Renewal Inspection Report

Sunderland Fertility Centre
0096

Date of Inspection: 16th January 2009
Date of Licence Committee: 8th April 2009

Centre Details

Centre Name	Sunderland Fertility Centre
Centre Number	0096
Centre Address	Sunderland Royal Hospital, Sunderland. SR3 1AA
Centre Telephone	0191 569 9779
NHS/Private Clinic	NHS and Private
Person Responsible	Mr Menem Yossry
Nominal Licensee	Mr Ken Bremner
Inspection Date	Friday 16th January 2009
Inspector(s)	Bhavna Mehta, Ellie Suthers, Wil Lenton
Licence Number	L0096-19-a
Licence Expiry Date	31/05/2009
Licence Fee Paid? Treatment Fees Paid?	69 days
Licence Committee Date	8th April 2009

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About the Inspection:
This inspection visit was carried out on 23rd of January 2009 and lasted for 8 hours.

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 make the decision about the centre's licence renewal application. The report is also available to patients and the public following the Licence Committee meeting.

At the visit the inspection team assesses the effectiveness of the centre through five topics. These are:
How well the centre is organised
The quality of the service for patients and donors
The premises and equipment
Information provided to patients and to the HFEA
The clinical and laboratory processes and competence of staff.

An evaluation is given at the end of each topic and for the overall effectiveness of the centre:
No Improvements Required – given to centres where there are no Code of Practice, legal requirements 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.

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 Sunderland Fertility Centre (0096) is small centre carrying out approximately 200 cycles of Intra Uterine Insemination (IUI) and a small number of Donor Insemination (DI) per year.

The centre is part of the Obstetric and Gynaecology service of City Hospitals Sunderland NHS Foundation Trust, is managed through the Division of Family Care and located within the Sunderland Royal Hospital.

The clinic is open 7 days a week and provides treatments to both National Health Service (NHS) and self funded patients.

The Person Responsible (PR) Mr Menem Yossry, Consultant Gynaecologist and Obstetrician; has completed the Person Responsible Entry Programme (PREP): is registered with the General Medical Council (GMC) and appears suitably qualified for the role.

The PR represents the centre at the North East Fertility Network.

Activities of the Centre[1] for the time period from July 2007 – December 2007

Intra uterine insemination (IUI)	58
Donor insemination	3

Summary for Licence Committee

The Sunderland Fertility Centre is a small sized assisted conception unit providing approximately 200 licensed IUI treatment cycles per year. The centre has previously recruited their own sperm donors but has seen a sharp decline in the number of donors. Three donor inseminations have been carried out since the last inspection.
The centre and staff are part of the Obstetrics and Gynaecology service of City Hospitals Sunderland NHS Foundation Trust is managed through the Division of Family Care and located within the Sunderland Royal Hospital.

The centre appears be to have suitably qualified and experienced staff and adopts appropriate clinical and laboratory procedures for licensed activity.

[1] 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 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.

Patients report satisfaction with the treatment and service they receive through the HFEA questionnaires issued prior to the inspection and during interview at the time of inspection.

On inspection the centre appears to be suitably equipped and staffed for the level of activity.

Following inspection, improvements should be considered in the following areas:

- Incidents;
- Payment of HFEA fee;
- Document control;
- Security of the premises;
- Competency assessments;
- Witnessing;
- Standard operating procedures;
- Selection and validation of laboratory procedures;

The inspection team recommends the renewal of the centres licence for five years without any additional conditions being imposed.

Plans for a change in premises in October/November of 2009 are being developed and will require further inspection before beginning licensed activity.

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 the Code of Practice, and their recommended improvement actions and timescales. The weight to be attached 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
It was noted that an incident/near miss relating to a pharmacy incident and a fertility service user had been recognised, reported and investigated but the out come had not been recorded in the centres documentation.	The PR should ensure that the centre documents the outcomes following the investigation of incidents. *(CoP S.9.4.2 (a))*	April 1st 2009
The centre has taken 69 days to pay their required HFEA fees 08/09	The PR should review payment processes to ensure that there are no barriers to the payment of fees within 28 days of the date of the notice of such additional fees according to the requirements of Standard Licence Condition *A.16.3*	By the time of the next inspection
Not all documentation seen at the time of inspection was document or version controlled. The fertility nurse specialist informed the inspectorate that she was in the process of reviewing all documentation control to bring it in line with local and Trust requirements.	The PR should ensure that there are procedures in place to control all documents (internally generated and from external sources) required by the quality management system in order to ensure that documents are regularly reviewed, revised as required, dated and re-approved promptly by authorised personnel *(CoP S.5.2.5)*	April 1st 2009
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 does not have a standard operating procedure for the response to dewar alarms.	The PR should ensure that the centre has an established documented procedure for the management of equipment and materials that include the operation of each piece of equipment, detailing the action to be taken in the event of the malfunction or failure. *(CoP S.6.4.3)*	1st April 2009
The laboratory and clinical staff have not completed the validation of procedures and equipment.	The PR should ensure the laboratory and clinical procedures are validated in order to meet the needs of the service users and ensure the safety and quality of gametes. *(CoP S.7.8.3)*	By the time of the next inspection.

