Interim Inspection Report

St Jude's Women's Hospital
0198

Date of Inspection: 2nd and 3rd of September 2008
Date of Licence Committee: 13th November 2008

Centre Details

Person Responsible	Mr Jude Harris Adeghe
Nominal Licensee	Dr Chaman Lal
Centre name	St Jude's Women's Hospital
Centre number	0198
Centre address	263, Penn Road, Wolverhampton, West Midlands WV4 5SF
Type of inspection	Interim
Inspector(s)	Ellie Suthers, Andy Leonard, Robert Sawyer
Fee paid	Not required
Licence Number	L0198/6/a
Licence expiry date	01 January 2010
NHS/ Private/ Both	Private

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About the Inspection:

This inspection visit was carried out on the afternoon of Tuesday 2nd and the morning of the 3rd of September 2008.

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 Person Responsible (PR) and Medical Director is Mr Jude H Adeghe. He is a specialist in obstetrics and gynaecology, completed the Person Responsible Entry Programme (PREP) in August 2008 and is registered with the General Medical Council (GMC).
(CoP: S.4.1.5:S.4.1.4)
Dr Chaman Lal is the centres Nominal Licensee and a General Practitioner.

St Jude's Women's Hospital is a standalone facility in a converted private house located on the outskirts of Wolverhampton. The hospital has been providing private fertility services since 2002. Licensable treatments offered include: In vitro Fertilisation (IVF), Intra Uterine Insemination (IUI) and Intra Cytoplasmic Sperm Injection (ICSI)

The hospital achieved International Standards Organisation 9001:2001 (ISO) in 2007.

A satellite centre, Newcastle Gynaecology Services, provides private patients with ovulation induction, pregnancy testing, scanning and counselling services: a third party agreement between the primary and satellite centre was seen at the time of inspection.

St Jude's Women's Hospital is open seven days per week between 7.30am and 7pm weekdays: 8.00am and 4.30pm Saturday and between 10.00am and 3pm on Sunday for all treatments and care.

The hospital website provides information for patients, downloadable patient information leaflets and details of other services such as gynaecology, antenatal and ultrasound services.

Before the inspection began the inspectorate and the PR agreed that there are no conflicts of interests which may impair or bias the inspection process and outcome.

Activities of the Centre[1] for the time period from 01/01/2007 – 31/12/2007

In vitro fertilisation (IVF)	84
Intra cytoplasmic sperm injection (ICSI)	71
Frozen embryo transfer (FET)	40
Intra uterine insemination (IUI)	0
Gamete intra fallopian transfer (GIFT)	0
Research	no
Storage gametes/embryos	yes

[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.

Summary for Licence Committee

The St Jude's Women's Hospital is a small assisted conception unit providing approximately 200 licensed treatment cycles per year. The hospital appears to have suitably qualified and experienced staff and adopts appropriate clinical and laboratory procedures.
Patients report satisfaction with the treatment and service they receive. On inspection the hospital appears to be suitably equipped and staffed for the level of activity.

Improvements should be considered in the following areas:

- Timely payment of HFEA invoices;
- Document control;
- Health and safety of staff;
- Submission to the HFEA of outstanding activity and outcome forms;
- Staff competency assessments;
- Validation of critical process procedures;
- Participation in inter laboratory and/or centre comparisons;
- Compliance with witnessing procedures;
- Development of policies and procedures as part of the Quality Management System;
- Further development of quality objectives and quality indicators.

It is recommended that improvements are made in these areas of practice within the prescribed timescales.

The licence committee should note that three recommendations from the last inspection remain outstanding:

- Timely payment of HFEA invoices;
- Validation of critical process procedures;
- Submission to the HFEA of outstanding outcome forms;

Following the inspection on 2nd and 3rd of September 2008 the inspectorate recommends the continuation of the hospitals licence.

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
For the year up to August 2008 the average time taken to pay HFEA invoices was 78 days. (*CoP A.16.3)*	The Person Responsible 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.	By the time of the next inspection.
It was observed that in some instances a number of different versions of some clinical policies and protocols were available to staff in the policy and procedure folder. For example the inspectorate observed that there were three different versions of the complaints procedure none of which had version control. *(CoP A.10.27 CoP S.5.2.5(c))* The document control footers in use do not appear to contain all the required information. Some detail the author, the hospital, the document name and the production date. They do not include the page number of total page number or the named authoriser. *(CoP S.5.2.6)*	The PR should review document control procedures, to ensure that reviews and changes are controlled and only current versions are in use. The document control procedure should also ensure that: (a) documents are approved by authorised personnel prior to use, (b) documents are uniquely identified: identification shall include a unique identifier, the edition or current revision date, or revision number, the number of page/total number of pages (where applicable), authority for issue, and author identification.	December 31st 2008
The procedure for responding to the low oxygen alarm required evacuation only after 10 minutes or more of the alarm sounding. *(CoP S.6.3.2)*	The PR should review procedures to ensure the safety of staff and/or patients in the event of oxygen depletion.	Immediately
It was noted at the time of inspection that there were a number of outstanding activity and outcome forms not submitted to the HFEA. *Direction 2006/6, paragraph 4 (v) that provides timescales*	The PR should ensure that there is an effective process in place to ensure the reporting of activity and outcomes to the HFEA.	December 31st 2008

