Interim Inspection Report

Homerton Fertility Centre
Centre 0153

Date of Inspection: 24th March 2009
Date of Licence Committee: 10th June 2009

Index

Centre Details

Person Responsible	Mr Anil Gudi
Nominal Licensee	Nancy Hallett
Centre name	Homerton Fertility Centre
Centre number	0153
Centre address	Homerton University Hospital, Homerton Row, London E9 6SR
Type of inspection	Interim
Inspector(s)	Bhavna Mehta Ellie Suthers Andy Glew Paula Woodward (Observing)
Fee paid	N/A
Licence expiry date	Not applicable
NHS/ Private/ Both	NHS

About the Inspection:

This inspection visit was carried out on 24th March 2009 and lasted for 8 hours.

The purpose of the inspection is to ensure that centres are providing a quality service for patients in compliance with the HF&E Act 1990, Code of Practice and to ensure that centres are working towards compliance with the EU Tissue and Cells Directive 2004/23/EC. Inspections are always carried out when a licence is due for renewal although other visits can be made in between.

The report summarises the findings of the licence renewal inspection highlighting areas of good practice, as well as areas where further improvement is required to improve patient services and meet regulatory requirements. It is primarily written for the Licence Committee who make the decision about the centre's licence renewal application. The report is also available to patients and the public following the Licence Committee meeting.

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

An evaluation is given at the end of each topic and for the overall effectiveness of the centre:
No Improvements Required – given to centres where there are no Code of Practice, legal requirements or conditions that need to be imposed.
Some Improvements Required – given to centres that are generally satisfactory but with areas that need attention. Recommendations will usually be made to help Persons Responsible to improve the service.
Significant Improvements Required – given to centres that have considerable scope for improvement and have unacceptable outcomes in at least one area, causing concern sufficient to necessitate an immediate action plan or conditions put on the Licence.

Where recommendations are made the HFEA will provide details of what needs to be addressed but not how they should be carried out as this is the responsibility of the Person Responsible.

The report includes a response form for the Person Responsible to complete following the inspection.

The HFEA welcomes comments from patients and donors, past and present, on the quality of the service received. A questionnaire for patients can be found on the HFEA website www.hfea.gov.uk .

Brief Description of the Centre and Person Responsible

Homerton Fertility Centre holds a treatment and storage licence. The centre has been licensed for treatment since 1995 and is located on the site of the Homerton University Hospital NHS Trust.

On the 15th October 2008, the centre's licence was varied to:
1. Re-locate the clinical and laboratory areas to new premises at the same address, Homerton University Hospital, Homerton Row, Hackney London, E9 6SR and
2. Change the centre's name to Homerton Fertility Centre (from Homerton Fertility Unit).

Following the move into new premises all administrative, patient consultations and most clinical work is carried out in the new premises: egg collections are carried out in a designated theatre in the Trust's day surgery unit which is located in the same building. Embryo and sperm storage remain in the original cryo store area covered by this licence .

Embryos and sperm are frozen in the new laboratories and then transferred to the cryo store on a weekly basis.

There is a temporary storage facility in the new laboratories with separate storage tanks for sperm and embryos. These tanks are alarmed and monitored by the Facility Monitoring System (FMS) along with the other equipment in the new centre.

The PR has stated in the pre-inspection questionnaire (PIQ) that in the financial year 2009/10, the centre plans to pursue new developments:

1) Providing andrology services to North Middlesex hospitals for their IUI services.
2) Set up a satellite with Spire Roding hospitals.
3) HIV services. The PR has submitted a business plan to the Trust to build a new laboratory for HIV positive patients to receive IVF treatment. The service will be supported by the HIV service at the Homerton hospital.

Activities of the Centre[1]

for the time period from 1st January 2008 to 31st December 2008

In vitro fertilisation (IVF)	197
Intracytoplasmic sperm injection (ICSI)	181
Frozen embryo transfer (FET)	58
Donor insemination (DI)	83
Gamete intrafallopian transfer (GIFT)	No
Research	No

[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.

Storage gametes/embryos	Yes

Summary for Licence Committee

The Person Responsible (PR) has been in post since December 2007.

The centre has applied to vary their current licence to allow storage of eggs.

The centre has appropriate premises, suitably qualified and experienced staff and adopts largely appropriate procedures, except for those listed below. Patients report satisfaction with the treatment that they receive. The centre has been proactive in the continuous development and implementation of a quality management system.

Some improvements are required relating to the centre's organisation and information and significant improvements are required relating to the centre's laboratory and clinical processes.

The inspection team is concerned that the effect of the following two outstanding issues may be impacting on the effective operation of the centre. The issues include:

- The ongoing (since the 2007 renewal inspection) storage of cryopreserved material which is contrary to regulations and/or in the absence of written consent and
- errors in data reporting to the HFEA.

It is recommended that the PR provides information on the measures and steps to be taken to address all breaches highlighted in this report.

The inspection team recommends that the licence be varied to allow storage of eggs.
The inspection team recommends that the licence continues.

