Interim Inspection Report

Assisted Conception Unit,
Birmingham Women's Hospital
0119

Date of Inspection: 17th July 2008
Date of Licence Committee: 15th October 2008

Centre Details

Person Responsible	Dr Sue Avery
Nominal Licensee	Mrs Julie Burgess
Centre name	Birmingham Women's Hospital Assisted Conception Unit
Centre number	0119
Centre address	Assisted Conception Unit, Birmingham Women's Hospital, Edgbaston Birmingham, B15 2TG
Type of inspection	Interim
Inspector(s)	Andy Leonard (Lead) Bryan Woodward Janet Kirkland Bhavna Mehta (Observing)
Fee paid	Not required
Licence expiry date	L0119/15/a; 30/11/2012
NHS/ Private/ Both	NHS clinic; NHS and private patients

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About the Inspection:

This inspection visit was carried out on 17th – 18th July 2008 and lasted for 8 hours. The report covers the pre-inspection analysis, the visit and information received between 1st April 2007 and the inspection.

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 Assisted Conception Unit at the Birmingham Women's Hospital has been licensed by the HFEA since 1992. Treatment is provided to patients funded by the local PCTs and self funded patients who fall outside the eligibility criteria or who want to progress to treatment faster than current NHS waiting lists allows.

The centre performs DI, IVF and ICSI, treatment with donor gametes, and chemical assisted hatching. The centre has an egg sharing programme and recruits sperm donors. In the time period from April 2007 to 31st March 2008 the centre performed approximately 600 licensed treatment cycles including 17 cycles of treatment involving egg sharing and 557 cycles of IVF/ICSI. The service is centred on the nursing staff with patients being prepared for treatment in the outpatients' department.

The unit has a good history of regulatory compliance and the current licence has no additional conditions. The Person Responsible (PR) has held the position since August 2004 and has completed the PR Entry Programme. The unit has a robust Quality Management System (QMS) in place and has had a full-time Quality Manager since August 2007. The Embryology Consultant left his post 6 months ago and the post was made redundant; the PR has covered some of the roles in the interim. A Senior Embryologist has been appointed and will commence employment in September 2008. A member of staff is contactable 24 hours a day, 7 days a week via an emergency telephone which is carried by one of the unit Clinicians at all times outside of working hours. The number for this is provided in patient information.

The centre is open 6 days a week, 08:00 to 17:00 Monday to Friday and 09:30 to 12:00 on Saturday. Egg collections are carried out on Monday, Wednesday and Friday, whereas other procedures (e.g. IUI, DI and ET) are performed when required.

There have been no significant changes in the Centre in terms of activity, patient demographics or premises in the last year. The Centre has been modified in the last 2 years to bring it into compliance with the EUTCD.

Centre activities[1] for the time period 1st April 2007 to 31st March 2008

In vitro fertilisation (IVF)	268 cycles
Intracytoplasmic sperm injection (ICSI)	192 cycles
Frozen embryo transfer (FET)	55 cycles
Donor insemination (DI)	56 cycles
Gamete intrafallopian transfer (GIFT)	NO
Research	YES (R0173)
Storage gametes/embryos	YES

Summary for Licence Committee

The Assisted Conception Unit, Birmingham Womens Hospital is a medium sized unit providing approximately 520 licensed treatment cycles per year.

The Centre has been proactive in the development and implementation of a quality management system and the use of appropriate key performance indicators to monitor the quality of the Centre's activities. The Centre has appropriate premises and information and requires minor improvements only in issues related to the quality of service it provides. Several improvements are required in its organisation and clinical and laboratory procedures. Patients report satisfaction with the treatment that they receive.

Improvements should be considered relating to the following aspects of the centre's practice:

- The organisational chart
- Third party agreements
- Communicating with staff
- The review of documents and procedures
- Witnessing
- The documentation of training and assessment of competency;
- Validation of key processes

The inspection team would recommend that progress in addressing the issue outlined should be made within the timescales specified.

The inspection team recommend that the licence be continued.

[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.

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
The Centre's organisational chart was considered inaccurate by the inspection team.	The Centre should ensure that there is an organisational chart which clearly defines accountability and reporting relationships as required by COP Standard Licence Condition A.10.1.	To be monitored at the time of the next inspection.
The complaints policy reviewed in the course of the inspection was 13 months past its review date.	The complaints procedure should be reviewed, revised as required, dated and re-approved promptly by authorised personnel in compliance with the requirements of S.5.2.5 (a).	The review and any revision should be completed by 17 October 2008. The HFEA should be informed when the review is complete.
Not all third party agreements have been established.	Centre Management should continue to make progress in the establishment of documented agreements with third parties when an activity takes place which influences the quality and safety of gametes and embryos in compliance with the requirements of S.4.2.10.	To be monitored at the time of the next inspection.
For the year up to February 2008, the average time taken to pay HFEA invoices was 37 days. This is potentially a breach of standard licence condition A.16.3.	The Person Responsible should review the arrangements for payment of invoices and ensure that there are no barriers to the prompt payment of invoices.	At the centre's discretion. Progress to be monitored at the time of the next inspection.
Records are not kept of all staff meetings and some meetings are not scheduled regularly, reportedly as a result of workload pressures.	It is recommended that the PR ensures that there are effective means for communicating information to staff and that records are kept of meetings and made available to all staff in compliance with COP	To be monitored at the time of the next inspection

	S.6.2.13. This is considered especially important in relation to the communication of clinical decisions to the nurse led team.	
A quality policy was present in the Centre's Quality Manual but was not signed by the PR.	The Quality Policy should be signed and issued by a person with appropriate authority in line with the requirements of S.4.2.3.	To be monitored at the time of the next inspection.
Some deficiencies in the centre's documentation were identified in the course of the inspection.	The PR should continue to ensure that documents are regularly reviewed, revised as required, dated and re-approved promptly by authorised personnel in compliance with S.5.2.5.	To be monitored at the time of the next inspection.
There is no SOP for testing the low level liquid nitrogen alarms on the dewars or the low oxygen monitor in the dewar store, nor was a record available for testing of the alarms. The SOP for responding to the low oxygen level monitor and the low liquid nitrogen level alarms (Emergency Cryoroom Procedures) also does not describe procedures for responding to an alarm out of hours or reference procedures for ensuring the safety of lone workers when responding to alarms out of hours.	The PR should ensure that where equipment or materials affect critical storage parameters they must be the subject of appropriate monitoring, alerts, alarms and corrective action, as required in compliance with S.6.4.2 (b). SOPs for the monitoring of alarms should be developed in line with the requirements of standard licence condition A.11.1 and the SOP should document the appropriate procedures to ensure the welfare of for lone workers in compliance with S.6.3.2.	To be monitored at the time of the next inspection.
Not all staff whose training records were reviewed in the course of the inspection had completed mandatory health and safety training and signatures were not recorded against all competencies.	The PR should ensure that personnel are provided with initial and update training, as required. The training programme must ensure and document that each individual has demonstrated competence in the performance of their designed tasks in compliance with standard licence condition A.10.11	To be monitored at the time of the next inspection.