for submitting forms to The Authority.		
The PR, laboratory staff and nurse coordinator informed the inspectorate that competency assessments have not been done but will be done in the future. *(CoP A.10.9: S.6.2.9)*	The PR should ensure there is documented evidence of competency assessments for each member of staff.	December 31st 2008
There is a staff induction policy in place: the inspectorate did not see any record of staff completing induction or orientation. *(CoP S.6.2.12 (d))*	The PR should ensure that records are kept of new staff completing induction and orientation.	December 31st 2008
At the time of inspection the critical processing procedures affecting gametes and embryos quality and safety have not been identified and validated. *(CoP A.11.11:S.7.8.3)*	The PR should ensure that the critical processing procedures are validated.	By the time of the next inspection.
The laboratory staff undertake internal audits and evidence was observed by the inspector of changes and improvements made in practice but the laboratory does not participate in inter centre or inter laboratory comparisons. *(CoP S. 9.2.6)*	The PR should ensure that the hospital participates in inter-centre comparisons such as those organised by professional bodies and inter-laboratory comparisons schemes and by other external bodies	By the time of the next inspection
Witnessing signatures are not always documented contemporaneously, and signatures are not individually timed and dated. *(CoP S.7.8.15 :A.3.5: G.13.2.1))*	The PR should ensure that witnessing checks are completed and recorded at the time the clinical or laboratory process/procedure takes place and that the date and the time of the procedure is recorded.	Immediately

Non-Compliance

Area for improvement	Action required	Time scale
It was confirmed at the time of inspection that the PR is the hospitals	The PR should ensure that the hospitals documentation is	December 31st 2008

quality manager. Documentation submitted to the HFEA contained a number of names of people designated as quality manager. (CoP S.5.2.3)	amended to show the PR as quality manager	
During interview staff informed the inspectorate that witnessing does not always include positive verbalisation of the patient name and unique identifier by the embryologist and the witness. *(CoP G.13.7.3)*	Code of Practice guidance requires that upon egg or sperm collection, embryo transfer and sperm insemination patients and donors should be asked to actively supply identifying information (full name and date of birth) requested by verbally stating it, rather than confirming or rejecting information read out by a member of staff.	Immediately

Recommendations

Area for improvement	Action required	Time scale
The inspectorate recommends that the PR continues to develop the quality management system (QMS) and the quality manual to reflect the individual requirements of the hospital and its activity.		By the time of the next inspection.
The inspectorate recommends that the PR and staff continue to develop detailed objectives and quality indicators for review of the quality of the service provided in line with recommendations of CoP S.4.2.9.		By the time of the next inspection.
The PR was required to report their IUI activities, including live birth rates, for the period 5 July – 31 December 2007 to the HFEA by 31 March 2008. The HFEA has not yet received these data. It is recommended that this be submitted at the earliest possible opportunity.		

Changes/ improvements since last inspection:

Recommendations	Action Taken
The HFEA had not received the PR's. Person Responsible Entry Programme (PREP) at the time of the last inspection. (9th August 2007) The PR should submit the entry programme 10th March 2008: 14 days after licence condition implemented. *(CoP S.4.1.5)*	PREP completed and submitted on August 3rd and August 5th 2008 (PREP Unit 1 and Unit 2 respectively) The PR did not submit the PREP at the time agreed.
The PR had failed to disseminate Alert 23 to the embryologist. It was recommended that all HFEA Alerts are distributed to all relevant staff and respond to the recommendations as required. *(CoP S.4.1.7(d): S.4.1.8(c))*	It was observed on inspection, 2nd/3rd September 2008, that a protocol for dissemination of HFEA alerts is in place and a folder containing all HFEA alerts was available in the embryology laboratory.
Third party agreements had not been formalised. It was recommended that the PR formalise all third party agreements with parties who supply products or services that have the potential to affect the quality and safety of gametes and embryos. *(CoP S.4.2.10)*	It was observed on inspection 2nd/3rd September 2008 that third party agreements were completed and filed in a folder.
Payment of additional treatment fees were not paid within the required 28days. It was recommended that the PR ensure that all fees are paid to the Authority as defined by standard licence conditions. *(CoP A.13.3)*	The PR remains in breach of this requirement (2nd/3rd September 2008)
The centres complaints register did not accurately record all complaints they had received. It was recommended that all complaints and their investigations are logged together with corrective actions. *(CoP S.9.2.2)*	At the time of inspection, 2nd/3rd September 2008 it was noted that there is a complaints register in place and that no complaints were logged since the last inspection (9th August 2007) The PR stated that he had not received any complaints since the last inspection.
It was recommended that the PR ensure that effective nurse call systems	It was observed on inspection, 2nd/3rd September 2008, that functioning call bells have been fitted by

