Inspection Report

Purpose of the Inspection Report

This is a report of an inspection, carried out to assess whether this centre complies with essential requirements in providing safe and high quality care to patients and donors. The inspection was scheduled (rather than unannounced) and the report provides information on the centre's application for a renewal of its existing licence. Licences are usually granted for a period of four years. The Authority's Executive Licensing Panel (ELP) uses the application and this report to decide whether to grant a new licence and, if so, whether any additional conditions should be applied to the licence.

Date of inspection: 11 December 2013

Purpose of inspection: Renewal of a licence to carry out treatment (insemination using partner / donor sperm) and storage

Inspection details: The report covers the performance of the centre since the last inspection, findings from the inspection visit and communications received from the centre.

Inspectors: Vicki Lamb and Susan Jolliffe

Date of Executive Licensing Panel: 21 February 2014

Centre name	Sunderland Fertility Centre
Centre number	0096
Licence number	L/0096/20/d
Centre address	Sunderland Royal Hospital, Kayll Road, Sunderland, Tyne & Wear, SR3 1AA, UK
Person Responsible	Mr Menem Yossry
Licence Holder	Mr Ken Bremner
Date licence issued	1 June 2009
Licence expiry date	31 May 2014
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:

The Sunderland Fertility Centre has held a treatment (insemination using partner / donor sperm) and storage licence with the HFEA since 1992 and provides basic fertility services. The centre does not provide donor insemination treatment, but this licence type is the most suitable for the centre's range of activities as they also provide long-term sperm storage facilities. The inspection team is satisfied that the activities carried out at the centre are necessary or desirable in order to provide licensed treatment services.

The centre provided 95 cycles of partner insemination in 2012. In relation to activity levels this is a very small centre.

Centre's activity levels:

Type of treatment	Number of treatment cycles for the period 1 Nov 2012 - 31 Oct 2013
Donor insemination (DI)	0
	Number of cycles for calendar year 2012
Partner insemination	95

Other licensable activities	✓ or Not applicable (N/A)
Storage of gametes	✓
Storage of embryos	N/A
Embryo testing	N/A

Pregnancy outcomes[1]
In 2012, the centre reported 95 cycles of partner insemination with 10 pregnancies. This equates to a 11% clinical pregnancy rate which is consistent with the national average.

[1]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. The HFEA considers differences in a centre's success rates and multiple pregnancy rates from the national averages are only statistically significant if they occur at a significance level of $P \leq 0.002$.

Summary for licensing decision

Taking into account the essential requirements set out in the Human Fertilisation and Embryology (HF&E) Act 1990 (as amended), the HF&E Act 2008 and the HFEA Code of Practice (CoP), the inspection team considers that it has sufficient information to conclude that:

- the application has been submitted in the form required;
- the application has designated an individual to act as the Person Responsible (PR);
- the PR's qualifications and experience comply with section 16 (2) (c) of the HF&E Act 1990 (as amended);
- the PR has discharged his duty under section 17 of the HF&E Act 1990 (as amended);
- the premises (including those of relevant third parties) are suitable;
- the centre's practices are suitable;
- the application contains the supporting information required by General Direction 0008;
- the centre has submitted an application fee to the HFEA in accordance with requirements.

The ELP is asked to note that at the time of the inspection there were four 'other' areas of non-compliance. Since the inspection visit, the PR has provided evidence that the following recommendation has been fully implemented:

- The PR should ensure that the providers of gametes are screened for anti-HBc before their material is stored.

The PR has also committed to fully implementing the following recommendations:

- The PR should ensure that a suitable procedure for product recall is established.
- The PR should ensure that following audit, corrective actions are documented and implemented.
- The PR should ensure that wherever possible only CE marked medical devices are used.

Recommendation to the Executive Licensing Panel

The centre has no critical or major of areas of non- compliance.

The inspection team notes that the success rates are consistent with the national average. The PR is encouraged to continue to use the Quality Management System (QMS) to best effect to monitor and improve their success rates so as to improve the quality of the service offered to patients.

The inspection team recommends the renewal of the centre's treatment (insemination using partner / donor sperm) and storage licence for a period of four years without additional conditions subject to the recommendations made in this report being implemented within the prescribed timescales.

Section 2: Inspection findings

This section details what the centre does well and which areas need to be improved to meet essential requirements. We break this down in to four areas covering all the activities of a licensed centre:

1. The protection of the patient, and children born following treatment at this centre
2. The experience of patients at this centre
3. The protection of gametes (sperm) at this centre
4. How this centre looks after important information

1. Protection of the patient and children born following treatment

▶ **Witnessing and assuring patient and donor identification**
What the centre does well **Witnessing (Guidance note 18)** The centre's procedures for double checking the identification of gametes and the patient to whom they relate are compliant with HFEA requirements. This ensures that patients receive treatment using the correct gametes.
What the centre could do better Nothing identified at this inspection.

