# New Premises Site Visit Report

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|---|---|
| Name of Applicant | Salisbury Fertility Centre |
| Address of Proposed Premises | Salisbury District Hospital<br>Salisbury<br>Wiltshire SP2 8BJ |
| Has the applicant been licensed before | YES |
| If yes:<br>Centre Number and Address of previous premises | 0197<br><br>The centre is moving to additional space within the same hospital. As such, the unit will not be changing address. |
| Inspector(s) | Tony Knox |
| | Sarah Hopper |
| Date of visit | 7th August 2007 |
| Date of any previous visits to these premises | 23rd January 2007 |

## About the Site Visit

The purpose of the site visit report is to confirm to the PR the findings of the inspection highlighting areas of firm compliance and good practice, as well as areas where further improvement is required. The report may be shared with other regulators on a need to know basis, such as the HC and HTA.

## Brief Description of the Centre

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.

Patients are referred from the Wiltshire, Hampshire and Dorset Primary Care Trusts. Winning contracts to provide licensed treatments for these areas necessitated an increase in staff numbers, which was accommodated, and a greater need for space as the unit is currently housed within the Obstetrics and Gynaecology Department building of the hospital and therefore shares the facilities with non-fertility related patients.

The unit was last inspected in January 2007 (interim inspection), at which proposals for developing a purpose built fertility centre were discussed and a timeline specified for the proposed move to the new location by September 2007. This was included in the report sent to Licence Committee 21st March 2007. At that Licence Committee, a continuance of license was approved with no conditions. The risk assessment for the centre is calculated at 5% thereby showing a low risk centre.

The centre has a good history of Regulatory compliance.

## Summing up meeting notes

Pending successful completion of works detailed within this report and approval from the Fire Officer the HFEA inspection team would support the move of the centre and to the continuance of the centres existing licence.

In addition, having noted the security measures already installed for the area denoted to contain patient notes, the inspectorate would approve the request from the centre to transfer patient notes to the new centre prior to the equipment move pending authorisation for the continuance of this project by Licence Committee.

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 of: *(Delete areas not reporting on)*

- Leadership and management
- Organisation of the centre
- Resource management
- Risk management
- Incident Management
- Contingency arrangements
- Business planning
- Clinical governance
- Knowledge of the legal requirements and COP

| Summary of Findings |
|---|
| There will be no changes to the leadership, management or organisational structure of the unit.<br><br>Resource management remains unaltered and was considered suitable for the numbers of treatment cycles performed at the centre during the January 2007 inspection.<br><br>Risk management, incident management, business planning, clinical governance and knowledge of the legal requirements and Code of Practice remain unaltered since the centres' inspection in January 2007 where they were considered fit for purpose.<br><br>During the inspection in January 2007, it was recommended that a formal documented contingency service level agreement (SLA) should be put into place. This was evidenced during the inspection. |
| Areas for improvement |
| None |
| Points to consider/action for next inspection |
| None |

## 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: *(Delete areas not being reported on)*

- 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)

| Summary of Findings |
|---|
| Aspects such as live birth rates, 'Welfare of the Child' arrangements, choice of treatments, complaint handling, patient feedback and satisfaction, donor selection, egg sharing and surrogacy and protection of children arrangements were all covered during the centres' interim inspection in January 2007 and were considered fit for purpose. These remain un-altered. |
| **Highlighted areas of firm compliance** |
| Patient records will be transferred from their existing site to the office located behind the main reception desk. Centre staff explained that lockable units will be provided to store these records and that access into the room will be fitted with additional security to ensure that access is limited to authorised personnel only.<br><br>A quiet room has been provided close to treatment room where patients may be taken to discuss elements of their treatment in privacy prior to the treatment being performed.<br><br>A counselling room has been provided in the new unit in close proximity to the main waiting room. It was explained that this unit would be furnished with a couple of comfortable chairs and a sofa to provide a suitable environment for counselling sessions to be performed. It was further explained that when not in use by the counsellor, this room could also be used by staff for breaks. There will be no alteration in the service provided to patients for counselling, which were considered fit for purpose at the inspection performed in January 2007. |
| **Areas for improvement** |
| None |
| **Points to consider/action for next inspection** |
| None |