are fitted in the recovery areas and that the frame for the oxygen cylinder is repaired. *(CoP S. 6.3.4(b))*	each bed in the recovery area and that small portable oxygen cylinders with masks are available in the theatre and recovery areas.
It was recommended that the hatch between the theatre and embryology laboratory be kept closed in order to protect the security of gametes and embryos (*CoP S.6.3.2)*	It was noted that the PR stated that the hatch had been left open on the inspection of 9th of August 2007 to facilitate easy access by the inspection team. On the inspection of 2nd/3rd of September 2008 it was observed that the hatch remained closed.
Not all equipment and processes that affect the quality of gametes and embryos had been validated. It was recommended that the PR ensured this is carried out *(CoP S.6.4.2)*	It was observed during the inspection of the 2nd/3rd of September 2008 that laboratory equipment had been validated and documented. Validation of processes that affect the quality of gametes and embryos have yet to be validated but the embryologist informed the inspectorate that there are plans in place to begin this work in accordance with the Association of Clinical Embryologist (ACE) guidance.
A large number of pregnancy outcome forms had not been submitted by the hospital to the HFEA. It was recommended that the PR ensure that all pregnancy outcome forms are submitted. *(Direction 2006/6 (v))*	The nurse coordinator has liaised with the HFEA Registry staff to ensure forms are completed correctly and submitted on time. A number of pregnancy outcome forms (20) remain outstanding at the time of inspection 2nd/3rd of September 2008.
One of the ten dewars contained embryos that had expired their statutory storage period of June 2007. This is a breach of section 14(1)(c) of the 1990 HFE Act regarding storage periods for gametes and embryos as well as a breach of section 3(1A)(b)(i) of the 1990 HFE Act which provides that no person shall keep an embryo except for in the pursuance of a licence. A breach of section 3(1A)(b)(i) is an offence under section 41(2)(a) of the 1990 HFE Act. It was recommended that an effective review system should be put in place to review storage periods.	The PR provided written confirmation that these embryos have been allowed to perish. It was observed during the inspection of 2nd/3rd of September 2008 that a manual tracking system has been put in place to identify imminent expiry of storage periods.

Not all products that came into contact with gametes and embryos were traceable. Additionally the hospitals traceability protocol did not include all laboratory procedures. It was recommended that all laboratory procedures and protocols should be extended to include the critical processes identified in the Code of Practice. *(CoP S.7.3.1)*	At the time of inspection 2nd/3rd September 2008 it was observed that traceability of sperm and embryos is achieved through the appropriate labelling of all embryo/gamete containers with the patient name, date of birth and unique identifier, witnessing at all required steps on a witnessing sheet, using clinical and laboratory sheets for recording patient details. Consumables batch and storage logs were observed to be detailed and complete. *(CoP S.7.3)*
"Inconvenience payments" were being made to egg donors. It was recommended that this practice stop as it is in contravention of *Chairs Letter (06) 01* regarding payments for donation.	During the inspection of 2nd/3rd of September 2008 it was seen in hospital documentation and on discussion with staff and patients that inconvenience payments are no longer paid to egg donors.
One of the storage dewars in the laboratory was not connected to a local alarm system and auto dialler facility. It was recommended that all storage dewars should be connected to a local alarm or an auto dialler system in the event of dewar failure. *(Chairs Letter (04) 03*	All dewars are connected to a monitoring and dial out alarm system.
It was recommended that the practice of witnessing of processes should be reviewed with respect to the witnessing guidance outlined in the Code of Practice 7th Edition. *(CoP G.13)*	Witnessing documentation has been reviewed and the witnessing form is more detailed to cover the points raised at the last inspection.

