Unannounced Interim Inspection Report

Date of Inspection: 13 July 2010
Length of inspection: 6.5 hours
Inspectors: Sarah Brain, Ellie Suthers, Jenny Mclaughlin
Observer: Zakia Ezzouyar (HFEA Register team)

Inspection details:

The report covers the pre-inspection analysis, the visit and information received between 8 April 2009 and 23 September 2010.

This was a randomly selected unannounced interim inspection of the centre. A small number of centres are randomly sampled in this way for quality assurance purposes. The inspection team had no indication or evidence of any critical areas of non-compliance at the centre prior to inspection.

Date of Executive Licensing Panel: 7 October 2010

Purpose of the Inspection report

The purpose of the inspection is to assess whether centres are complying with the HF&E Act 1990 (as amended), the HF&E Act 2008 and the Code of Practice to ensure that centres are providing a quality service for patients. The report summarises the findings of the licence interim 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 Authority's Executive Licensing Panel which makes the decision about the continuation of the centre's licence.

Centre details

Centre Name	IVF Hammersmith
Centre Number	0078
Licence Number	L0078/14/f
Centre Address	Wolfson Family Clinic , Hammersmith Hospital, Du Cane Road, London, W12 0HS
Telephone Number	020 3313 4411
Person Responsible	Mr Stuart Lavery
Licence Holder	Mr Geoffrey Trew
Date Licence last renewed	1 January 2008
Licence expiry date	31 December 2012
Additional conditions applied to this licence	None

Contents

Report to Executive Licensing Panel

Recommendation to the Executive Licensing Panel:

The inspector considers that, overall, there is sufficient information available to recommend the continuation of the centre's licence without additional conditions.

At the time of inspection, it was recommended that improvements should be considered relating to the following aspects of the centre's practice:

- Submitting information to the HFEA (clearance of error reports)
- Validation of critical laboratory procedures
- Establishing quality indicators for embryo biopsy
- Documentation of the procedure for responding to patient or partner withdrawal of consent to parenthood
- Witnessing documentation

Following the inspection, the PR submitted documented evidence of compliance with the above recommendations.

Recommendations were also made in relation to the following practices:

- Assessing and documenting staff competence to perform their designated tasks
- Conducting internal audits on embryo biopsy and witnessing procedures
- Patient information on parenthood and donor anonymity
- Documented procedures for packaging, distribution and recall of gametes and embryos
- Documenting patient/donor identity check within medical records

The inspection team recommends that the Executive Licensing Panel directs the PR to ensure that these outstanding recommendations are implemented within the prescribed timeframes set out in the inspection report.

Details of Inspection findings

Brief description of the centre and its licensing history:

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

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

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

The centre's licence was last renewed in October 2007. Since this date there have been no significant licensing changes to note other than licence variations to include new PGD tests. The centre was last inspected on 8 April 2009 and the Licence Committee that considered the report on the 30 July 2009 agreed to continue the licence without additional conditions.

Activities of the Centre:

Type of treatment	Number of treatment cycles for the period [1 March 2009-28 February 2010]*
IVF	957
ICSI	906
FET	298
Egg donation (altruistic)	10 cycles (all abandoned)
Donor intra uterine insemination (DI)	43
Stimulated Partner intra uterine insemination (IUI)	163 (in calendar year ending 2009)
Unstimulated IUI	6 (in calendar year ending 2009)

Other licensable activities	✓ or Not applicable (N/A)
Storage of eggs	✓
Storage of sperm	✓
Storage of embryos	✓
Research	✓ R0187/2/a

*These data were extracted from the HFEA register for the period [01/03/09-28/02/10]. 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.

1. Focus of inspections for 2010-12

Providing information to patients in relation to costed treatment plans and parenthood

What the centre does well

Information about legal parenthood is provided to patients by the counselling team. This is outlined in the centre's standard operating procedure (SOP) for providing treatment to patients with donor gametes. The counsellor explained that she meets with all patients planning to undergo treatment cycles with donated gametes and that information about legal parenthood is provided verbally (Standard Licence Condition T60 and Code of Practice Guidance 6.1).

The inspection team audited two sets of medical records that belonged to patients who had treatment with donated gametes but were not married or in a civil partnership. In both sets of records it was seen that the patient and their partner had completed the relevant HFEA consent forms and these had been completed before treatment was provided (General Directions 0007).

