Renewal Inspection Report

St. Jude's Women's Hospital
0198

Date of Inspection: 13 August 2009
Date of Licence Committee: 4 November 2009

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	Renewal
Inspector(s)	Jenny McLaughlin Ellie Suthers Sarah Brain Sheila Pike
Fee paid	Yes
Licence Number	L0198/6/b
Licence expiry date	31 January 2010
NHS/ Private/ Both	Both

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About the Inspection:

This inspection visit was carried out on 13th August 2009 and lasted for 6.5 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

St Jude's Women's Hospital is a small assisted conception unit providing approximately 200 licensed treatments per year. It is a standalone facility in a converted private house located on the outskirts of Wolverhampton.

The hospital has been providing fertility services since 2002. Licensed treatments include: In vitro Fertilisation (IVF), Intra Uterine Insemination (IUI) and Intra Cytoplasmic Sperm Injection (ICSI). A satellite centre, Newcastle Gynaecology Services, provides ovulation induction, pregnancy testing, and scanning.

St. Jude's Women's Hospital is open seven days per week between 7:30am and 7pm weekdays, 8am-4:30pm on Saturdays and 10am-3pm on Sundays for all treatment and care. This centre's license expires on 31 January 2010.

The Person Responsible (PR), medical director and quality manager of the centre is Mr. Jude H Adeghe. He is a specialist in obstetrics and gynaecology and is registered with the General Medical Council (GMC).

Activities of the Centre[1] for the time period from 01/01/2008 – 31/12/2008

In vitro fertilisation (IVF)	123
Intracytoplasmic sperm injection (ICSI)	92
Frozen embryo transfer (FET)	65
Intra uterine insemination (IUI)	1
Gamete intrafallopian transfer (GIFT)	0
Research	No
Storage gametes/embryos	Yes

Summary for Licence Committee

It was observed that the centre had made progress in addressing some of the breaches and noncompliance identified at the last inspection and appeared to be committed to the continual improvement of their quality system. However, the centre remains in breach of standard licence condition A.3.5 – witnessing checks are not always completed and recorded at the time the relevant laboratory procedure takes place.

Suitability of the PR

The PR is suitably qualified and in considering overall compliance of the St. Jude's Women's Hospital, the PR is considered to have discharged his duties satisfactorily under S.17 of the HFE Act.

Suitable premises and equipment

[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.

Premises and equipment were unchanged since the last inspection and at the time of this inspection were considered suitable for the activities for which the centre is licensed.

Suitable practices
At the time of the inspection, practices observed were considered largely suitable.

Some improvements should be considered in the following areas of practice:
- payment of HFEA invoices within required timeframe
- witnessing
- reporting cases of severe OHSS as adverse incidents
- storage of gametes and embryos
- critical equipment validation
- critical process risk assessments
- donor consent documentation
- staff induction training

The inspectorate considers that there is sufficient information on which to recommend the renewal of the licence for St. Jude's Women's Hospital for four years subject to compliance with the recommendations of this report within the prescribed timeframes.

Evaluations from the inspection

Topic	No Improvements required	Some Improvement required	Significant Improvement required
1. Organisation		✓	
2. Quality of the service	✓		
3. Premises and Equipment		✓	
4. Information		✓	
5. Laboratory and clinical processes		✓	

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 12 month period up to 13 July 2009, the average time taken to pay HFEA invoices was 57 days. Recent prompt payments have decreased this average and the most recent invoice was paid in 33 days.	The PR should continue to ensure that the HFEA invoices are paid within 28 days of the date of the notice in accordance with CoP A.16.3.	To be assessed at the next inspection.
Laboratory staff reported that there are occasions when there	The PR should ensure that there is sufficient trained staff	This recommendation should be implemented

is only one embryologist in the lab and therefore witnessing is not always conducted contemporaneously.	to conduct witnessing checks and that witnessing takes place at the time of the clinical or laboratory process/procedure. (CoP A.3.5)	immediately and written assurance provided to the HFEA by 13 October 2009. **Update 19 October 2009:** Written assurance has been provided by the PR and is documented in appendix C.
There was no evidence of a documented procedure for the witnessing of sperm preparation.	The centre should have witnessing protocols in place to double check the identification of samples and the patients or donors to whom they relate at all critical points of the clinical and laboratory process, including sperm preparation. (CoP S.7.8.15)	This recommendation should be implemented immediately and written assurance provided to the HFEA by 13 October 2009. **Update 19 October 2009:** A documented procedure for witnessing of sperm preparation was received at the HFEA.
One case of severe OHSS was not reported to the HFEA.	The PR should ensure that cases of severe OHSS are reported to the HFEA. (CoP A.4.5)	To be assessed at the next inspection.
It was observed on inspection that screened donor sperm samples were being stored in an unscreened tank with samples from patients who have been partially screened.	The PR should ensure that storage facilities are provided that clearly separate and distinguish gametes and embryos prior to release/ in quarantine from those that are released and those which are rejected, in order to prevent mix up and cross contamination between them. (CoP S.6.3.7) The PR should assess the risks of cross contamination of the screened donor samples that have been stored in a dewar with partially screened material. The result of the assessment should be documented and any corrective actions should be implemented to minimise the risk of future cross contamination. Patients should be informed of any	The HFEA should be advised of the findings of the assessments and any actions taken as a result of the assessment by 13 November 2009. **Update 19 October 2009**: The PR provided written confirmation that an extensive literature search and consultation with Consultant Microbiologists confirm that there is no risk of cross contamination.

