Interim Inspection Report

IVF Hammersmith
0078

Date of Inspection: 8th April 2009
Date of Licence Committee: 30th July 2009

Centre Details

Person Responsible	Mr Stuart Lavery
Nominal Licensee	Mr Geoff Trew
Centre name	IVF Hammersmith
Centre number	0078
Centre address	Wolfson Family Clinic, Hammersmith Hospital, Du Cane Road London, W12 0HS
Type of inspection	Interim
Inspector(s)	Sarah Hopper Andrew Leonard Paula Nolan
Observer	Chris O'Toole
Fee paid	N/A interim inspection
Licence expiry date	31/12/2012
NHS/ Private/ Both	Both

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About the Inspection:

This inspection visit was carried out on the 8th April 2009 and lasted for 7.5 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 <u>what</u> needs to be addressed but not <u>how</u> 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 <u>www.hfea.gov.uk</u> .

Brief Description of the Centre and Person Responsible

IVF Hammersmith has been a licensed centre since 1992 and provides treatment to NHS and privately funded patients.

The centre is open 7 days a week, from 7am to 5pm on Monday – Friday and reduced hours, 8am-10am on weekends. A variety of treatments are offered at this centre including IVF/ICSI, frozen embryo transfers, preimplantation genetic diagnosis (PGD) and preimplantation genetic screening (PGS).

The PR, Stuart Lavery, has been in post since 2004, is registered with the General Medical Council (GMC) and is on the specialist register for obstetrics and gynaecology.

Activities of the Centre[1]

Time period from 1st January 2008-31 December 2008

In vitro fertilisation (IVF)	895 cycles
Intracytoplasmic sperm injection (ICSI)	708 cycles
Frozen embryo transfer (FET)	268
Donor insemination	45 cycles
Intra uterine insemination (IUI)	215 cycles
Gamete intrafallopian transfer (GIFT)	N/A
Research	Yes Research project R0187
Storage gametes/embryos	Yes

Summary for Licence Committee

There have been no significant changes in terms of premises, staffing or equipment since the last inspection.

The inspectorate agreed that some improvements are needed in the areas of organisation, quality of service, premises and equipment, information and laboratory and clinical processes. In particular, improvements should be considered relating to the following aspects of the centre's practice:

- Review of quality management system
- Competency assessments
- Donor screening
- Witnessing documentation

[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.

The inspection team recommends the continuation of the centre's licence without additional conditions.

Evaluations from the inspection

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

Breaches of the Act, Standard Licence Conditions or Code of Practice:
The table below sets out matters which the Inspection Team considers may constitute breaches of the Act, Standard Licence Conditions and/or the Code of Practice, and their recommended improvement actions and timescales. The weight to be attached to any breach of the Act, Standard Licence Conditions or Code of Practice is a matter for the Licence Committee;-

Breach	Action required	Time scale
The centre takes an average of 30 days to pay treatment fees. The HFEA payment terms are 28 days. Payment outside these terms is a breach of standard licence condition A13.3 which states that in consideration of the grant of the licence (or its variation to designate the individual named in this licence as Person Responsible), the Person Responsible agrees that s/he will pay to the Authority any additional fee, as defined in section 16(6) of the Act, within 28 days of the date of the notice of such additional fee.	The PR should review the arrangement 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.
Information required for this inspection was submitted 14 days after the deadline. It had been requested on the 23rd January 2009, with a set submission date of 11th March 2009, but was received on the 1st April 2009. The PR explained that the delay	The PR should put processes in place to ensure that in future information is supplied to the HFEA in accordance with Standard Licence Condition A13.2.	Prior to the next HFEA inspection.

was due to his absence from the centre, for personal reasons, at the time the papers were due. The PR was reminded of Standard Licence Condition A13.2 which requires that 'in support of an inspection the Authority shall be provided, within 28 days of a request being made, with such information as specified in the written request or in Directions.'		
A review of the quality management system has not been conducted in the past year. The quality manager explained that the meeting usually used for this review had a different focus last year. Code of Practice Standards 4.2.8 and 4.2.9 require that the centre management conduct a regular, at least annual, review of the quality management system and all its services.	The quality management system should be reviewed in accordance with Code of Practice Standard 4.2.8 and 4.2.9.	The quality management system to be reviewed at least on an annual basis. Progress to be monitored at the next inspection.
The inspectorate were unable to determine that documents have been subjected to review on an annual basis, as per Code of Practice Standard 5.2.5. The quality manager reported that this review is performed yearly by each department head but that a formal record of this is not kept.	It is recommended that a date of the review and re-approval is recorded in accordance with Code of Practice Standard 5.2.5 (a).	Progress to be monitored at the next inspection.
Not all members of staff have had their competency to perform designated activities assessed. Standard Licence Condition A10.9 and Code of Practice Standards 6.2.7 and 6.2.9 require that the competence of each person to perform designated activities shall be evaluated at intervals specified in the Quality Management System and re-training undertaken when required.	A programme of assessments for all staff should be developed immediately.	To be monitored in the course of the next inspection.