Before treatment is offered the centre provides the person seeking treatment, and their partner (if applicable) with a costed treatment plan. Staff explained that the plan is personalised by a consultant during the first consultation appointment with the patients. Costs are then reiterated verbally to patients by the Business Manager. Staff explained that the plan details the main elements of the treatment proposed (including phlebotomy and blood test charges). General costs for treatment are also available on the centre's website.

What they could do better.

Following the inspection the patient information provided on the centre's own website was reviewed by the inspection team and it was noted that this information does not include updated guidance on the new legal parenthood provisions (CoP Guidance 6.1). In addition the information about the anonymity status of donors on the website is inaccurate and refers to anonymous donation (CoP Guidance 20.2).

Procedures for responding to either patient or partner withdrawal of consent to legal parenthood have not yet been formally established (Standard Licence Condition T33). Although senior members of staff considered that the appropriate actions would be taken in such situations the inspection team had concerns that not all staff may be aware of what to do to assure compliance with standard licence conditions T64 and T65 and that there are risks involved with not documenting and communicating the procedures.

Consent - particularly consent to disclosure to researchers and consent to storage

What the centre does well

The centre is seeking consent to disclosure of patient information to medical or other researchers (so they can contact patients about specific research projects or carry out non-contact research). During an audit of six sets of patient medical records it was noted that the appropriate HFEA consent to disclosure had been completed in all sets of records (in accordance with General Directions 0007). Some of the patients had indicated their consent to contact or non contact research and in the other sets of records the consent forms clearly stated the patients' refusal to disclosure of information to researchers.

The centre's database which contains information on stored gametes and embryos was reviewed during the inspection and it was noted that all samples are stored in accordance with patient consents and regulatory requirements. Staff explained that patients are contacted a year before the end of the consented storage period to determine what they would like to do with their gametes/embryos. Staff were also aware of the recent changes to the statutory storage periods for gametes and embryos and understood the provision for a 12 month cooling off period if gamete providers are in dispute about what to do with stored embryos.

What they could do better.

Nothing noted at the time of inspection.

Multiple births

HFEA Register information

Data submitted to the HFEA by the centre indicates that overall, 30% of cycles conducted in 2009 resulted in multiple pregnancies. In 2008 the percentage of multiple pregnancies which resulted from treatment cycles was higher at 32%.

HFEA statistics have shown an increase in the percentage of elective single embryo transfers being carried out by the centre from 1% of all cycles in 2008 to 9% of cycles in 2009.

Centre staff reported an overall multiple pregnancy rate at the time of inspection of 26%. The centre is likely to meet the 2009/10 24% target multiple live birth rate but progress may be required if the centre is to meet the 2010/11multiple live birth rate of 20%.

What the centre does well

In accordance with General Directions 0003 the centre has a documented record of their multiple births minimisation strategy and is maintaining a summary log of cases in which multiple embryos have been transferred to a patient who meets the criteria for single embryo transfer (SET). The strategy was supplied to the HFEA in 2009 and the log was reviewed in the course of the inspection. The strategy includes guidance on:

- how the centre identifies suitable cases for SET, including criteria in relation to embryo assessment and patient selection criteria. (General Direction 0003 5(a))
- how the centre aims to reduce the multiple birth rate and how to ensure that the rate does not exceed the maximum specified rate of 20%. (General Direction 00035 (b))

The summary log indicated that between January and June 2010 there had been 37 circumstances where a patient who met the criteria for single embryo transfer actually had

two embryos transferred. In all cases the reason for deviation from the multiple births minimisation strategy was listed as patient choice and the log recorded the fact that patients had been informed of the risks of multiple pregnancies. The format of the log was in compliance with the requirements of General Directions 0003.

It was also noted that in cases where multiple embryos were transferred to patients meeting the criteria for SET the reasons for this had been recorded in the patient notes.

The centre has also maintained a summary log of every treatment cycle which involves the placing in a woman of three embryos. This log was provided during the inspection and recorded that between January and June 2010 ten patients had received three embryos during a transfer. The ages of the patient were documented (all above 42 years) and the log also stated that the reasons for the multiple transfers were age related and because of previous treatment failures.

What they could do better.

Nothing noted at the time of inspection.