Evidence of screening for syphilis was absent from a sample of donor records reviewed in the course of the inspection. This is potentially non compliant with standard licence condition A.7.2.	Donor screening procedures should be reviewed as a matter of urgency to ensure compliance with the relevant standards. Patient information and standard operating procedures should be reviewed to ensure they reflect practice.	Procedures should be reviewed immediately and the HFEA should be informed of the outcome of the review and of any planned corrective actions.
Validation of key processes and procedures has not yet been fully established. This is potentially a breach of S.7.8.3 and standard licence condition A.11.11.	It is recommended that a plan for validation is drawn up. The plan should take into account the particular needs of the unit and prioritise the validation of those processes considered to be most likely to impact on the quality of the service.	Progress to be monitored in the course of the next inspection.
Procedures for transportation of gametes and/or embryos are not compliant with requirements.	The PR should review and update the transportation procedure to ensure compliance with the requirements of Alert 21 and relevant aspects of S.7.7.	

Non-Compliance

Area for improvement	Action required	Time scale
A sample of third party agreements reviewed in the course of the inspection were not fully compliant with guidelines at G.2.1.2.of the COP.	The content of third party agreements should be reviewed in consideration of the guidance.	To be monitored at the time of the next inspection.
It was reported that the Clinical Director, who has overall clinical responsibility for IVF treatments is not present in the centre frequently with the majority of the clinical work undertaken by the fertility nurses backed up by a Clinical Research Fellow and a Staff Grade Clinician.	The PR should review the provision of clinical input in consideration of G.1.2.1 of the COP which requires that the individual with overall clinical responsibility for treatment services involving IVF should be on the General Medical Council Specialist Register and have completed training recognised by the Royal College of Obstetricians and Gynaecologists.	The review to be complete and HFEA to be informed of the outcome of the review by 17 October 2008.

Egg donors have not been screened for *Neisseria gonorrhoea* as recommended in BFS guidelines	The PR should review the standard operating procedures for screening of prospective donors after consideration of the BFS guidelines. The PR should also ensure that staff are aware of screening requirements and that all relevant screening tests are carried out on prospective egg donors. Alternatively, the rationale for non compliance with the guidelines should be documented. If screening procedures are changed, patient information should be updated to include all of the screening tests carried out.	Procedures to be reviewed immediately and any changes and/or corrective actions to be reported to the HFEA.
The centre does not maintain a record of signatures of nurses who witness laboratory procedures or carry out competency assessment of all witnesses.	The centre should maintain a separate record of the name, job title and signature of every person who carries out or is a witness to laboratory and clinical procedures. In compliance with G.13.2.2. and that is an induction programme in place for new staff to ensure that the principles of witnessing are fully understood and that centre specific protocols are followed in line with the requirements of G.13.6.1.	To be monitored at the time of the next inspection.

Recommendations

Area for improvement	Action required
Workload may be impacting on the abilities of staff to fulfil all of their responsibilities. It is recommended that the PR assesses how many cycles can safely be accommodated by the centre. The assessment should consider the centre's premises, equipment, staffing and the skills mix of staff members and activity should adjusted according to the findings of the assessment (A.10.9. and A.10.18).	Review to be completed by 17 October and the HFEA to be advised of the findings of the review.

Changes/ improvements since last inspection

Recommendations	Action Taken
Ensure storage tanks are secured and alarmed at all times when in use. .	All tanks are secured and alarmed.
The centre was reminded to ensure that all witnessing steps stated in the Direction D.2004/4 are contemporaneously witnessed and signed. Update witnessing protocol to include disposal of embryos and gametes as required by Direction D2004/4. It is recommended that a risk assessment is performed on the witnessing steps that occur in the GMP laboratory.	Witnessing procedure reviewed. Risk assessment of the witnessing process was submitted to the Authority .
Emergency contingency plans to be documented and formalised.	The contingency arrangement has been formalised

Additional licence conditions and actions taken by Centre since last inspection

The previous licence was issued with no additional 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
- Complaints management
- Contingency arrangements
- Establishment of third party agreements
- Meetings / dissemination of information
- Payment of licence/treatment fees

Areas of firm compliance
The PR is the Director of the Centre but delegates authority to departmental managers. Nursing matters are delegated to the Senior Nursing Sister, administrative matters to the Unit Administrator and quality management system issues to the Quality Manager. The PR is currently covering laboratory management. The Centre Management team have responsibility for resource management in their areas and these are integrated to provide centre-wide resource management at quarterly quality and management review meetings. The minutes of the meeting on 2nd April 2008 were reviewed by the inspectorate, and indicated it was attended by the PR, the Clinical Fellow, the Scientific Lead, the Quality Manager, the Unit Administrator and the Senior Nurse. The Centre utilises the local trust Clinical Governance Policy. Adverse clinical outcomes are reported to the local trust and the HFEA if appropriate. Hospitalised cases of ovarian hyperstimulation syndrome were said to be reviewed by Clinical Staff. The Centre were advised that such cases should now also be reported to the HFEA as serious adverse events. The Centre has performed risk assessment when required due to incidents and regulatory requirements in the last year. Process risk assessments have been written in the laboratory. Area risk assessments are normally done annually by the Trust Health and Safety unit however they have not been done in the last year. The Quality Manager will do the risk assessments in future but will require specialist training to perform this role. The PR should ensure this training is provided and that area and procedural risk assessments are performed/reviewed annually The Centre reports serious adverse events to the HFEA, the PR being the incident reporting officer. An incidents log is maintained which details investigations and actions taken to improve procedures to minimise the risk of recurrence. Adverse events at the Centre in the

last year have been dealt with appropriately. Discussions with centre staff indicate they understood incidents were to be reported to the PR and that there is an open and positive 'learning' attitude regarding incident reporting and investigation.

