Licence Interim Inspection Report

Sussex Downs Fertility Centre
The Esperance Hospital, Eastbourne 0015

Date of Inspection: 10th April 2008
Date of Licence Committee: 25th June 2008

CENTRE DETAILS

Centre Name	Sussex Downs Fertility Centre
Centre Number	0015
Licence Number	L0015-15-a
Centre Address	The Esperance Hospital, Hartington Place, Eastbourne, East Sussex BN21 3BG
Telephone Number	01323 410333
Type of Inspection	Interim
Person Responsible	Mr David Chui
Nominal Licensee	Mrs Susan Mulvey
Inspector(s)	Ellie Suthers, Andy Leonard, Janet Kirkland
Fee Paid – up-to-date	Fee paid
Licence expiry date	30th June 2012
NHS/Private/Both	NHS and Private

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About the Inspection:
This inspection visit was carried out on Thursday 10th of April 2008 and lasted for 6 hours. The report covers the pre-inspection analysis, the visit and information received since the last inspection.

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 licence renewal 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 makes 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 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.

NB: Where there are very minor issues to be addressed these are noted in the "minor issues to be addressed" section for each topic, and this will facilitate the evaluation of 'no improvements required'. Where recommendations are made the HFEA will provide details of what needs to be addressed but not how they should be carried out as this is the responsibility of the Person Responsible.

The report includes a response form for the Person Responsible to complete following the inspection.

The HFEA welcomes comments from patients and donors, past and present, on the quality of the service received. A questionnaire for patients can be found on the HFEA website www.hfea.gov.uk .

Brief Description of the Centre and Person Responsible

The Centre was first established in 1991 and offers a range of licensed treatment services. It is housed within the BMI Esperance Hospital in Eastbourne. It treats privately funded patients from the surrounding population in East Sussex (Hastings and Haywards Heath) and West Sussex (Brighton and Worthing) and provides 250 NHS funded treatments to the West Sussex PCT through a contract awarded to the centre since the last inspection.

It was estimated that the split between private and NHS funded patients is 50/50. Patients are generally referred by their GP.

The unit is open six days per week 8.30 – 16.30 Monday to Friday and 9.00 – 12.00pm Saturdays. Egg collections are performed mainly on Monday and Tuesday, although some are performed on Thursdays and Saturdays when required.

The last Healthcare Commission inspection was conducted on 19th November 2006. No recommendations for improvement for the Centre were made. The Centre achieved ISO 9000 certification in November 2006.

Dr David Chui is the Person Responsible for the Centre. He is registered with the GMC, is the accredited consultant and has completed the HFEA Person Responsible Entry Programme.

BMI Healthcare has recently been taken over by Netcare UK which has had some managerial impact on the Centre

Activities of the Centre

Activity: Number of treatment cycles initiated: (01/02/07 – 31/01/08) HFEA data*

Licensed treatment cycles	IVF ICSI FET (IVF+ICSI)	159 129 20
Donor Insemination		106
Unlicensed treatments		
Research	N/A	N/A
Storage	Yes	

*This data is supplied to the HFEA by individual clinics who are responsible for its accuracy and for verifying it. The data published by the HFEA on our website is a snapshot of the state of the Register at a particular time. The data in the Register may be subject to change as errors are notified to us by clinics, or picked up through our quality management systems."

Summary for Licence Committee

This is an interim inspection report for Sussex Downs Fertility Centre following an inspection of the Centre on the 10th of April 2008.
It was apparent on arrival at 9am that the staff were experiencing some difficulties that day:

- The web based appointment/scheduling system was not working so the staff were unaware of which service users would be arriving and when;
- The lead nurse was on unexpected leave;
- The Healthcare Assistant had recently left the employ of the Centre;
- The counsellor is on long term sick leave.

Despite all these difficulties the Centre had planned for the visit, had ensured all requested documentation was available to the inspection team. All members of staff were aware of the inspection and provided information and documentation when requested.

Following pre-inspection analysis and planning the inspection team decided to focus on:

- How the Centre is managing the increased activity;
- Resource management;
- Laboratory systems and processes including witnessing;
- Provision of counselling services;
- Recommendations from the last inspection.

The inspection team recommends the continuation of the Centre licence with no conditions.