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 has a few errors that need to be corrected to comply with Direction 2008/6 Collection, conformation and publication of Register data - 1/10/08.	The PR should resolve any issues that lead to errors in data reporting to the HFEA.	Within three months of the date of this report: 20th June 2009.
As at the time of this inspection, during the demonstration of the bring forward system, it was observed that the centre was storing cryopreserved material for six patients without written consent. Section 3(3)(c) of the Human Fertilisation and Embryology Act 1990, as amended, states that "A licence cannot authorise keeping or using an embryo in any circumstances which regulations prohibit its keeping or use"; Schedule 3 prohibits keeping embryos without written, 'effective', consent. Section 41(1) (b) states that "A person who – does anything which, by virtue of section 3(3) of this Act, cannot be authorised by a licence is guilty of an offence and liable on conviction on indictment to imprisonment for a term not exceeding ten years or a fine or both."	The PR should, as a matter of urgency, ensure compliance with the requirements of the Human Fertilisation and Embryology Act in relation to the storage of gametes and embryos and 1. notify the lead inspector of the date of the monthly audit and 2. submit to the inspectorate, until the date of the next inspection: a) the results of the monthly audit of expired consents within seven days of the audit being conducted, and b) all documentary evidence of the steps taken to obtain the written consent to satisfy the requirements of the HFE Act, 1990, and c) an action plan of how the PR will assure that this breach is avoided from now on.	Immediately.
It was noted at inspection that not all staff working at the centre have: initial basic and	The PR should review the requirement of licence	Immediately.

update training or competence assessments. This does not meet the requirements of licence condition A.10.11.	condition A.10.11 to ensure that this condition is met for all staff.	

Non-Compliance

Area for improvement	Action required	Time scale
The PR may also wish to consider the guidance in G.13.4.4 as to auditing the witnessing procedure to ensure compliance with regulations. At inspection, a review of the IVF witnessing procedure, identified a need to add and/or clarify steps in the freezing/thawing process.	It is recommended that the PR reviews the template witnessing records and updates it to include the steps missing in the current procedure.	Immediately.

Recommendations

Area for improvement	Action required
None	

Changes/ improvements since last inspection

Recommendations	Action Taken up to the date of this inspection
The centre has stored cryopreserved material without written consent. **S.7.8.11** At paragraph 1 of schedule 3 of the 1990 Human Fertilisation and Embryology Act it states that a consent under this Schedule must be given in writing. The protocol for disposal of samples past their expiry date should be reviewed and a more robust system should be considered. The PR should review the procedures for disposing of cryopreserved material for which there is no valid consent to storage as a matter of urgency. Any changes in procedure implemented as a result of the review should be communicated to the relevant staff and protocols should be amended as required. The PR should advise the HFEA when the issue is resolved and of the outcome of any review of practice.	The PIQ states that the centre has a new protocol for freezing gametes and embryos and their disposal. Please refer to section 5 of this report- Clinical, laboratory and counselling practice.
Transfer of cryopreserved material is not	The PIQ states that a new witnessing

witnessed. **G.13.1.1** Witnessing at the time of transfer of cryopreserved material should be implemented.	system is in place and that all aspects of witnessing, including those identified in the previous report have been implemented.
The laboratory does not have any internal or external quality assurance (QA) processes in place. **S.7.8.13; S.9.2.6** The centre should ensure that internal Quality control procedures are in place and that records of the results of quality control/assessment activities, non-conformities detected and action taken are kept. The centre should participate in inter-Centre comparisons and the results should be evaluated and documented and relevant findings be used to improve the service.	The PIQ states that both internal and external quality assurance procedures are in the process of being implemented.
There was no formal procedure or documentation for home procurement **S.7.7.9; S.7.7.10; S.7.7.2. (d)** The centre should develop a procedure for home procurement and appropriate documentation to ensure compliance with the relevant standards.	The PIQ states that an on site procurement of sperm room was built in the new premises.
Staff reported that workloads can be difficult to accommodate. **S.6.2.1** It is recommended that the PR undertake a risk assessment to ascertain how many cycles of treatment can be safely accommodated considering the staffing levels, skills mix, premises and equipment and that measures are taken to ensure that the centres capacity is not exceeded.	At inspection, the PR reported that he is exploring ways to better manage the staff workload which has had an affect on staff turnover. The PR is anxious to retain his new team and will be looking at the ACE guidelines, staff pay structure and is looking to work with the Trust to help him retain staff. In this review, the PR is referred to the CoP requirement: S.6.2.1: The Centre shall have sufficient numbers of staff, with the competence to perform their designated tasks, to ensure that the requirements of these Standards are met.

Additional licence conditions and actions taken by centre since last inspection

None

Report of inspection findings

1.Organisation

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

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

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

Areas of firm compliance
Leadership and management The person responsible (PR) has been in post since December 2007 and has used the HFEA Code of Practice (CoP) to improve the regulatory standard, including, quality and improved performance of the centre. Most of the embryology team is new and all staff at the centre are working well to assist the PR in this task. Evidence of joined up working was demonstrated at inspection by various staff, during discussion and also seen recorded in the minutes of staff meetings. The quality manager is also the lead nurse and has been in post for a number of years. **Organisation of the centre** The centre has a clearly defined management structure, which regulates all activities within it. This was clearly illustrated in the centre's organisational chart. **Resource management** The PR reviews the centre's activity and reported at inspection, that he is satisfied that the facilities (moved to new premises at the end of 2008), equipment and materials (including new equipment in laboratory) and the data information systems (Q Pulse) recently provided by the Trust, are sufficient to achieve the marginal increase in activity. The PR states that the improvement has resulted in an increase in the number of referrals, in the number of cycles leading to a further improvement in the centre's results. The PR reported that the satellite arrangement with Roding will increase the workload. **Clinical governance** The centre has in place the protocol for assessing and reporting clinical governance issues.

