Interim Inspection Report

Aberdeen Fertility Centre
0019

Date of Inspection: 11th October 2006
Date of Licence Committee: 18th January 2007

CENTRE DETAILS

Centre Address	Aberdeen Maternity Hospital Foresthill Aberdeen Scotland AB25 2ZD
Telephone Number	01224 554 482
Type of Inspection	Interim
Person Responsible	Dr Mark Hamilton
Nominal Licensee	Mrs Alison McTavish
Licence Number	L0019/11/a
Inspector(s)	Miss Sarah Hopper Dr Vicki Lamb Mr Tony Knox
Fee Paid - date	Not applicable
Licence expiry date	31st January 2008

Index

Page

About the Inspection:
This inspection visit was carried out on the 11th October 2006 and lasted for 7 hours. The report covers the pre-inspection analysis, the visit and information received between July 2005 and October 2006.

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

The report summarises the findings of the interim inspection highlighting areas of good practice, as well as areas where further improvement is required to improve patient services and meet regulatory requirements. It is primarily written for the Licence Committee who 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

Aberdeen Fertility Centre has been licensed since 1992 and offers a wide variety of treatments to NHS and self-funding patients from a wide geographical area.

Within the centre there are two units: the Assisted Reproduction Unit and the Fertility Unit. Both operate under the same licence and are directed by Dr Mark Hamilton, the Person Responsible.

The Aberdeen Fertility Centre is situated on the first and second floor of Aberdeen Maternity Hospital. Two waiting rooms, two scan rooms, consulting rooms, a counselling room, a storage room, offices, a staff cloakroom and kitchen are located on the first floor. The second floor comprises of additional offices, a consulting room, a sperm production room and adjacent shower room, an andrology laboratory, an andrology cryostore, an embryology laboratory, a theatre and a dedicated ICSI laboratory.

Funding has been allocated for refurbishment of these facilities so that they can meet the requirements of the European Tissue and Cells Directive (EUTD). It is planned that the Centre will be shut from January 2007 to June 2007 whilst this upgrade takes place. Contingency arrangements for future patients are currently being developed.

Treatments are provided to patients 7 days a week and the opening hours of the centre are typically 07:45-16:15.

The centre has a system in place for Quality Management and achieved ISO 9001:2000 certification in 2004.

Activities of the Centre

Licensed treatment cycles	780 *	IVF IVF with donor eggs/donor sperm ICSI ICSI with donor eggs/sperm Chemical Assisted Hatching Mechanical Assisted Hatching
Donor Insemination	101 *	
Unlicensed Treatments	✓	Intra-uterine insemination (natural cycle and stimulated) Ovulation induction with Gonadotophins
Research	✓	RO164/1/a R0159/1/a R0157/1/a
Storage	✓	Storage of eggs (patient) Storage of sperm (patient and donor) Storage of embryos

*HFEA statistics from August 2005-August 2006

Summary for Licence Committee

Some improvements are required but the Inspectorate were satisfied with the key areas of service provided by the centre and recommend continuation of the centre's licence without 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 0%.

(Updated risk data has been requested so that the tool can be refreshed to show a current risk score).

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
One storage dewar is not connected to an autodialler system. This is a breach of CH (04)03.	The PR should ensure all dewar alarms are connected to an autodialler system in accordance with CH (04)03.	Immediately
The inspectorate noted discrepancies in the documentation of witnessing procedures for DI cycles. This is non compliance with Directions D2004/4.	Staff should review their own witnessing protocol for DI procedures and ensure compliance with D2004/4	Immediately

Non-Compliance

Area for improvement	Action required	Time scale
Mouth pipetting is still employed as a technique for manipulation of gametes and embryos by one member of the laboratory team. This contravenes the Association of Clinical Embryologists (ACE) Guidelines for Good Practice in IVF Laboratories	The PR should ensure that this practice ceases immediately.	Immediately

(Accreditation Standards and Guidelines for IVF laboratories, Appendix 1, Section 3.3). The PR should ensure that suitable practices are used in the course of HFEA licensed activities (Code of Practice part 1.4iv). Records belonging to patients attending the Fertility Clinic for donor insemination do not include consent to disclosure consent forms. Although a breach of confidentiality was not evidenced, the PR should remember to gain consent before disclosing information to other parties, eg GPs, in line with Code of Practice part 11.10 and 12.2.	 Consent to disclosure forms should be completed by all patients attending the centre for licensed treatments.	 Immediately