The Centre's complaints policy was on display in the patient waiting room. Verbal complaints are passed by staff to the PR. The Centre has a defined complaints procedure which is followed for all complaints which can not be immediately resolved. Complaints are all logged, even if made verbally, as is their review and any follow up actions. The complaints log was reviewed and appeared to be appropriate. The Centre has resolved all of the complaints it has received in the last year.

The Centre has a formalised contingency plan with the Centre for Reproductive Medicine, Walsgrave Hospital, for emergency service provision in the event of significant failure(s) in the Centre. This document was recently revised and when inspected, had been signed by the PR and Nominal Licensee (NL) at the Walsgrave but not by the PR and NL at Centre 0119. The PR assured the inspectorate it would be signed after the inspection. The Centre also has a procedure for providing cover in the PR's absence.

Centre activity is coordinated through weekly operational meetings, the minutes of which were reviewed on inspection and are available to all staff by email and hard copy in a folder in the staff room. Centre activity and difficult cases are discussed to ensure activity levels are safe given the resources available. Staff meetings and quality and management review meetings are held quarterly and minutes of the meetings are taken. Research seminars are provided at all staff meetings twice a year and research carried out by the Centre for Human Reproductive Sciences within Centre 0119 is showcased annually on a research day. Minutes from a quality and management review meeting were provided to the inspectorate and were considered well presented and provided clear descriptions of subjects discussed and actions required. Staff suggestions are considered at departmental and all staff meetings.

HFEA Alerts are disseminated by the PR to management and staff by email, if urgent, and/or to management and staff at regular departmental meetings. Alerts are also discussed, if appropriate, at all staff meetings. A file of Alerts is kept in the laboratory.

Areas for improvement

The Centre's organisational chart was considered inaccurate by the inspection team. For example, the organisational chart describes unregistered embryologists as Clinical Scientists. 'Clinical Scientist' is a legally protected job title to be used only by registrants of the Health Professionals Council (HPC); it is not appropriate to use the term to describe the unregistered embryologists. In addition, the name of the Scientific Lead (JKB) was not included in the chart the chart. The staffing complement at the centre raised concern and was not accurately portrayed in the chart.

In the absence of a Consultant Embryologist in the laboratory, the PR has provided cover as much as possible however this has potentially left trainees under-supervised, the review and validation of laboratory procedures has been limited, the laboratory HFEA Alerts file was missing the last 2 Alerts issued and the NEQAS quality assurance in andrology programme has been suspended. A Senior Embryologist will soon be appointed.

It was reported that the Clinical Director listed in the organisational chart seldom visits the

Centre. The majority of the clinical work is undertaken by the fertility nurses backed up by a Clinical Research Fellow and a Staff Grade Clinician. The staff are experienced however it is clear that strong clinical leadership is not present and some clinical protocols (e.g. Prevention and Management of OHSS) have not been updated or validated for some time.

The complaints policy reviewed in the course of the inspection was 13 months past its review date.

A file of third party agreements was reviewed in the course of the inspection. The PR reported that some third party agreements are in place while others have been sent to suppliers and/or have yet to be returned.

A sample third party agreement was reviewed. Its contents were compliant with the requirements of Licence Condition A.5.4 with the following exceptions: it was not stated in the agreement when the agreement was due to be reviewed and who is responsible for the review; the agreement was signed by representatives of the Centre and the company but spaces within the agreement to describe the third party employee responsible for service provision and the contact person at the Centre were not completed; the third party provided an unsigned quality policy last reviewed in October 2002, yet also provided certification that they are ISO 9001:2000 compliant.

This Centre had on the 15th July 2008 two invoices outstanding. The Centre takes on average 37 days to pay invoices according to HFEA Finance Department.

Areas for consideration

Centre activity is coordinated through operational meetings. These should be held weekly but inspection of the minutes for these meetings suggests they are sometimes cancelled. Difficult clinical cases are discussed at these meetings.

Laboratory staff meetings are held weekly and medical staff meetings fortnightly, but records of these meetings are not kept.

Meetings of the nursing team have been held on an ad hoc basis due to pressure of work however new staff appointments have been made and it was reported that these meetings will be held on a more scheduled basis in future.

A file of Alerts was evidenced in the laboratory. It was noted that Alerts 24 and 25 were missing from this file. The PR should ensure that Alerts are effectively communicated to all relevant staff and that the Alerts file is kept up to date for reference purposes.

Executive recommendations for Licence Committee

The Centre should ensure that there is an organisational chart which clearly defines accountability and reporting relationships as required by COP Standard Licence Condition A.10.1. Progress to be monitored at the time of the next inspection.

The PR should review the provision of clinical input in consideration of guidance at G.1.2.1 of the COP which requires that the individual with overall clinical responsibility for treatment services involving in vitro fertilisation should be on the General Medical Council Specialist Register and have completed training recognised by the Royal College of Obstetricians and

Gynaecologists.

The complaints procedure should be reviewed, revised as required, dated and re-approved promptly by authorised personnel in compliance with the requirements of S.5.2.5 (a).

Centre Management should continue to make progress in the establishment of documented agreements with third parties when an activity takes place which influences the quality and safety of gametes and embryos in compliance with the requirements of S.4.2.10. The content of third party agreements should be reviewed in consideration of guidance at G.2.1.2 of the COP. Progress with these recommendations should be monitored at the time of the next inspection.

The Person Responsible should review the arrangements for payment of invoices and ensure that there are no barriers to the prompt payment of invoices.

It is recommended that the PR ensures that there are effective means for communicating information to staff and that records are kept of meetings and made available to all staff in compliance with COP S.6.2.13. This is considered especially important in relation to the communication of clinical decisions to the nurse led team.