Non-Compliance

Area for improvement	Action required	Time scale
It was noted at the time of inspection and following a previously recorded incident that the centres security alarm system is not connected to the main hospital security network. This could compromise the security of stored gametes and patient confidentiality if security of the centre were to be breached and no one responded.	The PR should ensure that any alarms are responded to appropriately *(CoP S.6.3.8***)**	1st April 2009

Recommendations

Area for improvement	Time scale
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 compliant and consistent air quality control throughout the year and for each sample of gametes processed within laboratory. (CoP S.6.3.6 (b)) 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
Witnessing The centre has a standard operating procedure for witnessing but there are some steps which are not included. E.g. the final step of witnessing the hand	By the time of the next

over of prepared sperm between the biomedical scientist and clinician for insemination; the time of witnessing steps should be timed in the documentation. The PR should consider including this step and part of the centres witnessing protocols *(CoP S.7.8.15)*	inspection

Changes/ improvements since the last inspection.

Breach	Action required	Time scale
Quality Management System (QMS) incomplete. *(S.5.1.1, S.5.2.1, S.5.2.6) Directive 2004/23/EC, Art.16*	Development of a comprehensive QMS. Within three months from report being presented to a Licence Committee (LC).	QMS is developing as required and is in the process of being transferred on to Q Pulse (electronic system) in partnership with the laboratory
Changing area and secure storage for personal effects. *(S 6.3.10)*	Provision of adequate staff facilities. Within three months from report being presented to a (LC).	The PR and staff assured the inspectorate that adequate staff facilities are available with which they are content.
Counselling facilities are not provided in suitable surroundings. *(S 6.3.5) (G 1.4.1)*	Comfortable room for counselling. Within three months from report being presented to a (LC).	A newly refurbished counselling room is now available which provides quiet and comfortable surroundings in which sessions can be held that are private, confidential and without interruption.
Records are not kept of the materials used in the laboratory. *(S 6.4.3)*	Recording of materials used in the laboratory. Immediately.	A log was seen at the time of inspection of materials used in the laboratory.

Additional licence conditions and actions taken by centre since last inspection

None

Report of inspection findings

1. Organisation

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

Summary of the findings from the inspection of the following areas of practice:

- Leadership and management
- Organisation of the centre
- Resource management
- Clinical governance
- Risk management
- Incident management
- Alert management
- Complaints management
- Contingency arrangements
- Establishment of third party agreements
- Meetings / dissemination of information
- Payment of licence/treatment fees

Areas of firm compliance
Leadership and management: The Person Responsible (PR) Mr Menem Yossry, Consultant Gynaecologist and Obstetrician; has completed the Person Responsible Entry Programme (PREP) *(CoP S.4.1.5)* is registered with the General Medical Council (GMC) and appears suitably qualified for the role. *(CoP S.4.1.1)* The centre is represented on the Trust board by the Nominal Licensee (NL) who is the Chief Executive Officer for the City Hospitals Sunderland NHS Foundation Trust. There has been a recent restructuring of the laboratory/pathology services within the Trust which has provided for a dedicated service to the centre. The centres' laboratory now has a dedicated scientist who is accountable for the service provided and appears qualified for the role (CoP S.4.1.3) The fertility nurse specialists are line managed via the Division of Family Care and informed the inspectorate that they feel supported in their work and continuing professional development (CPD) The staff report into the City Hospitals Sunderland NHS Foundation Trust clinical governance structure for risk, incident and complaint management. It was noted on the day of inspection that the centres licence was seen to be clearly displayed in the centres main thoroughfare and is readily observable by persons who are receiving treatment services. *(CoP A.13.4)* **Organisation of the centre:** The Quality Management System (QMS) contains an organisational chart describing in detail the management structure and reporting responsibilities within the centre as well as reporting responsibilities through the Division of Family Care and the City Hospitals Sunderland NHS Foundation Trust. (*CoP S.4.2.5)* During the inspection staff demonstrated an understanding of the leadership, management and reporting roles and responsibilities.