Recommendations **Time scale**

It was suggested that the complaints procedure should be revised to ensure that all complaints are initially directed towards the unit, before being passed on to the Trust. The complaints notices should include the name of the Complaints Officer. It was also suggested that HFEA contact details could be added to the complaints information.	3 months

Proposed licence variations

N/A
N/A

Changes/ improvements since last inspection

Recommendation from last inspection	Action taken
To ensure compliance with CH (04)03 and fit all storage dewars with low nitrogen alarms	All storage dewars have now been fitted with low nitrogen alarms but one dewar alarm was not plugged in on the day of inspection.
To ensure compliance with CH (04)03 and ensure that all dewar alarms are connected to an autodialler system	One dewar remains unconnected to this system.
In accordance with CH (04)03 the PR was advised to split oncology samples where patients have two or more straws stored.	The andrologist informed the inspectorate that all oncology samples are now split.
The complaints procedure was not clearly separated from the patient feedback process and it was suggested that the centre should have a clear and identifiable complaints procedure on display in the patient waiting room.	A poster providing details for the Trust's complaints department is now on display in the patient waiting room but the inspectorate considered that the process should be made still clearer for patients (see Section 2)

Additional licence conditions and actions taken by centre since last inspection

C	**N/A**
A	**Complied Y/N**
C	**N/A**
A	**Complied Y/N**
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 centre appears to be well organised. An established Quality Management system exists which considers all areas of the service provided to patients. The centre has a clear management structure which is explained in their Quality Manual through use of diagrammatic figures. Monthly meetings are held between the managers of each department; according to the Quality Manual these meetings are used to discuss management issues, to review quality objectives and to review organisational goals. Each area manager then meets with members of their department on a monthly basis. Staff also attend weekly multidisciplinary meetings which are used to discuss current clinical and business issues. All meetings are minuted and evidence of this was seen during the inspection. Meeting minutes are made available to all staff via a shared central department hard drive. Risk management is addressed in monthly meetings. The PR explained that recommendations made during these meetings may lead to an audit of Standard Operating Procedures (SOPs) and review of practices to reduce risk. A back up generator is in place which ensures continued supply to certain pieces of essential equipment in the event of a break in the main electricity supply. The generator is capable of providing a power supply for twenty four hours. Business planning occurs in January each year and comes into force each April. The Quality Manual details the basic process involved with such planning. One example of business planning by the PR is that plans have been formulated so that a skeleton service can still be provided to patients during the centre shutdown, currently scheduled for January 2007-June 2007. Payment of treatment fees is timely and the Centre is not listed 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 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)
- 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
Audits of treatment outcomes are undertaken annually. Evidence of the auditing practice was provided by the PR. According to the PR, the number of cycles has increased in the past year by 20%. This is a result of the planned shutdown of the facility from January-June 2007: the centre had agreed to complete all National Health Service funded cycles in advance of the closure. Data generated by the HFEA Success Rate Assessment (see Licence Committee papers) shows that IVF/ICSI success rates for age bands 40-42 years and below 35 years were lower than the national average in the period 30/03/02-01/04/05. However, success rates for patients aged 35-37 and 38-39 years were higher than the National Average. Success rates with Frozen embryo transfers for age band 40-42 and for patients below 35 years were higher than the National Average whereas success rates were lower than the National Average for age bands 38-39 and 35-37 years. Unvalidated HFEA statistics on DI success rates in the period 01/08/04 to 01/08/05 indicate that the live birth rate per cycle was 4.61%. When questioned about this, the PR reminded the inspectorate that most of the DI cycles were unstimulated. Prenatal data from the period August 2005-August 2006 has indicated a clinical pregnancy rate of 6.93% per treatment cycle. The PR is not satisfied with the high multiple pregnancy rate. According to unvalidated HFEA statistics the percentage of multiple births resulting from IVF/ ICSI cycles and ovum recipient cycles was 13.3% and 33.33% of live births respectively (Data from August 2005-August 2006). Due to his concerns, the PR is planning to promote Selective Single Embryo Transfers when the centre reopens next year.

