Interim Inspection Report

Date of Inspection: 2 November 2010
Length of inspection: 7.5 hours
Inspectors: Mim Glenn – Lead

Inspection details:
The report covers the pre-inspection analysis, the visit and information received between 16 January 2009 and 18 February 2011.

Date of Executive Licensing Panel: 18 February 2011

Purpose of the Inspection report
The purpose of the inspection is to assess centres are complying with the Human Fertilisation & Embryology (HF&E) Act 1990 (as amended), the HF&E Act 2008 and the Code of Practice to ensure that centres are providing a quality service for patients. The report summarises the findings of the licence interim inspection highlighting areas of good practice, as well as areas where further improvement is required to improve patient services and meet regulatory requirements. It is primarily written for the Executive Licensing Panel which makes the decision about the continuation of the centre's licence.

Centre details

Centre Name	Sunderland Fertility Centre
Centre Number	0096
Centre Address	Fertility Department Sunderland Royal Hospital Kayll Road Sunderland Tyne & Wear SR4 7TP
Telephone Number	0191 5699779
Person Responsible	Mr Menem Yossry
Licence Holder	Mr Ken Bremner
Date of Licence Expiry	31/05/2014
Licence Number	L0096/20/c

Version: 1.3

Trim:

Contents

Report to Executive Licensing Panel

Recommendation to the Executive Licensing Panel:

At the time of the inspection improvements were recommended in relation to 2 major non compliances and four other areas of practice.

The lead inspector acknowledges that information provided by the PR after review of the draft report, has clarified that contrary to initial findings, validation of critical processes (cited as a major non compliance) has been carried out.

The person responsible (PR) has responded to the recommendations in the report and no further action is required in relation to the following;

- documentation of regular cleaning and decontamination of equipment
- use of CE marked equipment

The PR has given a commitment to the implementation of recommendations made in relation to the following:

- development of a standard operational procedure (SOP) which informs staff of the process for submitting data to the Human Fertilisation and Embryology Authority (HFEA) in compliance with Directions 0005 in relation to donors
- review of the centre's SOP in relation to donor screening against the quarantine requirements of licence condition T53(c))

At the time of the inspection one major area of non compliance requiring improvement was noted and improvements were recommended in relation to the following:

- The storage of 12 sperm samples for oncology patients in store without effective consent or a medical practitioner certification of continued impairment to fertility.

Although the PR has given written confirmation that the issue will be resolved in a timely manner, he has not provided an update on the original action plan or anticipated timescales for obtaining relevant consents.

The lead inspector recommends that the Executive Licensing Panel requires the PR to submit an update on the implementation of the action plan and an indication of the anticipated timescale for obtaining relevant consents.

The inspector considers that, overall there is sufficient information available to recommend the continuation of the centre's licence without additional conditions.

Details of Inspection findings

Brief description of the centre and its licensing history:

The Sunderland Fertility Centre is a small centre which is part of the Obstetrics and Gynaecology service of City Hospitals Sunderland NHS Foundation Trust (the Trust), and is located within the Sunderland Royal Hospital. The centre has held a HFEA treatment and storage licence without additional conditions since 1993.

The centre provides treatments to both National Health Service (NHS) and self funded patients and is currently licensed for the following activities:

- Insemination
- Storage of Sperm
- Processing of Gametes
- Procurement and Distribution of Gametes
- Treatment with Donor Gametes
- Donor Insemination

The centre was last inspected on 27 April 2010, when a new premises inspection was undertaken which only looked at the centres move to new premises on the second floor of Charter House, within the grounds of Sunderland Royal Hospital.

Activities of the centre:

Type of treatment	Number of cycles 1 January 2009 – 31 December 2009
Inter uterine insemination (IUI)	80
DI	0

Other licensable activities	✓ or Not applicable (N/A)
Storage of sperm	✓

*These data were extracted from the HFEA register for the period 01/01/2009 – 31/12/2009. 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.