Workload may be impacting on the abilities of staff to fulfil all of their responsibilities. It is recommended that the PR assesses how many cycles can safely be accommodated by the centre. The assessment should consider the centre's premises, equipment, staffing levels and the skills mix of staff members and activity should adjusted according to the findings of the assessment (A.10.9. and A.10.18).

Evaluation
Significant improvement required
Areas not covered on this inspection
All areas covered

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]
In the last year (April 2007 – March 2008), the Centre reported 515 IVF and ICSI treatment cycles whereas in the previous year 569 cycles were performed Considering age stratified (<35 years; 35-37 years; 38-39 years; 40-42 years and >42 years) data recorded between April 2004 and March 2007, IVF/ICSI, frozen embryo transfer and donor insemination live birth rates were in line with national averages, except for IVF/ICSI in patients aged less than 35 years in whom live birth rates were lower (22.4%) than the national average.
Areas of firm compliance
The Centre has a well developed quality management system and a Quality Manager (QM) employed 50% by the Centre and 50% by the University of Birmingham. The QM's time is split between the two employers albeit some of the University of Birmingham work relates to research activity within Centre 0119. The department heads are the quality representatives in their areas and attend quarterly quality and management review meetings at which quality management issues are discussed; detailed minutes of these were reviewed in the course of the inspection. The Centre has a quality manual with an extensive index which has recently been incorporated into the Qpulse document management system which is now coming on line at the Centre. The quality manual is available on the Centre server and further copies of Standard Operating Procedures (SOPs) can be printed but are marked as uncontrolled. The departmental managers are responsible for documents in their areas. The Quality Manager uses the Qpulse system to index all documents with review dates, version numbers and authors. This will be regularly reviewed so the Quality Manager can advise departmental managers that documents require review. Documents for review are discussed at relevant departmental meetings, then reviewed and presented at the next departmental meeting. Further revisions are performed if necessary, then the documents are released to the quality manual through the Quality Manager on the Qpulse system. Newly released documents are notified to staff at departmental meetings and by email generated through the Qpulse system. Documents provided on the day of inspection had newly introduced document control footers.

Quality management review and evaluation are undertaken. Key performance indicators (KPIs) have been defined which include administrative (phone records analysis; complaints received; error rate on HFEA forms), clinical (OHSS rate; cancelled cycles), laboratory (oocytes recovered; fertilisation rate; cleavage rate; clinical pregnancy rate; birth rate; and embryo grade compared to successful pregnancies) and nursing (waiting times; embryo transfers performed; waiting time in waiting rooms) indicators. KPIs are reviewed monthly in an ad hoc meeting to allow rapid identification of trends, and quarterly in the formal quality and management review. Records are kept of the quarterly meeting. This monitoring system has been in place for 6 – 9 months; within a year the data set will be large enough to allow statistical analysis so that appropriate quality targets and warning limits can be set for each KPI. At the moment the PR and management team are assessing KPIs against their experience of the sector, the centre and its historic performance.

The Centre has had an active programme of audit since January 2008 which involves 2 audits per month, with one audit carried out every two months in each activity area (i.e. clinical, laboratory, nursing and administration) In the last 6 months the audit programme has included procedural audits of surgical sperm retrieval, insemination, embryo transfer, laboratory cleaning, sperm freezing, stock control for traceability purposes and unit security. No non-conformities were noted. Evidence that audit results were discussed in the quality and management review meeting in April 2008 was reviewed in the course of the inspection..

Feedback from patients is obtained through patient satisfaction questionnaires which are available in the recovery area. The take-up rate for these questionnaires was very low (2-3 per year) therefore the Centre have recently redesigned the questionnaire to incorporate simple Yes/No answers available in 8 languages; 50% of the Centre's patients do not speak English as their first language. The questionnaires will also be made available in the patient waiting area as well as in the recovery area. The importance of obtaining patient feedback is recognised by the PR and Quality Manager; staff will in future promote the questionnaire to patients to increase provision of feedback.

Areas for improvement

Evidence of an appropriate quality policy was present in the Centre's Quality Manual but was not signed by the PR.

The Centre has a quality manual with an extensive index which has recently been incorporated into the Qpulse document management system. To achieve this, existing protocols were assembled and added to the database. Sometimes this occurred without thorough review with a number of errors observed within documents some of which were critical. The Centre recognise the deficiencies in some documentation and the situation would appear to be improving given the contrast between protocols supplied pre-inspection and those supplied on the day of inspection. To ensure further improvement, the Centre aim to review all documents over the next year. The Quality Manager also noted that clinical forms and patient information and consent forms are being reviewed, while laboratory forms are fit for purpose.

Area for consideration

None

Executive recommendations for Licence Committee
The Quality Policy should be signed and issued by a person with appropriate authority in line with the requirements of S.4.2.3. The PR should continue to ensure that documents should be regularly reviewed, revised as required, dated and re-approved promptly by authorised personnel in compliance with S.5.2.5.
Areas not covered on this inspection
All areas covered
Evaluation
Some improvement required.

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
The inspectorate considered that the premises were appropriate for the Centre's activities. On entry from the main hospital lift area to the Centre through lockable doors (open during service hours), there is a corridor with 3 counselling/consulting rooms that enters a reception area, with two further corridors leading and access to two scanning consultation rooms, a secure notes store and a consumables storage/sluice room. One short corridor leads off to a waiting area, another longer corridor to the clinical/laboratory area. The latter consists on the left side of the treatment room and a patient changing room/toilet, and on the right side a four bed recovery area with adjacent sitting area. The clinical corridor then continues through double doors and comprises on the left; the laboratory (incorporating embryology and andrology and connecting to the treatment room via a warmed hatch), the laboratory anteroom, an office, staff toilet, a clinician's office, the PR's office suite, the lead scientist's office, the embryologist's office, two male production rooms and a key card accessed stairwell which also functions as a fire escape route. On the right of the clinical corridor is; the cryostore, the theatre/laboratory consumables store, an office, a researcher's office, a staff toilet, a diagnostic andrology laboratory, a research laboratory, the quality manager's office, a staff rest room and the unit administrator's office. This waiting area contains seating for approximately 15 patients, access to toilets and a drinks machine. The centre licence and complaints' procedure were on display, as well as a range of patient information related to fertility treatment, counselling and contact details for patient support groups. Clinical areas were clean and appeared comfortable and appropriately equipped. Bays in the recovery area were fitted with oxygen and suction lines, and emergency call buttons, and oxygen and suction lines were available in the treatment room. An emergency resuscitation trolley was present adjacent to the treatment room: checks of contents and cleanliness had been performed and recorded on working days. The scanning and consulting rooms also appeared comfortable and clean. The laboratory premises were also considered compliant, having been refurbished in 2006/07 to provide Good Manufacturing Practice grade facilities. Laboratory equipment showed evidence of annual servicing and laboratory incubators and other key equipment were

connected to a power supply which is backed up by the hospital's emergency generator, which is tested monthly.