Validation of critical equipment and processes

What the centre does well

All critical equipment and technical devices have been identified and validated in compliance with Standard Licence Condition T24. The inspection team sampled the validation reports and noted that the Association of Clinical Embryologist validation templates had been used. The team saw evidence that the benchtop incubators in the laboratory had been validated and that they had also been subject to recent inspection and maintenance (Standard Licence Condition T24).

What they could do better.

Not all critical procurement and processing procedures have been validated. This is non-compliant with Standard Licence Condition T72. The laboratory team has written a SOP that identifies which procedures need to be validated and the process of validation has now begun. A documented validation report for the semen preparation procedure was provided as evidence of this. The Senior Embryologist reported that it is anticipated that all procedures will be validated by October 2010.

Witnessing

What the centre does well.

The inspection team were satisfied that the identification of samples and the patients/donors to whom they relate is witnessed by two members of staff at all critical points of the clinical and laboratory process (Standard Licence Condition T71). The inspection concluded this through review of the centre's documented SOP for witnessing and also through observation of ICSI and embryo biopsy procedures.

What they could do better.

Four patient records were audited for evidence of witnessing. The witnessing checks were seen to be documented in all sets of records but it was noted that this documentation did not include the name and status of the person who performed the activity or the person who witnessed the procedure (Standard Licence Condition T71 requires that that witnessing records "must be kept in each patient's/donor's medical records. These records must include the name, status and signature of the person performing the activity and the

name, status and signature of the person who witnesses the procedure"). Records only contained the time of the witnessing step and the initial of the persons involved (operator and witness). The Senior Embryologist explained that a separate list is maintained which includes the name, status and signature of each member of the embryology team (Code of Practice Guidance 18.8). This list was provided to the inspection team. However, it was noted that this list did not include the details of other members of staff who may be involved in witnessing, the nursing and clinical teams for example. This meant that the inspection team were unable to trace back who had been involved in all of the witnessing steps seen in the four patient records.

Gamete and embryo donation – reimbursement, information provision and screening

What the centre does well.

This centre does not have a donor recruitment programme; all the donors involved in treatment at this centre are altruistic. Centre staff explained that compensation is not provided to any of these donors. An audit of donor records confirmed this.

Four sets of medical records pertaining to gamete donors (egg and sperm donors) were audited during the course of the inspection. This sample of records provided evidence that:

- Donors are being selected on the basis of their health and medical history, provided on a questionnaire and through a personal interview performed by a qualified and trained medical professional (Standard Licence Condition T52).
- Donors are being selected in accordance with the screening requirements of Standard Licence Condition T52 and relevant professional bodies[1]
- The laboratory tests required by Standard Licence Condition T52 have been carried out by a qualified laboratory which has been accredited by CPA (UK) Ltd (Standard Licence Condition T53).
- Donor sperm is being quarantined for a minimum of 180 days, after which repeat testing is required.

The donor screening procedures are supported by a documented SOP and a checklist which is completed for every donor. The checklist lists the screening tests that must be conducted, copies of these checklists were included in all the donor records audited.

What they could do better.

Nothing noted at the time of inspection.

Welfare of the Child (in relation to basic partner treatment services only)

What the centre does well.

Not reviewed as this centre provides more than just basic partner treatment services

What they could do better.

Not reviewed as this centre provides more than just basic partner treatment service

[1] The 2008 UK guidelines for the medical and laboratory screening of sperm, egg and embryo donors produced by BFS, BAS, ACE and RCOG) .

Embryo testing (if applicable)
What the centre does well. The procedure for biopsying embryos for embryo testing has been documented in a SOP (Standard Licence Condition T33b). A copy of this SOP was provided to the inspection team. The Senior Embryologist assured the inspection team that no sex selection for social reasons has been conducted and that they have not transferred biopsied embryos in the same cycle as non-biopsied embryos. The diagnostic analysis of blastomeres for PGD and PGS is undertaken by an external laboratory This laboratory has not yet been accredited by CPA UK Ltd or an alternative body accrediting to an equivalent standard. Centre staff explained that Reprogenetics UK is however in the process of obtaining accreditation, they have applied for CPA UK Ltd accreditation but they have not yet been inspected. Evidence of this was supplied in the form of the third party agreement that IVF Hammersmith holds with Reprogenetics UK. This document states that “Reprogenetics UK Ltd’s Quality Management System has been submitted to Clinical Pathology Accreditation (UK) Ltd and is awaiting approval”.
What they could do better. The centre has not yet established quality indicators or objectives related to biopsy procedures. This is non-compliant with Standard Licence Condition T35. Biopsy procedures have not yet been audited to assess compliance with the approved protocol, regulatory requirements and quality indicators in the past two years. This is non compliant with Standard Licence Condition T36. The two members of staff who have been trained to perform embryo biopsy have not had their competence to perform this task documented.

