Interim Inspection Report

The Assisted Conception Unit
Ninewells Hospital
(0004)

Date of Inspection: 7th March 2007
Date of Licence Committee: 20th June 2007

CENTRE DETAILS

Centre Address	Assisted Conception Unit, Ward 35, Ninewells Hospital Dundee Scotland, DD1 9SY United Kingdom
Telephone Number	01382 632111
Type of Inspection	Interim treatment and storage
Person Responsible	Dr Madhurima Rajkhowa
Nominal Licensee	Mr Gerry Marr
Licence Number	L0004/13/a
Inspector(s)	Miss Sarah Hopper (HFEA Executive) Dr Neelam Sood (HFEA Executive) Miss Grace Cunningham (HFEA Executive) Mr Stephen Lynch (External Inspector)
Fee Paid - date	N/A – interim inspection
Licence expiry date	30/09/2009

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About the Inspection:
This inspection visit was carried out on 7th March and lasted for 7 hours. The report covers the pre-inspection analysis, the visit and information received between March 2006 and March 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 Assisted Conception Unit at Ninewells Hospital has provided licensed treatments since 1992. Around 647[1] cycles a year are offered to NHS and self funded patients from a wide geographical area. In addition, unlicensed treatments are offered and these include IUI, ovulation induction and reproductive surgery.

The unit is situated on the 7th floor of Ninewells Hospital and comprises of a waiting room and reception area, two consulting rooms, laboratory with embryo transfer room, dedicated theatre, male production room, recovery area with four beds, nursing station, an open area used for ultrasound procedures and phlebotomy, two offices, a counselling room (which is also used as the staff room) and a variety of store rooms.

The unit is open from 8:00-17:00 on Monday to Friday and from 8:00-12:00 on Saturdays.

There have been no changes to the premises since the last inspection. However, a project is well underway for upgrading the unit so that it will comply with the requirements of the EU Tissue and Cells Directive (EUTD). It is hoped that building work will commence this summer.

Madhurima Rajkhowa has held the position of PR since October 2004 and is currently completing the PR entry programme for submission by the 30th April 2007.

Activities of the Centre

Licensed treatment cycles	598*	IVF IVF with donor eggs/sperm ICSI ICSI with donor eggs/sperm Chemical assisted hatching ZIFT
Donor Insemination	49*	
Unlicensed Treatments	✓	IUI Ovulation induction Tubal/reproductive surgery
Research	✓	R0154
Storage	✓	Storage of sperm (patient and donor) Storage of embryos

*HFEA unverified statistics from December 2005-December 2006

[1] Unverified HFEA data from December 1st 2005- 30th November 2006.

Summary for Licence Committee

The inspectorate were satisfied with the level of organisation at the centre and agreed that no improvements are currently required in this area. Some improvements are required in the areas of quality of service, premises and equipment, information and laboratory & clinical practice. The key issues resulting from the inspection were that a breach of the witnessing directions, D2004/4, was noted and that concerns were raised regarding the security of patient records. In addition, a number of recommendations were made; these are listed on page six.

Overall, however, the inspectorate were satisfied with the key areas of service provided by the centre and recommend continuation of the centre's licence without any additional conditions.

There will be a requirement for another inspection of the premises once the planned refurbishment is complete. This should occur before licensed treatments commence.

Risk Assessment

On the last completed risk matrix tool the centre scored 11%.

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
The inspectorate noted discrepancies in the documentation of witnessing procedures for IVF cycles. This is non compliance with Directions D2004/4.	Staff should review their own witnessing protocol for licensed procedures and ensure compliance with D2004/4.	Immediately

Non-Compliance

Area for improvement	Action required	Time scale
Patient records are stored in filing cabinets along the main unit corridor. Although these cabinets can be locked, they were not seen to be secured on the day of inspection. In addition, a number of patient records were seen to be left unsupervised on top of a cabinet.	Compliance with the Code of Practice part 11.14. The PR should risk-assess the security of patient records and ensure that the security and confidentiality of patient records is maintained at all times.	Immediately