Patient Questionnaire Assessment
The Patient Questionnaire Assessment (see Licence Committee Papers) indicated overall patient satisfaction with all five areas investigated; Clinic and Staff, Information, Counselling, Consent and Treatment, Drugs and Sharing Information. However, the last HFEA patient questionnaire was received on the 16th June 2006. Further questionnaires were not sent out prior to this inspection as it was anticipated that the inspection would be postponed due to centre closure for refurbishment.
Areas of firm compliance
In the sample of records examined by the inspectorate "Welfare of the Child" forms were found to be completed clearly and issues reported by GPs acknowledged. One couple interviewed on the day of inspection stated that they were happy with the care they had received from all staff and that they felt that they had been treated with privacy and dignity during their treatment cycle. Patient feedback is assessed continuously through use of suggestion slips on display in the waiting rooms. In addition to these, targeted patient questionnaires are used bi-annually to focus on a particular area of service, for example the quality of the waiting room. The PR explained that he aims to use these questionnaires at least twice a year and that the information gathered will be used as part of an audit process. Evidence of such an audit was provided to the inspectorate. The counselling audit for the period October 2005 to September 2006 indicated that 252 patients attended counselling sessions. This is a slight increase in comparison to the previous year when 230 sessions held. Although the majority of counselling sessions are held within the unit, the Counsellor stated that she can hold sessions at another location within the University if patients request this in advance. Counselling notes were found to be stored within the counselling room in a locked and secure filing cabinet. Access to these notes is restricted to authorised members of staff; namely the Counsellor and Unit Manager.
Areas for improvement
Records were seen to be stored in lockable cabinets behind lockable doors. On the day of inspection the cabinets and doors were not locked but the inspectorate were informed that this is only the case if members of staff are in attendance. The PR was reminded to ensure the security and confidentiality of patient records at all times (see Code of Practice part 11.14.) Information about the complaints procedure is present within the waiting room. This provides contact information for the Trust complaints department but does not mention a named individual within the unit. It was suggested that this procedure should be revised to ensure that all complaints are directed towards the unit first, before being passed on to the Trust. The inspectorate reminded the PR that it is possible that incidents could be highlighted through a complaint and that using their current system these incidents may not be received and reported to the HFEA within the required timeframe.

It was also suggested that the address for the HFEA could be included in the patient information for those who may wish to complain directly to the HFEA
Executive recommendations for Licence Committee
None
Areas not covered on this inspection
Protection of children arrangements (for patients under 18yrs) Donor selection Egg sharing and surrogacy

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
In order to meet the requirements of the EUTD, funding has been granted by the University of Aberdeen and NHS Grampian Board so that the premises can be refurbished. It is planned that the refurbishment will take place from January 2007 to June 2007. Extensive plans for the redevelopment of the unit were presented to the inspectorate. Key changes are that the patient recovery area will be extended to provide 6 recovery bays with a permanent nursing station and an extra procedure room will be built to accommodate embryo transfer and intra-uterine procedures. An air system will be fitted which will provide positive air pressure and grade C quality air.
Areas of firm compliance
The inspectorate considered that the premises are fit for purpose. According to the Quality Manager, each room in the premises has been assessed for security, privacy and confidentiality. A protocol for centre security has been developed. Key pieces of laboratory equipment were seen to be serviced regularly. A data logging system is used which monitors conditions in incubators as well as temperature of hot blocks and heated stages. Appropriate warning signs relating to the dangers of liquid nitrogen are in place on the door of the cryostore.
Areas for improvement
All storage dewars were seen to be fitted with alarms, however it was noted that one dewar alarm was not plugged in to the power supply. This was corrected during the inspection. The same dewar is not currently connected to the autodialler system. This is non-compliance with CH (04)03. During the interview with the counsellor, the door to the room opened three times on its own accord. Although it was noted that this did not normally occur, it was suggested that this should be repaired by the maintenance department as it could disturb the privacy of patient counselling sessions.
Executive recommendations for Licence Committee
To note non compliance with CH (04)03.

Areas not covered on this inspection
Prevention of incidents/ accidents The crash trolley for the unit is stored in the Maternity Unit on the ground floor and the equipment was not checked during this inspection.