Risk Assessment

Following the interim inspection on April 10th 2008 and with information and data available to the HFEA inspection team the risk score is assessed as 11%. This constitutes a low level risk status analysed by the HFEA Regulation Risk Assessment Tool Version 3.

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 Standard Licence Conditions or Code of Practice: The table below sets out matters which the inspection team considers may constitute breaches of the Act, Standard Licence Conditions and/or Code of Practice and their recommended improvement actions and timescales. The weight to be given to any breach of the Act, Standard Licence Conditions or Code of Practice is a matter for the Licence Committee

Breach	Action required	Time scale
Not all laboratory standard operating procedures (SOPs) were seen to be effectively document controlled. Documentation should include author, reviewer, date and review date. Some of the SOPs observed appeared to have not been reviewed within the last year. *(CoP S. 5.2.5 plus NOTE)*	All SOPs to have effective document control and be subject to regular review.	30th June 2008
The Centre has a protocol for responding to the low oxygen monitor. The protocol is not displayed on the outside of the cryostore door, nor are any hazard warning markings. The lack of warning of cryostore hazards and how to respond to them is a health and safety hazard to staff and other visitors to the centre *(CoP S.6.3.2)*	The PR should seek advice and a health and safety assessment should be carried out on the cryostore in order to identify any potential hazards to staff and/or visitors.	Immediate

Non-Compliance

Area for improvement	Action required	Time scale
The Centre is experiencing some difficulties with staff absence and frozen job vacancies. The PR and Fertility Services Manager (FSM) informed the inspectors that the host organisation has refused all requests for further recruitment; this policy remains for the foreseeable future. This position may be unsustainable. At the time of inspection the inspectors considered the workload to may be too high for the number of laboratory and clinical staff available. *(CoP S.6.2.1)*	A thorough risk assessment of centre activity given the personnel and equipment resources available should be conducted by the Centre. An action plan should be developed and any appropriate risk control measures implemented if this assessment indicates excessive risk at the current activity level. An assessment should be carried out by the Centre of how many cycles can be safely carried out given the available resources and ensure activity levels remain within these levels. A copy of the assessment should be submitted to the HFEA	August 30th 2008
The Esperance hospital has its own corporate system and questionnaires for patient satisfaction surveys which the Centre is obliged to use. Analysis of these questionnaires does not appear to provide sufficient information relating to user perception of the Centre as to whether the service has met their needs and requirements *(CoP S.9.2.1)*	The Centre should monitor information relating to user perception as to whether the service has met their needs and requirements. Records should be kept of the information collected and actions taken.	By the next inspection
The delivery of consumables into the laboratory is documented on a computer log but not the date when the box or container is opened and the contents are used. This may compromise the Centre's ability to demonstrate traceability.	The Centre shall establish documented procedures for management of equipment and materials that include traceability of any materials that come in contact with gametes or embryos. (CoP S.6.4.3 (d))	Immediate

Centre protocol ACU lab024 states that *all witnessing procedures signed for on the day of procedure.* *(CoP S. 7.8.15)*	The protocol should be amended to reflect that witnessing checks should be completed and recorded contemporaneously	Immediate

Recommendations	Time scale
Not all of the clinical/nursing staff competency assessments had been signed off in their training logs. This should be done in order to provide documented evidence of competency. *(CoP S.6.2.12)* S6.2.12 requires that a record of education and training including continuing professional development is maintained	By the next inspection

Proposed licence variations by last L.C.

None

Changes/ improvements since last inspection	**Action taken:**
Witnessing steps were not always recorded in accordance with Directions 2004/4.	Laboratory sheets have been amended to ensure that all steps are suitably witnessed. All staff have been advised that witnessing must now include date and time as well as signature
A formal contingency Service Level Agreement (SLA) must be documented to ensure continuance of service for patients should treatment services at the Centre be suspended for any reason.	A formal, documented and signed contingency SLA has been developed with; ➢ Brabourne Suite: BMI, The Chaucer Hospital ➢ ACU, BMI Chelsfield Park Hospital
Activity levels within the unit to be monitored, and staffing of the unit to be adjusted as necessary to cope with any increase in treatment cycles performed.	Ongoing – remains an area of concern. Please see section 1 of this report.
Complaints log to be modified to contain a more detailed account of how complaints are handled.	The complaints log was seen by the inspector to have been modified to include a more detailed account of complaints investigation and resolution
Consideration should be given to employing a second counsellor to act as backup for the existing counsellor. Again, this should take particular account of increased numbers of patients being treated within the centre.	A second part time counsellor has been employed to provide backup for activity increase. The existing counsellor is on long term sick leave.