Recommendations	Time scale
In the rare cases where the counsellor has concerns and feels that it necessary to discuss a case with other members of the clinical team it is recommended that she informs the patient and if possible obtains consent that issues raised can be discussed with the licensed team.	As appropriate
Consider the privacy of patients undergoing phlebotomy procedures.	3 months
Formalise the on-call rota for response to dewar alarms.	3 months
Ensure that the emergency trolley is monitored and maintained on daily basis, in accordance with the centre's protocol.	Immediately
Update patient and donor information as recommended in Section 4.	3 months
Evaluate the current procedure for compensating embryologists for working weekends. It is also recommended that a risk assessment is carried out on working hours within the laboratory.	3 months

Proposed licence variations

N/A

Changes/ improvements since last inspection

Recommendation	Action taken
The Licence Committee considering the previous inspection report had concerns about the lack of privacy for patients undergoing ultrasound. They noted that the arrangements were not ideal and that the centre had planned for an upgrade to address this. The Committee requested that the centre reviews the problem in consultation with Dr Sood.	The ultrasound area has not been changed since the last inspection and the planned upgrade has been delayed. It is now set to commence in July 2007 and the privacy of patients undergoing ultrasounds will be considered in the new design of the unit. The PR stated that they are closely monitoring patient views about the privacy of this area through their patient questionnaires. She also reiterated that discussions about treatment are not conducted in this area, patients are taken to private consultation rooms for this purpose.
A formal on-call rota for liquid nitrogen dewar alarm should be developed.	The rota for response to dewar alarms has not yet been established (see Section 3).
Detailed OHSS information and the OHSS protocol should be made available to the staff to follow in the event of an emergency.	Soon after the previous inspection, the PR reported that the protocol has been distributed to all referring centres and to the gynaecology ward where patients may be admitted for management.
The Centre should start distributing patient questionnaires.	Patient questionnaires have now been introduced and examples of these were provided to the inspection team.
Counselling protocols need to be included in the information book. The counsellor should include the donor anonymity protocol in her notes	Was implemented following last inspection. Information about counselling forms part of the general treatment information provided to patients.
Scientific protocols should be updated.	Protocols submitted for inspection were considered to be fit for purpose.
Patients producing sperm at home must sign consent forms before handing over their samples to the laboratory.	The PR stated that patients who produce samples at home confirm that it is their sample by signing the treatment sheets.
Screened and unscreened embryos must be split up in separate dewars.	The PR reported that this has been implemented and that from 17th May 2006 all screened and unscreened embryos have been stored in separate dewars.
Separate nursing protocols should be created.	The PR reported that new nursing protocols were written and implemented following the last inspection and before the report was considered by a Licence Committee.

Additional licence conditions and actions taken by centre since last inspection

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

Report of Inspection findings

1. **Organisation**

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

Summary of findings from inspection
Evidence is drawn from:

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

Areas of firm compliance
The inspectorate agreed that the unit appears to be well organised and managed effectively. Clear organisation charts have been drawn up and these were submitted with the pre-inspection questionnaire. Regular meetings are held between clinic staff: multidisciplinary meetings are held on a weekly basis and management meetings are held every month. Minutes are taken at these meetings and stored on the ACU computer system. All staff are asked to sign a register to confirm that they have read the minutes. Minutes from these meetings were supplied to the inspectorate. A quality management system has been introduced and the centre hopes to achieve ISO 9001: 2000 certification by Spring 2007. As part of the movement towards a quality management system regular quality management meetings are held each month. The meetings are minuted and evidence of this was provided to the inspection team. The PR stated that risk management meetings are held every three months. At these meetings incidents are discussed and root-cause analysis (RCA) performed when appropriate. Outcomes from the root-cause analysis are then communicated to all members of staff at the weekly team meetings. On a temporary basis the unit will be acting as a primary centre for satellite patients from centre 0019. This relationship was established because centre 0019 is undergoing refurbishment work. A written agreement dictating the responsibilities for each centre is in place and was submitted to the HFEA before the arrangement was formalised. The PR reported that the SOP created for management of the satellite service appears to be working well. The PR also stated that staff from the Aberdeen unit have visited the centre so that they would be familiar with practices and procedures at Ninewells. Contingency arrangements have been established with Aberdeen Fertility Centre (0019). This agreement has been documented and a detailed SOP, including the arrangements for