This protocol is compliant with the requirements of the Code of Practice (CoP) and the HFEA Direction. The PR has stated that the Trust/centre promotes a 'no blame culture' and that all staff are aware of need to report incidents. Any incidents are fed into the Trust's risk register. Clinical governance is a standard agenda item for the weekly team meeting. A review of the minutes of meetings verified this. The management team and the quality manager meet monthly when clinical governance issues are discussed and minutes of the meeting are distributed to all staff. The laboratory manager attends the Trust's clinical governance meetings.

Risk management
Processes are in place for the recording of all non-conformities identified in processes along with corrective/preventative actions taken. The pre inspection questionnaire (PIQ) states that all work areas risk were assessed in 2008 at the time of moving to these premises and that risk assessment is an on going process. Examples of the centre's risk assessments include assessment of the embryology laboratory Class 2 cabinet, supplied without a partition, indicated a risk and led to the addition of a partition in the work station to prevent any mix up of samples. Another example is the assessment of the storage labelling which identified a better method to label was to print the information electronically on a label instead of writing on the straw.

At the inspection, staff explained that risk assessments are conducted as per the centre's protocol. The risk assessment folder was reviewed by the inspectorate at inspection. All protocols are available electronically to all staff on the centre's shared drive.

Incident management
The PR states that staff are encouraged to complete an adverse event report for incidents. The Trust holds a regular review of the reports for all its clinical governance groups within the hospital. In response to a previous incident, the centre has implemented a standard operating procedure (SOP) to deal with incident management. The laboratory staff reported that no incidents have occurred in the laboratory in the past twelve months. The PR and other staff reported to the inspectorate that there have not been any recent incidents.

Complaints management
The centre has a written protocol for handling complaints. Complaints may be made either to the named person in the centre or via the Trust's Patient Advice and Liaison Services (PALS) procedure. On the day of inspection, leaflets for both these complaints procedures were displayed in the waiting room. The induction training for all new staff covers complaints handling. The centre logs, reviews and uses the data to improve the service. Records are kept of the complaints received, their investigation and corrective actions and correspondence with the complainant. The complaints folder was reviewed at inspection and showed progress on the outstanding complaints.

The staff are in the process of transferring the written complaints file to the electronic Q Pulse system. This will then feed into the Trust's clinical governance system.

Patients are sent the complaints information in the pre-treatment information pack. The centre displays notices prominently in reception areas explaining the complaints procedure, and giving the name and contact information for the complaints officer.

Alert management

HFEA Alerts are received by the PR and disseminated to relevant departmental managers. The PIQ states that alerts are discussed in team meetings and staff are required to sign a copy of the alert to confirm that alerts are understood. Alerts are also discussed at the management team meetings as a standard agenda item and at monthly departmental meetings. Urgent action is taken if required. Staff and the PR reported at inspection that the lessons learnt from the alerts are incorporated into protocols and any non-compliance is reported as an incident.

Contingency arrangements
The centre has a protocol in place to provide contingency cover. The centre has procedures in place for transfer of managerial responsibility during the absence of the PR and systems in place for updating the PR on his return.

If the service cannot be continued, the centre has an agreement with St Bartholomews IVF unit to arrange for patients to continue with their treatment there.

Staff at the centre participate in a rota to offer out of hours contact for patients. Written contact details are given to patients as part of their initial consultation. The PR has automatic admitting rights in the hospital.

Establishment of third party agreements
Third party agreements (TPA) have been established with supplies of goods or services that may impact on quality of gametes/embryos. The TPA log and a sample of these agreements, reviewed by the inspectorate, demonstrated compliance with HFEA guidelines.

Meetings / dissemination of information
There is an effective means for communicating with and receiving information from staff. The PR and staff stated that minutes of all meetings are saved electronically on the centre's Q Pulse system and are available to all staff as read only documents. The centre's Q Pulse system sends out minutes of meetings to all staff members and a receipt email is sent back as acknowledgement. The quality manager reported that this is part of her role. Monthly team meetings are held. However, the embryologists reported that as their team is only three in number, their meetings/discussions are held informally and each member takes their own notes of the meetings. Embryologists interviewed said that they are well informed and that they work as a team.

Payment of licence/treatment fees
The centre's annual and inspection HFEA fees have been paid on time.

Areas for improvement

None.

Areas for consideration

Resource management
The PR is concerned about staffing levels and retention of staff. The PR is to report to the Trust board with his concerns, especially as there are plans to further increase the work at this centre. The PR is referred to the CoP requirement: S.6.2.1: The Centre shall have sufficient numbers of staff, with the competence to perform their designated tasks, to ensure that the requirements of these Standards are met.

Executive recommendations for Licence Committee
None.
Evaluation
None.
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 time period from the 1 January 2005 to 31 December 2007 the centre's outcomes were in line with the national average.
Areas of firm compliance
Quality management system The centre's quality manager recently left the centre and since then the centre manager is also quality manager until a new quality manager is appointed. A Quality Management System (QMS) is in place, and is continually being further developed and improved. The QMS includes the documented procedures required by the CoP standards. The PIQ states that the centre has a new quality management system, Q Pulse, in place since December 2008. The quality manager demonstrated the system to the inspectorate on the day of inspection. 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 Q Pulse 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 Q Pulse system. Newly released documents are notified to staff at departmental meetings and by email generated through the Q Pulse system. Documents provided on the day of inspection had newly introduced document control footers. Reviews are documented and include corrective actions necessary in areas such as: Participation in inter-centre/Inter-laboratory comparisons- National Quality Assessment Scheme (NEQAS); Quality Indicators for monitoring performance in patient care- Internal QA for embryo and sperm quality witnessed; and identification, investigation, control, recording and notification of serious adverse events and reactions- no incidents reported to HFEA in last 12 months.

