaging; documentation of the provision of information about risks to patients; procedures for preparing and assessing transport dewar. It was reported that staff are trained in transfer procedures but that the training and competency assessment is not documented. It is recommended that all training is documented in line with the requirements of COP S. 6.2.2.
Executive recommendations for Licence Committee
None
Areas not covered on this inspection
None

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:

- Assessment of patients and donors
- Procedures in practice
- Laboratory processes and practice
- Clinical practice
- Recruitment and retention of staff
- Staff competence, qualifications, training and CPD

Full time equivalent staff

GMC registered doctors	3
NMC registered nurses	3.5
Non NMC registered nurses	1
HPC registered scientists	2
Scientists working towards registration	2 (the director of embryology is in the final stages of achieving HPC registration under the grand parenting scheme)
Ultrasonographer	1
Support staff (receptionists, record managers, quality and risk managers etc)	4

Summary of laboratory audit
An audit of cryopreserved material was completed in November 2006. No discrepancies were reported to the HFEA.
Summary of spot check of stored material
One embryo and one sperm sample were tracked from record to dewar and one sperm and one embryo sample were tracked from dewar to record. No discrepancies were observed.
Areas of firm compliance
A surgical sperm retrieval was observed during the inspection and witnessing of the patients identity was observed to be compliant with requirements. Witnessing practices were discussed in detail and the inspector was satisfied that the procedures in place are robust. The centre has carried out an assessment of the risks of their witnessing practices in line with the requirements of Chair's letter CH(07)02. The documentation of witnessing in a sample of patient records was considered complete. The newest member of the nursing team (a nursing auxiliary) met with an inspector to discuss training and induction. The member of staff reported receiving three weeks of induction training. A second member of the nursing team was able to demonstrate that her competency had been assessed in key areas of clinical practice. A member of the embryology team has been designated as the person with responsibility for

ensuring that staff receive mandatory health and safety training and life support training when relevant. Records documenting participation in this training were reviewed on the day of the inspection. The record showed that all members of the medical team had received advanced life support training in the last year.

The centre maintains a log of all three embryo transfers. The log records brief reason for all three embryo transfers carried out.

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. The director of embryology also reported that the centre has enrolled to participate in an online quality assurance service called FertAid.

Areas for improvement

The centre has comprehensive documentation for recording training of members of the nursing team and assessment of competency. It is recommended that the use of this documentation is extended to non NMC registered members of the nursing team in line with the requirements of COP S. 6.2.2.

Not all members of the unit's staff completed mandatory health and safety and life support training in the last year. This was also the case at the time of the 2006 renewal inspection when it was recommended that the centre develop a training programme to ensure that all staff participate in mandatory training and BLS training (where appropriate) in the next year. The PR agreed to ensure that all staff participate in the required training at the next available opportunity. It was considered likely that training could be completed by March 2008. The PR should advise the HFEA when all staff have been brought up to date with training.

The centre carried out five three embryo transfers in patients aged between 35 and 39 years in the time since the last inspection. No ongoing higher order pregnancies resulted from the treatments but on review of the records of one of the patients it was noted that three sacs were seen at the time of the initial scan with two foetal hearts detected: unfortunately the pregnancy miscarried at an early stage. G.8.5.1(a) of the COP states that where a woman is to receive treatment using her own eggs or embryos created using her own eggs, whether fresh or previously cryopreserved where the woman is aged under 40 at the time of transfer the centre should not transfer more than two eggs or two embryos in any treatment cycle, regardless of the procedure used.

Executive recommendations for Licence Committee

None

Areas not covered on this inspection

Recruitment and retention of staff

Evaluation

Some improvement required

Report compiled by:

Name…Debra Bloor…….

Designation……Inspector…….

Date……21 November 2007…….

Appendix A: Centre staff interviewed

James Hopkisson (PR), seven other members of the centres staff and the NL met with inspectors in the course of the inspection. Three patients also met with an inspector.

Appendix B: Licence history for previous 3 years

Licence	Type	Active From	Expires
L0087/13/a	Treatment with Storage	05/07/2007	31/05/2011
L0076/12/a	Treatment with Storage	01/03/2007	31/05/2011
L0076/11/a	Treatment with Storage	01/09/2005	28/02/2007
L0076/10/a	Treatment with Storage	01/03/2004	28/02/2007

First licensed 1992

L0076/12a, L0076/13/a

Licences issued without any additional conditions or recommendations

L0076/11/a, L0076/10/a

Conditions

- The centre should formalise the protocol detailing the procedure that is followed when a patient's GP does not respond to a request for information relating to the Welfare of the Child assessment or when concerns are raised.
- The centre should carry out an audit of consent forms held within patient records by the end of March 2004.

Recommendations

- Whilst acknowledging the centre's stance regarding the fitting of low-nitrogen level alarms to storage dewars, these should be fitted to all dewars used for the storage of patient material.

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 an electronic version of Appendix C of the report to Debra.Bloor@HFEA.gov.uk
Or a hard copy of Appendix C to:
Regulation Department
Human Fertilisation & Embryology Authority
21 Bloomsbury Street
London
WC1B 3HF