patients undergoing licensed treatment, patient records and stored samples, was presented to the inspection team. An arrangement with the Edinburgh Assisted Conception Unit (Centre 0058) is also planned but this has not yet been formalised. In addition to these agreements the Trust has created a business continuity plan which addresses hospital wide emergency issues, this includes how ACU services would be affected in the event of an emergency. Payment of treatment fees is timely and the unit does not appear on the HFEA debtors list.
Areas for improvement
None noted during the inspection.
Executive recommendations for Licence Committee
None
Areas not covered on this inspection
Clinical governance

Evaluation
No improvements needed

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

Unverified HFEA statistics on IVF, FET and DI indicate the following success rates:

	IVF	FET after IVF	ICSI	FET after ICSI	DI
Clinical pregnancy rate per treatment cycle: 01/12/05-30/11/06	28.47%	33.33%	36.84%	21.43%	10.20%
Live birth rate per treatment cycle: 01/12/04- 30/11/05	20.78%	16.67%	22.35%	10.53%	14.75%

According to HFEA statistics[2], in the period December 2005-December 2006 there were no multiple pregnancies resulting from donor insemination cycles. A multiple pregnancy rate of 21.43% resulted from IVF and ICSI cycles.

Data generated by the HFEA Success Rate Assessment[3] (see Licence Committee papers) shows that the IVF/ICSI success rates for age band 40-42 years were significantly lower than the National Average but that the success rates for age bands 38-39 years, 35-37 years and for patients below 35 years were higher than the National Average. Success rates for patients undergoing frozen embryo transfers in the age bands 40-42 years were significantly lower than the National Average. However, FET success rates for age bands 38-39 years and below 35 years were higher than the National Average and for patients in age band 35-37 years they were significantly higher than the National Average. The success rates with donor insemination for patients in the age band 40-42 years were significantly lower than the National Average and for patients aged 35-39 years the success rates were lower than the National Average. Patients younger than 35 years old had success rates with donor insemination which were higher than the National Average.

[2] HFEA unverified data from 01/12/05-30/11/06
[3] Unverified data from 31st March 2002 to 1st April 2005.

Patient Questionnaire analysis
HFEA patient questionnaires have not been received since June 2005, so analysis of recent questionnaires has not been possible. The PR stated that the questionnaires have been handed out and was unsure as to why they had not been returned to the HFEA.
Areas of firm compliance
A system for gathering patient feedback has been established. The PR stated that periodic patient satisfaction surveys are carried out; recent surveys have included a generic survey of IVF treatment cycles, a survey of male patients' views and surveys about action scan visits. Examples of these surveys were supplied to the inspection team. The PR explained that responses from surveys are analysed and results discussed at unit meetings. Three patients were interviewed during the course of the inspection. All expressed satisfaction with the treatment they had received at the centre and were complimentary about the centre staff. All patients stated that they would not change anything about the centre. The detailed counselling audit for the period January 2006-January 2007 was submitted prior to the inspection. This indicated that 214 counselling sessions were held. This is a similar number of sessions compared to the previous year when 217 sessions were conducted.
Areas for improvement
To date patient views about counselling have not been collated. It was suggested that feedback on the counselling service could be gathered through questions in their own patient questionnaires. The PR appreciated this suggestion and plans to incorporate counselling issues into the questionnaire in the future. The counsellor reported that if she encounters a difficult case, with potential welfare of the child issues, she may discuss the case with the PR and with the rest of the team during weekly meetings. Although the PR stated that patient identity is not disclosed in these events, it was suggested that patients are made aware that, and perhaps consent to the fact that, issues raised within the counselling sessions may be discussed with other members of staff. Patient records are stored in filing cabinets along the main corridor in the unit. Although these cabinets are lockable it was noted that on the day of inspection they were not secured. In addition, a number of patient records were left unaccompanied on the top of one of the cabinets. The issue of security of records was raised with the PR and she stated that patients are always escorted around the unit so that they could not access these notes. Furthermore, she stated that it would create difficulties if the cabinets were locked as the notes are accessed frequently throughout the day. The PR was reminded to ensure the security and confidentiality of patient records at all times (see Code of Practice part 11.14[4].) and it was recommended that PR risk assesses the current security of patient records. Issues have been raised by previous inspection teams with respect to the privacy of patients undergoing ultrasound scans. The PR had planned to modify the arrangements by inserting partition walls between the two bays and the corridor. However, due to the planned upgrade of the facilities, either an entirely new build or complete refurbishment of the current premises, the PR has postponed these plans. The PR stated that patients' views on the privacy of the