Quality management review and evaluation are undertaken. Key performance indicators (KPIs) have been defined which include administrative (copying patient notes), laboratory (Audit on anaesthetic management during oocyte recovery, Blastocyst audit, Egg collection audit, Egg collection procedure audit, Failure to fertilise audit) and nursing (Chlamydia screening before HSG) and Implications counselling audit indicators. The centre has had an active programme of audit since the last interim inspection in 2008. The KPIs are reviewed regularly. Evidence that audit results were discussed in the quality and management review meetings was reviewed in the course of the inspection.

Feedback
Feedback is obtained from patients by use of an electronic keypad machine, electronic patient satisfaction tracker (PET), in the patient waiting area. This is linked to the Trust's marketing department who evaluates the feedback and sends it to the centre's quality manager. This information is then used by the centre to review the service provided. The quality manager reported a high degree of patient satisfaction with the service. .A notice board in the main waiting area provided patients with the outcome of the survey which appeared to have been updated recently. The quality manager is planning the centre's own, specific, user satisfaction survey in this financial year. The PIQ states that the centre has an ongoing patient display tracking the centre's performance.

Areas for improvement
None.
Areas for consideration
None.
Executive recommendations for Licence Committee
None.
Evaluation
No improvement required.
Areas not covered on this inspection
All areas covered.

3. Premises and Equipment

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

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

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

- Staff facilities
- Storage of records

Areas of firm compliance
Premises The centre is located on first floor of the hospital. The centre has been 'purpose built' to provide infertility treatments. The entrance to the centre is secure with staff access using a swipe card or keypad entry system to all of the rooms. Patients and visitors access the centre via an intercom/ videophone system and are thereafter chaperoned. On the day of the inspection, the premises and facilities appeared well maintained and suitably equipped. The Trust's support services provide arrangements for cleaning, facilities maintenance and waste disposal. **Clinical facilities** It was observed at inspection that clinical facilities ensure that patient/donor privacy and dignity are maintained. These facilities were seen to be secure, fitted with facilities including emergency call facilities and lockable storage. The treatment room, used for embryo transfer treatments, is accessed via the patient changing room and the laboratory. The treatment room has positive air pressure circulation. The treatment room is equipped with emergency clinical facilities, appropriate to the degree of risk involved in any treatment. The production/procurement room, with a hatch through to the seminology laboratory has a bell fitted, which alerts staff that a sample has been left in the hatch. On inspection, the production room appeared to meet regulatory requirements. **Counselling facilities** The counselling room holds a lockable filing cabinet in which the counsellor keeps her notes. The counsellor keeps the key to the cabinet. It was observed that the counselling facilities provide quiet and comfortable surroundings in which sessions are held that are private, confidential and without interruption. **Laboratory facilities** The PIQ sates that the laboratory has also invested in the FMS (fertility monitoring system) to monitor the quality of the variables in the laboratory on a constant basis. It was observed at inspection that the laboratory facilities (ie equipment, premises and materials) are designed and maintained for their intended purpose, minimising risks to gametes and embryos and hazards to patients and staff. The embryology laboratory is accessed via a key pad locked door and goes through into the treatment room. This laboratory is fitted with a low oxygen alarm. The seminology laboratory houses the two dewars in here – one of sperm and one of embryos. The centre continues to use the theatre in the main day care unit for egg collection. The theatre was in use on the day of inspection so not seen in detail by the inspectorate. The

recovery area in the day surgery suite appeared suitably equipped and resourced for its purpose. Patients are seen by centre staff before they are discharged.

Air quality
Air quality is monitored and documentation regarding air quality is maintained.
The last test results available, seen at inspection, show that the processing of gametes and embryos occurs in an environment of Grade A air quality, with a background of Grade C.

Management of equipment and materials
The PIQ states that CE marked consumables only are used by the centre. Some of the equipment in the laboratory is less than a year old and is covered by a manufacturer's warranty. The older equipment is covered by maintenance service contracts. The new equipment in the laboratory was CE marked and the laboratory staff stated that established equipment has been determined as fit for purpose by being regularly serviced and maintained. All critical equipment is identified and a log was seen at inspection on the centre's Q Pulse system. The FMS system has been validated for use.

Documented procedures are in place for each piece of critical equipment detailing the actions to take in the event of failure or malfunction.

All equipment is cleaned and disinfected regularly and these activities are recorded.

Storage facilities for gametes and embryos
It was observed by the inspectorate that the gamete and embryo store is appropriate for the volume and activities conducted. Storage facilities for gametes and embryos are monitored and fitted with alarms to detect malfunctions and defects. The auto dialler is connected to the alarm, which in turn, is connected to the main hospital switchboard to provide out of hours cover. The switchboard has a list of on-call embryologist to contact in case of emergency. In addition, the centre has spare dewars available in case of an emergency.

There is a documented procedure to deal with damage to dewars (N2 leak) or non-conformities in storage conditions (temperatures).

It was observed at inspection that gametes and embryos are stored in a secure dewars in a secure area, with restricted access to authorised staff only.