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
Sixteen patient records were reviewed by the inspectorate. Discrepancies were noted in records belonging to patients undergoing donor insemination cycles in the Fertility Clinic. Consent to disclosure forms had not been completed by patients and a number of gaps in witnessing documentation were noted. Records maintained for patients attending the Assisted Reproduction Unit were deemed to be thorough and contained all required consent forms. One inconsistency was noted on a HFEA (00)6 form, the PR plans to resolve this before the patient attends for further treatment. The last operational audit occurred on the 12th and 13th of April 2005. It was not selected for a visit in 2006 as it was considered to be medium risk by the Audit team.
Self Assessment
The Self Assessment document was returned to the HFEA within the required time scale. It was completed in detail and the PR indicated that he had evidence of compliance for all five sections. For 27 of the 29 standards requiring assessment the PR considered that no improvements were required. The PR noted that some improvements were needed to satisfy two standards.
Areas of firm compliance
Records are stored in paper copy and on an electronic database system. The Quality Manager stated that the database is password protected and that information is backed up on the NHS Grampian central server overnight. It is centre policy to archive patient records after five years. The PR stated that a Service Level Agreement (SLA) exists between the hospital and the off-site company responsible for archiving the records. Documents produced within the centre are subjected to a document control system which was designed to meet ISO 9001:2000. All documents requiring changes are stored in a specific database. This was evidenced during the inspection and it indicated what changes were made to documents and when the documents were revised. In addition to the documents stored on the centre database, a folder of control documents is maintained by the Quality Manager and can be accessed by all staff. These folders were seen to be available in the laboratory, offices and treatment rooms.

Staff interviewed during the inspection appeared to have a clear understanding of the incident alert system. The PR receives the alerts via email from the HFEA and circulates these to the entire team electronically.

Two patients interviewed during the inspection stated that they were provided with information verbally and that this was then backed up by written information. They also stated that the various consent forms were well explained and that they felt satisfied with the information provided.

It is the centre's policy to send copies of the stimulation protocol to each patient's GP. In addition patients are provided with letters explaining what treatment that they have undergone. These can be provided to other hospital staff in case of emergencies. Patients interviewed during the inspection confirmed that they were provided with emergency contact details for centre staff.

The HFEA Register are satisfied with the information provided by the Centre.

Areas for improvement
Consent to disclosure forms are not currently completed for patients attending the Fertility Clinic for donor insemination. The nurses plan to develop consent to disclosure forms and ensure that all patients attending for DI complete these forms. The PR should review Code of Practice part 11.10 iii and 12.2 for further information.

Executive recommendations for Licence Committee
None

Areas not covered on this inspection
Protocols

Evaluation
Some improvements needed

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
NMC registered nurses	10
HPC registered scientists	2
Scientists working towards registration	3
Support staff (receptionists, record managers, quality and risk managers etc)	5.3

Summary of laboratory audit
The laboratory carried out an audit of stored gametes and embryos between January-August 2006. According to the Senior Embryologist, no discrepancies were recorded.
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 was also carried out within the andrology department: one sample was tracked from tank to notes. No discrepancies were noted.
Areas of firm compliance
Regular audits are carried out on elements of the centre's service. The PR provided evidence that 13 such audits have been carried out so far this year. The audits have included an assessment of embryo cleavage checks, disposal of sperm samples and Clomid consultations. All staff interviewed expressed satisfaction with the provision for Continuing Professional Development (CPD). Evidence of CPD for members of staff in all departments was provided to the inspectorate: in the last year four members of staff were supported to attend the European Society of Human Reproduction and Embryology (ESHRE) annual meeting, 3 nurses provided with funds to attend the British Fertility Society conference and one nurse supported to attend the American Society for Reproductive Medicine (ASRM) conference.

The PR has planned that further training will take place whilst the centre is shut down for refurbishment. For example; the accounts administrator stated that she plans to use the time to visit the University to increase her knowledge of billing systems.

Annual appraisal sessions are held for all members of staff. Information gained during these sessions are stored within the staff training files and used for training needs analysis. Training records for the medical and nursing staff were examined and considered to be thorough and detailed.

Retention of staff does not appear to be a concern for the PR; many members of staff have worked at the centre for a number of years and a number of those interviewed expressed their satisfaction with the stability of the team.