Door to the cryo store to be kept locked at all times when not in use.	The door to the cryo store was seen to be closed and locked on the day of inspection 10th April 2008
Consideration should be given to introduce a system to record all treatment service provision. This system to be used alongside the current paper based system which can be backed up and recovered in the event of destruction of paper records.	A web based appointment system has been installed and is being used for the scheduling of appointments and recording of treatments.

Additional licence conditions and actions taken by centre since last inspection

Date	Action taken
	None

1. Report of Inspection findings

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

Summary of findings from inspection

1. Leadership and management
2. Organisation of the centre
3. Resource management
4. Risk management
5. Incident management
6. Contingency arrangements
7. Business planning
8. Clinical governance
9. Payment of treatment fees

Areas of firm compliance
Leadership and management: The Person Responsible has completed the HFEA PR entry programme. He has been in his present post since 2003 and appears to be appropriately qualified, registered with the General Medical Council, and experienced for the role. *(CoP S.4.1.5: S.4.1.4).* The Centre is managed by the Fertility Services Manager (FSM) who is also the Senior Embryologist and Quality Manager. The Nominal Licensee is the Director of the Esperance Hospital who was on leave at the time of the inspection. **Organisation of the centre:** There are clear organisational accountability and reporting relationships that were demonstrated via an organisational chart and during interviews between the inspection team and Centre staff. *(CoP: S.4.2.6)*. The PR and FSM were present for the inspection and provided all the information requested, both written and verbal. Each member of staff approached appeared to the inspectors to know about the inspection and quickly provided information and comment when asked. *(CoP S.4.1.3)* The finance department at the HFEA, have confirmed that all payment of treatment fees are up to date and timely payments are made. (*CoP A.16.3)* HFEA registry reported no problems with reporting from this Centre pre-inspection, and stated that they were in receipt of regular updates via the EDI system. *(CoP 4.2.12)* **Contingency Arrangements:** Formal documented contingency arrangements were seen by the inspectors between the Sussex Downs Fertility Centre, the Brabourne Suite: BMI, Chaucer Hospital and the ACU,

BMI Chelsfield Park Hospital *(CoP S.6.3.4b)*

Incident management:
All incidents are reported to and investigated by the PR and FSM. The inspectors observed documented procedures for handling incidents and a record of corrective action and outcomes. *(CoP 9.4)*

During interviews staff demonstrated knowledge of the requirements of reporting to the HFEA *(CoP S.9.4.4).* Two incidents have been reported since the last inspection in the required manner.

Clinical governance:
The quality manager informed the inspector that the Centre follows the BMI Esperance Hospital clinical governance policies.

Areas for improvement

Resource management:
The Centre is experiencing some difficulties with staff absence and unfilled job vacancies: the counsellor has been on long term sickness leave; a healthcare assistant recently left the Centre and has not been replaced. The PR and FSM informed the inspectors that the host organisation have refused all requests for further recruitment, this policy remains for the foreseeable future.

The inspectors were informed by all staff interviewed that they were working over their contractual hours especially when staff were on sickness absence, training or on leave. The inspectors were informed that extra pressure has been placed on staff at weekends as two members of staff are required in the Centre to ensure compliance with witnessing requirements. Contingency arrangements are in place to provide “cover” for staff on leave but this is not considered sustainable.

At the time of inspection the inspectors considered the workload to be relatively high for the number of laboratory and clinical staff available and for the activity level. *(CoP S.6.2.1).*It was discussed at the time of inspection with the FSM and PR that a risk assessment should be done on staffing and activity levels as part of the business case to be put to the Management Board of BMI.

Areas for consideration

None

Executive recommendations for Licence Committee

The Licence Committee is asked to endorse the recommendations made in relation to the areas of improvement cited above.

Areas not covered on this inspection

Business planning & risk management.

Evaluation
Some 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:

1. Quality Management System
2. Quality Policy
3. Quality Manual
4. Quality objectives and plans
5. Quality Management review/evaluation
6. Monitoring and resolution of complaints
7. Staff suggestions
8. Document control
9. Live Birth Rates

Live Birth Rates

Relative live-birth success rate: (April 1st 03 – March 31st 06) HFEA data. For this time period these outcomes are in line with national averages.