2. Changes / improvements since the last inspection on 8 April 2009

Area for improvement	Action required	Action taken as evidence during this inspection
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. Progress to be monitored at the time of the next inspection.	The HFEA finance department have reported that the centre has been paying invoices well within the 28 days payment terms.
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 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.'	Prior to the next HFEA inspection 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.	This was an unannounced inspection so no information was requested prior to the visit. The HFEA Executive has not noted any other instances of late submission of information since the inspection last year.
A review of the quality management system (QMS) has not been conducted in the past year. The quality manager explained that the	The quality management system should be reviewed in accordance with Code of Practice Standard 4.2.8 and 4.2.9.	The Quality Manager explained that a review of the QMS had taken place in the past year. Slides from the presentations made during

Area for improvement	Action required	Action taken as evidence during this inspection
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 to be reviewed at least on an annual basis. Progress to be monitored at the next inspection.	the QMS review were provided as evidence of this. The review was seen to include reviews of internal and external audits, non-conformities, user complaints, user comments and clinical incidents. The Quality Manager also explained that staff had been informed of the results of the QMS review via a presentation made at an all staff meeting. The inspection team saw a copy of the slides that had been shared with staff.
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.	The Quality Manager has taken action in response to this. The date of document review is now included on the master index of all documents. This index was reviewed by the inspection team and it provided evidence that documents have been reviewed on an annual basis.
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.	Staff explained that templates for the documentation of laboratory and clinical staff competence at designated tasks have now been developed. The inspection team saw copies of the templates for documentation of laboratory competence assessments. Furthermore the inspection team saw that the laboratory team have begun the process of having their competence to perform designated tasks assessed. However, it was evident on inspection that this remains a work in progress.
Critical laboratory processes have not yet been validated. The validation of equipment	It is recommended that the PR identifies the key processes and equipment	On inspection it was noted that the validation of equipment is now complete.

Area for improvement	Action required	Action taken as evidence during this inspection
is not yet complete.	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.	However, the centre staff confirmed that they are still working towards validating all of the laboratory processes. Evidence of this was supplied to the inspection team and the laboratory manager explained that they anticipate that all processes will be validated by October 2010.
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 was 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.	The external laboratory is in the process of obtaining accreditation from Clinical Pathology Accreditation UK Ltd. (CPA) Laboratory staff provided evidence that the external laboratory has submitted information about their QMS to CPA and are awaiting approval.

Area for improvement	Action required	Action taken as evidence during this inspection
	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.	N/A. This strategy was submitted on 20 March 2009.
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.	With immediate effect it is recommended that the PR reviews the template used for recording witnessing and updates it to include the time of procedure.	The time of this witnessing check is now documented. The inspection team saw evidence of this during an audit of patient records.
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.	During the inspection staff confirmed that the removal of samples from the main dewar is now witnessed contemporaneously. This process was also seen to be documented within the centre's documented witnessing SOP.
Since the last inspection, one three ET was performed for a	The PR should ensure compliance with Code of	The centre keeps a log of three embryo transfers in line

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

Area for improvement	Action required	Action taken as evidence during this inspection
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.	Practice Guidance 8.5.1. Progress to be monitored at next inspection.	with the requirements of General Directions 0003. This log was reviewed and it was noted that between January and June 2010 10 patients had received three embryos transfers but all were aged over 42 years. The documented reasons for conducting three embryo transfers were age related and previous treatment failures.
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 Gonorrhoea, Glucose 6 phosphate dehydrogenase or HTLV-1/HTLV-2.	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 from the relevant professional bodies[3] (CoP Guidance 4.9.1).	Four sets of donor records were audited and it was noted that the donors had been screened in compliance with the professional guidance.
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.	The inspection team visited the areas of the centre where the notes had been kept insecurely at the last inspection. It was seen that the arrangements for storage of notes have now changed and they are stored away from patient areas. The embryo transfer notes are now held in a lockable cupboard and the scan notes are stored in a lockable ante room which is normally occupied. The centre is planning to introduce an electronic database shortly which will eventually mean that the paper notes will be replaced entirely.
The centre's protocol for the transport of gametes is not	The PR should review the procedures for transport of	Following the last inspection the PR reported that the