Areas for improvement

During the review of patient records it was noted that a number of witnessing steps required for the preparation of semen for donor insemination procedures were not completed consistently. When questioned regarding this the fertility nurses explained that these gaps were a result of problems with witnessing at the weekends. The PR must ensure compliance with Directions D2004/4.

Mouth pipetting is still employed as a technique for manipulation of gametes and embryos by one member of the laboratory team. This contravenes the Association of Clinical Embryologist (ACE) Accreditation Standards and Guidelines for IVF laboratories, Appendix 1, Section 3.3, which states that mouth pipettes must not be used for manipulating human gametes and embryos. The PR should ensure that suitable practices are used in the course of HFEA licensed activities (Code of Practice part 1.4iv).

The Quality Manual delineates the actions to be taken if discrepancies are noted during the annual storage audit. However, the guidance does not include what actions should be taken with respect to the patients concerned. It was suggested that this information should be developed to include this requirement.

Executive recommendations for Licence Committee

To note non-compliance with Directions D2004/4.

To require compliance with the ACE Accreditation Standards and Guidelines for IVF laboratories on the basis of Code of Practice part 1.4 iv.

Areas not covered on this inspection

PGD/ PGS

Recruitment practices: Registration numbers for staff not checked

Evaluation

Some improvements needed.

Report compiled by:

Name…Sarah Hopper………………………………………………………….

Designation…Inspector………………………………………………….

Date………12th October 2006……………………………………………………

Appendix A: Centre Staff interviewed

Dr Mark Hamilton (PR)
Mrs Alison McTavish (NL)
8 other members of staff

Appendix B: Licence history for previous 3 years

Licensing History

Centre: Assisted Reproduction Unit, University of Aberdeen

Number: 0019

2005

Licence Committee 12th October 2005

The Committee noted the progress made by the centre and agreed that the centre's licence should continue with no additional conditions.

Inspection 29th June 2005

Licence Committee 28th April 2005

Following an application by the centre to have their licence varied so as to remove the condition, LC agreed to have the condition removed.

Licence Committee 20th January 2005

Licence Committee agreed to renew the centres licence for three years with one additional condition.

- The centre must carry out a full audit of stored embryos and sperm, including consents, focusing on problems bought to light in the examination of the patient records carried out by the inspection team. The Committee suggests that the centre may wish to bring an external embryologist or andrologist to help them with this task, and that the results from the audit be submitted to the Executive within six months from the date of the Committee meeting.

2004

Licence Committee 23rd June 2004

Licence Committee agreed to grant a variation to the centres licence to recognise a new person, Dr Mark Hamilton

2003

Licence Committee - 5th September 2003

The Licence Committee agreed to continue the Centre's licence with three additional conditions.

Licence Committee - 24th June 2003

The Licence Committee agreed to grant a variation tio the Centres Licence in order to carry out a trial to compare two different freezing solutions for the cryo-preservation of human embryos. The Committee agreed to grant the variation with one additional condition.

Inspection visit -10th June 2003

Licence Committee - 29th January 2003

The Licence Committee discussed the Centre's application to carry out a clinical freezing trial to compare two different freezing solutions for the cryo-preservation of human embryos. The Committee agreed that the Centre should be asked to provide evidence (animal or human) which demonstrates that the use of a freezing solution containing 0.3M sucrose will not in any way compromise embryo survival rates.

2002

Licence Committee - 25th September 2002

The Committee agreed to grant the renewal of research project R0118 for the period of one year.

Licence Committee - 29th July 2002

The Committee agreed to grant a temporary licence for the research project R0118 until the 30th November 2002.

Appendix C:

RESPONSE OF PERSON RESPONSIBLE TO THE INSPECTION REPORT

Centre Number 0019

Name of PR MARK HAMILTON

Date of Inspection 11TH OCTOBER 2006

Date of Response 12TH DECEMBER 2006

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

Page 7: The remaining storage dewar is connected to the local alarm system. The dewars as you know will be moving to new premises during our upgrade work and all will be connected to the auto dialler system at that point. The expense and upheaval to connect the outstanding dewar at this point we have felt was unjustified for the purposes of only a few weeks. The risk assessment on this suggested that current arrangements were satisfactory with the regular assessment of the dewar level of N2 in place at present and the daily presence of staff in the premises.