	risks identified.	
At inspection, although there was evidence of servicing and maintenance, there was no evidence of critical equipment validation.	The PR should ensure that all critical equipment and technical devices are indentified and validated. (CoP A.10.13)	To be assessed at the next inspection.
A fire hazard assessment was seen to have taken place at the centre since the last inspection however there was no evidence that all activities impacting on the quality and safety of gametes and embryos have been formally risk assessed. At inspection, the PR stated that there are plans to conduct risk assessments for clinical and laboratory practices in the near future.	The PR should ensure that all activities impacting on the quality and safety of gametes and embryos are formally risk assessed. (CoP A.10.4)	To be assessed at the next inspection.
Two sets of patient notes contained inaccurately recorded consent. The centre was proactive in ensuring the consent forms were corrected and copies were received by the inspectorate on 1st September, 2009.	The PR should ensure that patient/donor consent is properly documented. (CoP S.7.5.4(c)) It is recommended that the centre carry out a consent audit to ensure the forms reflect the consent provided by the patients/donors. In consideration of the new HFEA consent forms taking affect on 1st October, 2009, the PR should ensure that staff receives training on how to take valid consent.	A summary report of the audit findings and any required corrective actions and a timeline for implementation should be provided to the HFEA by 13 November 2009. **Update 19 October 2009**: The PR provided written confirmation to the HFEA that the centre has conducted a consent audit to ensure that consent forms and storage of gametes are all in line and in order. The audit was carried out in September and will be on-going on a monthly basis.
In one set of notes, it was observed that a female patient consented to the posthumous use of embryos created using her gametes but was not screened as a donor.	The PR should ensure that patients consenting to the posthumous use of embryos created using their gametes are screened in accordance with standard licence condition A.7.2.	Immediately

A copy of an amended consent form was received by the inspectorate on 1st September 2009, showing that the patient no longer consents to the posthumous use of the embryos created using her eggs.		
There was no evidence that the new counselor had completed an induction or initial training programme.	The PR should ensure that the counsellor is provided with initial induction training and that this training is documented. (CoP S.6.2.7 (c))	To be assessed at the next inspection.
Documentation submitted pre-inspection indicated that the most recent laboratory audit was carried out between 23rd June 09 and 5th July 09. There were no discrepancies noted. However, in the course of the records review the inspection team noted that the consent form related to the stored donor sperm did not indicate the storage period.	The PR should ensure that the storage of gametes is in accordance with relevant patient consent and that storage audits include a review of the consented duration of storage. (CoP S.7.8.9 & S.7.8.12) It is recommended that the reason for the failure to identify that sperm was being stored without properly documented consent is investigated and that procedures are subject to corrective action if required.	A summary report of the findings and any required corrective actions and a timeline for implementation should be provided to the HFEA by 13 November 2009. **Update 19 October 2009**: The PR provided written confirmation to the HFEA that the centre has conducted a consent audit to ensure that consent forms and storage of gametes are all in line and in order. The audit was carried out in September and will be on-going on a monthly basis.

Non-Compliance

Area for improvement	Action required	Time scale
Patient records observed at inspection contained evidence of witnessing but in some instances the time and date of the witnessing check had not been recorded.	A record should be made in the patient/donor notes at the time the procedure takes place confirming the date and time of the procedure. (CoP G.13.2.1)	Immediately

Recommendations

Area for improvement	Action required	Time scale

Although the centre's screening protocols include consideration of requirements as recommended by professional guidelines[2] donor records observed at inspection did not include evidence of the additional recommended screening. (CoP G.4.9.1)	The PR should ensure that screening protocols reflect the centre's practice and deviations from protocols should be documented.	To be assessed at the next inspection.
The procedure for responding to the low oxygen alarm required evacuation only after 10 minutes or more of the alarm sounding.	Laboratory staff reported that should the oxygen depletion alarm go off unexpectedly, the procedure is to vacate the area immediately and wait for the warning light before re-entering the lab. This should be documented in the procedure.	To be assessed at the next inspection.
The centre's quality management system had been further developed since the last inspection and the PR reported that a quality management review/evaluation will be conducted by the end of the year.	In compliance with CoP standards S.4.2.8, S.9.2.4 and S.9.2.5 the PR should ensure that a regular review of the centre's quality management system and all its services is conducted. The review should assess the need for changes to the quality management system and opportunities for improvement. The maximum interval between management reviews should be twelve months.	To be monitored at the next inspection.