Access and treatment criteria/algorithms were observed as part of the QMS. *(CoP G.5.3.1)* The inspectorate observed documented protocols and procedures that are readily available for staff in files in the main nursing office. On inspection it appeared that the organisational structure and operational procedures are appropriate to the activities for which it is licensed. *(CoP S.4.1.1)*

Resource management:
The PR has ensured that the centre provides the resources needed for licence activity in terms of personnel, facilities, equipment and material, and data and information systems. *(CoP S.6.1.1)*
The PR demonstrated that there were sufficient members of staff, with the competence to perform their designated tasks. Evidence of this was observed in staff training logs and in discussions during the inspection *(CoP S.6.2.1)* Evidence was seen in staff training logs of appropriate qualifications and registrations for clinical and scientific staff working in the centre *(CoP.S.6.2.2)*

A recent change in the structure of the pathology department in the Trust now ensures the availability of a designated biomedical scientist at all times. This will enable the work to be scheduled within clinic working hours rather than after 5pm which has been the previous practice. The staff said that this will provide for a good outcome for the service and users.

Risk management:
A Trust risk management strategy is in place which has been localised to the requirements of fertility services.

Incident management:
The centre follows the City Hospitals Sunderland NHS Foundation Trust policy on incident reporting. Evidence was observed at the time of inspection that this documented policy (available both electronically and in a folder in the nurses' office) for the identification, control and recording of adverse incidents including: log of incidents, analysis, investigation and outcome: who is responsible for management and the criteria for reporting to the HFEA. During interview the specialist nurse demonstrated an awareness of both Trust and HFEA policy and procedure. *(CoP S.9.4)*

Alert management:
It was observed at the time of inspection that HFEA Alerts are distributed to staff at meetings (evidence of the dissemination of information from Alerts was observed in meeting minutes) and are emailed to each member of staff. During interview staff demonstrated an understanding of the Alerts process.*(CoP S.6.2.13)*

Complaints management:
The centre has a written procedure in place for the acknowledgment and investigation of complaints, as well as collecting suggestions and compliments from service users. There is a designated individual who has responsibility for the management of complaints. Any complaints made about the service will be addressed initially by the PR and if unresolved will be referred to the gynaecology department complaints manager. The complaints process is facilitated through the Patient Advisory Liaison Service (P.A.L.S) based at the Trust. Inspectors observed that records of complaints and their investigation together with the corrective action are kept in the centre. *(CoP S.9.2.2).* No complaints have been received since the last inspection.

Contingency arrangements:
The centre is part of the City Hospitals Sunderland NHS Foundation Trust which provides all infrastructure backup to the centre e.g. backup generator, water supply, I.T etc. Arrangements are in place for cleaning, facilities maintenance and waste disposal via the Trust.
(CoP S. 6.3.1) In the event of the PR not being available the Clinical Director will take over managerial responsibilities: seen to be documented in a policy in the quality manual.
A written contingency agreement between the centres participating in the North West Fertility Network (NWFN) was seen as part of the quality management system.

Establishment of third party agreements:
During the inspection a log of third party agreements was seen. The centre has third party agreements for the consumables they use. The agreements seen at the time of inspection were complete. *(CoP S.7.7.6)*

Meetings / dissemination of information:
During interview the PR and staff informed the inspectorate that meetings are held monthly for all members of the centres staff. Minutes of each these meetings reflect discussions about the organisation and day to day running of the centre: clinical decision making: incident management and any changes in protocols. The centre appears to have an effective means of communicating information between staff. *(CoP S.6.2.13)*

Areas for improvement

Incidents:
It was noted that an incident/near miss relating to a pharmacy incident and a fertility service user had been recognised, reported and investigated but the out come had not been recorded in the centres documentation. The PR should ensure that the centre documents the outcomes following the investigation of incidents. (CoP S.9.4.2 (a))

Payment of licence/treatment fees:
The centre has taken 69 days to pay their required HFEA fees 08/09
The PR should review payment processes to ensure that there are no barriers to the payment of fees within 28 days of the date of the notice of such additional fees according to the requirements of Standard Licence Condition A.16.3

Areas for consideration

No areas for consideration

Executive recommendations for Licence Committee

The Licence Committee is asked to endorse the recommendations made in relation to:

- Recording of incidents;
- Payment of licence/treatment fees

Evaluation

Some improvements required

Areas not covered on this inspection
None

2. Quality of service

Desired Outcome: Patients receive a good standard of service, appropriate treatment and are treated with courtesy and respect.