Page 8: We have installed consent to disclosure forms for the DI patients.

Page 8: The complaints procedure is revised as requested, although this is as we said at the time a change from a previous inspection recommendation.

Page 12: DI success rates. Our in house records suggest that in the year to March 2006 our LBR/Ongoing pregnancy rate per cycle is 9.02%. We will continue to monitor this.

Page 13: I note the responsibility to have records secure.

Page 15: The door of the counselling room will be attended to.

Page 17: The patient concerned with respect to the (00)6 form has been contacted.

Page 20: The Andrology lab response to the queries re witnessing procedures for DI cycles.

After looking at the HFEA comments, staff have checked the patient notes to determine the specific witness failures, they reviewed the requirements of the Code of Practice and compared this with the OP for IUI sample preparation.

- Specific witness failures

Patient number	Witnessing failure noted
0557035	Transfer of pellet to media
1372464	Transfer of pellet to media Delivery of sample to clinic
1194374	Sample and tube labelling Transfer of sample to gradient Transfer of sample to pellet

	Delivery of sample to clinic
1127268	Transfer of sample to gradient Transfer of sample to pellet Delivery of sample to clinic

· Requirements of the Code of Practice

Directions D2004/4 state:

2 Sperm Collection
a) Ask the male partner to identify himself (name and date of birth).
b) An appropriate person must witness that the patient's details correspond with the details written on the sample container and all corresponding paperwork.
c) Where patients have similar names a unique patient identifier must be used

3 Sperm Preparation
a) Identifying information marked on all tubes must be cross-referenced to the male partner and all corresponding documentation by the embryologist / andrologist and another appropriate person (preferably a second embryologist / andrologist).
b) Where patients have similar names a unique patient identifier must be used
c) Centres must avoid having more than one unprocessed sample on the bench at any one time.

· Witnessing steps on our record sheet for IUI sample preparation

The IUI preparation record sheet includes 5 steps:

1. Acceptance of fresh or frozen samples
2. Labelling of all tubes to be used in the sample preparation
3. Transfer of the sample to the preparation gradient
4. Transfer of the pellet to the media
5. Delivery of the sample to the nursing team who undertake the insemination.

· Comment

Comparison of the Code of Practice and the witnessing aims of the Centre OP for IUI preparation reveal different aims in the witnessing process.

The Code of practice aims to ensure that patients are correctly identified, that all the laboratory ware used in the preparation of a sample is clearly and correctly labelled, and that all corresponding paperwork is correct.

When the Centre IUI preparation OP was updated to include witnessing, the requirements of the Code of Practice were included, but staff also decided that they would aim for a higher standard by including all steps where the sample is transferred from one tube to another.

The one occasion where sample and tube labelling was not witnessed was a breach of the Code and all staff have been advised that they must ensure that this is checked for all preparations.

The rest of the discrepancies listed above fall into the category of the additional steps. While staff aim to have every step witnessed, this has proved to be very difficult at weekends when staffing levels are at a minimum. Step 5 will be easy to improve. It was probably the result of a distraction at the time of accepting the sample that resulted in a failure to sign the form, as the Andrologist gives samples to the nursing staff in person. Steps 2 and 3 are more difficult to achieve as the processor cannot leave the step to wait for a witness to be available as this would compromise the quality of the sample. We will continue to explore areas of improving this part of the process as we consider it to be best practice.

Page 20: Mouth pipetting has ceased.

Page 20: At the next review of our Quality Manual we will incorporate remarks on communication with patients in the aftermath of laboratory audit discovery of storage discrepancies.

The impression gained at the time of the inspection was that the inspectorate were enthusiastic about the standard of service offered within the Unit. As ever the tone of the HFEA inspection report is at best restrained and lukewarm. We do not seek undue praise where not required but HFEA inspection reports could perhaps enthuse staff inspected a little more. The 3 categories of summative evaluation I would imagine leave most units in the 2nd category, within which there will be a spectrum of units with excellent qualities and others with adequate service only. The evaluation reports certainly when examined in the public domain, where most often the summary section is all that will be looked at, may give little help to the public in determining differences in quality of service in different units.

Thanks again for coming up.

MH

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

Signed

Name MARK HAMILTON

Date 12.12.06

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).

Nil

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