Changes/ improvements since last inspection

Recommendations	Action Taken
For the year up to August 2008 the average time taken to pay HFEA invoices was 78 days. (*CoP A.16.3)* It was recommended that 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.	For the 12 month period ending 13 July 2009, the centre was taking 57 days to pay HFEA invoices. Due to recent prompt payments, the average number of days has decreased and the last invoice was paid within 33 days.
It was observed that in some instances a number of different versions of some clinical	Documents observed at the time of the inspection were seen to be version controlled

[2] UK guidelines for the medical and laboratory screening of sperm, egg and embryo donors (2008). Association of Biomedical Andrologists, Association of Clinical Embryologists, British Andrology Society, British Fertility Society, Royal College of Obstetricians and Gynaecologists. December 2008 Human Fertility 11 (4): 201-210

policies and protocols were available to staff in the policy and procedure folder. The document control footers in use did not appear to contain all the required information. It was recommended that the PR should review document control procedures, to ensure that reviews and changes are controlled and only current versions are in use.	with dates and unique identifiers. (CoP S.5.2.6)
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)* It was recommended that the PR should review procedures to ensure the safety of staff and/or patients in the event of oxygen depletion.	Laboratory staff reported that should the oxygen depletion alarm go off unexpectedly, the procedure is to vacate the area immediately and wait for the warning light before re-entering the lab. The documented procedure reviewed at inspection did not explain this practice but stated that the lab should be evacuated after 10 minutes or more of the alarm sounding.
It was noted at the time of inspection that there were a number of outstanding activity and outcome forms that had not been submitted to the HFEA. It was recommended that the PR should ensure that there is an effective process in place to ensure the reporting of activity and outcomes to the HFEA.	The centre was visited by HFEA IT and hardware issues were resolved, resulting in improved reporting. Since the last inspection, the centre has reported activity and outcomes to HFEA in a timely and accurate manner.
The PR, laboratory staff and nurse coordinator informed the inspectorate that competency assessments have not been done but would be done in the future. *(CoP A.10.9: S.6.2.9)* It was recommended that the PR should ensure there is documented evidence of competency assessments for each member of staff.	The competence of laboratory staff was observed to be documented at regular intervals and the senior nurse specialist confirmed that competency assessments are conducted for clinical staff. (CoP S.6.2.9)
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))* It was recommended that the PR should ensure that records are kept of new staff completing induction and orientation.	There were no new clinic or laboratory staff since the last inspection but the senior nurse specialist confirmed that induction and orientation records will be kept in the personnel records of any new staff members. A new counsellor started providing services at the centre in March 2009 but there was no evidence that a formal induction or orientation had been completed. (CoP S.6.2.12(d))
At the time of inspection the critical processing procedures affecting gametes and embryos quality and safety had not been identified and validated. *(CoP A.11.11:S.7.8.3)* It was recommended that	The centre provided a copy of their "Process for Clinical and Embryology Validation Documentation" at inspection. This document provides a description of each critical process and identifies key controls and monitoring

the PR should ensure that the critical processing procedures are validated.	and data supporting process validation. Validation is based on retrospective evaluation of the centre's own data.
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)* It was recommended that the PR should ensure that the hospital participates in inter-centre comparisons.	Evidence provided at inspection showed that the laboratory is participating in inter-centre comparisons and NEQAS.
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))* It was recommended that 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.	Laboratory staff reported that there are occasions when there is only one embryologist in the lab and therefore witnessing is not always conducted contemporaneously. (CoP A.3.5) The time of each witnessing step is not always recorded in the patient/donor file.
It was confirmed at the time of inspection that the PR is the hospital's quality manager. Documentation submitted to the HFEA contained a number of names of people designated as quality manager. (CoP S.5.2.3)The PR should ensure that the hospital's documentation is amended to show the PR as quality manager.	An organisational chart, submitted pre-inspection, is included in the centre's quality manual and identifies the PR as the quality manager. (CoP S.5.2.3)
During interview staff informed the inspectorate that witnessing does not always include positive verbalization of the patient name and unique identifier by the embryologist and the witness. *(CoP G.13.7.3)*	The centre's documented witnessing procedure includes active identification of the patient upon egg/sperm collection, embryo transfer and sperm insemination and laboratory staff verbally confirmed this practice. (CoP G.13.7.3)
The inspectorate recommended 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.	At inspection it was observed that the centre's quality management system had been developed to include defined quality objectives and plans, document controlled procedures and a quality manual that reflects the individual requirements of the hospital and its activity.
The inspectorate recommended 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.	The centre has identified 4 measurable quality objectives and has conducted internal audits on patient satisfaction, occurrence of OHSS and fertilisation rate.