Summary of the findings from the inspection of the following areas of practice:

- Quality management system
- Quality policy
- Quality manual
- Quality objectives and plans
- Quality management review/evaluation
- Feedback
- Document control
- Live birth rates

Live birth rates[1]
Outcome data reported to the HFEA for the period 5 July - 31 December 2007 indicated that 58 IUI cycles were performed, which resulted in 8 clinical pregnancies. The overall clinical pregnancy rate was approximately 14% for this time period.
Areas of firm compliance
Quality management system: The PR and staff within the centre have demonstrated a commitment to the establishment and maintenance of a Quality Management System (QMS). *(CoP: S.4.2.1)* The development of the QMS is led by the fertility nurse specialist who also has the role of quality manager as part of her remit. *(CoP S.4.2.7)* At the time of inspection the quality manual was seen to be easily accessible by all members of staff in files in the fertility nurse specialists' office. The inspectorate was informed by the staff interviewed that protocols and procedures are amended and authorised by the PR and the fertility nurse specialist. *(CoP S.4.2.7)* **Quality manual:** A quality manual is being developed and will, during 2009, be transferred to an electronic system. (Q Pulse) and marry up with all the laboratory policies and standard operating procedures. *(CoP S.5.2.3)* The quality manager has developed a rolling schedule and review programme for policies and audits which are included in the quality manual. Since the last inspection it was noted that audits have been carried on: witnessing procedures both for the laboratory procedures and for IUI: counselling audit (seen on inspection): stored gametes: IUI consent forms and welfare of the child forms. *(CoP S.9.2.4)* A complete list/index off all policies and procedures with their relevant versions and review dates was provided prior to inspection. This list/index was seen to be filed at the front of the quality manual. The centre has a signed, readily accessible quality policy which demonstrates a commitment

Comment [C1]: I couldn't see the data caveat anywhere?

to develop and improve the quality management system and its continual effectiveness: quality objectives: respect of the needs of patients: health, safety and welfare of patients and staff and upholding professional values and good professional practice. (CoP S.4.2.3)

Quality indicators have been developed for the service including: pregnancy rate: multiple pregnancy rate: complications of treatment and patient satisfaction. The staff interviewed at the time of inspection demonstrated an understanding of the policy and its contents *(CoP S.4.2.3)*

Quality management review/evaluation:
Interview with staff and meeting minutes were seen that described the review of audits, quality indicators and intra centre comparisons of pregnancy rates for each IUI practitioner, complaints and significant incidents *(CoP S.4.2.9)*

During interview the newly appointed biomedical scientist reiterated that all systems, processes, standard operating procedures and ways of working in the laboratory will be reviewed, audited and amended where necessary during 2009.

Feedback:
At the time of inspection a service user questionnaire and comments box was seen in the main waiting area. Staff commented that very few service users use this as they are encouraged to make comments at the time of consultation or treatment in order to resolve any issues immediately. *(CoP S.9.2.1)*
During inspection staff said that they are actively encouraged to participate in meetings and make suggestions for improvements or changes in the services provided. These discussions were seen to be recorded in meeting minutes. *(CoP S.9.2.3)*

Areas for improvement

Document control:
Not all documentation seen at the time of inspection was document or version controlled. The fertility nurse specialist informed the inspectorate that she was in the process of reviewing all documentation control to bring it in line with local and Trust requirements.
The PR should ensure that there are procedures in place to control all documents (internally generated and from external sources) required by the quality management system in order to ensure that documents are regularly reviewed, revised as required, dated and re-approved promptly by authorised personnel *(CoP S.5.2.5)*

Areas for consideration

No areas for consideration

Executive recommendations for Licence Committee

The Licence Committee is asked to endorse the recommendations made in relation to: ➢ Document control
Evaluation
Some improvements required
Areas not covered on this inspection
None

3. Premises and Equipment

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

Summary of the findings from the inspection of the following areas of practice:

- Premises
- Clinical facilities
- Counselling facilities
- Laboratory facilities
- Air quality
- Management of equipment and materials
- Storage facilities for gametes and embryos
- Staff facilities
- Storage of records

Areas of firm compliance

Premises:

The premises are within one of the oldest buildings on the City Hospitals Sunderland NHS Foundation Trust campus. During interview the PR informed the inspectorate that there are plans to move the centre to a newer and refurbished part of the Trust in October /November 2009.