[4] Code of Practice part 11.14: Centres are expected to have appropriate security measures in place for all record keeping systems. These are expected to include data held on paper, electronically or any other type of system.

treatment areas are closely monitored and kept under review. It was noted during this inspection that phlebotomy is conducted within the open bay areas and that patients are not shielded from the main corridor. It was recommended that the privacy for these patients should be considered and maintained. The PR stated that a curtain will be ordered and fitted to increase privacy in this area.
Executive recommendations for Licence Committee
Note the need for the PR to assess security of patient records and the privacy of patients attending for treatment.
Areas not covered on this inspection
Donor selection Egg sharing and surrogacy Protection of children arrangements (for patients under 18yrs)

Evaluation
Some improvements needed

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

Background information
Within the next 6 months it is planned that work will commence on upgrading the premises so that it will meet with the requirements of the EUTD. Funding has now been obtained for this project and a design team and architects have been appointed. The options for the upgrade are either to refurbish the current unit or to build a new unit on a different site. A decision is due to be made on the location of the unit within the next month. The PR anticipates that work will begin in July 2007 and should be completed by September 2008.
Areas of firm compliance
The premises were considered to be clean and of a suitable size to cater for the number of cycles currently conducted at the centre. Storage dewars are kept in the laboratory. All dewars were seen to be locked and alarmed. The low nitrogen alarm is connected to the main hospital switchboard. In the event of an alarm being activated the switchboard team follow a documented procedure and contact ACU staff using a list of emergency contact numbers. The protocol and current list of contact numbers were provided to the inspection team. The PR stated that the business manager is responsible for regularly checking that these numbers are updated. Although a ventilation system is not in place within the laboratory personal low oxygen level alarms are held by staff. The topping up of dewars takes place outside in the main corridor beside the liquid nitrogen filling vessel. A low oxygen alarm was seen to be fixed to the adjacent wall. Laboratory equipment undergoes frequent monitoring and maintenance. A data logging system is used which monitors conditions in incubators as well as temperature of heated stages. Records are kept of the service history of equipment; these were provided to the inspectorate and considered to be comprehensive.
Areas for improvement
Although an on-call rota is in place for response to dewar alarms, this works on a volunteer basis as the embryologists are not paid. The PR is aware that the rota needs to be properly formalised and stated that this will be resolved by senior management within the next few weeks. It was noted that equipment stored on the emergency trolley has not been monitored on a daily basis. This is non compliance with the centre's own protocol for monitoring and maintaining this trolley which states that daily checks should be performed.

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

Evaluation
Some improvements required

4. Information

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

Summary of findings from inspection:

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

Outcome of audit of records
Twelve patient records were audited by the inspection team. The records were considered to be well organised and easy to navigate. All patient records contained consent to disclosure, "welfare of the child" forms and relevant HFEA consents. One set of records contained an incomplete consent for insemination treatment form; this was discussed with the quality manager and will be amended. A checklist for consent form completion was seen to be present in all notes. This is completed by the business manager to ensure that all required consent forms are completed prior to commencement of treatment. The last audit conducted by operational audit was in December 2005; no major issues were reported.
Areas of firm compliance
The patient information was judged to be detailed and comprehensive. Patient records are filed manually and electronically. The PR and quality manager stated that all computers within the unit are password controlled and that only staff on the unit's licence have access to patient data. A system for document control is in place. All documents, patient information and protocols are stored on a separate electronic folder accessible to staff on a read-only basis. The quality manager is the only person with authorisation to change the documents and all superseded documents are moved into an archive folder. In addition a log is maintained of revisions; this includes the date and reasons for revisions made. This system was demonstrated to the inspection team. Some documents are available in hard copy and these are controlled by destroying all superseded documents once new versions of documents have been approved. The quality manager stated that relevant staff are notified about document changes via email. The HFEA Registry department are satisfied with the information provided by the Centre.
Areas for improvement
Certain patient information sheets require amendments:

- IVF /ICSI patient and donor information information needs to be updated to state that children born as a result of donated gametes/embryos can obtain identifying information about the donor (s) once they reach 18years[5]
- Sperm cryostorage patient letters should be updated to reference new HFEA consent forms[6]
- It was suggested that the patient information about embryo freezing should be updated as the referenced survival statistics date from 2002
- ICSI information should be updated to include information about the possible inheritance of cystic fibrosis gene mutations[7]
- Sperm donor information should be updated to include the possibility that a child born disabled as a result of a donor's failure to disclose defects, about which the donor knew or ought reasonably to have known, may be able to sue the donor for damages [8]
- Information about the putative risk of cancer involved with treatment should be added to patient information sheets[9]
- Live birth rate is included within the patient information but this is not compared to the National Average, as required by part 5.5 iv of the Code of Practice[10]

All information should be updated accordingly.

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

Evaluation
Some improvements required

[5] Human Fertilisation and Embryology Authority (Disclosure of Donor Information) Regulations 2004 (S.I. 2004 No. 1511
[6] MS HFEA consent forms for storage of sperm.
[7] As required by Code of Practice part 16.7 iia
[8] As required by Code of Practice part 5.7*vi*
[9] As required by Code of Practice part 5.5 v
[10] Code of Practice part 5.5 iv: Data provided in all relevant patient resources are expected to be the centre's own most recent live birth rate per treatment cycle as verified by the HFEA, and the national live birth rate per treatment cycle.

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	2.5
NMC registered nurses	6.1
HPC registered scientists	3
Scientists working towards registration	2
Support staff (receptionists, record managers, quality and risk managers etc)	4

Summary of laboratory audit
The laboratory conducted an audit of stored gametes in December 2006 and stored embryos in May 2006. The results from this were provided with the pre-inspection questionnaire. The PR reported that there were no major discrepancies and that the minor discrepancies have now been rectified.
Summary of spot check of stored material
Two sets of embryos were tracked from records to tank and two other sets of embryos from tank to records. No discrepancies were noted. A spot check of stored sperm samples was conducted in the same manner, two sperm samples tracked from tank to records and two more sets of samples tracked from records to tank, and again no discrepancies were noted.
Areas of firm compliance
As part of the quality management system, a series of key performance indicators (KPIs) have been set and are monitored. These indicators include elements of laboratory, clinical and administration practice such as pregnancy rates and ET practitioner rates. Analysis of a selection of the KPIs was shared with the inspection team. A programme for internal audits is in place and a copy of this was given to the inspection team: in the last twelve months a number of audits have been carried out, including audits into compliance with SOPs in different departments, rates of elective freezing following OHSS and patients' response to embryo storage letters. The quality management team meet to plan the audit programme for each year and then meet regularly to discuss the audit results and any non-compliance events. Evidence that actions have been taken in response to audits was provided.

The laboratory team participate in the National External Quality Assessment Service (NEQAS) andrology schemes. The results from these are stored within a QA folder, which was supplied to the inspection team.

Training induction programmes are in place for the nursing, clinical and laboratory team and training records were considered to be satisfactory by the inspectorate.

The nursing team receive in-house training on ultrasound scanning. This course is accredited by the British Fertility Society and log books are maintained by staff undergoing the training. The PR reported that three nurses have attended the course so far and it is planned that further members of staff will participate in the training in the near future.