Age	DI %		FET %		IVF/ICSI%	
<35	17.857	N/D	10	N/D	25.21	N/D
35-37	15.19	N/D	18.182	N/D	25.714	N/D
38-39	9.231	N/D	0	N/D	26.829	N/D
40-42	5	N/D	0	N/D	14.286	N/D
>42	0	N/D	0	N/D	0	N/D

N/D – no significant difference from national average

*"This data is supplied to the HFEA by individual clinics who are responsible for its accuracy and for verifying it. The data published by the HFEA on our website is a snapshot of the state of the Register at a particular time. The data in the Register may be subject to change as errors are notified to us by clinics, or picked up through our quality management systems."

Areas of firm compliance

Quality Management System:

The PR and staff within the Centre have demonstrated a commitment to the establishment and development of an electronic Quality Management System (QMS). The electronic system is managed by the FSM who is also the Quality Manager *(CoP S.4.2.1)* and is only accessible for changes and alterations from her computer in her office *(CoP S.4.2.2: S.4.2.3).* Another member of staff has been trained in the use of the Quality Management System if the FSM is absent. The Quality Manager informed the inspector that she has received external training in quality management; this was demonstrated in her corporate objectives.

The policies and procedures are held on a computer, accessible to staff in read only format. It was explained by the PR and the FSM Manager that these are reviewed annually by the most relevant member of staff and then changes are made to the master copy on the computer. Two folders containing all of the policies and procedures are also produced. These were seen by the inspectors to be located in the main office and the Embryology

laboratory. These are stamped to indicate that they are original copies. It is the responsibility of the FSM to ensure that these folders are updated when a change is made to the computer copy of the policy

Staff Suggestions:
Staff suggestions and participation in day to day changes and new developments are demonstrated in meeting agendas and minutes. This was corroborated by staff interviewed by the inspection team. *(CoP S.9.2.3)*

Service User complaints:
Service user complaints are received, managed and resolved according to the BMI Esperance Hospital policy. The complaints officer is the Centre's Nominal Licensee who is the Hospital Director The inspector observed a complaints policy document and a complaints form for completion. There have been three complaints in the last year, all resolved locally and none reported to the HFEA. *(CoP S.9.2.2)*

Areas for improvement

Document control:
Not all Laboratory Standard Operating Procedures (SOPs) were seen to be effectively document controlled. Control factors should include author, reviewer, date and annual review date. *(CoP S.5.2.5 plus NOTE)*

Areas for consideration

Patient satisfaction surveys:
The Esperance hospital has its own corporate system and questionnaires for patient satisfaction surveys which the Centre is obliged to use. The FSM and PR discussed their reservations as to whether the information contained in the returns gave useful information to the Centre to help service improvement (*CoP 4.2.9 (a))* During the inspection the FSM suggested that she will monitor the present system and if necessary approach the host organisation with any changes or amendments which could make the service user feedback more useful in improving fertility services

Executive recommendations for Licence Committee

The Licence Committee is asked to endorse the recommendations made in relation to the areas of improvement cited above.

Areas not covered on this inspection

Quality objectives and plans
Quality Management review/evaluation

Evaluation

Some improvement required

3. Premises and Equipment

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

Summary of findings from inspection:

1. General Suitable premises
2. Clinical facilities
3. Counselling facilities
4. Laboratory facilities
5. Air quality
6. Storage facilities for gametes and embryos
7. Staff facilities
8. Management of equipment and materials
9. Control of records
10. Risk assessments

Brief Description
The Sussex Downs Fertility Centre is located on the top floor of the BMI Esperance Hospital. Access is via a reception on the ground floor of the hospital and a further reception within the fertility centre. There is observed access during working hours and the FSM assured the inspectors that the Centre is locked out of hours. The Centre, which is well signposted within the hospital, consists of a counselling room, treatment room (used for IUI and delivering drug administration training to patients), main office used by nurse co-ordinators and administrators, consulting room, patient waiting room (where the HFEA licence, counselling information, complaints procedure and fees information is displayed), office for the FSM, locked drug store and male production room. These areas are all located on the third floor of the hospital and were considered adequate for the activities carried out in them. The operating theatre, embryology laboratory, cryostore and three-bay recovery area are all located on the lower ground floor of the hospital. All procedures conducted within the operating theatre are performed in the presence of a consultant anaesthetist, who can offer a choice of either sedation of general anaesthetic. Service users are transferred from the waiting area to the operating room via a patient designated hospital lift. During the inspection premises and facilities appeared suitable for the activities for which they are licensed *(CoP S.6.3.2)* Service users are cared for by operating theatre staff during their stay in the operating department and recovery.
Areas of firm compliance
Counselling facilities: Counselling takes place in a designated counselling room within the Centre which on inspection appeared to provide quiet and comfortable surroundings in which sessions can be held that are private, confidential and without interruption. *(CoP S.6.3.5)*