Critical laboratory processes have not yet been validated. The validation of equipment is not yet complete.	It is recommended that the PR identifies the key processes and equipment which will need to be validated to ensure compliance with Licence Condition 11.11 and Code of Practice Standard 7.8.3. A programme of validation should be developed: the programme 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. It is recommended that the programme should include a validation of the procedures for air quality testing to provide evidence that air quality is maintained in the interval between testing.*(S.7.8.3, G.9.4.7)*	Progress to be monitored at the next inspection.
The centre uses an external laboratory to perform their diagnostic PGD work. This laboratory has not yet obtained accreditation from CPA (UK) Ltd or another body accrediting to an equivalent standard. The inspectorate were informed that the laboratory is working towards gaining accreditation through the ESHRE accreditation scheme.	The PR is reminded of Code of Practice Standard S.7.8.2 which requires that 'If the Centre has laboratories or contracts Third Party laboratories or practitioners to undertake the diagnosis and investigation of Patients, Patient Partners or Donors, or their gametes, embryos or any material removed from them, these laboratories shall obtain suitable accreditation'. 'Suitable accreditation' means accreditation by CPA(UK) Ltd or another body accrediting to an equivalent standard. It is recommended that the PR reviews the appropriateness of using a non-accredited laboratory for PGD diagnostic work.	Progress to be monitored at the next inspection.
The centre did not provide a copy of their multiple birth minimisation strategy to the Authority by 31 January 2009 as required by General Direction D2008/5.[2] The strategy was submitted on the 20th March 2009.	No further action is required but the PR is reminded of the need to provide information in accordance with General Directions.	No further action required.

[2] A copy of the multiple births minimisation strategy was to be submitted no later than 31st January 2009

Non-Compliance

Area for improvement	Action required	Time scale
On review of patient records it was noted that the witnessing records did not include the time of the procedure when male patient identification is confirmed prior to sperm production. Code of Practice Guidance 13.2.1 states that witnessing records should include the date and time of the procedure.	It is recommended that the PR reviews the template used for recording witnessing and updates it to include the time of procedure.	With immediate effect.
The removal of samples from the main dewar is not witnessed contemporaneously. This activity is performed by an unaccompanied embryologist who places samples from the dewar into a small liquid nitrogen vessel for transport to the embryology laboratory. On arrival the samples are then checked and witnessed as correct with another embryologist. Code of Practice Guidance 13.1.1 (i) states that at the removal of gametes or embryos from storage, information on the storage container should be cross checked against information in the patient/donor records to confirm that the gametes/embryos are the correct ones to remove from storage.	It is recommended that the PR reviews this practice against the Code of Practice Guidance 13.1.1 (i) and assesses the risks involved with deviating from this guidance, taking corrective action as necessary.	With immediate effect.
Since the last inspection, one three ET was performed for a patient <40 years old. Code of Practice Guidance 8.5.1 states that where a woman is to receive treatment using her own eggs, or embryos created using her own eggs, whether fresh or previously cryopreserved: where the woman is aged under 40 at the time of the transfer the centre should not transfer more than two eggs or two embryos in any treatment cycle, regardless of the procedure used.	The PR should ensure compliance with Code of Practice Guidance 8.5.1.	Progress to be monitored at next inspection.
Patients who donate eggs are not routinely screened in line with professional body guidelines. The patient record for one egg donor was reviewed and did not include evidence of screening tests for Chlamydia, Neisseria	It is recommended that the PR reviews the professional guidelines on screening for egg donors and ensures that donors of gametes and embryos are screened in accordance with	Immediately.

Gonorrhoea, Glucose 6 phosphate dehydrogenase or HTLV-1/HTLV-2.	current guidance from the relevant professional bodies[3] (CoP Guidance 4.9.1).	