Additional licence conditions and actions taken by centre since last inspection

There are no additional licence conditions

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
- 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) is Mr Jude Adeghe who is a specialist in obstetrics and gynaecology, completed the Person Responsible Entry Programme (PREP) in August 2008 and is registered with the General Medical Council (GMC) *(CoP: S.4.1.5: S.4.1.4)* Dr Chaman Lal is the centre's Nominal Licensee and a General Practitioner. Organisational accountability and reporting relationships were demonstrated via an organisational chart in the quality management manual. These relationships were also discussed during interviews between the inspection team and centre staff. Staff appeared to understand reporting relationships and the roles and responsibilities in the hospital. *(CoP: S.4.2.6)*. **Organisation of the centre:** The hospital is open seven days per week between 7.30am and 7:00pm weekdays: 8.00am and 4.30pm Saturday and between 10.00am and 3pm on Sunday: all aspects of treatment and care are carried out during these times. **Resource Management:** The PR and nurse coordinator informed the inspectorate that the hospital is open at times to meet the needs of service users. Working patterns and staff rotas are agreed accordingly. The nurse coordinator informed the inspectorate that service user appointments and treatments are managed around the availability of staff taking into account annual leave, professional leave etc. There has been no significant change in work load or staffing levels since the last inspection and additional temporary administrative staff are employed when required.

Incident management:
The hospital has an incident management policy which outlines the systems and processes in place for the investigation and recording of incidents. *(CoP S.9.4.1)* The PR informed the inspectorate that no incidents had been identified since the last inspection either in the laboratory or in the clinical areas. This was reflected in the incidents file/log therefore there were no remedial actions or corrections recorded.
During interviews the embryologist and nurse coordinator informed the inspectorate that any incident identified would be reported to the PR immediately.

Alert management:
The inspectorate observed that there is an alerts folder within the laboratory which contained HFEA alerts and the embryologist demonstrate her knowledge of the details of the last Alert 25. The PR and nurse coordinator informed the inspectorate that any alerts or incidents would be circulated by the PR and discussed in hospital meetings. Evidence was observed in meeting minutes of these discussions.

Third Party Agreements:
A sample of third party agreements was reviewed at the time of inspection and was seen to be compliant.

Meetings / dissemination of information:
The PR, embryologist and nurse coordinator informed the inspectorate that meetings are held monthly for all members of staff and a clinical meeting is held every six weeks. Minutes of some of these meetings was seen by the inspectorate including the minutes of the first annual review meeting. *(CoP S.6.2.13: S.6.2.10)*

Areas for improvement

Fee payment:
For the year up to August 2008 the average time taken to pay HFEA invoices was 78 days. The Person Responsible 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. *(CoP A.16.3)*

Areas for consideration

There are no areas for consideration from this inspection

Executive recommendations for Licence Committee

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

- Fee payment

Evaluation

Some improvements required.

Areas not covered on this inspection
Clinical Governance

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
Live Birth Rate: The reporting of live birth rates has not been accurate as a result of omission in the reporting of activity and outcomes from the hospital to the HFEA during 2006. This is being addressed by the hospital: the PR has been asked to report the data by the 25th of September 2008. From the data reported for the time period from 2004-2006 live birth outcomes appear to be in line with national averages.
Areas of firm compliance
Quality management system: The PR informed the inspectorate that he had been helped to develop a quality manual for the hospital by a commercial quality management consultancy. It was noted that the hospital does have a quality management manual and quality policy in place which includes a description of the hospital, the services it provides and legal information. *(CoP S.5.2.3)* **Quality management in the embryology laboratory:** The laboratory had a detailed set of protocols which were briefly reviewed and appeared to cover all relevant procedures. The embryologist informed the inspectorate that quality objectives have been set for the laboratory and the aim is to maintain the success rates as they are. The laboratory staff regularly review multiple quality indicators for IVF and ICSI patients, for IVF/ICSI combined and for frozen embryo transfers (FET), including numbers of patients, pregnancy rates, fertilisation rates, implantation rates, live birth rates and multiple pregnancy rates. Pregnancy rates for IUI, DIUI, IVF and ICSI 1st, 2nd, 3rd and 4th attempts, and for day 2, 3 and 4-6 embryo transfers, are also calculated. These data are prepared on an annual basis. In addition, pregnancy rates following IVF and ICSI are monitored monthly to allow trend analysis. The annual HFEA ICSI return is also used to monitor performance of ICSI practitioners.

Quality management for clinical care:
The Pre Inspection Questionnaire (P.I.Q) and documentation reviewed as part of the onsite inspection indicated three quality indicators have been identified as part of quality management: Counselling uptake; compliance with the Code of Practice and service user satisfaction. A set of minutes described discussions of an annual quality management review.