Clinical Facilities:
The clinical facilities: consulting room, IUI insemination room and waiting areas were all observed to provide for the privacy and comfort of service users who are considering donation and seeking treatment, undergoing examination and treatment or producing semen specimens.
Two service users confirmed that they were "very happy" with the premises and had felt "comfortable" at all times. *(CoP S.6.3.4)*

The operating facilities are in the basement of the hospital accessed by an internal lift only accessible by staff. Service users are cared for by operating department staff in a designated theatre. Recovery of patients post treatment is in the main three bed recovery room. Daily checked and documented emergency equipment were seen to be readily available. (*CoP S.6.3.4)*

Laboratory facilities:
The laboratory facilities are adjacent to the operating theatre with a "barn door" access between the two rooms. On the day of inspection the licensed laboratory facilities were seen to be suitable for the activity carried out in them with arrangements in place for cleaning, maintenance of facilities and for waste disposal. These facilities are maintained by the host organisation. *(CoP S.6.3.1: S.6.3.2)*

The 17 dewars were seen to be alarmed and are stored in a small cryostore fitted with a low oxygen monitor, which was considered appropriate except for issues referred to in areas for improvement. *(CoP S. 6.3.8)*

Air Quality:
The inspector observed that the Centre has a protocol for the measuring of air quality every two months in place and that monitoring documentation demonstrated environment air quality D and A in the critical work area at the time of monitoring. *(CoP S.6.3.6 (b) and G.9.4)*

Areas for improvement

The cryostore and laboratory are below ground level. The cryostore does not have an effective or automatic means of removing any escaped Nitrogen if one of the dewars were to fail or leak. The ventilation system (a simple Ventaxia fan in a window pane) is switched on by the light switch inside the room: there is no way of switching it on without entering the room. This would present a danger in the case of a dewar failure*. (CoP S.6.3.2)*

There should be an low oxygen alarm response protocol and hazard warning signage on the cryostore door to warn and inform staff of the hazard within and how to respond in the event of an emergency *(CoP S.6.3.2)*

Areas for consideration

None

Executive recommendations for Licence Committee

The Licence Committee is asked to endorse the recommendations made in relation to the areas of improvement cited above.
Areas not covered on this inspection
Staff facilities Risk assessments

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:

1. General Information
2. Meetings and communication
3. HFEA Alerts
4. Welfare of child
5. Confidentiality and access to health records
6. Traceability and coding
7. Coding/ identification of samples
8. Information for service users/consents
9. Donor information (n/a)
10. Donor registration (n/a)
11. Surrogacy (n/a)
12. Procurement and distribution of receipt of gametes and embryos
13. Home procurement report documentation (n/a)
14. Packaging &distribution
15. Labelling of packages containing procured gametes
16. Transportation, labelling of shipping container and recall
17. Receipt of gametes

Areas of firm compliance

General Information
Information for service users provided prior to inspection and on the day of inspection appeared to be clear and provided explanations of clinical, scientific and legal terminology used in assisted reproductive treatments *(CoP S.7.4.1)* During interviews with staff the inspectors were informed that service users are given the opportunity to discuss all aspects of their treatment throughout the process. This comment was corroborated during service users interviews *(CoP S.7.5)*

Confidentiality and access to health records:
All health records are stored in locked filing cabinets in the Centre. The filing cabinets are stored in the main administration area which is observed during working hours and locked over night. All typing of records and their administration is carried out in the Centre by HFEA licensed staff. *(CoP S.7.2.1 & S.6.5.1)* The staff interviewed (administrative, nursing and FSM) were able to demonstrate their awareness of the need for confidentiality, appropriate health records storage and IT security.