Recommendations

Area for improvement	Action required	Time scale
On inspection it was noted that records belonging to patients attending the unit for scan appointments were seen to be kept on top of a cupboard at the end of an open corridor near the scan rooms. In addition, patient records were seen to be stored on a window sill in a corridor outside the embryo transfer recovery room. The inspectorate considered that this practice could potentially allow unauthorised access to confidential identifying information in breach of S.33 of the 1990 Human Fertilisation and Embryology Act (HF&E Act).	It is recommended that the PR ensures that information provided in confidence is kept confidential and only disclosed in circumstances permitted by law. It is therefore recommended that the PR considers the risks associated with this practice of storing patient records insecurely at the end of a corridor and takes action as appropriate.	Immediately
The centre's protocol for the transport of gametes is not fully compliant with the recommendations of Alert 21: Transport Hazards.	The PR should review the procedures for transport of gametes in consideration of the recommendations of Alert 21.	With immediate effect.
Appropriate hazard notices are not on display on the door to the cryostore, neither is the door marked that the room should not be entered if the low oxygen alarm is sounding, or with the contact details of a responsible person.	It is suggested that appropriate signage be placed on the door of the cryostore to correct the deficits identified by the inspectorate.	Immediately.
The HFEA register department reported that the centre has not yet cleared their error reports for January and February 2009. This is contrary to the HFEA policy on collection, confirmation and publication of register data, as stated in Direction 2008/6.	It is recommended that the PR refers to the HFEA policy 'Collection, Confirmation and Publication of Register Data' and ensures compliance with paragraph 4.6.7 which requires that error reports made available by the authority are reviewed by their licensed centres on a weekly basis. This is in order to prevent a build up of unresolved data issues, which may affect the quality	To be monitored at the next inspection.

[3] 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

	of the data held by the Authority in its statutory register.	

Changes/ improvements since last inspection

Recommendations made at last inspection	Action Taken
The transfer of 3 embryos in three women aged <40 years is contrary to the CoP 6 paragraph 8.2 Action required – adherence to the Code of Practice	Since the last inspection one three embryo transfer has been conducted for a woman < 40 years old.
Two areas of non compliance were noted within the witnessing procedures – contemporaneous witnessing of the removal of cryopreserved semen samples was not occurring and not all stages of the sperm preparation process are directly witnessed. The laboratory manager to revise the witnessing protocol.	The witnessing protocol was reviewed and witnessing practice was discussed with staff at this inspection. It was noted that the witnessing procedures have been updated since the last inspection – the witnessing protocol now states that 'witnessing os performed at all stages where sperm is moved from one tube to another'. However, contemporaneous witnessing of the removal of cryopreserved semen samples is still not occurring.
The dissemination of HFEA alerts should be monitored in order to ensure they are reaching all staff groups.	The PR reported that he has not received the most recent HFEA alert and this is therefore being addressed at the HFEA. Other members of staff reported that they have organised their own access to the electronic HFEA alerts.
The centre may want to review its incident reporting to the HFEA.	The centre has been reporting incidents and has a protocol in place to support this.
HFEA patient questionnaires are to be made readily available to patients using the centre's services.	24 HFEA patient questionnaires were received prior to this inspection.
It is recommended that risk assessments be performed on i. the practice of patient notes being left insecurely on a trolley outside scan rooms on the ground floor whilst scans are being performed. ii. the transportation of gametes/embryos between floors within the unit.	Risk assessment on the transportation of gametes/embryos between floors at the unit was provided during this inspection. The PR explained that following the last inspection scan notes are now left in a different area. The inspectorate still had concerns about this as the notes are not held securely and recommend that the PR assesses the risks involved with this practice.
It is recommended that risk assessments be performed on:	The risk assessment on the new PGD suite was not provided during the inspection.

i. the new PGD suite when completed ii. the lack of distress alarms within the men's production rooms.	Laboratory staff explained that this room is seldom used. The inspectorate requested that this be submitted as soon as possible. Distress alarms have now been fitted to the men's production rooms.

Recommendations made by Licence Committee on the 10th October 2007	**Action Taken**
The centre should be asked to audit the outcome of all three embryo transfers over the past five years and to submit the results to the Executive	A copy of this audit, which covered the period January 2003-December 2007, was provided at this inspection.