1. Focus of inspections for 2010-12

Providing information to patients in relation to costed treatment plans and parenthood

What the centre does well

Costed treatment plans
NHS patients undergoing fertility treatments and oncology patients storing sperm prior to the commencement of chemotherapy and radiotherapy treatments are not required to pay for treatments or storage.

Senior nursing staff informed the inspector that all self-funding patients are sent a letter prior to their first consultation, which details the cost of the treatment (including investigations and tests). Patients are then provided with an opportunity to discuss these costs in detail at the first and subsequent consultations (Guidance 4.3). These discussions and a copy of a letter were seen in one patient record reviewed on the day of the inspection.

Legal Parenthood
The PR and senior nursing staff informed the inspector that the last donor insemination took place in 2008.

The centre has a documented SOP for consent processes including the circumstances when consent to legal parenthood should be taken. At inspection, the staff interviewed demonstrated an understanding of the legal parenthood provisions. Staff stated that these requirements would be discussed with the patients at the initial consultation and documented in the patient's records (Licence Condition (LC) T60 and T61).

The counsellor confirmed that all couples and donors and where applicable the donors partner in the case of known donors, are required to undergo a minimum of two implication counselling sessions.

What they could do better.

Nothing identified at this inspection.

Consent - particularly consent to disclosure to researchers and consent to storage

What the centre does well

Consent to disclosure to researchers
The theme does not apply to this centre for IUI patients.

The centre has not carried out any donor inseminations since 2008. However, at inspection, the senior nurse confirmed that the centre uses the relevant HFEA consent forms and demonstrated an understanding of the requirements to seek consent to disclosure of information to medical or other researchers.

Withdrawal of consent to storage
The centre only stores gametes and so this theme does not apply to this centre.

What they could do better.

Consent to storage
This centre provides sperm storage facilities for oncology patients. The laboratory staff informed the inspector that the 'bring-forward' system was overseen by several different staff in the hospital's main laboratory. Since the move to the current site the 'bring-forward' system is being overseen by the centre's andrology laboratory staff. A recent audit of stored samples by the centre has identified that 12 sperm samples are being stored without effective written consent (Schedule 3 Human Fertilisation & Embryology (HF&E) Act 1990 (as amended)). The laboratory staff identified that initial contact had been made with these patients, but it had not been followed up.

Following discussions at the time of the inspection with the PR and laboratory staff, an action plan has been submitted to the HFEA which demonstrates how the centre is going to ensure that an effective written consent form and medical practitioner's certificate are in place for all sperm currently in storage. The centre's laboratory staff have also given a commitment to review the 'bring-forward' SOP to ensure future compliance with Schedule 3 HF&E Act 1990 (as amended).

Multiple births

What the centre does well

This theme is not applicable to this centre

What they could do better.

This theme is not applicable to this centre

Validation of critical equipment and processes

What the centre does well

From the sample of documents seen at the time of the inspection the laboratory staff were able to demonstrate that critical equipment has been validated.

What they could do better.

Validation documentation for sperm preparation, which influences the quality and safety of gametes, was not provided on the day of inspection (LC T72).

Witnessing

What the centre does well.

The centre has witnessing protocols in place to double check the identification of samples and the patients or donors to whom they relate at all critical points of the clinical and laboratory process. Laboratory staff stated that these checks are completed and recorded at the time the relevant clinical or laboratory process/procedure takes place.

The centre has established a quality indicator of 100% compliance for witnessing for all patients records. Laboratory staff provided evidence on the day of inspection which demonstrated that the monthly audit undertaken in October 2010 showed 100%

compliance (LC T36).

Records of competency assessments and training were seen for all staff that carry out witnessing.

What they could do better.

Nothing identified at this inspection.

Gamete and embryo donation – reimbursement, information provision and screening

What the centre does well.

Both the PR and the senior nurse informed the inspector that the centre has not undertaken a donor insemination since 2008 and are not currently actively recruiting donors. Patients who require donor insemination use either known donors or donor sperm supplied through a third party agreement on an individual patient basis or are referred to another UK based licensed centre. The PR did state that the Trust does not reimburse donors.