All staff interviewed expressed satisfaction with the provision for the continual professional development (CPD). Evidence of CPD for members of staff in all departments was provided to the inspectorate: members of staff have attended a number of conferences including the annual meeting of the European Society of Human Reproduction and Embryology (ESHRE), British Fertility Society (BFS) QMS workshops, BFS scanning study days and Association of Clinical Embryologist meetings. An in-house programme for CPD has also been established: every three-four months multi-disciplinary training seminars will be held. The first is scheduled for the 30th March and the PR explained that the subject will be multiple pregnancies. In addition to this, a journal club is due to begin in April this year. This will involve all members of staff and the PR has decreed that staff will have to attend at least 50% of these meetings.

Areas for improvement

The Senior Embryologist stated that the disposal of embryos is witnessed by another member of laboratory staff. However, during the records audit it was noted that this step is not documented as required by D2004/4[11]. In addition, in some records the time of the procedure was not recorded. The PR should ensure that witnessing is documented in accordance with D2004/4. It was suggested that staff compliance with witnessing requirements should be audited.

Laboratory staff reported that they share the weekend work with embryologists working alternate Saturdays. The compensation for this is that they can take the time back at a later date. However, the embryologists stated that as a consequence of working pressures they have been unable to routinely take this time off; one embryologist stated that she is currently owed for 200 hours of overtime. It is suggested that the current procedure for compensating embryologists for working weekends is evaluated and that a risk assessment is carried out on working hours within the laboratory.

Executive recommendations for Licence Committee

Note non compliance with D2004/4.

[11] Directions 2004/4: 2. Each licensed centre must keep records of the witnessing of all clinical and laboratory procedures set out in the schedule to these Directions. A contemporaneous record must be made in each patient's medical records confirming: (a) the procedure undertaken; (b) the date and time of the procedure; (c) the name and status of the person undertaking that procedure and the signature of that person; (d) the name and status of the witness to the procedure and the signature of that person.

Areas not covered on this inspection
PGD/ PGS

Evaluation
Some improvements required.

Report compiled by:

Name……Sarah Hopper……..

Designation Inspector ……..

Date……8th March 2007……

Appendix A: Centre Staff interviewed

The PR and eight members of staff.

Appendix B: Licence history for previous 3 years

First licensed 1992

Licence	Status	Type	Active From	Expiry Date
L0004/13/a	Active	Treatment with Storage	01/10/2006	30/09/2009
L0004/12/a	Expired	Treatment with Storage	01/09/2005	30/09/2006
L0004/11/c	Replaced by New Version	Treatment with Storage	28/10/2004	30/09/2006

21st June 2006:
Renewal inspection report presented to Licence Committee. The Committee stated that taking into account the forthcoming refurbishment the Committee agreed to renew the centre's licence for a period of three years, with no additional conditions or recommendations.

23 September 2004:
Interim inspection report presented to Licence committee. Dr MacLennan chaired the inspection to Ninewells Hospital on 24 June 2004. Dr MacLennan informed the Committee that the centre has taken on board all the recommendations made during the inspection. The Committee agreed that the centres licence be continued, and varied to recognise Dr Madhurima Rajkhowa as Person Responsible.

24th April 2003:
The Committee agreed to renew the centre licence for 36 months to expire 30th September 2006 with two additional conditions: i) The centre must install a low level O_2 within three months of receipt of this licence. ii) The Person Responsible must ensure that prior to the commencement to the start of a new treatment cycle there must have been Welfare of the Child assessment which must be documented in the patient's notes and five recommendations: i) The centre should continue to reduce the counselling waiting lists. ii) The PR must ensure that one set of protocols are used in the laboratory and the line management of Ellen Drew is clearly demarked. iii) The reception area should be shut off from the waiting room; the use of the adjacent smoking room would be an ideal location for a private reception room. iv) The reserve nitrogen tank should be moved from its current location into a non patient area, with appropriate O_2 alarms. v) The patient information should be amended to include: Sex chromosomal risks associated with ICSI and that two embryo transfers can result in triplets being born.