[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

Area for improvement	Action required	Action taken as evidence during this inspection
fully compliant with the recommendations of Alert 21: Transport Hazards.	gametes in consideration of the recommendations of Alert 21.	procedures are compliant with the recommendations of Alert 21. During this inspection the transport of gametes/ embryos SOP was reviewed and it was noted that it needs to be revised to include the procedures for include guidance on the: • Verification of patient, patient's partner and donor (CoP Guidance 15.10) when gametes/embryos are received. • Recalling gametes and embryos (CoP Guidance 15.15 d).
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.	Hazard notices were seen to be on display on the door to the cryostore. The notices included the information requested at the last inspection.

Area for improvement	Action required	Action taken as evidence during this inspection
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 of the data held by the Authority in its statutory register. To be monitored at the next inspection.	The HFEA Register team have confirmed that this is still an issue. On 1 July 2010 the centre had a total of 290 errors to clear and the centre had not been clearing error reports within two calendar months (a requirement of General Directions 0005). On inspection this ongoing problem was discussed and the inspection team were satisfied that a commitment has been made to clearing the errors. Staff were able to explain to the inspection team the actions that they are taking to resolve the backlog of errors: • One member of staff has been recruited whose responsibility is to clear the errors. • The centre prints out error reports twice weekly and staff explained that they are determined to clear the errors so that they can then introduce an electronic database system (IDEAS) which is integrated with the HFEA EDI system.

3. Areas of concern

The analysis of the centre's self assessment questionnaire (SAQ) and the information the centre has submitted to the HFEA e.g. staff changes and the treatment cycles carried out at the centre, have identified that the following areas needed to be looked during the inspection visit to this centre.

Area of concern	Inspection findings	Assessment of whether the action taken meets requirement or whether any further action is required
Quality Management – Audits (Standard Licence Condition T36) The SAQ states that corrective actions have not been taken in response to audits on provision of information, taking consent, welfare of the child, biopsy procedures, procurement and processing procedures and training licence requirements (T36).	This was discussed with centre staff who explained that corrective actions were not taken in response to these audits because no areas of non-conformity were noted.	No further action required.
Quality Management – Audits (Standard Licence Condition T36) The SAQ states that the centre has not audited procedures for • Selecting and recruiting donors. (T36) • Submission of data to the HFEA	During the inspection the nurse manager explained that the procedures for selecting and recruiting donors are not audited as part of the internal audit programme. Instead, however, a system is in place for continuous audit of the procedures. The system involves either the nurse matron or senior nurse checking every set of donor records at the time of treatment to ensure that the SOP for selecting donors has been followed correctly. Centre staff supplied evidence that they are auditing the submission of data to the HFEA. The audits are focused	Further action required. Programme of internal audits to include embryo biopsy and witnessing procedures.

	on the number of outstanding data errors. Staff explained that they are printing out error reports on a two weekly basis and noting the non-conformities that exist. An annotated error report was seen during this inspection and this indicated what actions were required to resolve the identified non-conformities. Whilst audits do appear to have been conducted on these procedures it was noted during the inspection that internal audits on embryo biopsy and witnessing procedures have not yet been conducted.	
Quality Management - Quality Indicators (Standard Licence Condition T35) The SAQ states that quality indicators relevant to the submission of data to the HFEA have not been established	Evidence that a quality indicator for submission of data to the HFEA was not provided during the inspection. Furthermore it was noted that the centre also needs to establish a quality indicator related to the embryo biopsy procedures.	Further action required. Quality indicators to be established for submission of data to the HFEA and embryo biopsy procedures.
Research and Training The SAQ states that the centre does not supply embryos to another centre to whom a licence applies. A further SAQ question (6.1) has therefore not been answered. However, the HFEA is aware that the centre has an agreement to supply embryos for research at centre 0249 and also may be likely to transfer embryos and gametes to other licensed centres on patient request.	The Quality Manager clarified that embryos are supplied to other centres to whom a licence applies.	The PR is asked to provide the HFEA Executive with an answer to question 6.1 in the SAQ. No further action required.
Premises and Facilities	This was discussed with staff who confirmed that the	The PR is asked to keep the HFEA

