Interim Inspection Report

Salisbury Fertility Centre
0197

Date of Inspection: 23rd January 2007
Date of Licence Committee: 21st March 2007

TRIM: 06/5619

CENTRE DETAILS

Centre Address	Salisbury District Hospital Odstock Road Salisbury SP2 8BJ
Telephone Number	
Type of Inspection	Interim Inspection
Person Responsible	Mr Shaun Fountain
Nominal Licensee	Mr David Quayle
Licence Number	L0197-7-a
Inspector(s)	Tony Knox
	Elliot Lawrence
	Parvez Qureshi
Fee Paid - date	
Licence expiry date	30th April 2011

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About the Inspection:
This inspection visit was carried out on 23rd January 2007 and lasted for 7 hours. The report covers the pre-inspection analysis, the visit and information received between January 2006 and January 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

Salisbury Fertility Centre was first established as a licensed treatment unit in 2002. In the summer of 2004 the Salisbury Health Care NHS Trust took control of the Salisbury Fertility Clinic Ltd., which had run the service since its inception.

The centre can offer a maximum of 18 treatment cycles per month. This is an increase on the numbers of cycles previously reported in inspection reports. This has been primarily due to the centre winning NHS contracts for Wiltshire and Hampshire. In addition, some patient referrals are made from Primary Care Trusts (PCT's) in the Dorset area.

To accommodate the additional numbers of treatment cycles, staffing levels within the unit have been increased accordingly.

The centre has a good history of regulatory compliance.

During the course of the inspection, the inspectorate were provided with a copy of the proposed plans for the new site for the fertility unit. In addition, the inspectorate was given a copy of the "Project Initiation Document" detailing the steps to be taken for the change in on site premises. Mr David Quayle (Nominal Licensee) and Mr Frank Harsent (Chief Executive of the Trust) stated that work should begin around Easter with completion of the new unit around July 2007.

Activities of the Centre

Licensed treatment cycles	IVF ICSI FET Egg Sharing Egg Donation	48 37 39 12 3
Donor Insemination		8
Unlicensed treatments		GIFT IUI ZIFT Host Surrogacy
Research		None
Storage		YES

Summary for Licence Committee

The centre has a good history of regulatory compliance. The inspectorate would recommend the continuance of the centre licence with no additional conditions.

The PR is aware of their requirement to update the HFEA on any developments regarding the proposed move of premises.

Risk Assessment

Prior to the inspection being conducted, the centre had been awarded a risk score of 16%.

Following the inspection, the centre was re-assessed with a risk score of 5%. This takes into consideration the removal of a previously applied license condition.

Overall judgement of the effectiveness of the centre

No Improvements required	Some Improvement required	Significant Improvement required
	X	

Evaluations from the inspection

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

Breaches of the Act or Code of Practice

Breach	Action required	Time scale
None		

Non-Compliance

Area for improvement	Action required	Time scale
The quarantine dewar within the laboratory should be individually alarmed and linked to an autodial facility. (It was witnessed during the inspection that there were no samples currently stored within the dewar and the PR informed the inspectorate that an alarm had been ordered).	No samples should be stored in the quarantine dewar until an alarm has been fitted and commissioned. PR/senior embryologist to inform HFEA upon its commissioning.	After commissioning alarm on the quarantine dewar.

Recommendations	Time scale
Centre training and induction programme to be documented which is centre specific.	ASAP
Formal contingency arrangements to be developed and documented with fertility unit in Exeter.	3 Months

Proposed licence variations

None proposed.

Changes/ improvements since last inspection

Recommendation	Action taken
None	

Additional licence conditions and actions taken by centre since last inspection

C	None
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 found the centre to be well organised and appropriately staffed for the numbers of treatment cycles being performed within the unit. It was noted that there had been one incident at the centre since the last inspection. This had been reported within the required timeframe and had been resolved. Mr Frank Harsent (Trust Chief Executive) and Mr David Quayle (Nominal Licensee) presented the inspectorate with an updated copy of the Hospitals "Project Initiation Document" dated December 2006 and a copy of the plans for the proposed new clinic site. This document notes the progress being made with processing plans for the proposed move of unit. Clinical governance and risk management are conducted in line with the Trust policies and procedures. There were no reported problems noted from the HFEA Finance Department with regards the payments of treatment fees.
Areas for improvement
Contingency arrangements were not formally documented although the PR stated that links with the Fertility Unit in Exeter had been verbally made.
Executive recommendations for Licence Committee
None
Areas not covered on this inspection
All areas covered