Staff facilities
Staff facilities were seen at inspection and deemed to be compliant with the requirements of the CoP. Staff reported that they find the facilities suitable. The centre has provided staff with appropriate garments and equipment for personal protection and hygiene, toilet accommodation, a rest area with basic catering facilities and a supply of drinking water, a changing area and secure storage for personal effects and storage for protective clothing.

Storage of records
Patient health records are stored in a locked room in the centre only accessible via a staffed waiting area, busy administration office and two locked doors. The centre has an electronic tracking system for records. No fertility records are stored in the main hospital library.

Discussion with the counsellor provided information that counselling records held securely and confidentially in the locked filing cabinet in the counselling room. These notes are kept

separate from the patient's health records, although a note is made in the health file that the patient has been referred to the counsellor.
Areas for improvement
None.
Areas for consideration
None.
Executive recommendations for Licence Committee
None.
Evaluation
No improvement required.
Areas not covered on this inspection
All areas covered.

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
Consents The centre has conducted an audit of consents forms and the PR has reported that the audit noted inconsistency in where the consent forms were filed-some were filed in the patient notes and others in the laboratory. The centre has revised the consent protocol so that for all new patients, the original copy of the consent to store form is now filed with the storage records. For samples already in storage, where original consent to store forms are not filed along with storage sheet, the PR has to take a copy from the notes and file it with the storage sheet. The PR has reported that most of these have been completed but that he is waiting for the outstanding fifteen patient notes from offsite storage to be made available, to complete this process. **Access to health records** The PIQ states that the patient must provide a written request. The health records are photocopied and checked by two people. Before they are released to the patient, a final check is done by the consultant before he signs off the request. The patient is asked to collect the photocopied notes and must provide proof of identity.
Areas for improvement
Provision of information to the HFEA register The HFEA Register department reported that the centre is generally compliant with the reporting of data requirements, but that the centre needs to correct some backdated errors. The PR should resolve any issues that lead to errors in data reporting to the HFEA (Direction D.2008/6 Collection, conformation and publication of Register data - 1/10/08).
Areas for consideration
None
Executive recommendations for Licence Committee
The Licence Committee is asked to endorse the recommendations made in relation to: The PR resolving the issues that lead to errors in data reporting to the HFEA.
Evaluation
Some improvement required.

Areas not covered on this inspection
Information for service users Welfare of the child.

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	5
NMC registered nurses	5
Non NMC registered clinical staff	2
HPC registered scientists	2
Scientists working towards registration	2
Support staff (receptionists, record managers, quality and risk managers etc)	7
Counsellors	1

Summary of laboratory audit
Between January 2008 and March 2009, there were 44 samples that have reached the consented period and not discarded on time.
Summary of spot check of stored material
It was felt a spot check of stored material was not appropriate considering the ongoing audit of the banks and the current issues that exist with ongoing storage errors as per communication with the authority.
Areas of firm compliance
Clinical practice The nurse manager provided evidence of basic/initial training for clinical staff including mandatory annual updates for health and safety: fire evacuation; manual handling etc. The nurse manager has developed a cenre specific monitoring system with competenecy assessments for the nursing staff. These will be enveloped into the Trust based Knowledge Skills Framework over 2009/10. The nurse manager said that all nurses are supervised by a senior competent member of staff during on the introduction of new processes such as the new consent processes and forms: new equipment or newly instigated processes. It was seen

during inspection that nurses registrations and continued professional development is appraised annually and recorded in the nurses' files.

Laboratory practice

- **Procurement, distribution and receipt of gametes and embryos**

There are documented procedures for procurement, packaging, distribution, recall and receipt of gametes and embryos that ensure: quality and safety of the gametes; risk of contamination is minimised; evaluation, assessment and safety of the provider and that procurement conforms with appropriate age limits for gamete providers.

The inspectorate observed that the processing of cells and embryos is performed using sterile technique.

The centre uses a the patient's hospital number as an identification code for traceability of all gametes and embryos.

A review of the export log, a sample of patient records and discussions with staff responsible provided evidence that the centre meets European Tissue and Cells Directive (EUTCD) standards, in compliance with HFEA directions on exports.

- **Traceability and coding**

Procedures are in place to ensure all gametes and embryos and data relating to anything contacting them, are traceable from procurement to patient treatment or disposal. The centre has a written protocol in place and the staff demonstrated that the procedure is followed. The centre uses a system of identification for traceability of all gametes and embryos which ensures that all samples of gametes and embryos are labelled with at least the patient's/donor's full name and a unique identifier.

Comprehensive laboratory, clinical and embryology notes are kept and labelling of dishes, tubes and straws is also comprehensive.

Information contained with the procured gametes includes a unique code and split number of the donation, the type of gamete, the date and time, of the donation, the identity of the donor and in the case of known donations, includes the identity of the intended recipient. Staff explained that the dishes are labelled with the recipient's surname, date of birth IVF number and the freeze date.

The inspectorate reviewed the traceablity procedure and discussions with staff confirmed that the traceability procedure should be reviewed-please see Areas for Improvement below.

- **Selection and validation of laboratory procedures**

The PIQ states that Internal quality control for semen analysis and embryo grading is in practice . External quality assurance for all andrology is being organised through National Quality Assessment Scheme (NEQAS) for semen analysis. The centre will be joining the ACE embryo grading system when it is rolled out this spring.

Areas for improvement

Multiple births

The centre has a multiple births minimisation strategy and the clinical director PR is aware of the requirements of the HFEA Direction 2008/5 to keep a log for the documentation of cases in which multiple embryos have been transferred back but at present, this is recorded only in patient notes. The PR should ensure that a separate log of cases is also kept.