▶ **Donor selection criteria and laboratory tests** Screening of donors prior to procuring, processing gametes and embryos Payments for donors Donor assisted conception
What the centre does well The centre does not recruit donors, or perform donor insemination, therefore this guidance note does not apply to this centre.
What the centre could do better Nothing identified at this inspection.

Suitable premises and suitable practices

Safety and suitability of premises and facilities
Laboratory accreditation
Multiple births
Procuring gametes
Transport and distribution of gametes
Receipt of gametes
Imports and exports
Traceability
Quality management system
Third party agreements
Equipment and materials
Process validation
Adverse incidents

What the centre does well

Safety and suitability of premises and facilities (Guidance note 25)
The centre's premises are suitable. This is important to ensure that all licensed activities are conducted in a suitable environment that is fit for purpose.

The premises of the laboratories conducting tests that impact on the quality and safety of gametes (relevant third parties) are suitable.

The centre is compliant with HFEA requirements to processes gametes in an environment of appropriate air quality.

Laboratory accreditation (Guidance note 20)
The centre's third party laboratories which undertake the diagnosis and investigation of patients and patients' partners are compliant with HFEA requirements for accreditation by CPA (UK) Ltd or another body accrediting to an equivalent standard. This is important to assure the quality of the services provided.

Multiple births (Guidance note 7; Directions 0003)
The centre does not perform IVF or ICSI, therefore this guidance note does not apply to this centre.

Procuring gametes (Guidance note 15)
The centre's procedures are compliant with HFEA requirements to:

- document the justification for the use of the patient's gametes in treatment, based on the patient's medical history and therapeutic indications;
- where the sperm is procured at home, keep a record of this in the gamete provider's records.

Transport and distribution of gametes (Guidance note 15; Directions 0009)
The centre's procedures for the transport, distribution and recall of gametes are broadly compliant with HFEA requirements. This is important to ensure that all gametes sent to other licensed centres within or outside the UK are:

- packaged and transported in a manner that minimises the risk of contamination and preserves the characteristics and biological functions of the gametes;
- shipped in a container that is designed for the transport of biological materials and

that maintains the safety and quality of the gametes;
- appropriately labelled with the transport conditions, including temperature and time limit being specified;
- shipped in a container/package that is secure and ensures that the gametes are maintained in the specified conditions. All containers and packages are validated as fit for purpose.

Receipt of gametes (Guidance note 15)
The centre's procedures for the receipt of gametes are compliant with HFEA requirements. This is important to ensure that the centre only accepts gametes from other centres if the gametes are appropriately labelled and has enough information to permit the gametes be stored or used in treatment in a way that does not compromise their quality and safety.

Imports and exports (Guidance note 16; Directions 0006)
The centre's procedures for imports and exports of gametes are compliant with HFEA requirements.

Traceability (Guidance note 19)
The centre's procedures are compliant with HFEA traceability requirements. These requirements are important to ensure that the centre has the ability -
- to identify and locate gametes during any step from procurement to use for human application or disposal;
- identify the donor and recipient of particular gametes;
- to identify any person who has carried out any activity in relation to particular gametes;
- to identify and locate all relevant data relating to products and materials coming into contact with particular gametes and which can affect their quality or safety.

Quality management system (QMS) (Guidance note 23)
The centre has a QMS in place that is broadly compliant with HFEA requirements. The establishment and use of a QMS is important to ensure continuous improvement in the quality of treatments and services.

Third party agreements (Guidance note 24)
The centre's third party agreements are compliant with HFEA requirements.

Equipment and materials (Guidance note 26)
The centre uses equipment and materials that are broadly compliant with HFEA requirements. All of the equipment and materials used in licensed activity are designated for the purpose and are appropriately maintained in order to minimise any hazard to patients and/or staff, with one exception detailed below.

The centre is compliant with HFEA requirements to validate critical equipment.

The centre has documented procedures for the operation of critical equipment and procedures to follow if equipment malfunctions.

Process validation (Guidance note 15)
The centre's procedures are compliant with HFEA requirements to validate critical processes. This ensures that these processes are effective and do not render the gametes clinically ineffective or harmful to the recipient.

Adverse incidents (Guidance note 27)
The centre's procedures for reporting adverse incidents are compliant with HFEA requirements. The centre reports all adverse incidents (including serious adverse events and reactions) to the HFEA. The centre investigates all adverse incidents that have occurred. Reporting and investigation of adverse incidents is important to ensure that centres share the lessons learned from incidents and continuously improve the services it offers.