Appendix C:

RESPONSE OF PERSON RESPONSIBLE TO THE INSPECTION REPORT

Centre
Number……0004……

Name:……Dr Madhurima Rajkhowa

Date of Inspection…7 March 2007

Date of Response 20 April 2007

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

- page 6- Breach of Code of Practice- There has been a review of witnessing protocols. These have now been amended to include the following changes to ensure compliance with the D2004/4 and recent directive from the HFEA
  -There will be documented witnessing of perishing of embryos following embryo transfer, (and not suitable for freezing). All witnessing will have a date and time along with signature. The Business Manger keeps an up to date register of signatures of all staff members with Names and Designation. The revised laboratory sheet and SOP are attached. This has been implemented with immediate effect.
- Page 6- Non-compliance with Code of Practice 11.14. Following receipt of the inspection interim report, the following actions have been taken. No notes are left on top of filing cabinets at any time. The administrative and Nursing staff have all agreed to this protocol. Any notes awaiting filing are kept in the Business Mangers or Secretary's office. Regarding keeping the filing cabinets, which are in the passageway within the Unit (next to clinic rooms and offices)- a risk assessment meeting to discuss risk to confidentiality has been arranged for this week. Business/ Quality Manger, relevant administrative and nursing staff will participate in this exercise. Immediate action will be taken following the results of the risk assessment. It has to be pointed out that the filing cabinets with patient notes are located within the Unit, next to the Business Manger's office, beside clinic rooms, and theatre/ recovery area and Nursing station. The likelihood of any one having unauthorised access is low. The comments have however been taken on board and a full risk assessment will be undertaken.
- Page 6- Recommendations-
  1. Counsellor will now be taking written consent from patients if she wishes to discuss details with the team. An SOP and consent forms has been written and is enclosed.
  2. page 11- It has been agreed following discussion with the Counsellor that satisfaction survey of the counselling visit will be carried out. The timing and details of survey are to be finalised.
  3. For privacy of patients during phlebotomy a curtain has been provided for that bay, and staff are now aware that this must be closed if a procedure is to be undertaken. Privacy of patients will be considered and maintained at all times.
  4. The emergency trolley is now closely monitored by senior nursing staff and

maintained daily. A daily record is kept and form signed by the staff member who performs the check. This has been in place from 16 April 2007

5. The relevant patient information leaflets have been amended incorporating suggestions in report– IVF / ICSI and donor information to include identifying information access to child at age 18 and putative risk of ovarian cancer, live birth rates , embryo freezing with updated success rates, ICSI information re CF gene mutation inheritance, sperm donor information , and sperm cryostorage forms with Letters reference to new HFEA consent forms

- Embryologist Issues-

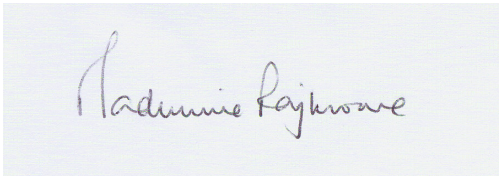
1. Compensating embryologist for working week ends- A meeting has been held with senior management on 16 April. Following the meeting it has been agreed that all out of hours that have so far been accumulated by all grades of embryologists will be paid in full. The current staffing level for embryologists in the Unit includes 2 full time senior embryologist, two full time clinical embryologists and a full time trainee embryologist adding to a total of 5 w.t.e. embryologists in the Unit. A review of the working practice of embryologists has been recommended at the meeting to incorporate weekend work within their weekly working timetable so that such additional hours are not accrued in the future. Unfortunately one of the senior embryologists has to take sick leave to undergo surgery in the next few weeks. It has been agreed at the meeting that during her absence any time accrued out of hours will be paid as overtime on a monthly basis.
2. Out of hours on call rota for embryologists- At the above meeting this was discussed in detail with the Human Resources dept of the Trust/The out of hours requirement has already been included in the job description for the Embryologists to the Agenda for Change offices. This will be with effect from 1 April 2007. However so far the embryologists posts have not been assimilated by the Trust and therefore the terms and conditions relating to on call have so far not been implemented. The intention has always been to implement this as soon as assimilation occurs. However taking the inspection report into consideration, the Trust has agreed. As an interim measure, to formalise the rota with relevant financial compensation as soon as possible. A draft agreement from another Unit has been obtained to see how this rota can be implemented, to serve as a template. The current embryologist profile would allow a 1 in 3 rota (including only state certified embryologists) till July and then 1 in 4 when the 4th member is certified. The Senior Embryologist have been asked to develop this rota and present it to the next management meeting held on 20 April. It is now agreed that the Embryologists will have a paid rota of initially 1 in 2 weeks for the 2 months that one of the Sr Embryologists is off sick, and then 1 in 3 weeks till July when we anticipate it becoming 1 in 4 weeks. This has been done with the agreement of all those involved in the rota.