Storage of gametes and embryos

A review of the bring forward system at inspection and an audit of stored material by the centre, conducted between January 2008 and March 2009, identified that there were 44 samples that have reached the consented period and have not been discarded on time.

This is an ongoing issue of concern at Homerton Fertility Centre. At the time of the 2008 interim inspection, a number of cryopreserved samples were in storage for which there was no effective consent. This is breach of the Human Fertilisation and Embryology Act, as amended (HFE Act).

The PR explained that this breach of the HFE Act is an issue that he inherited at the time of becoming PR of the centre. The PR now has a new team of embryologists who are actively seeking to clear the dewars of any material in storage without effective consent.

The ongoing storage of the gametes without effective consent was discussed with the PR who acknowledged awareness of the HFE Act, but explained that the decision to continue storage of material without written consent had been made in consideration of the clinical needs of the patients.

The PR has provided the inspectorate with a report on the audit of stored material which states that the new team of embryologists has conducted a full audit of all stored material. The audit found:

1. sperm straws and ampoules were appropriately labeled, but the hand written labels were difficult to read. Action taken: printed labels with patient details (Full name, date of birth and patient IVF number) to be used.
2. the patient's initials on the cryo-cane fading with frequent handling. Action Taken: a numbering system where each cryo-cane is given a serial number that corresponds to the sperm database is used.
3. A number of transcription errors were identified on the embryo storage forms and these were rectified during a review of the audit data.

The audit also found that sperm is being stored for six patients without effective consent. The PR's report states that the affected patients have been sent recorded delivery letters with the option to either extend storage or to let the sample be discarded: twenty one out of the forty four samples have already been discarded and the others will be dealt with in the next four to eight weeks.

In addition, the audit also identified a number of anomalies in the storage method and improvements are being made to comply with HFEA CoP:

Areas for consideration

Staff training and competency

Two embryologists working within the centre said that they hold the state registered embryologist qualification and that they are appropriately qualified and registered to perform their duties. Staff reported that the latest recruit to the laboratory is to attend the Trust induction training, but that some of the other staff were unable to attend due to the pressures of the workload. The importance of all staff attending this and any other training was stressed by the inspectorate. As a result, before the inspectorate left, another embryologist confirmed that he too, would be attending the next Trust induction training day.

At inspection, it was noted that training has not been provided for the member of the administration staff who acts as a witness. Also, no evidence of staff training or competency was provided. The PR should consider the requirements of licence condition A.10.11 which states that personnel must be provided with initial/basic training, updated training as required when procedures change or scientific knowledge develops, and adequate opportunity for relevant professional development. The training programme must ensure and document that each individual:

(a) has demonstrated confidence in the performance of their designed tasks,
(b) has an adequate knowledge and understanding of the scientific/ technical processes and principles relevant to their designated tasks,
(c) understands the organisational framework, quality system and Health & Safety rules of the Centre in which they work, and
(d) is adequately informed of the broader ethical, legal and regulatory context of their work.

However, the inspectorate acknowledges that the above comments do not apply to all staff and that the centre provides good opportunity for staff to meet their relevant continuous professional development (CPD) requirements. Staff reported attendance at relevant local and European training and workshops events.

The inspectorate also acknowledges that the centre has documented procedures in place to ensure that some staff working at the centre have: a job description; initial basic and update training; competence assessments; annual joint review or appraisal; continuous professional development; personnel records and appropriate access to meetings and communications. However, to fully meet the requirements of licence condition A.10.11, the PR should review the requirement of this licence condition to ensure that this condition is met for all staff.

Witnessing

The centre has a written protocol in place for witnessing. A risk assessment of the centre's manual witnessing system for some laboratory procedures has been performed and documented. Witnessing is, mainly, conducted in accordance with HFEA guidance. Discussion with staff suggested that no training has been provided for the member of the administration staff who acts as a witness. The PR is referred to licence condition A.10.11 and may wish to consider the guidance in CoP G.13.2.2 that witnesses are trained and that their competency is assessed.

The PR may also wish to consider the guidance in G.13.4.4 as to auditing the witnessing procedure to ensure compliance with regulations. At inspection, a review of the IVF witnessing procedure, identified a need to add and/or clarify steps in the freezing/thawing process.

Executive recommendations for Licence Committee
The PR should, as a matter of urgency ensure compliance with the requirements of the HFE Act in relation to the storage of gametes and embryos. It is recommended that a condition be applied to the centre's licence requiring the monthly submission of a report of the consents that expired in the previous month; the report should include the date of disposal or the date of expiry of any newly provided consent.
Evaluation
Significant improvement required.
Areas not covered on this inspection
Screening.

Report compiled by:

Name: Bhavna Mehta

Designation: Inspector

Date: 20th March 2009

Appendix A: Centre staff interviewed

PR Centre staff

Appendix B: Licence history for previous 3 years

Licence	Type	Active From	Expiry Date
L0153/13/c	Treatment with Storage	15/10/2008	31/08/2010

Variation to centre premises and change of name- on 15th October 2008

The Committee considered the inspection report and the update by the inspector confirming that all the areas of concern have been addressed. The Committee noted that the premises have been risk assessed and that they meet the requirements of the European Tissues and Cells Directives. The Committee concluded that it was satisfied that the new premises were suitable, and agreed to vary the centre's licence to record the change to the centre's premises and its change of name to Homerton Fertility Centre.