The competency of staff in selecting and recruiting sperm donors and information provision relating to donation of sperm was not assessed at this inspection.

The laboratory staff confirmed that the centre's andrology laboratory is part of the Sunderland Royal Hospital laboratory and is accredited by Clinical Pathology Accreditation (UK) Ltd (CPA). The hospital's main CP accredited laboratory would carry out any donor screening that may be required (LC T52).

What they could do better.

Several SOPs were submitted by the PR and there is no mention of reimbursement for donor of expenses. The SOP for donor screening makes a reference to all screening required in licence condition T53 including repeat screening, but does not specify the period of quarantine for a minimum of 180 days as stipulated in licence condition T53(c).

Welfare of the Child (in relation to basic partner treatment services only)

What the centre does well.

The senior nurse confirmed that before treatment commences welfare of the child forms are completed and signed by both partners. At inspection, evidence of this was seen in one set of patient's records.

What they could do better.

Nothing identified at this inspection.

Embryo testing (if applicable)

What the centre does well.

This theme is not applicable to this centre

2. Changes / improvements since the last inspections on 19 January 2009 and 27 April 2010

Area for improvement	Action required and taken	Action taken as evidenced during this inspection
Staff assessment During interview the biomedical scientist informed the inspectorate that competencies of the scientific staff are assessed as part of procedures from the Trust pathology department. At the time of inspection these competency assessments are not documented.	The PR should document that each individual has demonstrated competence in the performance of their designated tasks *(A.10.11)* By the time of the next inspection	The centre is now complaint with licence condition T12 & T15 (a) please see the body of the report under section 3 'Areas of concern' below. No further action required
Air Quality	The PR should consider, as the workload increases and there is an increase in the volume of people traffic through the laboratory whether annual air quality testing is adequate to demonstrate compliance and consistent air quality control throughout the year and for each sample of gametes processed within laboratory. (CoP S.6.3.6 (b)) By the time of the next inspection The centre should validate the procedures for air quality testing to provide evidence that air quality is maintained in the interval between testing.(S.7.8.3, G.9.4.6, G.9.4.7) By the time of the next inspection	This was reviewed at the time of the new premises variation of the licence when air quality testing was found to be compliant. Evidence seen at the time of the inspection demonstrated that the air quality is currently being monitored bi-annually. The last air test was undertaken in November 2010 with results showing that air quality is complaint with licence condition T20. No further action required
Witnessing The centre has a standard operating procedure for witnessing but there are	The PR should consider including this step and part of the centres witnessing protocols *(CoP S.7.8.15)*	The laboratory staff presented evidence at the time of the inspection which demonstrated that the centre

some steps which are not included. E.g. the final step of witnessing the handover of prepared sperm between the biomedical scientist and clinician for insemination; the time of witnessing steps should be timed in the documentation.		is now compliant with licence condition T71. No further action required.
Equipment and materials - a list of all critical equipment and records of validation and calibration of critical equipment were not available at inspection. Licence conditions T22, T24	The centre should provide the inspection team with a list of all critical equipment and records of validation and calibration. 5 May 2010 This was requested following the inspection on the 27 April 2010 in relation to the move to the new premises. A list of all critical equipment and an audit plan for validation and calibration of critical equipment has been received. The audit plan will be reviewed at the next inspection. No further action required.	Documentation was provided to show the revalidation of equipment at the time of moving into the new premises in May 2010 (LC T25). During the course of the inspection the laboratory staff were able to provide written evidence which demonstrates that validation and calibration of critical equipment has been achieved. No further action required

3. Areas of concern

The analysis of the centre's self assessment questionnaire (SAQ) and the information the centre has submitted to the HFEA e.g. staff changes and the treatment cycles carried out at the centre, have identified that the following areas needed to be looked during the inspection visit to this centre.