Evaluation
Some improvement 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
Data and graphs produced by the HFEA show only FET in the age group 35-37 fall below the national average statistics. OHSS rates for the unit are shown as 0.23% which is not considered to be significant.
Areas of firm compliance
Evidence of "Welfare of the Child" assessments being conducted was seen in the ten sets of notes audited during the course of the inspection, and was further evidenced by the HFEA audit Department during their inspection of the centres notes on 16th January 2007, where a further 20 sets of notes were checked. All patients' records are held within locked filing cabinets within the nursing office. This area is secured by key pad lock with codes known by authorised members of staff only. Computerised records held on the IDEAS database are password controlled with access only to authorised personnel only within the unit. Patient information clearly explains all treatment options available to them. This is further discussed during consultation. Every effort is made to ensure that all patients are treated with dignity and respect. This is reflected in the patient questionnaires returned to the HFEA. All responses received from the patient questionnaires indicated a high degree of trust in the unit staff, noted the staff professionalism and that the services offered to them were fully explained. All patients interviewed during the inspection commented on the professionalism of the staff and the high quality of service they had received during their treatment at the centre. Counselling facilities were inspected and were considered to be suitable for purpose by the inspectorate. Patient information clearly explains that two sessions with the independent counsellor are provided free of charge for those who would like to take advantage of the service. It was explained by the counsellor that counselling notes are taken home with her

and locked away securely there.
Areas for improvement
None
Executive recommendations for Licence Committee
None
Areas not covered on this inspection
Donor selection – Sperm donors are not recruited at this centre. Egg sharing and Surrogacy Protection of Children Policies.

Evaluation
No improvements required.

3. Premises and Equipment

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

Summary of findings from inspection:

- Suitable premises
- Storage facilities for embryos and gametes
- Safe equipment, servicing and maintenance
- Prevention of incidents/ accidents

Areas of firm compliance
There have been no changes in premises since the last inspection. It was noted that the unit is housed within the Obstetrics and Gynaecology building, and shares facilities such as the waiting room treatment room, scan room and male production room with the other Departments. It was however noted that these rooms are booked in advance for the use of the fertility unit. During the inspection, the Chief Executive for the Trust and the Nominal Licensee presented plans and other documents detailing a proposal for moving the fertility unit to another part of the hospital. It was explained that the new site (within the main hospital) would ensure that the fertility unit could be self contained, thus providing better facilities for the patients. The proposed site is also closer to the day surgery unit where the patients currently undergo surgical egg retrieval. All storage dewars are held within the embryology laboratory which is secured by keypad lock. All dewars themselves were locked individually. An autodial system is in place and appropriate emergency call out procedures were in place to respond to damaged vessels. All dewars (with the exception of the quarantine dewar) were seen to be fitted with low liquid nitrogen level alarms. A low oxygen alarm was in place within the laboratory. Maintenance and servicing logs for all critical equipment was evidenced by the inspectorate showing that all required checks had been performed. The centre has reported one incident since the last inspection which has been subsequently resolved.
Areas for improvement
All storage dewars should be individually alarmed and linked to an autodial facility.
Executive recommendations for Licence Committee
Whilst it was reported by the senior embryologist that the quarantine dewar within the laboratory did not contain any samples, the inspectorate noted that it should nevertheless be individually alarmed in accordance with Directives. The PR informed the inspectorate that an alarm had been ordered for this dewar and that they were awaiting delivery.

Areas not covered on this inspection
All areas covered.

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
An audit was conducted by the HFEA internal Audit Department on 16th January 2007. Twenty sets of patient records were examined and all were found to contain appropriate consents and welfare of the child arrangements within them. A further ten sets of patient records were examined during the course of the inspection. No discrepancies were found.
Areas of firm compliance
The centre uses the EDI system for registering patients' information directly with the HFEA. The Registry Department at the HFEA reported that all information provided from the centre was up to date. Patient records are stored alphabetically in locked storage cabinets within a locked room. The patient records inspected were found to be complete and well ordered. Policies and procedures are held on computer. Access to the records is password protected and accessible to authorised personnel only. Patient information reviewed prior to the inspection was found to be written in a clear and understandable format.
Areas for improvement
Nursing procedures are currently being developed at the centre. It was noted that these were not currently version controlled or in a format consistent with other procedures already documented. It was agreed by the PR that all policies should be version controlled, contain details of the author and have a version number assigned to them.
Executive recommendations for Licence Committee
None
Areas not covered on this inspection
All areas covered

Evaluation
Some improvements 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
- 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	3
HPC registered scientists	3
Scientists working towards registration	0
Support staff (receptionists, record managers, quality and risk managers etc)	1 x Independent counsellor and 1 x administrator