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
An organisational chart is in place which outlines the accountability and reporting relationships between centre staff. A copy of this was provided prior to the inspection and was also seen to be displayed in staff areas. Procedures are in place for the recording of all non-conformities identified in processes along with corrective/preventative actions taken. A log of non-conformity reports was provided during the inspection. Processes are in place for the identification, investigation, control, recording and notification to the HFEA of all adverse incidents. These processes are supported by a documented standard operating procedure and flow diagram. The centre has a complaints policy and this identifies two members of staff within the centre as complaints officers. Information about complaints was seen to be displayed in patient areas. Information is disseminated to staff via emails and meetings. A variety of different meetings are held by members of staff, these include monthly senior management meetings, quality management meetings and team meetings. The inspectorate saw evidence that records of the various meetings are kept and these are stored on the computer system. This system ensures that the minutes can be accessed by all licensed staff. Third party agreements have been established with parties when an activity takes place which influences the quality and safety of gametes and embryos. A sample of these agreements were reviewed during the inspection and seen to be compliant with Code of Practice Guidance 2.1.2.

Areas for improvement
Information required for this inspection was submitted 14 days after the deadline. The PR explained that the delay was due to his absence from the centre, for personal reasons, at the time when the papers were due. The PR was reminded of Standard Licence Condition A13.2 which requires that 'in support of an inspection the Authority shall be provided, within 28 days of a request being made, with such information as specified in the written request or in Directions.' The HFEA finance department has reported that the centre takes an average of 30 days to pay sales invoices. HFEA payment terms are 28 days. Payment outside these terms is a breach of standard licence condition A13.3 which states that in consideration of the grant of the licence (or its variation to designate the individual named in this licence as Person Responsible), the Person Responsible agrees that s/he will pay to the Authority any additional fee, as defined in section 16(6) of the Act, within 28 days of the date of the notice of such additional fee. The PR should review the arrangement for payment of invoices and ensure that there are no barriers to the prompt payment of invoices.
Areas for consideration
None
Executive recommendations for Licence Committee
The Licence Committee is asked to endorse the recommendations made in relation to: • Payment of licence/treatment fees
Evaluation
Some improvements required
Areas not covered on this inspection
None

2. Quality of service

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

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

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

Live birth rates[1]
For the time periods January 1st 2004 – December 31st 2006 and January 1st 2005 - December 31st 2007, success rates for donor insemination, frozen embryo transfer and IVF/ICSI for all age stratified groups did not differ significantly from national average figures.
Areas of firm compliance
A quality manager is in post. The quality manager also has clinical responsibilities but reported that she has sufficient time dedicated to this role. An established quality management system is in place. The centre was first certified under the ISO 9001:2000 standard in 2006. The system is due to be re-audited by an external company in May 2009. All relevant quality management documents are in place. At inspection it was noted that all documents required for the quality management system are stored on the centre's internal electronic server which can be accessed by all staff at IVF Hammersmith. The quality management system is underpinned by a quality manual which includes; a description of the centre and the services provided, the quality policy, text to accompany the organisational chart and an outline of the processes and documentation required to establish the quality management system. A quality policy has been developed and according to the quality manual is reviewed on an annual basis. The policy includes commitments to the provision of services which meet user needs and requirements (users include patients, referring hospital colleagues/general practitioners/PCTs and suppliers). The policy also includes a commitment to continual improvement of the service and to the support and development of staff. Copies of the quality policy were seen to be displayed in the patient reception area and in the staff kitchen. Quality objectives have been set within each discipline at the centre. For example, quality objectives for the counselling department include ensuring readiness for the new provisions stemming from the revised HFE Act (1990) which will impact directly on patients. A series of quality objectives have also been set for the embryology, clinical and administrative teams

and copies of these were provided to the inspectorate.

Feedback is gathered from patients using an annual patient satisfaction questionnaire. A copy of the most recent questionnaire was provided to the inspectorate and the PR explained that the next questionnaire will have more targeted questions about waiting times as this has been recognised as a possible area of concern. Questionnaires that are returned to the centre are analysed and evaluated. The analysis of questionnaires returned in 2007 was seen by the inspectorate.

Patients are also able to provide feedback on the service via comments boxes which are sited in the patient waiting areas. The PR reported that comments made in this box are regularly reviewed and gave examples of corrective actions that have been made in response to some of the comments. For example, some patients who had experienced failed cycles of IVF stated that they found the displays of baby photos in the waiting areas distressing. Other patients commented that they liked to see the photos. In light of this feedback, the majority of photos were removed and replaced in photo albums which are available within the waiting area.

The centre has a document control procedure in place. All current documents are stored on the electronic server. The quality manager explained that apart from some authorised exceptions staff have read-only access to these documents and unauthorised changes can therefore not be made.