Meetings and communication:
Evidence was observed of clinical review meetings and unit meetings which all staff are expected to attend. During interview staff informed the inspectors that these meetings included discussions about clinical treatments and care, incident management and any complaints received from service users. Staff not attending receive minutes in their personal "pigeon holes" in the Centre *(CoP 6.2.13)*

Information for service users and consents:

Consent forms reviewed in ten sets of service users health records were seen to be appropriately completed, signed and consistent with the treatment provided. Relevant signed consent forms were observed for storage and release of gametes and embryos *(CoP S.7.8.9: S.7.8.11)*

Two service users commented on interview that they were "more than happy" with the information they were given and felt comfortable in giving and signing consent.

Reasonable steps are in place to verify the identity of individuals this is done using photographic ID and signatures on registration forms. Administrative staff confirmed that service user identity is checked each time they are arrive at the Centre.*(CoP S.7.5.2)*

Welfare of the child:
Welfare of the child questionnaires are sent to all service users in the initial information pack. Welfare of the child issues are then discussed and the relevant forms signed during the initial patient consultation. Evidence of this process was seen in service user's healthcare records and in discussions with staff. An audit of ten service user health records showed all welfare of the child forms were completed appropriately.

During interview the counsellor confirmed that if she had any concerns over welfare of the child issues she will discuss them with the Centre staff (CoP S.7.1.2: S.7.1.3: G 3.2)

Areas for improvement

None

Areas for consideration

None

Executive recommendations for Licence Committee

The Licence Committee is asked to endorse the recommendations made in relation to the areas of improvement cited above.

Areas not covered on this inspection

Donor information : Donor registration : Surrogacy : Transportation, labelling of shipping container and recall, HFEA Alerts

Evaluation

No 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:

1. Laboratory processes
2. Selection and Validation of laboratory procedures
3. Laboratory's documented procedures
4. Storage of gametes and embryos
5. Counselling
6. Witnessing

Full time equivalent staff

GMC registered doctors	0.6
NMC registered nurses	1.8
HPC registered scientists	0.8 (also 1 embryologist on maternity leave)
Scientists working towards registration	1.75
Support staff (receptionists, record managers, quality and risk managers etc)	1 HCA (post unfilled) 1 receptionist
Counsellors	0.13 (1 counsellor is on long term sickness absence

Summary of laboratory audit / Audit of records
All cryopreserved gametes and embryos were audited between May 07 and Feb 08. The full audit trail was completed from dewar to laboratory record to service user record according to the Centres Standard Operating Laboratory Policy (ACULab021) **Embryos**: A total of 114 embryos were audited. No discrepancies were found between embryos in storage, storage records and patient records. Some discrepancies or inconsistencies were found in consents and health records. – These have been rectified as part of the audit follow up. **Sperm:** A total of 514 sperm samples were audited. No discrepancies were found between embryos in storage, storage records and patient records. Some discrepancies or inconsistencies with service user records and consents have been rectified as part of the audit follow up.
Summary of spot check of stored material
A spot check of stored material was not conducted by the inspector as the Centre had recently completed their own audit within the last two months.
Areas of firm compliance
All staff working within the Centre appears to be suitably qualified to perform the duties they were employed to perform. Staff interviewed felt supported in their continuing professional

development (CPD) and received ongoing mandatory training provided internally at the centre. The staff appear to work as a cohesive team with staff commenting on how supported they feel by both the management of the Centre as well as their colleagues.

Laboratory and Clinical Staff training and CPD:
Until this financial year funding has been made available by the host organisation for professional development and education for staff but the FSM has been informed that this may stop in light of the recent corporate changes. Alternative funding sources will be sought. Staff have electronically based training logs on the QMS. All staff were seen to have received annual mandatory training provided by the host organisation along with regular and relevant training courses and updates. *(CoP S.6.2.11 S.6.12)*

It was noted that laboratory staff have a signed competency log and that the Senior Embryologist assesses their competencies against *SOP*s regularly.

The inspection team did not see evidence that the clinical staff have a similar system of observations and competency sign off.