Area of concern following the submission of the SAQ in December 2009	Inspection findings	Assessment of whether the action taken meets requirement or whether any further action is required
2: Staff 1.7 The SAQ stated that the centre were fully compliant in being able to supply evidence to demonstrate that all staff had been assessed as to their competence to perform their designated tasks (T12 and T15 (a)). However, in several other areas of the SAQ it was stated that staff were either **almost, partially or not complaint,** in the requirement to be able to provide documented evidence of competence to perform the following: • donor recruitment; • storage of gametes; • witnessing; • traceability; • procedures to maintain confidentiality and privacy;	Laboratory staff were able to present evidence which demonstrated that all andrology laboratory staff have had their competence to perform all their designated tasks assessed. This assessment included written tests and direct observation undertaken by the hospitals laboratory quality manager. Laboratory staff also informed the inspector that all laboratory staff are assessed annually. Laboratory staff also stated they also participate in inter-laboratory comparisons, via the National External Quality Assessment Service (NEQAS), to assess staff competence to perform sperm and motility analysis and use NEQAS quality indicators as their own internal quality indicators (LC T15(a)). Senior nursing staff confirmed that they have also been assessed as to their competence to perform their designated tasks by the PR and that this is documented in their personal training records, although no files were reviewed at the time of the inspection	The evidence presented at the time of the inspection demonstrated that the centre is complaint with licence condition T15 No further action required

3:Counselling 1.7Is the centres counsellor(s): 1.7.1the holder of a recognised counselling, clinical psychology, counselling psychology or psychotherapy qualification to diploma of higher education level or above? [see 2.12(a)] **NO** 1.7.2.1 Counsellor can provide evidence that they are working towards British Infertility Counselling Association (BICA) accreditation (2.12(b)) **SAQ stated that, YES, can provide evidence**	The inspector saw evidence of the day of the inspection which demonstrated that the counsellor obtained BICA accreditation in August 2010	Evidence seen demonstrated that the counsellor is accredited with BICA No further action required
23: Quality Management System The centre SAQ stated that they have established quality indicators (QIs) for all licensed activities and for other activities carried out in the course of providing treatment services that do not require a licence and have in the last two years, audited and findings and corrective actions documented (LC T36). However in other sections of the SAQ the it has been stated that there is **no QI** relating to the following activities: • provision of information; • consent; • donor selection; • procuring and processing of gametes; • storage of gametes;	The PR and laboratory staff were able to present written evidence in the form of an audit plan with quality indicators and time frames as to when the centre undertakes audits. Evidence was presented which demonstrated that audits are being undertaken and where applicable the centre is also completing corrective and preventive action (CAPA) plans. Audits of consent practices (September 2010) and witnessing (October 2010) were reviewed in the course of the inspection: the audit found that the centre had achieved 100% compliance with witnessing and consent practices. .	Centre staff were able to present evidence which demonstrated that they are complaint with licence conditions T32 to T36 No further action required

• traceability; • record keeping and document control. and **no audits** have been undertaken for the following • provision of information; • donor selection; • procuring and processing of gametes; • storage of gametes; • traceability; • record keeping and document control.		
31: Record Keeping and Document Control 1.1 Is there an SOP for the process for submitting data to the HFEA in compliance with Directions 0005? (LC T33 (b)) **SAQ stated No**	The senior nurse confirmed that there is currently no SOP in place informing staff of the process for submitting data to the HFEA in compliance with Directions 0005 in relation to donors. It is acknowledged that the centre submits very little data to the HFEA and that the errors in submissions are minimal.	The PR should develop a SOP which documents the process to be followed for submitting data to the HFEA in compliance with Directions 0005
25: Premises and Facilities 4 Does your centre keep records of regular cleaning and disinfection of the premises? (LC T26) **SAQ stated 2 – Almost compliant**	The laboratory and nursing staff both confirmed that regular cleaning of the premises is undertaken by the hospital staff. Senior staff stated that a record of when cleaning has been undertaken is maintained by the hospital cleaning supervisor. This record was not reviewed in the course of the inspection.	No further action required.