The PR was required to report IUI activities, including live birth rates, for the period 5 July – 31 December 2007 to the HFEA by 31 March 2008.	The PR reported that there were no IUI activities during this period.

Additional licence conditions and actions taken by centre since last inspection

N/A

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 PR has completed the HFEA PR Entry Programme (PREP) and is considered appropriately qualified and experienced for the role. (CoP S.4.1.5; S.4.1.4) An organisational chart was supplied pre-inspection that indicates lines of responsibility. (CoP S.4.2.5) **Organisation of the centre** At inspection the centre was observed to have an organisational structure and operational procedures that are appropriate to the activities for which the centre is licensed. (CoP S.4.1.1) **Resource management** The PR informed the inspectorate that there are sufficient staff and resources available for the activity of the centre. (CoP S.6.2.1) **Alert Management** The laboratory staff demonstrated an awareness of the most recent HFEA alerts. The senior nurse specialist reported that HFEA alerts are stored in the laboratory, circulated to all staff and discussed at the staff meetings. **Complaints management** The centre has a documented procedure for the resolution of complaints received from service users. Records of complaints and related correspondence were observed at inspection. (CoP S.9.2.2) The procedure for making a complaint was posted in the patient waiting area and provided contact information for the centre, the HFEA and the Health Care Commission.

Contingency arrangements
The PR reported that the centre has an understanding with the ACU, Birmingham Women's Hospital to provide backup and emergency clinical facilities. (CoP S.6.3.4)

Establishment of third party agreements
Signed and dated third party agreements specifying the responsibilities of the third parties and detailed procedures were observed at inspection. (CoP S.4.2.10)

Meetings/dissemination of information
Clinical meetings take place every month and all staff are invited. This was reflected in the meeting minutes observed at inspection. Records of staff meetings are stored on a shared network and are accessible to all staff. Centre staff reported that they felt they could discuss anything at these meetings. (CoP S.6.2.13) A new counsellor joined the centre in March 2009 and will be providing a counselling information session for all staff in the near future.

Areas for improvement

Payment of licence/treatment fees
For the 12 month period up to 13 July 2009, the average time taken to pay HFEA invoices was 57 days. Recent prompt payments have decreased this average and the most recent invoice was paid in 33 days. The PR confirmed that measures are being taken to ensure HFEA invoices are paid within 28 days. (CoP A.16.3)

Incident management
At inspection, a documented procedure was observed for the identification, investigation, control and recording of adverse incidents. (CoP 9.4.1) An incident log was also observed. However, the PR was not aware that severe cases of OHSS resulting in hospitalisation are considered by the HFEA to meet the definition of an adverse reaction and should therefore be reported to the HFEA. (CoP A.4.5) The PR agreed to report any future cases of severe OHSS to the HFEA.

Risk management
A fire hazard assessment has been undertaken at the centre since the last inspection. (CoP S.6.3.2) However there was no evidence that all activities impacting on the quality and safety of gametes and embryos have been formally risk assessed. (A.10.4) At inspection, the PR stated that there are plans to conduct risk assessments for laboratory and clinical practices in the near future.

Areas for consideration

None.

Executive recommendations for Licence Committee

The PR should continue to try to ensure that the HFEA invoices are paid within 28 days of the date of the notice in accordance with CoP A.16.3.

Cases of severe OHSS resulting in hospitalisation should be reported to the HFEA.

Activities impacting on the quality and safety of gametes and embryos should be formally risk assessed.

Evaluation
Some improvements required.
Areas not covered on this inspection
Nil

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]
For the time period from 01 Jan 2004 to 31 Dec 2007 live birth outcomes were in line with national averages.
Areas of firm compliance
Quality management system The centre operates a quality management system that has gained ISO:9001:2000 certification. Quality management system documentation including documented procedures was provided to the inspectorate on the day of the inspection. (S.5.2.1) This documentation included a quality policy, some quality objectives, and a quality manual. (S.5.2.2) Standard operating procedures appeared relevant to key activities and processes. The centre's quality management system had been further developed since the last inspection and the PR reported that a quality management review/evaluation will be conducted by the end of the year. **Quality policy** The signed quality policy includes commitments to the provision of services which meet user needs and requirements and continual improvement of the effectiveness of the quality management system. (CoP S.4.2.3) **Quality manual** The quality manual includes the quality policy, an organisational chart and an outline of the processes established for the quality management system. (CoP S.5.2.4) **Quality objectives and plans** The centre has established the following four measurable quality objectives:

- continually improve the quality management system
- enhancement of patient satisfaction
- to achieve a live birth rate that is consistently within the top 10 in the UK
- to keep multiple pregnancy rate within acceptable limits

Documented internal audits against these objectives were observed at inspection. (CoP S.4.2.4)

Feedback

The centre conducted an assessment of patient questionnaire's that were completed between January 2009 and July 2009. Documented results, analysis of the feedback, and proposed actions was observed at inspection. (CoP S.9.2.1)

Three patients interviewed in the course of the inspection gave positive feedback about the quality of service they received at the centre. HFEA feedback questionnaires received pre-inspection reported a high rate of patient satisfaction.