Counselling: The counsellor interviewed on the day of inspection was providing a part time service (from Feb 08) as the Centre counsellor is on long term sick leave. *(CoP S.7.6.2 & S.7.6.3)* The new counsellor is suitably qualified for her role (Fertility nursing, qualified counsellor, MA in Psychology); she is also a member of BICA. Service users access the service through the Centre staff. The counselling is free, sessions unlimited and is provided independently of the clinical decision making process *(CoP 7.6.3 (a))*

Traceability:
During observation and discussion with staff the inspector confirmed the Centres use of an identification code for traceability of all gametes and embryos. *(CoP S.7.3.1: S.7.8.5: 7.8.10)*

Equipment management:
Evidence was observed by the inspector that critical equipment is identified, validated and inspected according to the manufacturer's instructions and that equipment is subject to monitoring and has alert alarms. Maintenance, service and cleaning of all equipment was demonstrated in a full servicing file along with a scheduling sheet.

Evidence of ongoing monitoring of equipment including: carbon dioxide and temperatures in incubators, incubator alarms, servicing. Dewar top ups with weekly alarm tests were observed in laboratory logs. (*CoP S.6.4.)*

Areas for improvement

Witnessing:
The protocol for witnessing is inconsistent with the protocol for sperm preparation. The former does not include that the final sperm preparation tube, other preparation tubes, their identifiers and the patient records, should be witnessed as consistent, whereas the latter does. Discussion with laboratory staff and review of the service user health records indicates the witnessing step is performed. The sperm preparation protocol is correct and the witnessing protocol needs updating to reflect current practice in the centre.

Staff informed the inspector that the witnessing of a sperm provider's identification documents is performed but no witness signatures are collected in the service users' records. There should be documented evidence that the man's identity has been confirmed as part of the witnessing process. (CoP G.13.2.1 and G13.2.2).

Centre protocol ACU lab024 refers to *all witnessing procedure signed for on the day of procedure.* These checks should be completed and recorded at the time the clinical or laboratory process/procedure takes place. *(CoP S. 7.8.15)*

Training and Competency assessment:
Not all of the clinical/nursing staff competency assessments had been signed off in their training logs. This should be done in order to provide documented evidence of competency. *(CoP S.6.2.9)*

Traceability of materials:
The delivery of consumables into the laboratory is documented on a computer log but not the date when the box or container is opened and the contents are used. This should be recorded.

Areas for consideration
None
Executive recommendations for Licence Committee
The Licence Committee is asked to endorse the recommendations made in relation to the areas of improvement cited above.
Areas not covered on this inspection
None

Evaluation
Some improvements required

Report compiled by:

Name **Mrs Ellie Suthers**

Designation **Inspector – HFEA Executive**

Date **17th April 2008**

Appendix A: Centre Staff interviewed

Mr David Chui – Person Responsible
6 members of staff
2 service users

Appendix B: Licence history for previous 3 years

2007
Renewal Inspection 6th December 2006
The Licence Committee agreed to renew the Centres licence for a period of 5 years

2006
Unannounced inspection visit 3rd August 2006
No problems identified.

2006
Interim Inspection 26th January 2006
Licence Committee noted that because of inconsistencies found in consent forms during the inspection, the focus of the next inspection should be on the consent forms. The Committee agreed that the centre's licence should continue with no additional conditions.

Appendix C:

RESPONSE OF PERSON RESPONSIBLE TO THE INSPECTION REPORT

Centre Number……

Name of PR…….

Date of Inspection……..

Date of Response……

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

Signed……

Name…….

Date……

1. 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).

1. Page 7 of 26, Breach no 1 – All policies and procedures are reviewed annually. Every time a change is made, the old policy is archived electronically on the main QMS PC, by the Fertility Services Manager (FSM) and the new up to date version is printed as the hard copy located in the office and the lab. On the hard copy the following is detailed: the original date the policy was created, the author, the reviewer and the date of the most recent review. The version number detailed on this copy is the most up to date version and does not therefore necessarily indicate the last review date. In order to do this the FSM would need to retrospectively sign the new document, to indicate a review that took place a year ago. All archived policies are accessible demonstrating clear evidence that all policies are reviewed at least annually. In the case where a policy remains unaltered, each annual review date remains detailed on the hard copy.