26: Equipment and Materials 1.8 Does your centre keep records of regular cleaning and disinfection of the equipment? [(LC T26) **SAQ stated 4 not compliant**	Laboratory staff confirmed that regular cleaning and decontamination of equipment is undertaken in accordance with manufacturer's instructions, but the actual cleaning and decontamination is not being documented. (LC T26).	The PR must ensure that there is documented evidence of regular cleaning and decontamination of equipment in accordance with manufacturer's instructions (LC T26).
1.11Where possible are the medical devices used at your centre CE marked? (LC T30) **SAQ stated 2 – almost compliant**	It was noted on the day of the inspection that the petri dishes and disposable pipettes in use in the laboratory are not CE marked (LC T30).	The PR should ensure that wherever possible only CE marked equipment is used.

Areas of practice that require the attention of the Person Responsible

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 require are given as well as the timescales in which these improvements should be carried out.

Critical area of non compliance

A critical are of non compliance is an area of practice which poses a significant direct risk of causing harm to a patient, donor or to an embryo. 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
Nothing identified at this inspection.			

Major area of non compliance

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

- which poses an indirect risk to the safety of a patient, donor or to an embryo through the procurement, use, storage or distribution of gametes and embryos, which do not comply with the centre's licence;
- 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
Consent to store After the centre conducted an audit of the oncology stored sperm	The PR has submitted a follow up action plan to ensure the stored oncology sperm samples have the	All relevant parties (patients, general practitioners, and involved clinicians) have been	All though the PR has given written confirmation that the

samples currently in storage it was discovered that 12 samples were being stored without effective consent and/or a medical practitioners certificate (Schedule 3 HFE Act 1990 (as amended).	appropriate consents. The PR should submit an update on the implementation of the action plan and provide an indication of the anticipated timescale for obtaining relevant consents by the time he responds to this report. The PR should submit quarterly update reports to the centre's inspector regarding the progress of implementation of this plan until it is completed.	contacted to provide information or consent. The process is being completed in a timely manner.	process will be completed in a timely manner, he has not provided an update on the original action plan or anticipated timescales. The lead inspector requests that the Executive Licensing Panel require the PR to submit an update on the implementation of the action plan and provide an indication of the anticipated timescale for obtaining relevant consents.
Validation of critical processes Validation documentation for sperm preparation, which influences the quality and safety of gametes, was not provided on the day of inspection. LC T72	Relevant clinical processes should be validated and this validation should be documented, to comply with LC T72. The PR should submit an action plan and provide an indication of the anticipated timescale for validation of critical processes by the time he responds to this report. The PR should submit quarterly update	Sperm preparation procedures are validated by retorospective evaluation of the clinical results of treatments in comparison to national results published by the HFEA. This process has been always implemented through a continuous audit of clnical outcomes,	The PR has explained that validation is carried out by retrospective evaluation of the clinical results. This method of validation is compliant with the requirements of licence condition T72.

	reports to the centre's inspector regarding the progress of implementation of this plan until it is completed.		

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 good practice.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
Senior nursing staff confirmed that there is currently no SOP in place informing staff of the process for submitting data to the HFEA in compliance with Directions 0005 in relation to donors	The PR must develop a SOP which informs staff of the process for submitting data to the HFEA in compliance with Directions 0005 by the 31 January 2010	An SOP has been developed and in the process of ratification / implementation	The lead inspector accepts the PR assurances that the SOP has been developed and is in the process of ratification and implementation. This will be reviewed again at the next inspection
Laboratory staff confirmed that regular cleaning and decontamination of equipment is undertaken in accordance with manufacturer's instructions, but that this is not documented (LC T26)	The PR must ensure that there is documented evidence of regular cleaning and decontamination of equipment in accordance with manufacturer's instructions. To be reviewed at the next inspection	A register of cleaning and decontamination processes have been created.	The lead inspector accepts the PR assurances that a register of cleaning and decontamination processes has been created.