(Standard Licence Condition T21) The SAQ states that laboratories that undertake the diagnosis and investigation of the centre's patients', patients' partners or donors, their gametes, embryos or any material removed from them, are not accredited by CPA (UK) Ltd or another body accrediting to an equivalent standard	external laboratory is in the process of obtaining CPA accreditation. Laboratory staff provided evidence that the external laboratory has submitted information about their Quality Management System (QMS) to CPA and are awaiting approval.	Executive informed of the accreditation status of this external laboratory.
Record keeping and document control (Standard Licence Condition T46) The centre has assessed itself as 2 (almost compliant) for maintaining a record for each patient/donor which contains how, and by whom, the patient/donor has been reliably identified.	This was discussed with the nursing team who stated that whilst patients' identity is confirmed using passports this check is not recorded.	Further action required. For each patient/donor the centre must maintain a record containing how, and by whom, the patient/donor has been reliably identified.
Staffing and activity level Prior to the inspection the Executive reviewed HFEA patient questionnaires about centre 0078. In total 15 responses to the patient questionnaires were received in the year ending 30 May 2010. On review of these	These issues were discussed with staff during the inspection. According to the centre's own data, they provided 860 cycles of IVF and 910 cycles of ICSI in 2009. This is a total of 1770 cycles which is within their maximum activity limit of 1800 cycles (this was set in 2008 and was discussed at the last interim inspection). The Quality Manager explained that they expect to provide fewer cycles in 2010 and data	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.

questionnaires it was noted that they included comments about the busy nature of the centre. 46% of the respondents stated that they did not have sufficient opportunity to ask questions and were not given the opportunity and time to discuss anxieties. Comments were also made by respondents about the poor communication skills of some staff.	on the number of cycles between January to June 2010 was supplied in support of this. The Quality Manager stated that the centre is working at full staff complement.	
The activity level of the centre was reviewed prior to inspection and HFEA data indicated that the total number of cycles (IVF/ICSI, FET and DI cycles) had increased by 253 cycles in the year 1 March 2009-28 February 2010 compared to the previous year.	The centre has continued to gather patient feedback via their patient questionnaire and also comment cards. The Quality Manager explained that they had noted some comments about the issues with the telephone contact system and communication skills of staff. In response to these comments corrective action has been taken. For example, in response to comments about the attitude of administrative staff the entire team was replaced. The Quality Manager explained that they have made staff changes and have developed a business case for additional staffing to operate a patient helpline.	

Areas of practice that require the attention of the Person Responsible

The section sets out matters which the Inspection Team considers may constitute areas of non compliance. These have been classified into critical, major and others. Each area of non-compliance is referenced to the relevant sections of the Acts, Regulations, Standard Licence Conditions, Directions or the Code of Practice, and the recommended improvement actions require are given as well as the timescales in which these improvements should be carried out.

Critical area of non compliance

A critical are of non compliance is an area of practice which poses a significant direct risk of causing harm to a patient, donor or to an embryo. A critical area of non compliance requires immediate action to be taken by the Person Responsible

Area of practice	Reference	Action required	Timescale for action	PR Response	Executive Review

Major area of non compliance

A major area of non compliance is a non critical area of non compliance:

- which poses an indirect risk to the safety of a patient, donor or to an embryo through the procurement, use, storage or distribution of gametes and embryos, which do not comply with the centre's licence;
- which indicates a major shortcoming from the statutory requirements;
- which indicates a failure of the Person Responsible to carry out his/her legal duties
- a combination of several "other" areas of non compliance, none of which on their own may be major but which together may represent a major area of non compliance.