Counselling rooms are available in the Centre and were considered by the inspectorate to be private, quiet and comfortably furnished. The Counsellor was also happy with the facilities.

Air quality in the laboratory is compliant with the requirements of the Code of Practice, 7th edition. An SOP is in place for air quality monitoring which was seen on inspection. It describes that air quality is monitored every three months, testing in laboratories (air flow rates, pressure differentials, airborne particulates and microbiological counts) and air flow cabinets (air flow rates, airborne particulates and microbiological counts). The last test showed that the air quality in the clean room is grade B, and the adjacent sperm preparation laboratory, which is designed to run at grade C as a minimum, is also grade B. In addition, the laboratory facilities have a complex on-line computerised monitoring system that logs air flow rate, humidity, temperature and pressure differentials between laboratory rooms. This monitoring is connected to an alarm that links directly to the hospital Estates Department who, staff said, attend immediately if an alarm sounds. A warning light in the laboratory anteroom also illuminates if air filter integrity is compromised. Air quality monitoring results show that air quality in critical work areas is grade A.

All equipment at the Centre is covered by contracts for annual servicing and maintenance and equipment sampled was within servicing intervals. The Centre has a maintenance activity log for each piece of equipment. Evidence of real-time equipment monitoring was seen for laboratory equipment, e.g. incubators, hot blocks and fridges with computer logging of data.

Access to the cryostore is by key card with only certain centre staff having access. The store I also monitored by CCTV. The cryostore is equipped with a low oxygen alarm. It contains 14 small dewars and 4 medium sized vapour phase storage dewars; separate dewars are used for quarantined and non-quarantined samples. The room also contains 2 large vapour phase storage tanks which are not yet validated and are therefore not in use, as well as a large liquid nitrogen reservoir for re-filling the small dewars. Vapour phase tanks are fitted to liquid nitrogen lines connecting to a reservoir outside the unit which automatically refill the dewars when required. All dewars are equipped with low nitrogen alarms connected to a central monitoring and dial out facility.

Staff are provided with facilities in changing room/toilet suites and a common room. The former was considered small but the staff facilities were compliant with the requirements of the Code of Practice, 7th edition.

When records are in use in the clinic, they are tracked using a computer based system to ensure their security. All offices and consulting rooms are locked when not occupied, thus any records within are secured. The Centre records store is accessible by key card and is adjacent to the reception desk. If consent for disclosure is provided, the licensed treatment records are included at the back of the patient's hospital record and they are stored in the hospital system. The Birmingham Women's Hospital is an Obstetric and Gynaecology Hospital only and these hospital records remain at the hospital. Records are sent for off-site storage individually in sealed bags identified only by a numerical code. Counselling records are stored in a locked filing cabinet in the counselling room, which is itself kept locked when not in use.

Areas for improvement
There is no SOP for testing the low level liquid nitrogen alarms on the dewars or the low oxygen monitor in the dewar store, nor was a record available for testing of the alarms. The SOP for responding to the low oxygen level monitor and the low liquid nitrogen level alarms (Emergency Cryoroom Procedures) also does not describe procedures for responding to an alarm out of hours or reference procedures for ensuring the safety of lone workers when responding to alarms out of hours.
Areas for consideration
None
Executive recommendations for Licence Committee
The PR should ensure that where equipment or materials affect critical storage parameters they are the subject of appropriate monitoring, alerts, alarms and corrective action, as required in compliance with S. 6.4.2 (b). SOPs for the monitoring of alarms should be developed in line with the requirements of standard licence condition A.11.1 and the SOP should document the procedures required to ensure the welfare of lone workers in compliance with S.6.3.2.
Areas not covered on this inspection
All areas covered
Evaluation
Some improvement required.

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
After referral, patients can attend an orientation session at the clinic which is regularly held on Saturday mornings. At this meeting, verbal information regarding the licensed fertility treatments counselling provision and access is provided by the Scientific Lead. Patients are also provided with written information on all of these subjects to take away and consider. Prospective patients are also given a tour of the laboratory and clinical facilities. Patients sign some clinical consents and the HFEA registration forms at the end of the clinical group meeting. The patients next attend a consultation with a fertility nurse during which they discuss their treatment plan and sign specific HFEA treatment consent forms. The Centre has a procedure and check-list, evidence of which was seen in patient records, to ensure that all necessary information is provided to patients and that they have an opportunity to ask questions, prior to consent forms being signed. Thus appropriate informed consent would appear to be taken by the Centre. Consent forms in 7 sets of patient records were present and compatible with the treatments provided. The Centre has a Welfare of the Child procedure in place which was last reviewed in January 2008. It ensures that the assessment is completed and reviewed and that consent for disclosure is taken. Nursing staff with any concerns in this area report them to the PR who reviews the situation with clinical staff if needed. If still concerned a report can be obtained from the patients' General Practitioner and/or the Centre Counsellor. If the case is considered difficult, the Centre can access specialist services through the local hospital trust and have access to an ethics committee. Access to patient records is well controlled through appropriate security arrangements and the computerised records tracking system. Patients can obtain a copy of their patient records within a 40 day target time, by written application, signed by both patients. Patient details are logged in the administration office and the patients are sent an invoice and the official notes release consent form (DPA1). When the DPA1 form and payment have been received, the PR authorises the release of the records, which are then copied and sent to the patient by recorded delivery or collected by the patient with a valid photo identity card. Patient records are subjected to a HFEA compliant records control policy which describes the appropriate 10, 30 and 50 year document retention periods. The Centre collects all required patient information on paper copies of the HFEA forms, filled in by the nurses during their patient consultations. These are then passed through to a single person responsible for all data entry on the HFEA electronic data interface (EDI). The paper

copies are then retained as a back-up. This method places some workload on the fertility nurses, however it significantly reduces the workload on the person responsible for EDI entry. Moreover it ensures that data collection and EDI entry are accurate and timely and HFEA Registry say that the Centre have relatively few errors outstanding.
Areas for improvement
None
Areas for consideration
None
Executive recommendations for Licence Committee
None
Areas not covered on this inspection
Written patient information was not inspected during this interim inspection. It was inspected at the renewal inspection in 2006 when it was found to be fit for purpose
Evaluation
No improvements required.