Document control

A register of current approved documents was observed at inspection and documents were found to be dated and approved by the PR. (CoP S.5.2.5)

Areas for improvement
No improvements required.
Areas for consideration
In compliance with CoP standards S.4.2.8, S.4.2.9, S.9.2.4 and S.9.2.5 the PR should ensure that a regular review of the centre's quality management system and all its services is conducted. The review should assess the need for changes to the quality management system and opportunities for improvement. The maximum interval between management reviews should be twelve months.
Executive recommendations for Licence Committee
None.
Evaluation
No improvement required.
Areas not covered on this inspection
Nil

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 centre is considered to have premises and facilities suitable for the activities for which it is licensed. (CoP S.6.3.2) A copy of the centre's licence is displayed in the patient waiting room. (CoP A.13.4) **Clinical facilities** Clinical facilities were considered appropriate for the activities for which the centre is licensed. The operating theatre was is equipped with resuscitation equipment that had been serviced in March 2009 and a log recorded daily checks of the emergency equipment. Equipment in the operating theatre had passed electrical testing in July 2009. The two recovery rooms have oxygen tanks and emergency call bells. The senior nurse specialist confirmed that the recovery rooms are always monitored by a nurse assistant when occupied. The sperm production room is private and comfortable. (CoP S.6.3.4) **Counselling facilities** The counselling room is located in an annex next to the main hospital. At inspection it was considered to provide quiet and confidential surroundings. (CoP S.6.3.5) **Laboratory facilities** The laboratory facilities are comprised of two laboratories: one used for the processing of gametes and embryos and one for the storage of gametes and embryos. At the time of the inspection, the laboratory was considered suitable for licensed activities. Documentation observed in patient records showed that the centre uses a CPA accredited laboratory for diagnostic blood tests. (CoP S.7.8.2) The laboratory has two low oxygen level alarms – one in the cryostore and one in the general laboratory where an additional tank is stored. (S.6.3.2) Laboratory equipment is connected to a monitoring system that detects low/high temperatures in the dewars and carbon dioxide, temperature and humidity in the incubators. This system works via sensors, the data from which is logged on a computer. The embryologists explained that the monitoring system triggers an alarm if the parameters become unacceptable. The alarm system is an autodial system which calls members of the team in succession. Manual

records are also maintained and were reviewed at inspection.

Air Quality
Records from 12th August 2008 reported grade A air quality in the area where gametes and embryos are processed and grade C background air quality. The most recent test was done on the 10th August 2009 and draft results showed grade A air quality in the area where gametes and embryos are processed with a background air quality of grade C. (CoP A.10.19)

Management of equipment and materials
Laboratory staff reported that all laboratory equipment is CE marked. Cleaning logs for incubators were observed at inspection and records indicated that the incubators are cleaned and calibrated on roughly a three monthly basis. Records reviewed indicated that equipment is subject to regular servicing. (CoP S.6.4.1, S.6.4.2)

Storage facilities for gametes and embryos
The nine storage dewars are fitted with low nitrogen level alarms connected to a monitoring and alarm system (see above) and are stored in a laboratory fitted a key pad lock. Embryologists reported that they have backup tanks in case of an emergency. (CoP S.6.3.8 & G.9.3.1)

Staff facilities
The laboratory staff reported that they have an area in the staff room for storing their personal belongings. A kitchen is available for use by all staff. (S.6.3.10)

Storage of records
Patient and donor records are stored in locked cabinets in a room with a coded lock: the room is only accessible to authorised personnel. Laboratory records which have patient identifying information are stored in the laboratory during treatment cycle. The laboratory is secured with a key pad lock and is accessible to licensed personnel only. (CoP S.7.2.1) The counsellor reported that counselling records are stored at her home in a locked cabinet. (CoP G.10.2.1) At inspection, the PR indicated that a filing cabinet could be made available at the centre to store counselling records, which would only be accessible by the counsellor.

Areas for improvement

Management of equipment and materials
Laboratory staff provided evidence of regular servicing and maintenance of critical equipment. (CoP A.10.15) However, there was no evidence of critical equipment validation. (CoP A.10.13)

Storage facilities for gametes and embryos
Laboratory staff reported that screened donor sperm samples are currently being stored in one of the unscreened tanks as there was no space to store them elsewhere. This unscreened tank also contains samples from patients who had been partially screened. This is a breach of standard licence condition A.10.22 which requires that storage facilities must clearly separate and distinguish gametes and embryos prior to release/ in quarantine from those that are released and those which are rejected, in order to prevent mix up and cross contamination between them.