			This will be reviewed again at the next inspection
The SOP for donor screening makes reference to repeat screening, but does not specify the period of quarantine for a minimum of 180 days as stipulated in licence condition T53(c).	The PR should review the centre's SOP in relation to donor screening against licence condition T53(c)) and submit a copy of the amended SOP by the time the PR responds to this report.	Amendaments to the SOP are being made.	The lead inspector accepts the PR assurances that amendments to the SOP are being made. This will be reviewed again at the next inspection
It was noted on the day of the inspection that the petri dishes and disposable pipettes in use in the laboratory are not CE marked (LC T30).	The PR must ensure that wherever possible the centre will only use CE marked equipment by the time the PR responds to this report.	We had confirmation from our suppliers that all our equipment is CE certified.	The lead inspector accepts the PR assurances that all equipment used is CE marked. This will be reviewed again at the next inspection

Additional Information from the Person Responsible

HFEA Executive Licence Panel Meeting

18 February 2011

21 Bloomsbury Street London WC1B 3HF

Minutes – Item 2

Centre 0096 (Sunderland Fertility Centre) – Interim Inspection Report (Treatment and Storage)

Members of the Panel:	Committee Secretary:
Peter Thompson, Director of Strategy & Information (Chair) Mark Bennett, Director of Finance & Facilities Nick Jones, Director of Compliance	Joanne McAlpine

Declarations of Interest: members of the Panel declared that they had no conflicts of interest in relation to this item.

The Panel also had before it:

- HFEA Protocol for the Conduct of Meetings of Executive Licensing Panel
- 8th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- Decision trees for granting and renewing licences and considering requests to vary a licence (including the PGD decision tree)
- Guidance for members of Authority and Committees on the handling of conflicts of interest approved by the Authority on 21 January 2009.
- Guidance on periods for which new or renewed licences should be granted
- Standing Orders and Instrument of Delegation
- Indicative Sanctions Guidance
- HFEA Direction 0008 (where relevant), and any other relevant Directions issued by the Authority
- Guide to Licensing
- Compliance and Enforcement Policy
- Policy on Publication of Authority and Committee Papers

Consideration of Application

1. The Panel noted that this is a small centre which is part of the Obstetrics and Gynaecology service of City Hospitals Sunderland NHS Foundation Trust and is located within the Sunderland Royal Hospital.

2. The Panel noted that the centre has held a treatment and storage licence without additional conditions since 1993.

3. The Panel noted that the centre provides treatments to both National Health Service (NHS) and self funded patients.

4. The Panel noted that the centre offers a full range of assisted reproduction treatments including Insemination, Storage of Sperm, Processing of Gametes, Procurement and Distribution of Gametes, Treatment with Donor Gametes, Donor Insemination.

5. The Panel noted that the centre was last inspected on 27 April 2010, when a new premises inspection was undertaken which only looked at the centre's move to new premises.

6. The Panel noted that at the time of the inspection in November 2010 the Inspectorate identified two major areas of non compliance relating to consent to store and validation of critical processes and four other areas of non compliance.

7. The Panel noted that, following information provided by the Person Responsible (PR) after review of the draft report, the Inspectorate is now satisfied that contrary to its initial findings, validation of critical processes (cited as a major area of non compliance) has been carried out.

8. The Panel noted that the one major area of non compliance requiring improvement related to the storage of 12 sperm samples for oncology patients without effective consent or medical practitioner certification of continued impairment to fertility.

9. The Panel noted the PR's response in relation to the consent to storage and his commitment that this area will now be addressed. However the Panel endorsed the Inspectorate's recommendation that the PR should provide written confirmation indicating when this issue will be resolved.

10. The Panel noted the Inspectorate's recommendation that the centre's licence should continue with no additional conditions.

Decision

11. The Panel endorsed the Inspectorate's recommendation to the continuation of the centre's licence, with no additional conditions. The Panel urged the PR to rectify the outstanding area of non-compliance relating to consent and to provide written confirmation of when this will be completed when submitting the quarterly update to the Inspectorate at the end of March.

Signed: Peter Thompson Date: 2/3/11.
Peter Thompson (Chair)