Area of practice	Reference	Action required	Timescale for action	PR Response	Executive Review
Documenting competence assessments Not all staff have had their competence to perform designated tasks assessed or documented. This was an area of non-compliance which was previously identified at the April 2009 inspection.	**Standard Licence Condition T12:** Personnel in the centre must be available in sufficient number and be qualified and competent for the tasks they perform. The competency of the personnel must be evaluated at appropriate intervals. **Standard Licence Condition T15a:** The training programme must ensure and document that each individual has demonstrated competence in the performance of their designated tasks.	The PR should ensure that the competency of all personnel to perform key activities as stipulated in the 8th Code of Practice is evaluated and documented. The PR is asked to provide the HFEA Executive with an action plan listing all the staff and their competence assessments that need to be completed. This plan should include proposed timescales for completion of the competence assessments.	14 January 2011 for compliance with T12 and T15a. Action plan to be submitted to the HFEA immediately.	An action plan detailing all members of staff and their outstanding competency assessments is being prepared with a plan to complete these. This will be submitted within the next few weeks when all staff have returned from holiday.	As of 23 September 2010 this recommendation was still outstanding.
Submission of information to the HFEA The HFEA register department reported that the	**General Directions 0005 (4):** All licensed centres must ensure that EDI forms submitted to the Authority are completed	The PR should ensure that the backlog of error reports are cleared as a matter of urgency. It is also recommended	14 October 2010 for clearance of error reports. Documented	This has now been completed. There is one outstanding case (surrogacy which we are awaiting a response	The Executive considers this response to be acceptable. On 6 September 2010, the HFEA register

Area of practice	Reference	Action required	Timescale for action	PR Response	Executive Review
centre is not clearing its error reports within two calendar months as required by General Directions 0005. As of 1 July 2010 there were 290 error reports that needed to be cleared. This was an area of non-compliance which was previously identified at the April 2009 inspection.	according to the guidance issued by the Authority (the most recent versions of which are available, alongside the forms, on the HFEA website). Where an error is identified, centres must correct the error within 2 calendar months.	that the PR puts documented procedures in place to ensure that when the new electronic database system is introduced information is submitted correctly and that error reports are cleared within two calendar months as required by General Directions 0005.	procedures for submission of information to the HFEA (including guidance on clearance of errors) to be submitted to the HFEA before the new electronic database system is used for this purpose.	from the Lister Hospital, the HFEA are aware of this case.	department confirmed that the centre had cleared all of their outstanding errors, with the exception of one or two minor errors.
Validation of processes Not all critical procurement and processing procedures have been validated. This is non-compliant with Standard Licence Condition T72.	**Standard Licence Condition T72:** The critical processing procedures must be validated and must not render the gametes or embryos clinically ineffective or harmful to the recipient. This validation may be based on studies	The PR should ensure that all critical procurement and processing procedures are validated in accordance with Standard Licence Condition T72. The PR should submit a list of all critical processing procedures to the HFEA	14 October 2010.	Such a list is being produced and will be submitted by 14/10/10.	The Executive considers this response to be acceptable. Following the inspection, centre staff confirmed that validation on the following laboratory procedures have been completed -

Area of practice	Reference	Action required	Timescale for action	PR Response	Executive Review
This was an area of non-compliance which was previously identified at the April 2009 inspection.	performed by the establishment itself, or on data from published studies or from well-established processing procedures, by retrospective evaluation of the clinical results of tissues provided by the establishment.	that documents the proposed timescale for completion of the validation process by 14 October 2010.			sperm preparation, egg retrievals and embryo freezing.
Quality Indicators Quality indicators for submission of data to the HFEA and embryo biopsy procedures have not been established.	**Standard Licence Condition T35:** Required standards of quality and safety, in the form of quality indicators for all activities authorised by this licence and other activities carried out in the course of providing treatment services that do not require a licence, must be established.	Quality indicators to be established for submission of data to the HFEA and embryo biopsy procedures.	14 October 2010	Will be submitted by 14/10/10	The Executive considers this response to be acceptable. Following the inspection, evidence was provided to demonstrate that a quality indicator for embryo biopsy has been established.
Audit of licensed activities: Audits on embryo biopsy and	**Standard Licence Condition T36:** Trained and competent persons must audit the activities authorised by	The PR must ensure that the witnessing and biopsy activities are audited as per Standard Licence Condition T36.	14 October 2010	Will be submitted by 14/10/10	The Executive considers this response to be acceptable.