Areas for improvement

The quality manager explained that a review of the quality management system is normally conducted on an annual basis at an all staff awayday. Evidence that this review had occurred in previous years was gathered by looking at the minutes from previous away days. However, the inspectorate did not see evidence that a review of the quality management system has occurred in the past year. The quality manager explained that the focus for the most recent away day was on activity levels rather than on the quality management system. This was clear from the minutes of the meeting which did not mention a review of the QMS. The PR is reminded of the requirement for the QMS to be reviewed on an, at least, annual basis (Code of Practice Standard 4.2.8).

The inspectorate was unable to determine that documents have been subjected to review on an annual basis, as per Code of Practice Standard 5.2.5. The quality manager reported that this review is performed yearly by each department head but that a formal record is not kept. It is recommended that a date of the review and re-approval is recorded in accordance with Code of Practice Standard 5.2.5 (a).

Areas for consideration

Twenty six HFEA patient questionnaires were received since the last HFEA inspection. Of these, 19 included comments about the service of which 9 contained a mixture of positive and negative comments, 5 contained negative comments only and 5 contained positive feedback. A number of patients stated that they felt the centre is busy and that this had influenced the quality of service they had received. These issues were discussed with staff during the inspection. According to the PR similar responses had been gathered using their own questionnaires and the centre is therefore currently working on corrective actions.

The PR also explained that the issue of activity level was discussed at an away day meeting

for all staff in December 2008. Minutes from this day were provided prior to the inspection and these indicated that the maximum level of activity had been discussed. The PR stated that this has been fixed at 1800 cycles. A scheduling system has recently been introduced in an attempt to steady out the workload and ensure that the number of cycles conducted remains even between months. The quality manager demonstrated this system to the inspectorate and explained that they are working to a target of 160 cycles a month. It was noted that this limit had been exceeded in one month in 2009 but the quality manager stated that the system had only recently been introduced at that time. The PR stated that he has asked the quality manager to conduct an assessment of the risks resulting from operating at 1800 cycles a year.

It is recommended that the PR continues monitoring workload against available resources, and regularly evaluates the centre's quality indicators and qualitative feedback gathered using patient questionnaires and the comment box.

Executive recommendations for Licence Committee
The Licence Committee is asked to endorse the recommendations made in relation to: • Review of the quality management system • Document review
Evaluation
Some improvements required
Areas not covered on this inspection
None

3. Premises and Equipment

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

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

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

Areas of firm compliance
The PR reported that there have been no significant changes to the premises or equipment since the last inspection. The counselling service is provided in quiet, comfortable, private and confidential surroundings. The centre has defined procedures for incubator and laboratory cleaning. Cleaning logs were seen to be displayed in laboratory areas. Air quality is monitored on a monthly basis via particle counting. The air quality monitoring results for the past year were reviewed by the inspectorate and it was noted that all testing performed showed air quality in the background to be grade D or better, and that in the critical work areas grade C or better. All equipment sampled during the inspection had evidence of recent servicing. It was noted that a system for monitoring environmental parameters for key equipment, including incubators, dewars, fridges and freezers is in place. All incubators are connected to an alarm system and the fridges and freezers are fitted with data loggers which record temperature. Gametes and embryos were seen to be stored in a secure area. The dewar store has key pad controlled access. All dewars were seen to be equipped with low level nitrogen and temperature monitors connected to the environmental monitoring and alarm system. Staff are provided with facilities including a rest area with basic catering facilities and a supply of drinking water, a changing area, toilets and secure storage for personal effects.
Areas for improvement
The centre uses an external laboratory to perform their diagnostic PGD work. This laboratory has not yet obtained accreditation from CPA (UK) Ltd or another body accrediting to an equivalent standard. The inspectorate were informed that the laboratory is working towards gaining accreditation through the ESHRE accreditation scheme. Code of Practice Standard S.7.8.2 requires that 'If the Centre has laboratories or contracts Third Party laboratories or

practitioners to undertake the diagnosis and investigation of Patients, Patient Partners or Donors, or their gametes, embryos or any material removed from them, these laboratories shall obtain suitable accreditation'. 'Suitable accreditation' means accreditation by CPA(UK) Ltd or another body accrediting to an equivalent standard. It is recommended that the PR reviews the appropriateness of using a laboratory which has not been accredited to CPA (UK) or equivalent standards for PGD diagnostic work.

On inspection it was noted that not all equipment has been validated but there is an ongoing programme. The PR should ensure that all critical equipment is identified and validated in accordance with Code of Practice Standard 6.4.2(a).