The fabric of the centre is tired and has received little restoration in light of the planned move later in the year. All areas seen during the inspection appeared clean and well presented. The centre staff have worked hard to ensure that the care they deliver is of an acceptable standard within the facility.

The main entrance to the centre is off a main hospital corridor and consists of two treatment rooms, consulting rooms, waiting area and administrative offices. Routine scanning takes place in the radiology department in another part of the hospital.

On inspection it appeared that the centre has premises and facilities suitable for the activities for which it is licensed that include, as appropriate, facilities for reception, clinical and counselling activity, laboratory work, storage of gametes and staff. *(CoP S.6.3.2)*

The centre appears to provide a safe working environment for all staff. A lone working policy was seen as part of the quality manual at the time of inspection. A number of health and safety risk assessments have been carried out within the centre and are documented in the quality manual. *(CoP S.6.3.2)*

Clinical facilities:

There are two treatment rooms in the centre both of which appeared to be suitably equipped and appropriate for the activities for which the centre is licensed. (CoP S.6.3.3)
It was observed that the clinical facilities have emergency equipment on site. The inspection logs for resuscitation equipment were seen to be completed as required by the City Hospitals Sunderland NHS Foundation Trust policy. *(CoP 6.3.4 (b))*

Counselling facilities:
Following a recommendation from the last inspection the centre has a newly refurbished designated room for the sole use of the counsellor. It is located on the opposite side of the corridor to the main centre and provides quiet and comfortable surroundings in which sessions can be held in private, confidential and without interruption. *(CoP S.6.3.5)* During interview the independent counsellor confirmed that she is content with facilities provided for counselling.

Laboratory facilities:
The laboratory is located off the main patient waiting area has restricted access and provides a secure environment for the preparation and storage of gametes. The laboratory includes dewar storage.
It was observed at the time of inspection that the laboratory facilities were suitable for licensed activities *(CoP S.6.3.6)*

Air quality:
Air quality in the processing area and laboratory background has been tested (using particle counter) once over the last year by the Trusts Estates department. The biomedical scientist provided documentation that demonstrated compliance with air quality requirements in the laboratory environment. *(CoP S.7.8.5 (a))*

Management of equipment and materials:
Maintenance and service logs documenting regular maintenance of equipment were seen to be complete at the time of inspection. All equipment was seen to be maintained to suit its intended purpose. *(CoP S.6.3.6).* Prompts for review are via the laboratories Q-Pulse electronic quality management system.

Storage of gametes:
Gametes are stored in the main laboratory which has restricted access and is secure.
The dewars were seen to have alarms connected to an auto-dialler which contacts the Trusts switchboard and then the on call biomedical scientist *(CoP S.6.4.2 (b))* The storage facilities seen at the time of inspection provide conditions designed to ensure their quality and safety. *(CoP S.6.3.7)*

Staff facilities:
Facilities for staff are provided by the Trust and include changing and secure storage facilities. An area for refreshments and rest breaks is provided for within the centre. At the time of inspection the staff said they were satisfied with the facilities provided. *(CoP S.6.3.10)*

Storage of records:
Active health records are stored in locked filing cabinets in a designated room in the administrative offices of the centre to which only centre staff have access. All doors are lockable and staff assured that the inspectorate that all doors are locked out of hours. The PR informed the inspectorate that archived records are stored in sealed boxes in a separate locked area in the main Trust records library. *(CoP S.7.2 & G.10.2.1)*
During interview the counsellor informed the inspectorate that counselling records are stored at her home in locked filing cabinets and archived in secure arrangements in her house.