## 3. Premises and Equipment

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

Summary of findings from inspection: *(Delete areas not being reported on)*

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

| Summary of Findings |
| --- |
| The newly developed area consists of the following: -<br>A waiting room with hatch through to the receptionist area. All patients will be required to report to this desk upon arrival at the unit. From the waiting room, a door leads into a corridor containing a counselling room, administration office where patient notes will be stored, an examination/consulting room, patient toilet (with disabled access) and a staff changing room. Further along the corridor is a store room, treatment room (IUI and embryo transfers will be conducted here), a quiet room (which can be used to speak to patient prior to their embryo transfer, a second consulting room and an office. A security door leads into a small corridor with an embryology office and a further door leading into the embryology laboratory. A hatch is in place within the embryology laboratory leading into the treatment room for the purpose of passing loaded catheters through. A dewar store is accessed from the furthest end of the embryology laboratory. This area is also equipped with a hatch, but this provides access to the male producing room next door.<br><br>A courtyard outside the unit has been made available for the storage of gases, which will be piped into the embryology laboratory, and top up store of liquid nitrogen. The embryologist explained that the gases and liquid nitrogen within this area will be contained in cages for additional security.<br><br>Staff explained that scanning would continue to be performed in its current location until a new scanning machine can be purchased. It was explained by the Project Manager that a request for capital approval had been made to purchase a scanning machine and staff were awaiting a decision from the Trust.<br><br>Processes for the prevention of incidents/accidents are in place and was considered fit for purpose at the inspection conducted in January 2007. |
| Highlighted areas of firm compliance |
| A detailed timetable is in place to cover the centre move. This includes the provision of a "deep clean" of the laboratory and treatment room in week commencing 13th August 2007 followed by the transfer, validation, calibration and testing of all equipment.<br><br>An inspection of the facility had been scheduled for 13th August by the Fire Officer to ensure access/egress points were satisfactory.<br><br>Air quality testing is scheduled to be performed week commencing 20th August 2007. |

It was noted that office where notes will be stored had been fitted with a keypad security locking system. It was explained that an access code would be programmed and only authorised members of staff would be provided with this access code. Centre staff stated that upon authorisation by Licence Committee, they would like to move the patient notes to this area in advance of the remaining equipment move.

Areas for improvement

At the time of the inspection, not all security locks had been installed. It was explained that this work was ongoing and would be completed prior to equipment being moved from its current location. It was further explained by the Project Manager that a proximity card security system was being purchased which would allow staff security cards to be programmed with varying access levels for increased security purposes.

Recommendation was made to ensure that means of raising an audible alarm are introduced to the treatment room, consulting rooms and the producing room.

At the time of the inspection, the low oxygen alarm had not been installed within the area designated as a dewar store. It was recommended that this alarm be installed to ensure that its alarm is audible to the embryologists as well as to other centre staff in order that emergency procedures can be initiated. As the dewar store is also positioned next to the producing room, it was further recommended that all patients using this room be warned beforehand of the actions they would need to take in the event of an alarm sounding.

Recommendation was made to purchase signs for the new area including vacant/engaged signs for areas such as consulting rooms, counselling room, producing room and treatment room, and that appropriate health and safety warning signs are purchased and installed to warn people of the proximity of liquid nitrogen.

Points to consider/action for next inspection

None

The standard of the premises and equipment

The premises provide suitable space to conduct licensed treatment in. At the time of the inspection, not all security measures were in place and the alarm system for the dewar storage area was awaiting installation. Recommendation was made to extend the nurse call system in the disabled toilet (if possible) to the consulting rooms, treatment room and to the producing room. Once these issues have been resolved, and the unit has received a satisfactory report t from the fire office, the executive would recommend the centre transfer.

The equipment to be used within this area will be transferred from the existing space occupied by the centre. This equipment has been seen during previous inspections and has been considered on each inspection to be fit for purpose.