Licence	Type	Active From	Expiry Date
L0153/12/a	Treatment with Storage	05/07/2007	31/08/2007

Application for variation of licence to change Person Responsible- on 5th December 2007

On the basis of the evidence before them, the Committee agreed that they were satisfied as to the character, qualifications and experience of Dr Gudi, and furthermore that they were satisfied that Dr Gudi will discharge the duties required of him under Section 17 of the Act. The Committee therefore decided to grant the application to vary the centre's licence to designate Dr Gudi as the Person Responsible.

First licensed in 1995

Appendix C: Response of Person Responsible to the inspection report

Centre
Number……0153……

Name of PR…M r Anil Gudi …….

Date of Inspection…24th March
2009……..

Date of Response……19th May
2009……

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

Signed……

Name……Mr Anil
Gudi…….

Date……19th May
2009……

1. Correction of factual inaccuracies

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

- It was noted in the report that not all the staff in the centre had updated training and competency. Though all the staff has the basic initial training and competency, it was only one person in the lab who was a locum who was found to have inadequate training. We have a very strict policy of initial trust wide induction and local induction with emphasis on continued training.

The person in the lab was a locum from the admin area. Though she had local induction, she had limited training. This was to fill a gap for the seminology admin and was an urgent replacement. Since then she has undergone complete training.
All the other staff had appropriate induction and competency.

- Some of the the cryo preserved samples , which were not discarded were done so because , they were consented for 1 year storage (In surgically derived sperm) We did not want to discard them since these patient were coming for treatment and waited for letters to be sent out. The previous embryologist had not sent letters at the right time.
- Many of these I had inherited and have started a major change in the audit processes.

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

I took over as the Director of the unit in December 2007 . During the past 1 year the unit has changed its face and its nature. From an averagely performing unit in old premises . The past year has shown a change towards improved success and patient experience within brand new premises with emphasis on better patient care and experience .
When I took over in December 2007 /Jan 2008, I planned major changes to improve performance, reduce risk and implement proper clinical governance .
The past year has seen

- Change in the embryology team (Complete change – by sudden departure of people)
- Appointment of senior and extremely good embryologists of proven track record
- Move to a new unit
- Implementing successfully a new quality management system in line with the highest standard in the industry
- Improving results (The success has improved by 20% in terms of clinical pregnancy rates in the younger age group)
- The team has become more cohesive and there are regular discussion and dialogue.
- The team is happier and is more aware of the HFEA rules. These are openly discussed at regular meeting

I had asked for a major audit to be done by the new team of embryologist , due to the change in embryology team and also because I was the new PR and wanted to start on a clear platform to build continual audit
A complete review of all embryology practices was taken and every bit of material stored was accounted for.
During this review certain errors of previous audits were noted. We have done a huge , exhaustive audit and unearthed every bit of information which would give a good foundation for future audits .

During the audit and review the issues reviewed and addressed are

- Documentation and consent
- Reviewing letters sent and timing
- Uniform protocol for document storage and auditing

This exercise was taken without any directive from the HFEA and was a self imposed major review to improve the service. I have explained this to the Inspectors that we took this major review to look at our practices and have come out with the findings truthfully , informed the HFEA and planned and executed a recovery . I had inherited a system and lead the lead in trying to make it easy to obtain data, interpret it and follow the HFEA directions improving patient care .

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

Action on breaches

Embryology breaches on

- No consents

- Failure to discard embryos on time

only 2 cases remain from the earlier mentioned cases

Causes of the breach

- **We have always consented patients prior to freezing**. The reason why consents were not found in some cases is that for many years consents were stored in patient files, IVF files or with storage record and some of these could not be found.
  Remedial : all consents will now be stored with storage records and a uniform practice has been implemented

- **Discarding of expired embryos**
  During the audit we realised that the previous laboratory had not sent the embryo expiry forms and hence many patients did not receive letters.
  Remedial action: There is now a robust system in place and letters for the next 6 months have already been sent. The audit has placed us firmly in control of the situation and further breaches will thus be prevented
  Sperm and embryos are now frozen for fixed periods of 5 years and 10 years . Freezing for 1 or 2 years has now been stopped.

The Remaining issues that are present are

HFEA Consent Forms

All the semen samples in storage now have the appropriate consent forms except for two patients whose details are given below:

Patient 1

Patient 2

We would like to know what HFEA wants us to do in these circumstances where we are unable to know the whereabouts of the patients.

We cannot discard these 2 samples without having more information about the. We will continue with our efforts to locate these patients and would look for the HFEA for advise .

- **Maximum storage period & Breech of Code of Practice**

All the samples (14 from previous report) were either discarded or stored with appropriate consent

How do we prevent further breaches ?

The six-month letters prior to expiry of stored samples are being sent regularly and the samples are discarded at appropriate times at present, so that no samples will be stored past their consented storage period.

We have a robust mechanism in place and do not see such breaches occurring in the future

The earlier practice of

- Storing consent forms in varied storage in the unit has been stopped and all consents are stored with cryo preserved material .
- The Practice of consenting patient for varied periods for cryo preservation has been stooped with fixed freezing duration of 5 yrs and 10 yrs . This will prevent increase in administrative workload
- Letters are now sent out 6 months in advance and this is strictly followed
- Every bit of the freezing programme has been reviewed and documented

Repeat Audit

We plan to do a re-audit of our Dewars in December 2009 and submit the report to the HFEA.