What the centre could do better

The centre does not have a procedure that defines the responsibilities and actions required when cryopreserved material has to be recalled (CoP mandatory requirements 15C). See recommendation 1.

The audit report for provision of information to patients did not include the corrective actions required, and the corrective actions had not been implemented (standard licence condition (SLC) T36). See recommendation 2.

Serological pipettes used are not CE marked (SLC T30). See recommendation 3.

Staff engaged in licensed activity

Person Responsible (PR)
Staff

What the centre does well

Person Responsible (Guidance note 1)
The PR has complied with HFEA requirements.

The PR has academic qualifications in the field of medicine and has more than two years of practical experience which is directly relevant to the activity to be authorised by the licence. The PR has successfully completed the HFEA PR Entry Programme (PREP number T/1074/7).

Staff (Guidance note 2)
The centre is compliant with HFEA requirements. The centre has suitably qualified and competent staff, in sufficient number, to carry out the licensed activities and associated services. The centre has an organisational chart which clearly defines accountability and reporting relationships.

The centre has access to a nominated registered medical practitioner, within the UK, to advise on and oversee medical activities.

What the centre could do better

Nothing identified at this inspection.

Welfare of the child

What the centre does well

Welfare of the child (Guidance note 8)
The centre's procedures for taking into account the welfare of the child are compliant with HFEA requirements. This is important to ensure that the centre takes into account the welfare of any child who may be born as a result of the licensed treatment, and of any other child who may be affected by that birth before treatment is provided.

What the centre could do better

Nothing identified at this inspection.

2. The experience of patients

Patient feedback

What the centre does well

During the inspection visit the inspectors spoke to three patients who provided feedback on their experiences. A further three patients also provided feedback directly to the HFEA in the time since the last inspection. Two of the individuals providing written feedback to the HFEA commenting that they have compliments about the care that they received.

On the basis of this feedback and observations made in the course of the inspection it was possible to assess that the centre:

- has respect for the privacy and confidentiality of patients in the clinic;
- gives patients sufficient, accessible and up-to-date information to enable them to make informed decisions;
- provides patients with satisfactory facilities for their care.

What the centre could do better

Nothing identified at this inspection.

Treating patients fairly

Counselling
Complaints
Confidentiality and privacy

What the centre does well

Treating patients fairly (Guidance note 29)
The centre's procedures are compliant with the HF&E Act 1990 (as amended) to ensure that staff members understand the requirements for a conscientious objection to providing a particular licensed activity governed by the Act.

The centre's procedures are compliant with the Equality Act 2010 requirements. This is important to ensure that all persons are treated fairly.

Counselling (Guidance note 3)
The centre's counselling procedures are compliant with HFEA requirements. This is important to ensure that counselling support is offered to patients providing relevant consent.

Complaints (Guidance note 28)
The centre's procedures are compliant with HFEA requirements to seek patient feedback and to be responsive to patient complaints. This is important to ensure that the centre uses patient feedback and any complaints as an opportunity to learn and improve their services.

Confidentiality and privacy (Guidance note 30)
The centre's procedures are compliant with HFEA requirements to ensure it has respect for the privacy, confidentiality, dignity, comfort and wellbeing of prospective and current patients.

What the centre could do better

Nothing identified at this inspection.

Information

What the centre does well

Information (Guidance note 4; CH(11)02)
The centre's procedures for providing information to patients are compliant with HFEA requirements. This ensures that the centre gives prospective and current patients sufficient, accessible and up-to-date information to enable them to make informed decisions.

What the centre could do better

Nothing identified at this inspection.

Consent

What the centre does well

Consent (Guidance note 5)
The centre's procedures for obtaining consent are compliant with HFEA requirements. This ensures that patients have provided all relevant consents before carrying out any licensed activity.

What the centre could do better

Nothing identified at this inspection.

3. The protection of gametes

Screening of patients
Storage of gametes

What the centre does well

Screening of patients (Guidance note 17)
The centre's procedures for screening patients are broadly compliant with HFEA requirements. It is important that gamete providers are appropriately screened to minimise the risks of cross infection during treatment, processing and storage of gametes.

Storage of gametes (Guidance note 17)
The centre's procedures for storing gametes are compliant with HFEA requirements. These measures ensure that the gametes are stored appropriately to maintain their quality and safety. Furthermore, the centre only stores gametes in accordance with the consent of the gamete providers. The storage of gametes is an important service offered by fertility clinics, as it can enable patients to preserve their fertility prior to undergoing other medical treatment such as radiotherapy.