## 4. Information

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

Summary of findings from inspection: *(Delete areas not being reported on)*

- Information management
- Information to patients and donors
- Information to the HFEA
- Protocols
- Record keeping (including consents)

| Summary of Findings |
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| Information management, information to the HFEA and record keeping processes and procedures will remain unaltered. These were inspected in January 2007 and were considered fit for purpose.<br><br>Some of the information to patients and donors and protocols will require minor adjustments to ensure they accommodate the new premises. |
| **Outcome of audit of records** |
| No audit was performed. |
| **Highlighted areas of firm compliance** |
| See above. |
| **Areas for improvement** |
| Recommendation was made to amend the patient/donor information for men producing samples to include actions to be taken in the event that an alarm is sounded.<br><br>Recommendation was made to amend the security policies taking into consideration the new centre layout and any proposed change in practice necessary, and to ensure that all close down procedures are documented. |
| **Points to consider/action for next inspection** |
| Policy and procedure amendments as noted above. |
| **The standard of information provided** |
| Not applicable for this inspection. |

## 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: *(Delete areas not being reported on)*

- Assessment of patients and donors
- Safe handling systems
- Laboratory processes and practice
- Clinical practice
- PGD/ PGS
- Recruitment and retention of staff
- Staff competence, qualifications, training and CPD

| Summary of Findings |
|---|
| All processes mentioned above remain unaltered and were considered suitable for the number of treatment cycles performed at the centre during the interim inspection conducted in January 2007. |
| **Highlighted areas of firm compliance** |
| During the interim inspection in January 2007, the following recommendations were made: -<br>• A training and induction program to be devised. Evidence of a training and induction program was provided during the inspection to include general induction as well as a specific induction program produced for the move of the centre.<br>• All staff were requested to have a training folder. These have now been introduced. |
| **Areas for improvement** |
| Nursing procedures were noted in the last inspection as requiring version control. This is still being worked on by staff within the unit and it is anticipated that this will be completed soon.<br><br>Recommendation was made to alter the form for recording/witnessing the sperm-thawing step. The form was seen to have been modified slightly to incorporate this requirement, however could still lead to some misunderstanding for purposes of auditing. It was agreed that this form would again be reviewed. |
| **Points to consider/action for next inspection** |
| To review the changes to the witnessing form for sperm thawing, and to ensure that nursing policies and procedures have been version controlled. |
| **The provision and quality of staff** |
| There are no changes in staffing at the centre since the last inspection. |

**Topic 1**

(a) The applicant meets the requirements for **organisation**

**Topic 2**

(a) The applicant meets the requirements for **quality**

**Topic 3**

(b) The following actions need to be taken by the date shown before the applicant meets the requirements for **premises**

Action needed:

Inspection and report from the Fire Officer to detail that the centre meets with all requirements for fire safety.

All security locks to be correctly installed to ensure access to departments is restricted to authorised personnel only.

Expansion/introduction of audible alarm system to be incorporated into consulting rooms, treatment room and producing room.

Purchase and display of appropriate signage to indicate when rooms are in use, and to ensure correct health and safety warning signs are in situ to warn of the danger of liquid nitrogen within areas it is being stored.

Air quality within the treatment room and laboratory to be tested to ensure it meets with standards as set out in the EU Tissue and Cells Directive and Standards.

Upon confirmation from Licence Committee that a move of premises is agreed, that all equipment to be shut down, moved, re-installed appropriately, re-calibrated and monitored accordingly prior to commencing any further treatment cycles in the new area.
Upon confirmation of the move by Licence Committee 15th August 2007.

To be completed by: End August 2007

**Topic 4**

(b) The following actions need to be taken by the date shown before the applicant meets the requirements for **information**

Action needed:

Patient/donor information to be amended to reflect practices within the new area prior to commencing further treatment cycles there, and that all staff to be aware of the changes made.

To be completed by: End August 2007

**Topic 5**

(a) The applicant meets the requirements for **laboratory and clinical practices**

**Next Action**

The centre must ensure that: -

- All security measures are in place.
- Protocols and procedures are adjusted to ensure they take into account the new area.
- Either an extension of the existing nurse call system should be looked into or a new system to provide a means of calling for emergency assistance in the treatment room, consulting rooms and producing room.
- Low oxygen alarm, autodiallers and dewar alarms to be installed within the dewar store and to ensure that the alarm is audible to all staff and patients using the producing room.
- A satisfactory assessment and report of the centre to be provided by the Fire Officer.
- Pending successful completion of the above and agreement by Licence Committee for the centre to be moved, all validation and calibration of equipment to be completed prior to any further treatment cycles being commenced and air quality within the treatment room and laboratories to be tested and meet with required standard.

**Summary of findings for Licence Committee**
**(If final visit before Application considered by LC)**

Pending successful completion of works detailed within this report and approval from the Fire Officer the HFEA inspection team would support the move of the centre and to the continuance of the centres existing licence.