Service user feedback including suggestions and complaints:
It was observed that the hospital has a complaints procedure displayed on the wall of the waiting room which contained instructions on how, where and to whom service users can make complaints including the address of the Healthcare Commission and HFEA.

There is a folder which contains past letters of complaints from service users. The PR informed the inspectorate that these complaints have been resolved. The PR informed the inspectorate that no verbal, written or emailed complaints have been received by the hospital since the last inspection. This was reflected in the complaints file/log therefore there were no remedial actions or corrections recorded.

The nurse coordinator informed the inspectorate that service user questionnaires were distributed and the results collated. (*CoP S.9.2.2).* A service user forum is available on the hospitals website: this was not reviewed by the inspectorate.

During the inspection the inspector had the opportunity to interview four service users at varying stages of treatment. All of them were content with their treatment and the care that they received at the hospital.

Areas for improvement

Document control:
It was observed that there were a number of different versions of some policies and protocols that were available to staff in the policy and procedure folder. For example the inspectorate observed that there were three different versions of the complaints procedure none of which had version control. *(CoP A.10.27: S.5.2.5(c))*

The document control footers in use do not appear to contain all the required information. Some detail the author, the hospital, the document name and the production date. They do not include the page number or total page number or the named authoriser: The document control procedure should be reviewed to ensure that: (a) documents are approved by authorised personnel prior to use, (b) documents are uniquely identified: identification shall include a unique identifier, the edition or current revision date, or revision number, the number of page/total number of pages (where applicable), authority for issue, and author identification. *(CoP S.5.2.6)*

Quality Manager
It was confirmed at the time of inspection that the PR is the hospitals quality manager. Documentation submitted to the HFEA contained a number of people designated as quality manager. This should be clarified and amended in the hospitals documentation. *(CoP S.5.2.3)*

Areas for consideration

The inspectorate recommends that the PR continues to develop the quality management system (QMS) and the quality manual to reflect the individual requirements of the hospital and its activity. The inspectorate recommends that the PR and staff continue to develop detailed objectives and quality indicators for review of the quality of the service provided in line with recommendations of (CoP S.4.2.9).
Executive recommendations for Licence Committee
The Licence Committee is asked to endorse the recommendations made in relation to: ➢ Document control ➢ Designated quality manager
Evaluation
Some improvement 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: St Jude's Women's Hospital is a standalone facility in a private house located on the outskirts of Wolverhampton. The main entrance is locked and access is via door bell and the main staffed reception. On the ground floor there is the main reception area, one nurse consulting room, the PR's consulting room, comfortably appointed waiting room, staff room and kitchen and toilet facilities. Health records storage is in a locked room off the nurse consulting room. The first floor can be accessed via a staircase or small lift. The operating theatre, two recovery rooms and embryology laboratory are located on the first floor. A central nurse's station ensures that anyone accessing the clinical area is visible by staff. It was observed that the laboratory containing gametes, embryos and confidential information and the operating theatre doors have key pad locks. At the time of inspection the hospital appeared to have 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 embryos, and staff. *(CoP 6.3.2)* The hospital has a neighbouring facility which includes a suitably equipped, private and quiet counselling room which appeared suitable for counselling purposes. *(CoP S.6.3.5)* There is also an office which the PR informed the inspectorate was for his own use. A small adjacent room is used for the PR's own personal use. Neither of these rooms were seen at the time of inspection. **Clinical facilities**: Clinical facilities are located on the first floor and comprise an operating theatre, two recovery rooms, sperm production room and toilet facilities. The two recovery rooms have accessible call bells next to each bed, a small portable oxygen cylinder and arm chairs. The operating theatre has a stocked resuscitation trolley and there is a locked drug cabinet in the operating theatre. Documented checking procedures for both emergency equipment and drug storage were seen to be completed and up-to-date. It was observed that the clinical facilities seen at the time of inspection provide for the privacy and comfort of service users undergoing examination and treatment and are equipped with emergency clinical facilities *(CoP S.6.3.4)*

Counselling facilities:
Counselling facilities are provided in the annex next to the main hospital. The room appeared to provide quiet and comfortable surroundings in which sessions can be held that are private, confidential and without interruption. *(CoP S.6.3.5)*

Laboratory facilities:
The laboratory facilities comprise two laboratories: laboratory one is used for the processing of gametes and embryos. Laboratory two provides an appropriate environmentally controlled, secure environment for the storage of gametes and embryos in alarmed dewars. Doors to the laboratory were seen to be keypad locked making the rooms accessible only by authorised staff. *(CoP S.6.3.8)*

Logged regular cleaning schedules were seen by the inspectorate; the inspectorate considered the laboratory environment suitable for licence activities.