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	2.5
NMC registered nurses	6.0
Non NMC registered clinical staff	1.5
HPC registered scientists	3.0
Scientists working towards registration	3.0
Laboratory support staff	0.8
Support staff (receptionists, record managers, quality and risk managers etc)	7.0
Counsellors	1.0

Summary of laboratory audit
The Centre provided audits of stored gametes and embryos from May 2008. These audits were considered compliant by the inspectorate, with the exception of the issue raised in areas for improvement The audit described 8 non-conformities in embryo storage: 6 involved use of embryos without update of the tank log but with update of patient records and the freeze sheet; 2 involved broken straws. The audit also described 7 non-conformities of sperm storage; 3 involved use of sperm without update of the tank log but with update of patient records and the freeze sheet; 4 involved use of sperm without update of the freeze sheet but with update of patient records and the tank log. Appropriate remedial action was taken in response to each non-conformity.
Summary of spot check of stored material
A limited spot check of one sperm and one embryo sample was performed with no errors in paperwork or sample position being found

Areas of firm compliance

The Centre has a written induction procedure in which all new staff are informed of the Centre's activities, as well as undergoing the standard local trust induction programme including fire safety and manual handling for all staff, and basic or advanced life support for selected staff where needed. Induction in the Centre involves active mentoring and signing off of induction components, which vary depending on the role of the new employee.

Training opportunities at the Centre are in general appropriate with some exceptions. At the Centre, all staff can attend a twice yearly Ethics Group meeting and an annual science day, and research seminars are provided every 6 months. The Quality Manager described attendance on a quality management course and that this was logged in his training file, as well as his future attendance on a risk assessment training course. The Counsellor had also been provided with appropriate training and continual professional development (CPD) opportunities.

For nursing and medical staff there is a range of courses available for CPD purposes, including mandatory fire safety, manual handling, and basic and/or advanced life support training, which must be attended annually. These mandatory courses are organised by the Trust and staff attendance is logged and warnings issued when training must next be attended. Attendance was logged in a nurses training record, along with several other courses. Nursing and clinical staff also attend conferences although they have not done so in the last year.

Embryology staff also attend conferences and take part in the Association of Clinical Embryologists (ACE) CPD programme. It is intended that embryology trainees will follow the ACE training programme which includes competency assessment. As an interim measure the PR has obtained a training programme and trainees are using it as a training guide. The trainees will also have one day per month for ACE course work.

The PR and Senior Nurse both considered the training budget to be reasonable, providing staff with good access to training and CPD. Both also however consider time for training is limited due to several staff departures from the laboratory and nursing staff in the last few months.

A member of medical staff is contactable 24 hours a day, 7 days a week via an emergency number provided in patient information.

The Centre has egg donor and sperm donor programmes. All donors and recipients are referred to the counsellor for donor counselling. The Centre has a procedure is in place to ensure that the 10 families limit is not breached.

The Centre does not transfer more than one embryo in patients where there is a known risk of multiple pregnancy and are developing a model based on the local pattern of multiple births. The patients at highest risk are those under 38, with any previous pregnancy recorded. Patient information is being written in line with this, and single embryo transfer will be promoted in these patients. The Centre is also developing blastocyst culture methods using MINC incubators to improve success rates.

Patients attending the Centre for the first time are asked to bring a passport or driving licence

as proof of identity. These are photocopied and kept in patient records to facilitate later identification of patients.

The Centre only uses CE marked or sperm motility tested consumables and has established traceability procedures. Records are maintained for media and consumables, detailing the batch number and the dates first used.

The PR has prepared a risk assessment of the manual witnessing procedures and this has been submitted to the HFEA. All staff used in witnessing have appropriate training and an audit of manual witnessing has been performed recently. At the weekend when limited embryology staff are on duty, nursing staff are used as witnesses. The inspectorate has some concerns with the witnessing procedures and these are detailed below. The Centre are in the process of moving to electronic witnessing using the Matcher system, which is currently running alongside the manual system so that validation can be performed. Once the system has been validated, the Centre will risk assess its use relative to the existing manual system.

The Fertility Counsellor has 12 years experience and has been at the Centre for 5 years, providing an average of 2 days per week. A back-up counsellor is also available to cover holidays and times of increased activity. Counselling is provided free of charge to all patients and there is no limit on counselling sessions provided to each patient, however patients are usually referred on to other agencies if long term counselling is required. The Counsellor has the regular supervision required to maintain chartered status. Counselling information is provided to patients from first attendance at the unit and throughout their treatment. Patients assess the Counsellor either through referral by Centre staff or by self referral. Patients may have to wait up to a month for implications counselling, however support counselling can be provided within a week. Interpreters are provided for non-English speaking patients. The Counsellor considers that a good counselling service is provided which is well supported by the PR and other Centre staff. The Clinical Inspector concurs with this opinion. A detailed counselling audit was submitted prior to the inspection which showed that 348 counselling sessions were arranged between April 2007 and March 2008 and that 302 were performed. More than half of sessions were for support and therapeutic counselling.

The compliance of embryo and gamete storage premises was discussed in Section 3. The Centre has comprehensive paper and electronic logs of samples in store and operates a bring-forward system. Separate dewars are used for quarantined and non-quarantined samples.