What the centre could do better

Prior to the processing of patient gametes intended for treatment or storage the centre does not carry out anti-HBc testing (SLC T50). See recommendation 4.

4. Information management

Record keeping
Obligations and reporting requirements

What the centre does well

Record keeping and document control (Guidance note 31)
The centre's procedures for keeping records are compliant with HFEA requirements to ensure that accurate medical records are maintained. Good medical records are essential for the continuity of the patient's care.

Obligations and reporting requirements (Guidance note 32 ; Direction 0005)
The centre's procedures for submitting information about licensed activities to the Authority are compliant with HFEA requirements.

What the centre could do better

Nothing identified at this inspection.

Section 3: Monitoring of the centre's performance

Following the interim inspection in 2012, recommendations for improvement were made in relation to one area of critical non-compliance and one area of major non-compliance.

The PR provided information and evidence that both of the recommendations were fully implemented.

Areas of practice requiring action

The section sets out matters which the Inspection Team considers may constitute areas of non compliance. These have been classified into critical, major and others. Each area of non-compliance is referenced to the relevant sections of the Acts, Regulations, Standard Licence Conditions, Directions or the Code of Practice, and the recommended improvement actions required are given, as well as the timescales in which these improvements should be carried out.

Critical area of non compliance

A critical area of non-compliance is an area of practice which poses a significant risk of causing harm to a patient, donor, embryo or to a child who may be born as a result of treatment services, or a significant shortcoming from the statutory requirements. A critical area of non-compliance requires immediate action to be taken by the Person Responsible.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
None			

Major area of non compliance

A major area of non compliance is a non critical area of non compliance:

- which poses an indirect risk to the safety of a patient, donor, embryo or to a child who may be born as a result of treatment services
- which indicates a major shortcoming from the statutory requirements;
- which indicates a failure of the Person Responsible to carry out his/her legal duties
- a combination of several “other” areas of non-compliance, none of which on their own may be major but which together may represent a major area of non-compliance.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
None			

Other areas of practice that requires improvement

Areas of practice that requires improvement is any area of practice, which cannot be classified as either a critical or major area of non compliance, but which indicates a departure from statutory requirements or good practice.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
1. The centre does not have a procedure that defines the responsibilities and actions required when cryopreserved material has to be recalled. CoP mandatory requirements 15C.	It is acknowledged that recall is likely to be infrequent, but should a recall be necessary staff should have clear instruction for how to proceed. The PR should ensure that a suitable procedure is established and a copy provided to the HFEA by 11 March 2014.	An SOP for the recall of cryopreserved sperm is being developed.	The inspector looks forward to receiving a copy of the SOP by 11 March 2014.
2. The audit report for provision of information did not include the corrective actions required, and the corrective actions had not been implemented. SLC T36.	The PR should ensure that the corrective actions are documented and implemented. The PR should inform the inspector when the corrective actions have been documented and implemented. By 11 March 2014	Re-audit is in progress.	The inspector will follow up this issue to ensure that the corrective actions have been documented and implemented by 11 March 2014.
3. Serological pipettes used are not CE marked. SLC T30.	We would not recommend the implementation of precipitous changes that might impact on the quality of treatment that	The centre is contacting the suppliers to ensure that CE marked pipette are supplied if available.	The inspector expects that the list requested will be submitted by 11 March 2014.

	you are providing to your patients. In consideration of this, the PR should provide the HFEA with a list of all medical devices currently in use in the clinic. The list should document the CE mark status of each device and where devices are not CE marked the list should document either the anticipated time by which a CE mark is expected to be obtained or the action that will be taken to ensure compliance within the next year. The list should be submitted to the HFEA by 11 March 2014.		
4. Prior to the processing of patient gametes intended for treatment or storage the centre does not carry out anti-HBc testing. SLC T50.	The PR should take immediate action to ensure that the providers of gametes are screened for anti-HBc before their material is stored. The HFEA should be advised of the measures taken to ensure that this happens by the time the PR responds to this report. Commission Directive 2006/17/EC (from which the screening requirements of T50 are derived) stipulates that in the case of sperm processed	The requirement of screening for anti-HBc has been added to the relevant SOPs.	Further information received from the PR has clarified that all men having sperm stored or used in treatment are now screened for anti-HBc. No further action required.

	for IUI and not to be stored, if the tissue establishment can demonstrate that the risk of cross contamination and staff exposure has been addressed through the use of validated processes, biological testing may not be required. The PR should provide a summary report to the HFEA outlining how the risks of cross contamination and staff exposure are mitigated by the use of good laboratory practice by 11 March 2014.		

Reponses from the Person Responsible to this inspection report
All identified areas needing improvement are being addressed.