Areas for consideration

On inspection it was noted that records belonging to patients attending the unit for scan appointments were kept on top of a cupboard at the end of an open corridor near the scan rooms. In addition, patient records were seen to be stored on a window sill in a corridor outside the embryo transfer recovery room. The inspectorate considered that this practice of leaving notes unattended in areas which could be accessed by patients, could potentially allow unauthorised access to confidential identifying information in breach of S.33 of the 1990 Human Fertilisation and Embryology Act (HF&E Act). This issue was discussed with the PR who reported that patients do not walk past the area where scan notes are held and that since the last inspection, when the security of scan records was raised as an issue, the location of the notes has been changed. The inspectorate recommended that the PR assess the security risks associated with holding records in both locations and take corrective action as deemed appropriate.

The inspectorate also suggested that hazard notices be placed on the door of the cryostore to alert staff and patients that liquid nitrogen is stored in this area and that staff/patients are made aware of what to do in the event of an alarm.

The inspectorate had concerns regarding the high position of the low oxygen monitors in the cryostore and recommend that the laboratory manager contacts the suppliers of the monitors to ensure that the monitors are positioned correctly.

Executive recommendations for Licence Committee

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

- Validation of equipment
- Security of patient records
- Low oxygen monitors
- Suitably accredited external diagnostic laboratories

Evaluation

Some improvements required

Areas not covered on this inspection

None

4. Information

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

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

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

Areas of firm compliance
Service users are provided with information about the counselling service: leaflets about the service were seen to be available in the patient waiting areas. The HFEA audit team visited the centre on the 6th and 7th of April and reported that they obtained reasonable assurance that Centre systems are operating effectively in relation to completeness and quality of data reporting. Counselling records were seen to be kept securely within the counselling room in locked filling cabinets. The counsellor explained that the two counsellors are the only people with keys to access these files.
Areas for improvement
The HFEA register department reported that the centre has not yet cleared their error reports for January and February 2009. This is contrary to the HFEA policy on collection, confirmation and publication of register data contained within Direction 2008/6. Paragraph 4.6.7 of this policy states that "The Authority requires Persons Responsible to ensure that the error reports made available by the Authority are reviewed by their licensed clinics on a weekly basis. This is in order to prevent a build up of unresolved data issues, which may affect the quality of the data held by the Authority in its statutory Register". Furthermore, paragraph 4.6.8 states that failure to clear errors reports for 2 consecutive months, or a consistent pattern of failure to respond to reminders to clear error reports, will be brought to the attention of the Authority's Licence Committee. It is recommended that the PR puts processes in place to ensure that error reports are reviewed and corrected on a weekly basis.
Areas for consideration
None
Executive recommendations for Licence Committee
The Licence Committee is asked to endorse the recommendations made in relation to: • Error reports
Evaluation
Some improvement required

Areas not covered on this inspection
Information for service users – interim inspection Consent and Welfare of the child - reviewed by HFEA audit team on the 6th and 7th April 2009 Access to health records – interim inspection

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	7
NMC registered nurses	12
Non NMC registered clinical staff	0
HPC registered scientists	3
Scientists working towards registration	7
Support staff (receptionists, record managers, quality and risk managers etc)	17
Counsellors	2

Summary of laboratory audit
The PR submitted a report from the most recent audit of their storage tanks prior to the inspection. The audit was conducted between February and March 2009 and the PR confirmed that no serious errors were found. Minor administrative errors were noted and the PR confirmed that these have been corrected.
Summary of spot check of stored material
Not conducted as this was an interim inspection.
Summary of counselling audit
An audit of the counselling service provided in 2008 has been carried out. A copy of the report resulting from this audit was provided to the inspection team. This revealed that there had been a 12% increase in demand for the counselling service compared to 2007 but that all those requesting sessions had been accommodated. In total 343 clients were seen and 1050 sessions were held in the period 01/01/08 - 31/12/08.
Areas of firm compliance
Detailed induction programmes for nursing and embryology staff are in place. Documentation supporting the nursing induction programme was provided during the inspection.

Interviewed staff expressed satisfaction at the support they receive for their continual professional development. Trainee embryologists interviewed during the inspection explained that they are given study time (approximately one day every two weeks) so that they can work on their Association of Clinical Embryologists training certificate. Counselling staff reported that they have attended and presented at a number of conferences in the past year. One of the counsellor's training records was reviewed and was seen to contain evidence of continuing professional development .Both counsellors have been accredited by BICA, one as a senior accredited member (SAMBICA) and the other as an accredited member (AMBICA).