2. Corrections of minor typing errors have been amended on the report

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

Sussex Downs Fertility Centre
Action plan for draft Inspection report
03.06.08

Key Points

Breaches of the Act or Code of Practice

Breach	Action required	Time scale
Not all laboratory standard operating procedures (SOPs) were seen to be effectively document controlled. Documentation should include author, reviewer, date and review date. Some of the SOPs observed appeared to have not been reviewed within the last year. *(CoP S. 5.2.5 plus NOTE)*	All SOPs to have effective document control and be subject to regular review. Action by SDFC All SOP's are controlled and subject to regular review. Please see note in **factual inaccuracies report.**	30th June 2008
The Centre has a protocol for responding to the low oxygen monitor. The protocol is not displayed on the outside of the cryostore door, nor are any hazard warning markings. The lack of warning of cryostore hazards and how to respond to them is a health and safety hazard to staff and other visitors to the centre *(CoP S.6.3.2)*	The PR should seek advice and a health and safety assessment should be carried out on the cryostore in order to identify any potential hazards to staff and/or visitors. Action by SDFC Contact has been made with the risk manager of the local NHS Trust who will undertake a health and safety assessment of the cryostore. Hazard notices have been placed in the appropriate areas, and will be reviewed following full health and safety assessment.	Immediate As soon as possible. (Awaiting confirmation of a date from the Trust)

Non-Compliance

Area for improvement	Action required	Time scale
The Centre is experiencing some difficulties with staff absence and frozen job vacancies. The PR and Fertility Services Manager (FSM) informed the inspectors that the host organisation has refused all requests for further recruitment; this policy remains for the foreseeable future. This position may be unsustainable. At the time of inspection the inspectors considered the workload to may be too high for the number of laboratory and clinical staff available. *(CoP S.6.2.1)*	A thorough risk assessment of centre activity given the personnel and equipment resources available should be conducted by the Centre. An action plan should be developed and any appropriate risk control measures implemented if this assessment indicates excessive risk at the current activity level. An assessment should be carried out by the Centre of how many cycles can be safely carried out given the available resources and ensure activity levels remain within these levels. A copy of the assessment should be submitted to the HFEA Action by SDFC Permission for additional recruitment was issued by the host organisation immediately following the inspection, as well as a lift on the freeze to fill an existing vacancy. Consequently one new post has been created for a full/part-time trained nurse and the vacant healthcare assistant post will be filled. The two existing temporary embryologists have been given permanent contracts and the absent trained embryologist has now returned from maternity leave. The Senior Embryologist post will be filled in October following a regrade of one of the existing embryology team members.	August 30th 2008 Interviews for both posts being held week commencing 02.06.08
The Esperance hospital has its own corporate system and questionnaires for patient satisfaction surveys which the Centre is obliged to use. Analysis of these questionnaires does not	The Centre should monitor information relating to user perception as to whether the service has met their needs and requirements. Records should be kept of the information collected and actions taken.	By the next inspection

appear to provide sufficient information relating to user perception of the Centre as to whether the service has met their needs and requirements *(CoP S.9.2.1)*	Action by the SDFC Permission has been granted by the host organisation to reinstate the SDFC's own patient satisfaction questionnaires. Records of responses and actions taken will be kept.	Has been implemented immediately
The delivery of consumables into the laboratory is documented on a computer log but not the date when the box or container is opened and the contents are used. This may compromise the Centre's ability to demonstrate traceability.	The Centre shall establish documented procedures for management of equipment and materials that include traceability of any materials that come in contact with gametes or embryos. (CoP S.6.4.3 (d)) Action by SDFC The draft policy seen at the time of inspection is now in regular use. This ensures that the date the container is opened and its contents used, is documented.	Immediate
Centre protocol ACU lab024 states that *all witnessing procedures signed for on the day of procedure. (CoP S. 7.8.15)*	The protocol should be amended to reflect that witnessing checks should be completed and recorded contemporaneously Action by SDFC Protocol ACU024 has been amended to reflect actual practice and witness signatures are now recorded in the service users records, when receiving a samples from a sperm provider.	Immediate Has been implemented Immediately

Recommendations

Recommendations	Time scale
Not all of the clinical/nursing staff competency assessments had been signed off in their training logs. This should be done in order to provide documented evidence of competency. *(CoP S.6.2.12)*	By the next inspection

S6.2.12 requires that a record of education and training including continuing professional development is maintained Action by the SDFC All staff training records are held electronically and up dated accordingly as training is undertaken. External training is verified by means of certification or other means created by the provider. The assessor signs off other areas of training requiring competency assessment, where possible, and a hard copy of the training record is held in the staff members personnel file.	

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