Summary of laboratory audit
The last audit was conducted for the period 21/12/05 – 1/3/06. The errors reported were: - • 1 x sample had not been moved to another dewar during the splitting of samples exercise. This was corrected. • 8 x patients' samples recorded different numbers of straws stored against the documentation. These were reported as being administrative errors and were amended accordingly. • 1 x sample had been thawed prior to frozen embryo transfer (FET) but the records had not been amended to reflect this. This was later amended in the records. • Some typing errors had been made on the IDEAS database. These were corrected during the audit.
Summary of spot check of stored material
A sperm sample was tracked from records to dewar and one sample was tracked from dewar to records. No discrepancies were found.
Areas of firm compliance
The inspectorate was informed by the PR that all recruitment, reference checking, CRB checks and confirmation of registration is undertaken by the Trust Human Resource Department in accordance with Trust Policy. A list of all staff currently employed at the centre including registration numbers was provided during the inspection.

All staff interviewed commented on the close working relationship they had with their colleagues, that they felt well supported by the senior management and in their CPD despite there being limited funds available for this.

All patients and donors are assessed using information provided via referral letter, during discussions at consultation and in the taking of a relevant medical history. Patients receiving funded treatment have an additional checklist completed regarding the criteria for eligibility under the contract. These were evidenced in the patient notes.

The senior embryologist reported that air quality measurements had been taken for the laboratory and the embryo transfer room. It was reported that sample manipulation was performed within a Class II hood at Grade A, whilst background air measurements obtained show Grade D. This is in compliance with the EU Tissue and Cells Directive. Egg collections are performed in the "Day Surgery" unit. It was reported that all egg collections are performed in a laminar flow theatre ordinarily used for orthopaedic cases. An anaesthetist is on site for all operative procedures.

Areas for improvement

It was noted by the scientific inspector that all witnessing was being carried out in accordance with the witnessing directive. A witnessing check sheet is in place covering all witnessing steps. The witnessing step for sperm thawing was seen to require only a tick as evidence of checking. It was recommended that this be amended on the form to require a signature instead. This was agreed with the senior embryologists and the PR.

Recommendation was made to provide all staff with a training folder to include all evidence of training courses attended and CPD. This was agreed with the PR.

There is currently no formal centre induction programme for new staff. It was recommended that a centre specific policy be documented for new staff to follow, which should include details of competencies to be achieved and a record of when these have been achieved. It was further recommended that a suitably qualified member of staff should sign the record once the person has been assessed as competent. This was agreed with the PR.

Executive recommendations for Licence Committee

None

Areas not covered on this inspection

PGD/PGS are not performed at the centre.

Evaluation

Some improvements required.

Report compiled by:

Name	TONY KNOX
Designation	Inspector
Date	25th January 2007

Appendix A: Centre Staff interviewed

Mr Shaun Fountain – PR
Four other centre staff

Appendix B: Licence history for previous 3 years

2006

Licence Committee 9th March 2006

The Committee agreed to renew the centres licence for a period of 5 years, and agreed to vary the centres licence to include ZIFT and the storage of eggs. The condition placed on their licence at the previous inspection had been complied with. This was removed with no additional conditions recommended.

2005

Licence Committee 10th March 2005

The Committee agreed to renew the centre's licence for 12 months with one condition

Renewal Inspection visit 24th January

2004

Licence Committee 25th October

The Committee agreed to defer consideration of the inspection report to allow the Executive to carry out further interviews with staff following the moves by the centre's host NHS Trust to take over the operation of the centre from the private company originally set up to do so.
The Committee agreed to grant a three month temporary licence under the same conditions as that granted in September 2003

Renewal Inspection visit 18th May

Appendix C:

RESPONSE OF PERSON RESPONSIBLE TO THE INSPECTION REPORT

Centre Number 0197

Name of PR Shaun Fountain

Date of Inspection 23 Jan 07

Date of Response 19 Feb 07

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

To issue all staff with CPD folders asap.
To formally agree contingency arrangement with Exeter IVF unit by end of March 07.
To set up induction programme which is centre specific by end of March 07.
To commission alarm on quarantine dewar before using – within 3 months.
Ensure all policies are version controlled – asap.
Amend witnessing form for sperm thawing – within 2 months.

(Comments copied from PRs submitted handwritten comments).

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

Signed……

Name……

Date 19 Feb 07

2. Correction of factual inaccuracies

Please let us know of any factual corrections that you believe need to be made (NB we will make any alterations to the report where there are factual inaccuracies. Any other comments about the inspection report will be appended to the report).

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

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