Areas for consideration

None.
Executive recommendations for Licence Committee
The PR should ensure that all critical equipment and technical devices are identified and validated in compliance with A.10.13. The PR should ensure that storage facilities are provided that clearly separate and distinguish gametes and embryos prior to release/ in quarantine from those that are released and those which are rejected, in order to prevent mix up and cross contamination between them. The PR should assess the risks of cross contamination of the screened samples that have been kept in a dewar with partially screened material. The result of the assessment should be documented and any corrective actions should be implemented to minimise the risk of future cross contamination. The HFEA should be advised of the findings of the assessments and any actions taken as a result of the assessment by 13 November 2009.
Evaluation
Some improvements required.
Areas not covered on this inspection
Nil

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
At inspection, three patients were interviewed and all reported that they were given sufficient information on which to make treatment decisions. All three patients indicated that information is provided at the initial consultation and that they were able to call the centre at any time to ask questions. Written patient information leaflets were available at the reception desk and copies submitted pre-inspection were found to provide appropriate information in compliance with Code of Practice guidance. (CoP S.7.4.1)

Welfare of the child
Six sets of patient records were reviewed in the course of the inspection and all contained completed welfare of the child assessments. (CoP S.7.1.2)

Access to health records
Documentation submitted pre-inspection described the centres procedure for responding to patient requests for access to health records and identified the senior nurse specialist as the individual with responsibility to receive, check and arrange authorised access to confidential records. (CoP S.7.2.2)

Provision of information to the HFEA register
Since the last inspection, the centre has reported activity and outcomes to HFEA in a timely and accurate manner. (Direction 2006/06, paragraph 4(v))

Areas for improvement

Consent
During the course of the inspection, two HFEA consent forms were found to be incorrectly completed. In the first case, the proper consent form had been completed by a sperm donor but a single field had been omitted. The donor had consented to the use of his sperm in the treatment of others but did not indicate a storage period. It is a requirement of section 8(1) of Schedule 3 of the 1990 Human Fertilisation and Embryology Act that a person's gametes must not be kept in storage unless there is an effective consent by that person to their storage and section 1 of Schedule 3 requires that consent under this Schedule must be given in writing.

In the second instance, it was noted that embryos created using donated eggs were used in

treatment without the documented consent of the egg donor. Although the donor had consented to the use of her eggs in the treatment of others, a single field on the consent form was completed incorrectly. It is a requirement of section 6(3) of Schedule 3 of the 1990 Human Fertilisation and Embryology Act that an embryo the creation of which was brought about in vitro must not be used for any purpose unless there is an effective consent by each person whose gametes were used to bring about the creation of the embryo to the use for that purpose of the embryo and the embryo is used in accordance with those consents and section 1 of Schedule 3 requires that a consent under this Schedule must be given in writing.

The centre has been proactive in ensuring that the consent forms were corrected and copies were received by the inspectorate on 1st September, 2009.

In one set of patient records, it was observed that a female patient consented to the posthumous use of embryos created using her gametes but was not screened as a donor, as required by standard licence condition A.7.2. The centre was proactive in ensuring that the form was amended and a copy was received by the inspectorate on 1st September 2009 indicating that the patient no longer consents to the posthumous use of the embryos.

Provision of information to the HFEA register
At the last inspection, the PR was required to report IUI activities, including live birth rates, for the period 5 July – 31 December 2007 to the HFEA by 31 March 2008. This information has not yet been submitted.

Areas for consideration

None.

Executive recommendations for Licence Committee

The PR should ensure that patient/donor consent is properly documented and that staff are properly trained to take consent. Only a small sample of records was reviewed in the course of the inspection so it is recommended that the centre carry out a larger scale audit of patient consents to ensure that the findings of the inspection team are not indicative of systemic failures in the documentation of consent. A summary report of the audit findings and any required corrective actions and a timeline for implementation should be provided to the HFEA by 13 November 2009.

Evaluation

Some improvement required.

Areas not covered on this inspection

Nil

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	1.5
NMC registered nurses	2.5
Non NMC registered clinical staff	2
HPC registered scientists	2
Scientists working towards registration	0
Support staff (receptionists, record managers, quality and risk managers etc)	2
Counsellors	1

Summary of laboratory audit
Documentation submitted pre-inspection indicated that the most recent laboratory audit was carried out between 23rd June 09 and 5th July 09. There were no discrepancies noted. It should be noted however that in the course of the records review the inspection team noted that donor sperm was being stored without properly documented consent.
Summary of spot check of stored material
A physical dewar audit was not performed as the centre had carried one out in June/July 2009 and no discrepancies were noted.
Areas of firm compliance
Staff training and competency Staff records observed at inspection included CVs, job descriptions, and training records. A signed staff induction protocol was observed to be in place. Laboratory staff records showed evidence of competence assessment and the senior nurse specialist confirmed that nursing staff have regular competence assessments. (CoP S.6.2.2). Laboratory and clinical staff records were observed to contain evidence of participation in professional development

programmes, including attendance at international conferences and professional liaison activities. The counsellor provided evidence of relevant continuing education and professional development. (CoP S. 6.2.11 & S.6.2.2(e))

Clinical practice
Documented clinical procedures observed at inspection included: superovulation regimes, oocyte retrieval, embryo transfer, insemination procedures, and management of OHSS. (CoP S.7.6.10) A log observed at inspection contained a record of instances when single embryo transfer (SET) was not performed even though the patients fit the criteria outlined in the centre's SET policy. Clinical justification was provided in each case. (CH(08)03) The centre's multiple birth rate is currently 24%.