Areas for improvement

In the course of the review of the induction log of an embryologist it was noted that they had yet to complete Trust induction, fire safety training and manual handling training, 5 months after their arrival; the embryologist was also not signed off for 3 of the 7 elements of the infection control policy, nor for basic life support or manual handling. A recently employed nurse was also interviewed about induction and she informed the inspector that she had had induction in theatre procedures and recovery, and in consent taking, but that this was not documented.

Treatment at the Centre is nurse-led and nurses at the Centre are performing embryo transfers and ultrasound scanning as well as providing patient consultations. Evidence was provided in a nurse's training file regarding training in embryo transfers and ultrasound

scanning however no evidence of on-going competency assessment of nurses was documented. Likewise there was no evidence that the two clinicians have their competencies assessed. For nurses and clinicians, the absence of an effective Clinical Director has reduced opportunities for competency assessment. The PR said that she had assessed some competencies in the laboratory however no documented evidence of this was provided. The absence of a full-time Senior Embryologist in the laboratory may well have reduced opportunities for competency assessment.

It was reported that the Centre is in the process of implementing the Knowledge and Skills Framework (KSF) via the local Trust as a method of competency assessment; training in appraisal was completed 2 months before the inspection. The KSF programme will be applied to all staff groups. The appraisal process started recently however the programme was described as being 'rather behind schedule' and it is not clear that the key skills and activities requiring competency assessment have been defined for each staff group.

The issues related to the lack of an effective Clinical Director and Senior Embryologist have been raised in Section 1 and 2 where relevant recommendations are made. With only two clinicians active in the unit, it is questionable whether the rota to man the emergency telephone is effectively staffed: the Senior Nurse said there had been some complaints from patients that the on-call clinicians did not answer the emergency telephone immediately although they did call patients back who had left a message. The Clinical Inspector was also concerned that the level of staff cover on the weekend may be insufficient to allow effective and appropriate response to a patient emergency.

In the pre-inspection questionnaire, it was reported that gamete providers are subject to the following screening tests: Chlamydia, Neisseria gonorrhoea, Syphilis, HIV, Hepatitis B & C, Cystic fibrosis, HTLV I and II, Thalassaemia (if appropriate) and Sickle Cell (if appropriate). Inspection of sperm and egg donor records indicated that CMV testing was also performed in all cases, however in some records evidence of syphilis and/or gonorrhoea testing was absent.

The centre does not maintain a record of signatures of nurses who witness laboratory procedures or carry out competency assessment of all witnesses.

Critical clinical and laboratory processes have not been validated. The PR is aware of the need for validation but is waiting for the publication of professional body guidelines and the recruitment of a Senior Scientist.

The Centre has a transportation procedure which was reviewed by the Lead Inspector. This indicated that the procedure did not comply with some of the requirements of Alert 21 and CoP S.7.7 and referred to HFEA consent forms which were out of date, even though the document was last reviewed in April 2008.

Areas for consideration

The Scientific Inspector was concerned regarding the manual witnessing methods used at the Centre. When an embryologist is working alone in the laboratory and requires a witness, another embryologist is called. This second embryologist does not enter the laboratory, as it is a designated clean room requiring staff to change into specialist clothing. Instead the second embryologist stands in a corridor next to a window looking into the laboratory. The

first embryologist can then display markings on dishes and the laboratory sheet through the window to the second embryologist. The first embryologist then signs the witnessing box on the laboratory sheet and initials for the second embryologist to sign later. Thus the identifying details on dishes and tubes are witnessed but the second embryologist's signature is not contemporaneous. Review of witnessing signatures in patient records indicated that witnessing signatures were missing from 3 of 5 patient records reviewed. Furthermore, witnessing signatures were dated but not timed. In the opinion of the Scientific Inspector, implementation of the electronic witnessing system currently being validated will significantly improve the compliance of the witnessing procedures at the Centre. It is recognised however that the Centre have performed a risk assessment of their witnessing procedures.

Executive recommendations for Licence Committee

The PR should ensure that personnel are provided with initial/basic training, updated training as required. The training programme must ensure and document that each individual has demonstrated confidence in the performance of their designed tasks in compliance with standard licence condition A.10.11.

Donor screening procedures should be reviewed as a matter of urgency to ensure compliance with the standard licence condition A.7.2 and professional body guidelines and the HFEA should be informed of the outcome of the review. Patient information and standard operating procedures should be reviewed to ensure they reflect practice.

The centre should maintain a separate record of the name, job title and signature of every person who carries out or is a witness to laboratory and clinical procedures. In compliance with G.13.2.2 and that an induction programme is in place for new staff to ensure that the principles of witnessing are fully understood and that centre specific protocols are followed in line with the requirements of G.13.6.1.

It is recommended that the Centre identifies those processing procedures that are considered critical to quality and clinical effectiveness and that a prioritised plan for validation is drawn up in compliance with the requirements of standard licence condition A.11.11 and S.7.8.3.

The PR should review and update the transportation procedure to ensure compliance with all aspects of Code of Practice, 7th edition, Standards S.7.7.

Areas not covered on this inspection

All areas covered

Evaluation

Several improvements required.

Report compiled by:

Name Dr Andrew Leonard

Designation Scientific Inspector, HFEA

Date 26th August 2008

Appendix A: Centre staff interviewed

PR, Registered Embryologist, Administration Manager, Medical Manager, Nursing Manager, Counsellor, Junior Nurse, Junior Embryologist, Quality Manager

Appendix B: Licence history for previous 3 years

Expired Licences

Licence	Status	Type	Active From	Expiry Date	Integrity
0119/15/a	Active	Treatment with Storage	01/12/2007	30/11/2012	Active
L0119/14/a	Expired	Treatment with Storage	05/07/2007	30/11/2007	Reviewed but not Verified
L0119/13/c	Expired	Treatment with Storage	01/05/2006	30/11/2007	Reviewed but not Verified
L0119/13/b	Expired	Treatment with Storage	01/02/2006	30/11/2007	Reviewed but not Verified
L0119/13/a	Replaced by New Version	Treatment with Storage	01/09/2005	30/11/2007	
L0119/12/a	Expired	Treatment with Storage	01/12/2004	30/11/2007	

Appendix C:

RESPONSE OF PERSON RESPONSIBLE TO INSPECTION REPORT

Centre Number 0119

Name of PR Dr Sue Avery

Date of Inspection 17th July 2008

Date of Response By email, 17th Sept 2008

Please state any comments regarding the inspection and actions you have taken or are planning to take following the inspection with time scales

Breach	CENTRE ACTION
The organisational chart was not considered accurate.	The chart has been corrected and submitted
The complaints policy has not been reviewed	The Trust now has an up to date, reviewed complaints policy (attached). However, the Trust is about to implement a new and substantially different procedure, for which the SOP is not yet available.
Not all third party agreements have been submitted	A third party agreement is with the Trust's procurement department awaiting signature – this covers all outstanding supplies/services.
The average time taken to pay HFEA invoices was 37 days.	This has been drawn to the attention of the Trust finance dept, and will be actively monitored by the PR.
Records are not kept of all staff meetings and some meetings are cancelled due to workload pressures.	Records of laboratory meetings are now being kept. Nurses meetings have been scheduled and will be minuted. Nursing staff is back to full establishment. The minutes of all meetings are made available to all staff electronically and in paper copy. No clinical decisions are made at staff/operational meetings. There is a weekly patient meeting at which clinicians, nurses and embryologists are present, and all clinical decisions made here are recorded appropriately in the patient's records.
The quality policy was not signed by the PR	This has been signed and is displayed in the Unit.
Some deficiencies were identified in the centre's documentation	The SOPs have been reviewed that were due or overdue, and the appropriate copies are confirmed as being on the document management system. The incoming consultant has agreed to review the clinical SOPs (in consultation with existing clinical staff), prior to her arrival.

There is no SOP for testing the low level liquid nitrogen alarms or the low level oxygen monitor.	These SOPs are currently being drafted in collaboration with the medical physics department and will be submitted on completion.
Not all staff whose training records were reviewed in the course of the inspection had completed mandatory health and safety training and signatures were not recorded against all competencies.	Records inspected were those of new staff who are participating in the Trust annual cycle of induction and health and safety training. This training is not yet completed, and signatures are present against all training that has been completed. Signatures were absent where training was not complete. The induction procedure will be reviewed to include more specific competencies for embryologists and other specific professional groups.
Evidence of screening for syphilis was absent from a sample of donor records reviewed in the course of the inspection.	Donor screening procedures are compliant. In the case cited the result was available but had not been filed. All donor files have been audited and results are present in all files.
Validation of key processes and procedures has not yet been fully established.	Plans for validation were discussed. It is intended to use validation of the electronic witnessing system as a pilot, and this will be submitted when complete.
Procedures for transportation of gametes are not compliant with requirements.	Procedure being reviewed and will be submitted when complete (by 17th October)

Point of clarification

Embryology staffing.
The previous structure involved a consultant embryologist, with a senior embryologist/laboratory manager reporting to them. While the Consultant post was made redundant, the senior post remained. However, the senior embryologist left to take up another post at the end of May, and his replacement starts on September 22nd. There was never an intention not to appoint to this post, as clearly that would have left the unit understaffed permanently. The NEQAS programme was suspended for two months over the summer holiday period, as we clearly needed to prioritise work during this period of staff shortage, but was re-instigated in August when staff returned.

Witnessing
The system of witnessing through the door was raised as a risk in the previous inspection (by the same inspector) and a risk assessment was carried out and submitted to the Authority as required. No further action was considered necessary at that time. The introduction of the electronic witnessing system should solve this problem in any case.

Sue Avery 11.09.08

2. Correction of factual inaccuracies

Please let us know of any factual corrections that you believe need to be made (NB we will make any alterations to the report where there are factual inaccuracies. Any other comments about the inspection report will be appended to the report).

See Section above

Licence Committee Meeting

15 October 2008
21 Bloomsbury Street London WC1B 3HF

MINUTES Item 6

Birmingham Women's Hospital (0119)
Interim Inspection

Members of the Committee:	In Attendance:
Anna Carragher, Lay Member – Chair	Chris O'Toole, Head of Research Regulation
Emily Jackson, Lay Member	Claudia Lally, Committee Secretary
Richard Harries, Lay Member	
Maybeth Jamieson, Consultant Embryologist, Glasgow Royal Infirmary	Providing Legal Advice to the Committee: Mary Timms, Field Fisher Waterhouse Solicitors

Conflicts 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 (35 pages)
- one tabled paper: email from the Person Responsible (2 pages)

1. The papers for this item were presented by Andrew Leonard, HFEA Inspector. Dr Leonard informed the Committee that this centre is medium sized and provides approximately 520 licensed treatment cycles per year. Dr Leonard reported that the centre has been proactive in the development and implementation of a quality management system and in the use of appropriate key performance indicators to monitor its activities. In addition, the centre's premises and the information it provides to patients were found to be appropriate. However, improvements were required in the following areas:
   - the organisational chart
   - third party agreements
   - staff communications
   - reviews of documents and procedures
   - witnessing
   - documentation of training and assessment of competency
   - validation of key processes

2. Dr Leonard summarised the response to the inspection report from the Person Responsible, which was appended to the report at page 31. He stated that the Person Responsible had responded very positivity to the inspection and to recommendations of the inspection team. Dr Leonard tabled an email from the Person Responsible, dated 14 October, which provided an update on staffing arrangements at the centre in response to the findings of the report.

3. The Committee considered the report and the responses by the Person Responsible. It considered the email from the Person Responsible describing the steps which are being taken to address the staffing issues. In particular, the Committee noted that a full time embryologist started in September. It also noted, with some concern, that the deficit in number of clinical staff described in the inspection report will not be addressed until next June, though there will be some level of cover arrangement until then. The Committee asked that the Executive closely monitor the staffing situation at the centre over the next few months. In addition, the Committee asked that the centre conduct a review to determine whether the current level of activity is safely supported by the current level of staffing and other resources. The results of the review should then be communicated to the Executive.

4. The Committee asked that the centre informs the Executive when Health Professions Council (HPC) registration for the clinical embryologist has been confirmed.

5. The Committee noted the response to the inspection by the Person Responsible and decided that the centre's licence should continue with no additional conditions. It asked that the Executive report the matter back to a Licence Committee if there are concerns that insufficient progress is being made in relation to the staffing issues or in relation to the activity review.

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