A detailed competency programme was seen to be in place for the nursing department. Documentation for this programme was seen include assessment of competency at managing frozen embryo transfer cycles, operative nursing care and venepuncture.

Procedures are in place to ensure that anything coming into contact with gametes and embryos is traceable. Records of batch numbers and the incubators and work stations used during gamete/embryo processing for each patient are kept and were seen by the inspectorate.

Records relating to import/export of gametes and embryos were reviewed and were considered to be compliant with the requirements of General Directions D2008/1, D2008/2, D2008/3 and D2008/4.

Areas for improvement

In the time period 13/06/07 to 03/03/09 ninety embryo transfers have been conducted which involved the transfer of three embryos. The inspectorate were informed by centre staff that on one occasion since the last inspection a woman aged under 40 years had received a 3 embryo transfer. This was confirmed on review of the centre's three embryo transfer log. This is non-compliant with Code of Practice Guidance 8.5.1 which states that 'Where a woman is to receive treatment using her own eggs, or embryos created using her own eggs, whether fresh or previously cryopreserved and (a) where the woman is aged under 40 at the time of transfer the centre should not transfer more than two eggs or two embryos in any treatment cycle, regardless of the procedure used'.

The centre did not provide a copy of their multiple birth minimisation strategy to the Authority by 31 January 2009 as required by General Direction D2008/5.[4] The strategy was instead submitted on the 20th March 2009.

Whilst it was noted that a competency assessment programme is in place for the nursing department and forms part of the initial training of embryology staff, not all members of staff have had their competency to perform designated tasks assessed. The PR should ensure that the competence of each person to perform designated activities is evaluated at intervals specified in the Quality Management System and re-training undertaken when required as per Standard Licence Condition A10.9 and Code of Practice Standards 6.2.7 and 6.2.9.

Donors are not being screened in accordance with professional guidance. The patient record belonging to a known egg donor was reviewed and it was noted that the donor had not been screened for Chlamydia, Neisseria Gonorrhoea, Glucose-6-phosphate dehydrogenase

[4] A copy of the multiple births minimisation strategy was to be submitted no later than 31st January 2009

deficiency or HTLV-1/HTLV-2. This is non-compliance with joint professional body guidelines for screening of sperm, egg and embryo donors (2008)[5]. It is recommended that the PR reviews the professional guidelines on screening for egg donors and ensures that donors of gametes and embryos are screened in accordance with current guidance produced by the relevant professional bodies (CoP Guidance 4.9.1).

Witnessing record keeping was reviewed through an audit of four sets of patient records. It was noted that the time for verification of male identity at sperm production is not recorded. This is non-compliance with Code of Practice Guidance 13.2.1. It is recommended that the PR reviews the template witnessing records and updates it to include the time of procedure.

It was also found that the removal of samples from the main dewar is not witnessed contemporaneously. This activity is performed by an unaccompanied embryologist who takes samples from the dewar and places them into a small liquid nitrogen vessel before transporting them to the embryology laboratory. On arrival the samples identities are checked and witnessed with another embryologist. Code of Practice Guidance 13.1.1 (i) guides that the information on the storage container should be cross checked, with a witness, against information in the patient/donor records to confirm that they are the correct gametes/embryos to remove.

Critical laboratory processes have not yet been validated. It is recommended that the PR identifies the key processes which will need to be validated to ensure compliance with Licence Conditions 11.11 and Code of Practice Standards 7.8.3. A programme of validation should be developed, this programme should take into account the particular needs of the unit and prioritise the validation of those processes considered most likely to impact on the quality of the service. The inspectorate specifically recommend that the programme should include a validation of the procedures for air quality testing to provide evidence that air quality is maintained in the interval between testing*(S.7.8.3, G.9.4.7).*

Areas for consideration

The centre does not participate in inter-laboratory assessments. The laboratory manager explained that they do not engage in the NEQAS andrology schemes because the majority of their andrology analytical work is conducted by another centre (centre 0080). The laboratory manager did explain that they have volunteered to participate in a pilot inter-laboratory assessment of embryo morphology (organised by NEQAS). The PR and laboratory manager also explained that the premises, equipment and processes at the centre had recently been subjected to an external review and that comments made by the external reviewer have led to proposals for new laboratory equipment and techniques.

The centre's protocol for the transport of gametes is not fully compliant with the recommendations of Alert 21: Transport Hazards in relation to checking that the transport vessel does not contain other samples before use and procedures to be followed if labelling has degraded. It is recommended that the PR should review the procedures for transport of gametes in consideration of the recommendations of Alert 21: Transport Hazards.