Laboratory practice
Evidence provided at inspection demonstrated that the laboratory is participating in inter-centre comparisons and joined the NEQAS (National External Quality Assessment Service) scheme in May 2009. (CoP S.9.2.6) The first sent of results dated June 2009 were near the mean of all results.

Traceability and coding
The centre has a traceability procedure in place to ensure that all gametes and embryos are traceable from procurement of gametes to treatment or disposal. Records of the equipment and materials used in the processing of gametes and embryos are recorded on patient laboratory sheets. (CoP S.7.3) Laboratory staff reported that the centre uses a unique patient identifier when witnessing and that this number is created from a computer system.

Selection and validation of laboratory processes
The centre provided a copy of their "Process for Clinical and Embryology Validation Documentation" at inspection. This document provides a description of each critical process and identifies key controls and monitoring and data supporting process validation. Validation is based on retrospective evaluation of the centre's own data. (CoP A.11.11)

Distribution and receipt of gametes and embryos
The centre has established procedures for the distribution and receipt of gametes and embryos to and from other licensed centres. These procedures were reviewed pre-inspection and appeared to meet Code of Practice requirements. (CoP S.7.7.15) The centre requires the receiving and shipping centres to supply a suitable shipping container to ensure the safety and quality of gametes or embryos. (CoP S.7.7.12)

Counselling practice
A new counsellor joined the centre in March 2009 and is considered appropriately qualified. (CoP S.6.2.2 & G.7.1.1) A new information leaflet submitted pre-inspection includes the contact information for the new counsellor. The counsellor reported that up to a maximum of three counselling sessions are offered free to service users who may be referred by the centre or can contact the counsellor via the centre. Documentation submitted pre-inspection indicated that counselling is mandatory for couples prior to undergoing egg-sharing. A counselling audit had been conducted and for the period March 2009-August 2009 and documented results were provided at inspection. All three patients interviewed at the time of inspection indicated that counselling services were offered to them at their initial consultation. (CoP S.7.6.2)

Storage of gametes and embryos
At inspection, laboratory staff demonstrated the system used to ensure that gametes and embryos are not stored beyond the maximum storage period. Records observed at inspection indicated that there was no material being stored beyond the maximum storage period. (CoP S.7.8.11)

Screening of donors
The centre's donor screening protocols were reviewed and appeared to be largely compliant.(CoP A.6.3) One sperm donor and two egg donor screening records were reviewed and observed to be compliant with Standard Licence Condition A.7.2.

Areas for improvement

Witnessing
There were no procedures taking place at the time of the inspection so the inspectorate was unable to observe the centre's witnessing practice. The centre has a documented witnessing procedure which covers all stages of clinical and laboratory procedures with the exception of sperm preparation. (CoP S.7.8.15)

Laboratory staff reported that there are occasions when there is only one embryologist in the lab and therefore witnessing is not always conducted contemporaneously. (CoP A.3.5)

Storage of gametes and embryos
Documentation submitted pre-inspection indicated that the most recent laboratory audit was carried out between 23rd June 09 and 5th July 09. There were no discrepancies noted. However, in the course of the records review the inspection team noted that the consent form related to the stored donor sperm did not indicate a storage period. (CoP S.7.8.9 & S.7.8.12)

Areas for consideration

Screening of donors
Although the centre's screening protocols include consideration of requirements as recommended by professional guidelines, donor records observed at inspection did not include evidence of the additional recommended screening. For example, in one set of egg sharer records, there was no evidence of screening for glucose 6 phosphate dehydrogenase, HTLV-1/HTLV-2 and there was no evidence that the clinician had made an assessment of donor history in relation to prion-related disease, mitochondrial disease, chromosomal rearrangements or diseases with a major genetic component. (CoP G.4.9.1)

The PR should ensure that screening protocols reflect the centre's practice and deviations from protocols should be documented.