- Page 8 -Quality Management Systems. We have completed an inspection by external auditors on 19 March and the centre should receive ISO 9001 certification by 30 April

Enclosures:

1. Patient Information Leaflet for IVF and ICSI, Donor Information leaflet, Embryo freezing information leaflet with amendments
2. Amended sperm cryostorage patient letters
3. Counselling SOP for disclosure of information, consent for disclosure, amended HFEA counselling report

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

Signature 

Name……Dr Madhurima Rajkhowa

Date……23 April 2007

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).

- Page 17 - staffing numbers have been completed
- Page 18 – para 3- Two nurses and the subspecialty trainee have attended course and participating in in-house ultrasound scan training
- Page 18 CPD LINE 6- In house multidisciplinary meetings have been held in the unit regularly for the past three years and the last meeting on 30 March was on multiple pregnancies

We also welcome comments about the inspection on the inspection feedback form, a copy of which should have been handed out at the inspection. If you require a copy of the feedback form, please let us know.

Please return Appendix C of the report to:
Regulation Department
Human Fertilisation & Embryology Authority
21 Bloomsbury Street
London
WC1B 3HF

Licence Committee Meeting

20 June 2007
21 Bloomsbury Street London WC1B 3HF

MINUTES Item 2

Assisted Conception Unit Ninewells Hospital (0004)
Interim Inspection

Members of the Committee:
Sharmila Nebhrajani, Lay Member – Chair
Anna Carragher, Lay Member
Emily Jackson, Lay Member
Maybeth Jamieson, Embryologist
William Ledger, Clinician

In Attendance:
Frances Clift, Legal Adviser
Marion Witton, Head of Inspection
Shamima Rouf, Committee Secretary

Observers:
Andrew Leonard, Inspector
Rong Li and Joy Zhang from Peking University Third Hospital

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 (32 pages)
- no papers were tabled.

1. The papers for this item were presented by Sarah Hopper, HFEA Inspector. Ms Hopper drew the Committee's attention to the fact that the centre is planning to upgrade its facilities, either by a movement to new premises or development of the current unit, to comply with the requirements of the EUTD.

2. Ms Hopper informed the Committee that the Person Responsible has responded to 7 of the 9 recommendations made at the previous inspection. However, the lack of privacy for patients undergoing ultrasound examinations and blood tests remained an area of concern. Ms Hopper also stated that at the time of inspection a rota for response to the low nitrogen alarm had not been formalised.

3. Ms Hopper drew the Committee's attention to page 6 of the report which listed the improvements considered necessary by the inspectorate. This included the need to ensure security of patient records at all times and some revisions are required to patient information.

4. The Committee noted that the recommendation about lack of privacy was made a year ago. The Committee was concerned that there still remains an issue of privacy where sensitive examinations are taking place and felt that the use of a curtain is not sufficient for the privacy of patients. The Committee also had concerns that the current arrangements would not facilitate free discussion between the clinician and the patient. The Person Responsible should provide an opportunity for such discussions to take place in private at the time of examination.

5. The Committee agreed that the centre is required to submit a plan to the Executive within three months of receipt of these minutes showing how this problem can be resolved.

6. The Committee agreed to continue the centre's licence with no additional conditions.

Signed…….. Date…….
Sharmila Nebhrajani (Chair)