Air quality:
Air quality monitoring is provided annually by QC West Midlands, University Hospital Birmingham NHS Foundation Trust. Annual testing was recommended by the company who fitted the air cleaning equipment in the laboratory. The last monitoring report was observed and was seen to be detailed, consisting of a summary and all the results, as well as the test protocols and locations. The operating theatre and laboratory one, where gametes and embryos are processed, were at Grade B and laboratory two achieved Grade C. Air quality in the two air flow cabinets was at Grade A. It was considered at the time of inspection that the processing of gametes and embryos is performed using sterile technique and under conditions of appropriate air quality *(CoP S.7.8.5)*

Management of equipment and materials:
Portable electrical appliance testing (PAT) on equipment in the laboratories was seen to be present and up to date. The ultrasound scanners are serviced six monthly by a commercial supplier. (*CoP S.6.4.2)*

Clinical equipment in the operating theatres and recovery areas was seen to be functioning and in serviceable condition. New portable oxygen cylinders were delivered to the hospital on the day of inspection and placed in both recovery rooms.

Storage facilities for gametes and embryos
The storage facility for gametes and embryos was seen to be secure. Both laboratories and dewar store are secured with key pad locks. It was noted by the inspectorate that one large dewar is in stored in the laboratory rather than in the dewar store. This has its own low oxygen monitor adjacent to the dewar and temperature monitors.*(CoP S.6.3.8)*

Low oxygen monitors were in place and dewars are all fitted with two temperature monitors. The dewar store was labelled with appropriate safety signs and equipped with two extractor fans which were permanently on. There is a procedure for responding to the low oxygen monitor and the dewar temperature monitors.

Staff facilities:
A small changing/rest room with lockers and a separate small kitchen are provided for members of staff. *(CoP S.6.3.10)*

Storage of records:
Health records were seen to be stored in a designated locked room off the nurse consulting room. Bars protect windows and prevent unauthorised access. There is no off-site storage and in discussion with the PR and nurse consultant it was noted that storage space is becoming an issue and that alternative storage methods may be an option including electronic storage although the PR said that a move to bigger premises may be an option in 3-5 years time.

Areas for improvement

The procedure for responding to the low oxygen alarm required evacuation only after 10 minutes or more of the alarm sounding. The PR should review procedures to ensure the safety of staff and/or patients in the event of oxygen depletion. (CoP S.6.3.2)

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:

- The health and safety of staff and/or patients in the event of oxygen depletion.

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: Information for service users is available on the hospitals website: (Patients Guide: egg donation – information for donors: egg sharing – general information: information for egg recipient: information for egg provider: information on in-vitro fertilisation (IVF): donor insemination (DI): intra uterine insemination (IUI): frozen embryo transfer: intra cyto plasmic sperm injection (ICSI). The PR informed the inspectorate that all service user information leaflets were about to be reviewed. Some information leaflets were available behind the reception desk in the hospital and the nurse coordinator informed the inspectorate that service users are handed the appropriate leaflet at the time of consultation. This was confirmed by four service users that were interviewed at the time of inspection.
Areas for improvement
Provision of information to the HFEA register: It was noted at the time of inspection that there were a number of outcome forms have not been submitted to the HFEA. The Nurse Coordinator informed the inspector during interview that she had experienced some difficulty with submission of data via the Electronic Data Interchange (EDI) and has been working with the data quality officer at the HFEA to rectify this. *Direction 2006/6, paragraph 4(v) that provides timescales for submitting forms to The Authority.* The PR was required to report their IUI activities, including live birth rates, for the period 5 July – 31 December 2007 to the HFEA by 31 March 2008. The HFEA has not yet received these data.
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: ➢ The submission of activity and outcome forms to the HFEA

Evaluation
Some improvements required
Areas not covered on this inspection
Consent Welfare of the child Access to health records

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 WTE +2 x 0.3 support
NMC registered nurses	2
Non NMC registered clinical staff	1
HPC registered scientists	1.5 WTE
Scientists working towards registration	0 WTE
Support staff (receptionists, record managers, quality & risk managers etc)	1
Counsellors	1 sessional

Summary of laboratory audit
The centre has seven small dewars, one large dewar and one back up. A detailed rolling audit for Oct 2007 – Oct 2008 was submitted as part of the pre inspection documentation. The embryologist clarified the post dating (Oct 07 – Oct 08) of the report as she considers it ensures it is representative of compliance for this period. This was accepted by the inspector. Two errors mentioned in the audit were related to an embryo straw with a dislodged plug and a sperm sample which had been used and not noted as such in records. Both errors have now been amended. Both embryologists had just completed another dewar audit which was shown to the inspectorate on the day of inspection. It found only minor administrative issues.
Summary of spot check of stored material
No dewar audit was performed as this was an interim inspection and the Centre had provided a detailed audit for Oct 2007 – Oct 2008.