Regarding monthly audit of expired consents and discarding (Request)

My request to the HFEA is that we send a quarterly audit to the HFEA rather than a monthly audit. We now have a robust system in place with very senior embryologists in charge and have a belief that such breaches will no longer occur . The Unit has set policies for continual improvement and we are certain that the changes that have been put will help to have proper clinical governance and risk assessment .

Breach 2

Breach around collection, confirmation and publication of register data

Cause

- With increasing work load and with limited nurses putting in data , a large backlog was created
- We have completed the backlog and are at present trying to adhere to the direction

Plan to avoid any further breaches

- We have appointed a locum management person with immediate effect and will then plan to make it a permanent post during the year
- This management person will be responsible for the data input as per the directions of the HFEA . When on leave a specific individual will be given the role to stand in place. These will be very closely monitored by the Unit manager . We will have this process in place with all backlogs cleared and the process within the directives by the 20th of June 2009.
- We plan to audit this process in October 2009 and in February 2010

Competency breach

- We have a very good system of trust and local induction prior to the start of work
- The unit also has competency records of each person
- The area where this breach occurred was in 1 case alone. This was a case when our laboratory administration person went suddenly on leave . We had to ask one of the general admin team to help the laboratory. The essential of witnessing were explained . This was the only person not to have had a formal induction before starting. Thus she did not have competency records .We have done a formal induction for her and have a strict policy of the hospital trust , which will not allow any person to start without a formal induction. Our policy also prevents a person from starting without competency and induction. Every other person has completed a continual competency and induction record.
- We can confirm that we will adhere to the direction.

Non Compliance

IVF witnessing during freezing/thawing

- We have reviewed our practice and included steps to witness every aspect of freezing and thawing process .
- These changes have already be made and witnessing at these specific areas .
- The laboratory sheets have also been changed
- We will audit our witnessing practice in September/October to confirm that we have followed the witnessing standards.

Plan

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

10 June 2009

21 Bloomsbury Street London WC1B 3HF

Minutes – Item 3

Homerton Fertility Centre (0153) – Interim inspection report

Members of the Committee:	Committee Secretary:
	Kristen Veblen
Anna Carragher (lay)	
Rebekah Dundas (lay)	Legal Adviser:
Emily Jackson (lay)	Sarah Ellson, Field Fisher,
William Ledger (clinician)	Waterhouse
	Observers:
	Brandon Welsh, HFEA
	Charlotte Augst, HFEA

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 (32 pages)
- tabled papers (9 pages).

The Committee also had before it:

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

1. The Committee noted that this Centre's licence was varied on 15 October 2008 to change the Centre's name to Homerton Fertility Centre (from Homerton Fertility Unit) and to re-locate the Centre's premises to a new location within the same address.

2. The Committee considered the papers, which included the inspection report including the response of the Person Responsible (PR) and previous minutes and the tabled paper, which was the application to vary.

3. The Committee noted that the inspection was carried out on 24 March 2009 and found the following areas for improvement:
    - storage of cryopreserved material contrary to regulations and/or in the absence of written consent
    - errors in data reporting to the HFEA
    - training for staff and competence assessments
    - clarification of steps in the freeze/thaw process in relation to witnessing procedures.

4. The Committee noted that the response of the PR was full and had addressed many of the issues.

5. In the PR's response he referred to the fact that he only took over as the PR in December 2007. The Committee noted the breach of schedule 3 8(2) of the HFE Act 1990 (as amended) in relation to the storage of cryopreserved material in absence of written consent. The Committee agreed that the action described by the PR in his response showed that progress was being made in dealing with the absence of written consent. The Committee requested that the Executive follow up with the PR to ensure the actions outlined, in particular the re-audit of dewars in December 2009, take place and that evidence of this is provided to the HFEA.

6. Further to this breach, the Committee noted the request of the PR for direction in relation to patients whose whereabouts was unknown. The Committee reminded the PR that storage without written consent was in breach of the HFE Act 1990 (as amended) and that it was the duty of the Centre to take all reasonable steps to find the patients. The Committee suggested the Centre continue with efforts to track down patients with missing consent forms and suggested that using patient NHS numbers may be useful.

7. The Committee noted that the application was for the addition of the storage of eggs to the licence and that the Centre wished to add this

treatment for breast cancer patients who did not have partners, were very young or were not ready to proceed with IVF in order to freeze embryos.

8. The Committee noted that the report indicated that the premises and procedures were suitable and the recommendation that the application to vary be approved.

The Committee's Decision

9. The Committee decided to continue the licence without any additional conditions. The Committee considered that it would be disproportionate to add a condition to the licence requiring the Centre to submit monthly reports in relation to storage consents. The response of the PR, together with the proposed actions which the Executive were asked to follow up, were considered sufficient at this stage

10. The Committee noted that it was in receipt of a signed consent form to vary the licence.

11. The Committee agreed that it was satisfied as to the suitability of the Centre's practices and premises for this additional treatment service.

12. The Committee agreed that it was satisfied that it had sufficient and satisfactory information on which to make a decision, although it noted that this was limited to the information contained in the application form and that there was no supplementary material.

13. The Committee decided to vary the licence to include the storage of oocytes, subject to the Executive receiving and approving:
    - a detailed protocol for the storage of oocytes
    - patient information sheets in relation to the storage of oocytes which should include information about success rates.

Signed...Anna Carragher... Date...25.6.2009...
Anna Carragher (Chair)