[5] 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

Executive recommendations for Licence Committee
The Licence Committee is asked to endorse the recommendations made in relation to: • Staff competency assessments • Donor screening • Witnessing • Validation of processes
Evaluation
Some improvements required.
Areas not covered on this inspection
None

Report compiled by:

Name…Sarah Hopper…….

Designation…Inspector……..

Date…15th April 2009……

Appendix A: Centre staff interviewed

PR and 7 other members of staff.

Appendix B: Licence history for previous 3 years

Appendix C: Response of Person Responsible to the inspection report

Centre Number……0078……

Name of PR……Stuart Lavery…… …….

Date of Inspection……08/04/2009……

Date of Response……19/05/09……

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

Signed……

Name……Stuart Lavery…….

Date……19/05/09……

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.

1 'The centre takes an average of 30 days to pay treatment fees' Please see point 1 below 2 '. It is recommended that the PR reviews the appropriateness of using a non-accredited laboratory for PGD diagnostic work.' The external laboratory SOP's have all been accredited in the USA. An application to the UK CPA is underway.

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

1 The report suggests continued late payment of HFEA invoices. Below is our record over the last year:
April 08 - within 28 days
May 08 - within 28 days
June 08 - within 28 days
July 08 - within 28 days
Aug 08 - 2 days late
Sept 08 - within 28 days
Oct 08 - 2 days late
Nov 08 - within 28 days
Dec 08 - 8 days late (the cheque was lost and had to be re-issued)
Jan 09 - 2 days late
Feb 09 - within 28 days
Given our total relationship with the HFEA in terms of responses to licence applications etc we would like this taken into account.

2	An ISO inspection in May 2009 has found no non-conformances and our quality management system was highly praised. We are therefore unclear as to why the HFEA has suggested we need improvements in our quality management system. We therefore are confused and disappointed with this assertion and believe an accredited ISO quality manager inspector is extremely well placed to comment on this aspect and wish this to be reflected in any publication of this inspection.

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

Actions as recommended in the report will be completed within the timeframe recommended in the report. The only outcome where the timeframe is not certain is the CPA accreditation of our outsourced PGD cases where the Reprogenetics team are working towards accreditation. We believe at least 3 other IVF units are using them and so will be in similar positions.

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

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

HFEA Licence Committee Meeting

30 July 2009

21 Bloomsbury Street London WC1B 3HF

Minutes – item 3

IVF Hammersmith (0078) – Interim inspection report

Members of the Committee:	Committee Secretary: Alexandra Tydeman
Clare Lewis-Jones (lay) - Chair	
Ruth Fasht (lay)	Legal Adviser:
Sue Price (clinician)	Graham Miles, Morgan Cole
Apologies:	
Chris Barratt (andrologist)	
Roger Neuberg (clinician)	

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 (40 pages)
- no tabled papers.

The Committee also had before it:

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

18. The Committee noted that the Centre has been licensed by the HFEA since 1992 and provides treatment to NHS and privately funded patients.

19. The Committee considered the papers, which included the report of the interim inspection including the response of the Person Responsible (PR), previous Committee minutes, Executive update, invoice statement from the HFEA finance department and email correspondence between PR and HFEA about outstanding issues raised in the inspection report.

20. The Committee noted that the inspection took place on 8 April 2009 and found the following areas for improvement:
    - Quality management system
    - Competency assessments
    - Donor screening
    - Witnessing documentation

21. The Committee expressed particular concern about the issues relating to donor screening and the inappropriate storage of records but were satisfied with the PR's response that all actions as recommended in the report would be completed within the given timeframes.

22. The Committee endorsed the recommendations made in the report and requested the Executive to follow up with the Centre the actions requiring immediate effect:
    - Review of the template used for recording witnessing and update to include the time of procedure
    - Review of the practices in place for witnessing
    - Review of the professional guidelines on screening for egg donors and ensure that donors of embryos and gametes are screened in accordance with current guidance from relevant professional bodies (CoP Guidance 4.9.1)
    - Ensure that information provided in confidence is kept confidential. The PR to consider the risks of storing patient records insecurely
    - Review of the procedures for transport of gametes in consideration of the recommendation of Alert 21
    - Appropriate signage be placed on the door of the cryostore to correct the deficits identified by the inspectorate

<u>The Committee's Decision</u>

23. Subject to the recommendations set out above the Committee decided to continue the licence at this time without any additional conditions.

Signed..... Date..19/8/09
Clare Lewis-Jones (Chair)