Areas of firm compliance

Staff training and professional development:

During the inspection clinical and scientific staff provided evidence of continued professional development in training logs/folders. A review of the nurse coordinator's training log provided written evidence and certificates confirming continued training and education e.g. cervical cytology, ultrasound training, advanced life support, National Vocational Qualification (NVQ) in teaching and assessing and a diploma in reproductive technology.
The Nurse Coordinator informed the inspector that she carries out scanning and intra uterine insemination as part of her role and evidence of training in these tasks was observed in her training log. A more recently employed nurse is undergoing induction and training.
The PR and Nurse Coordinator informed the inspectorate that there is a local induction programme for new members of staff including health and safety, manual handling and fire training. The inspectorate did not review evidence of this.

Both laboratory embryologists have many years of experience and are Association of Clinical Embryologist (ACE) certified. Certificates of successful completion of Continued Professional Development were observed as were certificates of further qualifications and attendance on courses. The embryologist informed the inspectorate that monitoring of Key Performance Indicators (KPI) has acted as a proxy for competency assessments and that now that a second embryologist has been employed. Competency assessments will be carried out in the future.

From the evidence produced and discussion at the time of the inspection laboratory and clinical staff appear appropriately registered and possess the appropriate qualifications and/or experience set out in relevant HFEA and professional guidance. *(CoP S.6.2.2)*

Screening of donors:
The egg donor screening procedure was observed and seen to be compliant with licence requirements. *(CoP S.7.6.7)*

Three embryo transfer: (3ETs)
A summary, taken from the hospitals 3ET log, of three embryo transfers was provided pre-inspection. The summary showed that all 3ETs were for age-related reasons and were performed in patients over 40 years. *(CoP G.8.5.1)*

Traceability and coding:
Traceability of sperm and embryos is achieved through the appropriate labelling of all embryo/gamete containers with the patient name, date of birth and unique identifier, witnessing at all required steps on a witnessing sheet, using clinical and laboratory sheets for recording patient details. Consumables batch and storage logs were observed to be detailed and complete. *(CoP S.7.3)*

Selection and validation of consumables, media and equipment:
The embryologists have completed validation of laboratory consumables, media and equipment

Counselling practice:

Three counselling sessions are offered free of charge for each service user. There is a poster advertising the service in the main waiting area and the nurse coordinator informed the inspectorate that all service users are offered the counselling sessions during consultation. At the time of inspection the counsellor was not available for interview. The PR informed the inspectorate that the counsellor will be leaving the employ of the hospital in the near future and the PR has engaged the services of a local commercial counselling service. The PR agreed to forward information to the HFEA on their compliance with the requirements of the Code of Practice within four weeks of engagement.

Storage of gametes and embryos:
At the time of inspection the storage of gametes and embryos was seen to meet requirements and conditions of storage: detailed and complete records were observed.

Monitoring of critical parameters:
At the time of inspection the critical parameters (e.g. temperature, humidity, air quality) were seen to be controlled, monitored and recorded to demonstrate compliance with the specified storage conditions. *(CoP A.10.21)*

A monitoring system connects to a computer in the anteroom area adjacent to the laboratory/theatre area. Parameters are saved to the hard drive of the PC. Deviations from defined limits lead to activation of the dial out system which calls the PR, the lead nurse, and the two embryologists. *(CoP S.6.4.2)*

Areas for improvement

Competency assessments:
The PR, laboratory staff and nurse coordinator informed the inspectorate that competency assessments have not been done but there are plans for them to be done in the future.
The PR should ensure there is documented evidence of competency assessments for each member of staff. *(CoP A.10.9: S.6.2.9)*

Staff induction:
There is a staff induction policy in place: the inspectorate did not see any record of staff completing induction or orientation. Records should be kept by new staff completing induction and orientation. *(CoP S.6.2.12 (d))*

Selection and validation of laboratory procedures:
The embryologist informed the inspectorate that there are plans to begin a procedure validation exercise but at the time of inspection key procedures affecting gamete and embryo quality and safety had not been identified and validated. The laboratory shall use procedures that meet the needs of patients, ensure the safety and quality of gametes and embryos and are appropriate to the treatment plan concerned. These should conform with existing professional guidance for good practice and published evidence, where available. The centre should ensure that the critical processing procedures are validated. *(CoP A.11.11:S.7.8.3)*