In addition, having noted the security measures already installed for the area denoted to contain patient notes, the inspectorate would approve the request from the centre to transfer patient notes prior to the new centre prior to the equipment move pending authorisation for the continuance of this project by Licence Committee.

## Appendix A: The inspection team and staff interviewed

### *The inspection team*

| | |
|---|---|
| Tony Knox | Chair, Inspector, HFEA |
| Sarah Hopper | Inspector, HFEA |

Report compiled by TONY KNOX

Signed

Designation Inspector

Date 8th August 2007

RESPONSE OF PERSON RESPONSIBLE TO THE SITE VISIT

Centre Number 0197

Name of PR Mr Shaun Fountain

Date of Inspection 7th August 2007

Date of Response 10th August 2007

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

Action already taken or planned:
To be completed by:

Inspection and report from the Fire Officer: details that the centre meets with all requirements for fire safety.
Visit has taken place and report will be sent to HFEA before 15th August 2007
Security locks are compatible with fire safety requirements even when locked with personnel working in the room

Security locks have been installed. Full description of security for the centre and for each room has been documented (copy enclosed).
Centre will check their function, set codes, give codes and keys to to authorised personnel, check authorised personnel list includes all people who may require access, check compatibility of security procedures with emergency procedures.
Documentation complete
Practical application and staff training by end August 2007

Existing audible alarm system has been extended to treatment room and producing room.
Consulting rooms do not require audible alarm (see justification from S Davies, Consultant)
End August 2007

Display appropriate signage to indicate when rooms are in use: consulting rooms, counselling room, production room, embryo transfer room.
Display appropriate signage to indicate action if alarms are heard: on lab door, dewar room door, inside production room.
Display correct health and safety warning signs are to warn of the danger of liquid nitrogen within areas it is being stored: dewar room, door to cage area, liquid nitrogen cage.
Display correct “authorised personnel only” signs: door from reception, door to lab and dewar room.
End August 2007

Test air quality within the treatment room and laboratory to be tested to ensure it meets with

standards as set out in the EU Tissue and Cells Directive and Standards: particle counts and settle plates
Equipment available from 24th August; formal testing in week commencing 27th August

Existing equipment to be shut down, moved, re-installed appropriately, re-calibrated and monitored according to details already provided.
Low oxygen control system to be tested and alarm system to be moved before dewars are moved.
Installation, commissioning and full testing of 2nd flow hood: operation similar to existing hood, but required complete testing of heated stage.
Upon confirmation of the move by Licence Committee 15th August 2007, and scheduled for week commencing 20th August.

Installation of 2nd flow hood scheduled for week commencing 27th August

Full induction of all staff into the procedures of the new centre, using training checklist which covers all details.
Staff training will be ongoing once the move starts, with documentation via the training checklist

Check and amend all patient and donor information to reflect practices within the new area.
End August 2007

Inform all patients with appointments or treatments from September of the new location using list held by Administrator
End August 2007

Update procedures for semen samples including warning the man of what to do if he should hear the low oxygen alarm from the adjacent dewar room
Done (copy enclosed)

Update procedures for embryo transfer to specify the arrangements for the door and the privacy curtain
Done (copy enclosed)

Low oxygen alarm, autodiallers and dewar alarms are installed within the dewar store: requires testing including ensuring that the alarm is audible to all staff and patients using the producing room.
Check fire alarm audibility, especially for lab staff when equipment is in operation. Warning to men as a sign in production room and also as a verbal instruction on each visit: incorporated into Semen Sample procedure. Patient handout to be prepared with all information about fire alarms and low oxygen alarms and what to do in the event of an emergency.

To be completed before dewars are moved (planned for 21st August)

All other details to be completed before end August

Version control of nursing procedures: incorporation of nursing procedures into Quality Management System continues. Version control is now in place.
Done – see Embryo transfer procedure for evidence

Update paperwork to capture the signature of the two people who always are present when sperm is thawed for use in treatment, separately at the time of taking from the dewar and at the time of preparation
This documentation was weak in our system although the procedure was robust. Updated – copy of new sheet to be sent to HFEA by post/fax

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

Signed……

Name……

Date……

2. Correction of factual inaccuracies

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

No inaccuracies seen. The report is an accurate record of the inspection visit.

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 this section of the report to:
Dr Marion Witton
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