Areas for improvement
No areas for improvement
Areas for consideration
Security of the premises: It was noted at the time of inspection and following a previously recorded incident that the centres security alarm system is not connected to the main hospital security network. This could compromise the security of stored gametes and patient confidentiality if security of the centre were to be breached and no one responded. The PR should ensure that any alarms are responded to appropriately *(CoP S.6.3.8)* **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 compliant and consistent air quality control through out the year and for each sample of gametes processed within laboratory. (CoP S.6.3.6 (b)) 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)*
Executive recommendations for Licence Committee
The Licence Committee is asked to endorse the recommendations made in relation to areas for consideration : ➢ Security of the premises; ➢ Air quality monitoring.
Evaluation
Some improvements required
Areas not covered on this inspection
None

4. Information

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

Summary of the findings from the inspection of the following areas of practice:

- Information for service users
- Consent
- Welfare of the child
- Access to health records
- Provision of information to the HFEA register

Areas of firm compliance
Information for service users: Service user information literature is displayed in the main waiting area of the centre including: the centres licence, complaints procedure, HFEA leaflets and information and contact details for the counselling service. A number of treatment specific leaflets are also readily available in a display rack in the waiting area. During interview the PR and fertility nurse specialist informed the inspectorate that each consultation is tailored to the individual service user and that they are provided a "patient pack" at the first consultation. A "patient pack" seen at the time of consultation was seen to contain: consent forms: individual treatment chart; checklists; IUI regime including details of any drugs used in the regime; information about ovarian hyper stimulation syndrome and contact numbers for both in and out of hours contact details. **Welfare of the child:** The centres' nursing staff have completed the City Hospitals Sunderland NHS Foundation Trust child protection training. The welfare of any child born as a result of fertility treatment is discussed with service users and the relevant forms signed by service users at the first consultation before consent to treatment is taken. If there are any issues raised they will be discussed with the PR and at team meetings where necessary. **Access to health records:** The centre adopts the procedures of the City Hospitals Sunderland NHS Foundation Trust in relation to providing access to health records. An application is required in writing signed by both parties along with a proof of identity (*CoP S.7.2.2.(d))* **Provision of information to the HFEA register:** Activity is reported manually and on an annual basis: Staff at the HFEA registry report that there are no issues regarding timely and accurate reporting. *(Direction 2006/6, paragraph 4)*
Areas for improvement
No areas for improvement
Areas for consideration
No areas for consideration

Executive recommendations for Licence Committee
There are no recommendations for the Licence Committee to endorse.
Evaluation
No areas for improvement
Areas not covered on this inspection
None

5. Clinical, laboratory and counselling practice

Desired outcome: Clinical, counselling and laboratory practices are suitable and are provided by competent staff.

Summary of findings from inspection:

- Staff training and competency
- Clinical practice
  - Screening of donors
  - Three embryo transfer
- Laboratory practice
  - Procurement, distribution and receipt of gametes and embryos
  - Traceability and coding
  - Selection and validation of laboratory procedures
  - Coding/ identification of samples
  - Witnessing
- Counselling practice
  - Counselling audit
- Storage of gametes and embryos

Full time equivalent staff

GMC registered doctors	1
NMC registered nurses	2
Non NMC registered clinical staff	0.5
Registered biomedical scientists	6
Scientists working towards registration	0
Support staff (receptionists, record managers, quality and risk managers etc)	1.5
Counsellors	1

Summary of laboratory audit
The last laboratory audit of cryopreserved samples was undertaken on 02/10/2008. Nine discrepancies were observed which were all investigated and successfully resolved.
Summary of spot check of stored material
One sperm sample was tracked from database to dewar and vice versa with no discrepancies observed.
Areas of firm compliance
Staff training and competency: The fertility nurse specialist informed the inspectorate that all members of staff undergo mandatory training as per the City Hospitals Sunderland NHS Foundation Trust. Training logs seen at the time of inspection showed staff participation in mandatory training on an annual basis. *(CoP S.6.2.2)* Documented signed competency assessments for the clinical staff were seen in training logs. (CoP *S.6.2.9 G.1.3.1*) Both nurses have completed a recognised scanning course and are

currently under supervision of practice *(CoP S.6.2.9)* Both nurses have completed training in taking consent through a Trust programme and have been assessed and signed off as competent by the PR.

Clinical practice:
The PR and the nursing staff carry out consultations, information giving, treatments and intrauterine insemination and compare and audit their practice within the centre. The nurses run a nurse led IUI clinic, undertake consultations and taking of consent following the initial consultation with the PR. Appointments are flexible and the nurses and PR work flexibly in order to accommodate clinical and service user preference requirements.
Clinical practice is monitored and audited through intra centre audit of pregnancy rates for IUI, audit against protocols and supervision by the PR*. (CoP S.9.5.3)*
A Trust chaperone policy is in place as required and a health care assistant is available from a neighbouring hospital department when required.