Witnessing
At inspection it was observed that the centre has conducted an audit of their witnessing practice and noted some discrepancies. The inspectorate observed the same discrepancies when auditing patient records. For example, the time and date of the procedure was not always recorded in the patient notes. (CoP G.13.2.1)

Executive recommendations for Licence Committee
The PR should ensure that there is a sufficient number of trained staff to conduct witnessing checks at the time the clinical or laboratory process/procedure takes place. This recommendation should be implemented immediately and written assurance provided to the HFEA by 13th October 2009. The PR should ensure that witnessing protocols are in place for all critical points of the clinical and laboratory process, including sperm preparation. This recommendation should be implemented immediately and written assurance provided to the HFEA by 13th October 2009. The PR should ensure that the storage of gametes is in accordance with relevant patient consent and that storage audits include a review of the consented duration of storage.
Evaluation
Some improvements required.
Areas not covered on this inspection
Nil

Report compiled by:

Name…….Jenny McLaughlin…….

Designation……Inspector…….

Date……17 September 2009……

Appendix A: Centre staff interviewed

PR, Senior Nurse Specialist, 2 embryologists, counsellor, 3 patients.

Appendix B: Licence history for previous 3 years

Licence	Licence Reason	Type	Active From	Expiry Date
L0198/6/b	Variation of licence, new conditions 1st October 2009	Treatment with storage	01/10/2009	31/01/2010
L0198/6/a	Variation to include EUTD standards	Treatment with storage	05/07/2007	01/01/2010
L0198/5/a	Renewal of licence	Treatment with storage	01/02/2007	31/01/2010
L0198/4/a	Issued new licence due to Re-licensing	Treatment with storage	01/03/2006	31/01/2007

Appendix C: Response of Person Responsible to the inspection report

Centre Number……0198…St Jude's Women's Hospital, Wolverhampton

Name of PR……Mr J. Adeghe

Date of Inspection……13 August 2009……..

Date of Response……16 October 2009……

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

Name……Mr J. Adeghe

Date…… 16 September 2009

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.

None

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

All issues arising from the inspection have been addressed. Details are provided below.

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

1) Witnessing breaches were immediately rectified with effect from 7th September 2009 - All critical laboratory procedures, including Sperm preparation are always witnessed at the time of the procedure and properly documented. Written evidence have already been sent to you. 2) Consent form errors have been rectified. These were done soon after the inspection and the corrected consent forms have since been sent to you. 3) We have let you know that there were no IUI activities for the period between July and December 2007, and therefore no data is available. 4) 12 months ICSI data for the two embryologists have been sent to you. 5) The latest air quality report have already been sent to you.

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 Executive Licensing Panel Meeting
4 November 2009

21 Bloomsbury Street London WC1B 3HF

Minutes – item 2

St Jude's Women's Hospital (0198), Licence Renewal

Members of the Panel:	
Peter Thompson, Director of Strategy & Information (Chair) Trish Davies, Director of Compliance Hannah Darby, Policy Manager	Committee Administrator: Joanne McAlpine

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 (62 pages)
- no papers were tabled for this item

The Committee also had before it:

- HFEA Protocol for the Conduct of Licence Committee Meetings of the Authority's Executive Licensing Panel
- 8th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- Direction 0008 (where relevant), and any other relevant Directions issued by the Authority;
- Decision Trees for Granting and Renewing Licences and Considering Requests to Vary a Licence
- Guidance for members of Authority and Committees on the handling of conflicts of interest approved by the Authority on 21 January 2009
- Indicative applications guidance on the time period for which licences should be granted approved by the Authority on 21 October 2009
- Indicative sanctions guidance approved by the Authority on 18 March 2009
- Licence application and any relevant documentation

1. The Panel noted that this centre was inspected on the 13 August 2009.

2. The Panel considered the papers, which included an inspection report, application form and previous licence committee minutes.

3. The Panel noted that the centre has been providing fertility services since 2002, and licensed treatments include: In vitro Fertilisation (IVF), Intra Uterine Insemination (IUI) and Intra Cytoplasmic Sperm Injection (ICSI).

4. The Panel noted that the centre had a number of breaches highlighted in the inspection report, but since the inspection had addressed most of these breaches.

5. The Panel noted the positive response from the Person Responsible in the appendix of the report, and note that the Person Responsible states that the outstanding areas have been addressed and the supporting evidence has been submitted to the executive.

6. The Panel noted on pages 9, 10 and 11 of the inspection report that the inspector has provided an update in the report, to reflect the fact that evidence has been received from the centre which addressed the outstanding breaches.

7. The Panel noted the inspectorate's recommendation to renew the centre's licence for a period of four years.

8. The Panel noted that they are in receipt of a signed application form, and the appropriate licence fee had been paid and the PR had now completed the PR Entry Programme.

9. The Panel noted that the PR is a suitable character, and has the appropriate qualifications and experience necessary to perform his duties under section 17 of the HFE Act 1990 (as amended).

The Panel's Decision

10. The Panel decided to endorse the inspector's recommendation to renew the licence for a period of four years with no additional conditions.

Signed.....Peter Thompson.....Date.....18 November 2009.....
Peter Thompson (Chair)