Audit and inter- laboratory comparisons:
The laboratory staff undertakes internal audits and evidence was observed by the inspector of changes and improvements made in practice but the laboratory does not participate in inter centre or inter laboratory comparisons. The PR should ensure that the hospital participates in inter-centre comparisons such as those organised by professional bodies and inter-laboratory

comparisons schemes and by other external bodies. *(CoP S. 9.2.6)*

Witnessing:
Witnessing signatures are also not always documented contemporaneously, and signatures are not individually timed and dated. The PR should ensure that witnessing checks are completed and recorded at the time the clinical or laboratory process/procedure takes place. *(CoP S.7.8.15: A.3.5)* and that the date and the time of the procedure is recorded. *(G.13.2.1)*

During interview staff informed the inspectorate that witnessing does not always include positive verbalisation of the patient name and unique identifier by the embryologist and the witness. Code of Practice guidance requires that upon egg or sperm collection, embryo transfer and sperm insemination patients and donors should be asked to actively supply identifying information (full name and date of birth) requested by verbally stating it, rather than confirming or rejecting information read out by a member of staff. *(CoP G.13.7.3)*

Areas for consideration

Donor screening:
The PR explained that they have recently changed their method of testing for Chlamydia and Gonorrhoea as part of donor screening. The inspectorate recommended that the donor screening protocol is amended to reflect the changes.

Witnessing:
It is also recommended that all witnesses are trained and their competency assessed regularly (at least annually) to ensure consistent witnessing practices and that this is documented.

Executive recommendations for Licence Committee

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

- Competency assessments of staff;
- Staff induction;
- Selection and validation of laboratory procedures;
- Audit and inter- laboratory comparisons;
- Witnessing.

Evaluation

Some improvements required

Areas not covered on this inspection

Procurement, distribution and receipt of gametes and embryos

Report compiled by:

Name Ellie Suthers

Designation Inspector

Date 6th October 2008

Appendix A: Centre staff interviewed

Mr J H Adeghe and
3 members of staff

Appendix B: Licence history for previous 3 years

2008
25th February 2008: Minutes of the representation hearing
26. The Committee carefully considered the detailed submissions made by Mr Lawford Davies on behalf of Mr Adeghe. The Committee discussed all the individual matters raised in Mr Lawford Davies's representations and in each case noted the corrective action which had been taken following the inspection visit in August and then the Licence Committee meeting in October. The Committee welcomed all of the actions taken by the centre in response to the matters identified in the inspection report. The Committee decided that there was still a lack of clarity in relation to the complaints log. With the exception of this matter, however, the Committee agreed that it was satisfied that the breaches and areas of non-compliance identified in the inspection report had been correctly identified as such. However, the Committee concluded that in the light of the actions taken by the centre since the inspection and in the light of the clarification about a number of the issues raised in the inspection report it would be disproportionate for them to proceed to apply the licence condition which had previously been proposed.

2007
29th October 2007: Consideration of interim inspection report
Minutes: 29th October licence committee
17. The Committee agreed that the breaches identified in the report and the large number of significant improvements required called into question the suitability of the Person Responsible. On these grounds they agreed to send notice to the centre of their intention to vary the licence by the addition of a condition requiring the Personal Responsible to submit his completed PR Entry Programme (PREP) to the Authority, within 14 days of the date upon which the condition takes effect.

14th May 2007: Variation of Licence under the EUTD Legislation
The Committee agreed to vary the licence to incorporate the requirements of the EUTD.

2006
11th October 2006: Consideration of renewal inspection report
The Committee agreed to renew the centre's licence for a period of three years, with no additional conditions.

9th March 2006: Consideration of an interim inspection report

The Executive presented papers to the Committee that contained the reports of an unannounced inspection, an interim inspection and the report of an interview with the Person Responsible. The Committee decided that the centre's licence should continue with no additional conditions.

2005
10th March 2005: Consideration of interim inspection report
The Committee decided to vary the centre's license to add a condition requesting the Person Responsible demonstrate to the Executive at an interview that sufficient mentoring, education and training to have substantially improved his understanding of the duties of a Person Responsible.

Appendix C: Response of Person Responsible to the inspection report

Centre Number……

Name of PR……..

Date of Inspection……..

Date of Response…….

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

Signed……

Name……..

Date……

1. Correction of factual inaccuracies

Please let us know of any factual corrections that you believe need to be made. We will make alterations to the report where there are factual inaccuracies.

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

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

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