Laboratory practice:
At the time of inspection there are six histologists on rotation via the pathology department carrying our sperm preparation and sperm freezing. This work was mainly undertaken outside of normal working hours. (i.e. from 17-00h onwards) With the change in laboratory staffing structure there will be a dedicated biomedical scientist on rotation from pathology to carry out the daily work at the centre within normal working hours.

Storage of gametes:
The centre stores sperm for patients undergoing oncology treatment and a small amount of donor sperm.
The sperm storage dewars are stored in the main laboratory and were seen to have alarms connected to an auto-dialler which contacts the Trusts switchboard and then the on call biomedical scientist *(CoP S.6.4.2 (b))* The storage facilities seen at the time of inspection provide conditions designed to ensure their quality and safety. *(CoP S.6.3.7)*
Annual dewars audits were made available to the inspection team via the Q-Pulse system and found to be satisfactory.

Traceability and coding:
It was observed that the centre has a traceability log in place which records any materials that come in contact with gametes *(CoP 6.4.3 (d))*

Inter-centre comparisons:
Staff in the diagnostic laboratory participate in National External Quality Assessment (NEQAS) scheme and are regularly monitored against required quality standards. *(CoP S.9.2.6)*

Counselling practice:
During interview the centres independent counsellor described the services she provides which include; implications, therapeutic and support counselling. Counselling is discussed with service users at the first consultation before treatment begins and there is information material displayed in the centres waiting area. Counselling takes place independently of the clinical assessment and is offered before consent to treatment is taken *(CoP S.7.6.3)* All service users are offered the counsellor's contact details to make an independent appointment. The counsellor interviewed on the day of inspection informed the inspectorate that she would refer on to specialist counsellors if required *(CoP S.7.6.3)*

The counsellor has considerable experience and during interviewed offered an extensive portfolio of qualifications, continue professional development and membership of relevant organisations such as the British Infertility Counsellors Association (BICA) *(CoP S.6.2.11)* She informed the inspectorate that the centre is supportive in continued professional development (CPD) and she regularly attends regional and national meetings. The counsellor attends and contributes to centre meetings demonstrated in documented meeting minutes. There is also an appropriately qualified back up counsellor if required.

Areas for improvement

Competency assessments:
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)*

Equipment failure:
The centre does not have a standard operating procedure for the response to dewar alarms. The PR should ensure that the centre has an established documented procedure for the management of equipment and materials that include the operation of each piece of equipment, detailing the action to be taken in the event of the malfunction or failure. *(CoP S.6.4.3)*

Selection and validation of laboratory procedures:
The laboratory and clinical staff have not completed the validation of procedures and equipment. The PR should ensure the laboratory and clinical procedures are validated in order to meet the needs of the service users and ensure the safety and quality of gametes. *(CoP S.7.8.3)*

Areas for consideration

Witnessing:
The centre has a standard operating procedure for witnessing but there are some steps which are not included. E.g. the final step of witnessing the hand over of prepared sperm between the biomedical scientist and clinician for insemination; the time of witnessing steps should be timed in the documentation. The PR should consider including this step and part of the centres witnessing protocols. *(CoP S.7.8.15)*

Executive recommendations for Licence Committee

The Licence Committee is asked to endorse the recommendations made in relation to:

- Documentation of competencies;
- Equipment failure
- Selection and validation of laboratory procedures.
- Witnessing procedures.

Evaluation

Some improvement required

Areas not covered on this inspection
Procurement, distribution and receipt of gametes

Report compiled by:

Name	Mrs Ellie Suthers
Designation	Inspector
Date	11/02/09

Appendix A: Centre staff interviewed

Mr Yossry – Person Responsible
3 members of the centres team
2 service users

Appendix B: Licence history for previous 3 years

2008
Licence Committee 24th April 2008
The Committee agreed that the centre's licence should continue with no additional conditions

2007
Licence Committee 26h April 2007
The Committee agreed to vary the centre's licence pursuant to the Human Fertilisation and Embryology Act 1990, as amended by the Human Fertilisation and Embryology (Quality and Safety) Regulations 2007.

Licence Committee 16h April 2007
The Committee agreed that the centre's licence should continue with no additional conditions

2006
Licence Committee 30th October 2006
The Committee agreed to recognise Mr Menem Yossry as the new Person Responsible for the centre.

Licence Committee of 10th April 2006
The Committee agreed to issue the centre with a treatment and storage licence. This licence had no additional conditions attached and is to last for three years.

Appendix C: Response of Person Responsible to the inspection report

Centre Number……0096……

Name of PR…Mr Menem Yossry……

Date of Inspection……16/01/2009……

Date of Response……06/03/2009……

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. We will make alterations to the report where there are factual inaccuracies.

- Page 5, under **Brief Description of the Centre**, last line should read "the North *East* Fertility Network".*
- Page 5, under **Summary for Licence Committee**, first paragraph: the centre carried out 3 donor insemination cycles since the last inspection.*
- Page 14, under **Quality Management System**, an electronic version of the quality manual is also available online with easy access to all staff.*

* corrections made in the body of the report.

2. Please use the space below to document any comments or additional information that you would like to be considered by a Licence Committee.

No comments added.

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

- Arrangements have been made to ensure that the outcomes of incident investigations by the Trust's risk management team are communicated back the Unit and documented.

- Review of all existing documents to ensure they are up-to-date and version-controlled is already in progress, as well as review of the process of regular reviews of controlled documents.

- Lab staff competencies will be documented within the centre documents.

- A SOP for the response to dewar alarms is being finalised and will be implemented from April 2009.

- Arrangements are being developed with the Security Department to ensure adequate response to the Centre's alarms.

- Changes have been made to the witnessing procedure/document to include the final step of handover of the specimen.

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

Please return Appendix C of the report electronically to your inspector or in hard copy to:
Regulation Department
Human Fertilisation & Embryology Authority
21 Bloomsbury Street
London
WC1B 3HF

HFEA Licence Committee Meeting
8 April 2009

21 Bloomsbury Street London WC1B 3HF

Minutes – item 2

Sunderland Fertility Centre (0096), Licence Renewal

Members of the Committee:	
Anna Carragher, Lay Member (Chair) Emily Jackson, Lay Member William Ledger, Professor of Obstetrics and Gynaecology at the University of Sheffield	Committee Secretary: Claudia Lally Legal Adviser: Sarah Ellson, Field Fisher Waterhouse Solicitors
Attending via video conference link: Rebekah Dundas, Lay Member	Observing: Lillian Neville

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

The following papers were considered by the Committee:

- papers for Licence Committee (39 pages)
- no tabled papers.

The Committee also had before it:

- HFEA Protocol for the Conduct of Licence Committee Meetings and Hearings
- 7th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- HFEA (Licence Committees and Appeals) Regulations 1991 (SI 1991/1889)
- Decision Trees for Granting and Renewing Licences and Considering Requests to Vary a Licence; and
- Guidance for members of Authority and Committees on the handling of conflicts of interest approved by the Authority on 21st January 2009.

1. The Committee noted that this small centre carries out approximately 200 cycles of Intrauterine Insemination (IUI) cycles per year, for patients being treated with donor and partner sperm. The centre provided 58 such treatments in the period from July to December 2007.

2. The Committee noted that the licence renewal inspection of the centre took place on 16 January 2009 and found that some improvements were required in the following areas:

- incident reporting
- payment of HFEA fees
- document control
- security of the premises
- competency assessments
- witnessing procedures
- standard operating procedures; and
- validation of laboratory procedures.

3. The Committee noted that the report itself and the response to the report by the Person Responsible highlighted the fact that the areas for improvement are all in the process of being addressed. On the basis of this information the Committee agreed that they were satisfied as to the suitability of the centre premises and as to the use of suitable practices at the centre. The Committee also noted that there were no issues regarding the character, qualifications or experience of the Person Responsible or his ability to perform his duties under Section 17 of the 1990 Act, and agreed that they were satisfied that the Person Responsible was suitable.

4. The Committee further agreed that they were satisfied that they had sufficient and satisfactory information on which to make a determination. However, the Committee noted that they had not been informed about whether the renewal fee had been paid. The Committee decided to grant a licence for a period of 5 years, subject to the payment of this fee.

5. The Committee agreed that they expected outstanding areas for improvement identified at the inspection to have been addressed by the time of the next inspection of the centre, which should take place in the next two years.

Signed…….. … Date……..
Anna Carragher (Chair)