Area of practice	Reference	Action required	Timescale for action	PR Response	Executive Review
witnessing procedures have not yet been conducted.	this licence and other activities carried out in the course of providing treatment services that do not require a licence against compliance with the approved protocols, the regulatory requirements and quality indicators. These audits must be performed in an independent way, at least every two years. Findings and corrective actions must be documented.				
Legal Parenthood Procedures for responding to either patient or partner withdrawal of consent to legal parenthood have not yet been formally established.	**Standard Licence Condition T33:** The following documentation must form part of the quality management system: a. a quality manual b. standard operating procedures (SOPs) for all activities authorised by this licence and other activities carried out in the course of providing treatment	The PR should ensure that procedures for responding to either patient or partner withdrawal of consent to legal parenthood are established, documented and communicated to all staff.	Immediately	This has been actioned and an SOP is now in place.	The Executive considers this response to be acceptable. A copy of the SOP provided to the Executive on 29 August 2010 was found to be compliant.

Area of practice	Reference	Action required	Timescale for action	PR Response	Executive Review
	services that do not require a licence c. guidelines d. training and reference manuals, and e. reporting forms.				

Other areas of practice that requires improvement

Areas of practice that requires improvement is any area of practice, which cannot be classified as either a critical or major area of non compliance, but which indicates a departure from good practice.

Area of practice	Reference	Action required	Timescale for action	PR Response	Executive Review
Documentation of witnessing The witnessing documentation held in patient records does not include the name and status of the person who performed the activity or the person who witnessed the procedure. Although a separate list is	**Standard Licence Condition T71** which states that witnessing records "must be kept in each patient's/donor's medical records. These records must include the name, status and signature of the person performing the activity and the name, status and signature of the person who witnesses the procedure".	The PR must ensure that complete witnessing records are kept which document the details of staff, their name, status and signature, performing and witnessing procedures. These records should be retained for traceability purposes as per Standard Licence Condition T48.	Immediately	A sheet is held centrally with everybody's name, signature and initials on it.	The Executive considers this response to be acceptable. On 26 August 2010 the PR submitted an updated list of the name, status and signature of all staff performing and witnessing procedures.

Area of practice	Reference	Action required	Timescale for action	PR Response	Executive Review
maintained which includes the name, status and signature of each member of the embryology team (Code of Practice Guidance 18.8) this list was seen to be incomplete during the inspection.					
Patient records The records for each patient/donor do not contain how, and by whom, the patient/donor has been reliably identified.	**Standard Licence Condition T46:** For each patient/donor the centre must maintain a record containing: how, and by whom, the patient/donor has been reliably identified.	For each patient/donor the centre must maintain a record containing how, and by whom, the patient/donor has been reliably identified.	Immediately.	This has now been actioned with photocopies of the passports kept on record with the witnesses details.	The Executive considers this response to be acceptable. To be reviewed at the next inspection.

Area of practice	Reference	Action required	Timescale for action	PR Response	Executive Review
Patient information Patient information about legal parenthood on the centre's website does not include guidance on the new legal parenthood provisions. In addition the information about the anonymity status of donors is inaccurate.	**CoP Guidance 6.1** The centre should provide information to people seeking treatment about legal parenthood. This information should include who will be the child's legal parent(s) under the HFE Act 2008 and other relevant legislation. **CoP Guidance 20.2** The centre should provide information to people seeking treatment with donated gametes or embryos about legal parenthood, and the collection and provision of information, specifically: (a) who will be the child's legal parent(s) under the HFE Act 2008 and other relevant legislation (nationals or	The PR should update patient information on the centre's website and ensures that it is in accordance with CoP Guidance 6.1 and 20.2.	PR to provide an action plan detailing how and when this information will be updated on receipt of this inspection report. Information to be updated on or before 14 October 2010	plan to be submitted by requested date.	The Executive considers this response to be acceptable. An action plan from the PR was received on 13 August 2010.

Area of practice	Reference	Action required	Timescale for action	PR Response	Executive Review
	residents of other countries, or anyone treated with gametes obtained from nationals or residents of other countries, should be informed that the law in other countries may be different from that in the UK) (b) information that centres must collect and register with the HFEA about the donors (c) what information may be disclosed to people born as a result of donation and in what circumstances, and (d) a donor-conceived person's right to access: (i) anonymous information about the donor and any donor-conceived genetic siblings, from the age of 16 (ii) identifying information about the donor (where applicable), from the				

Area of practice	Reference	Action required	Timescale for action	PR Response	Executive Review
	age of 18 iii) identifying information about donor-conceived genetic siblings, with mutual consent, from the age of 18 (iv) information about the possibility of being related to the person they intend to marry or enter into a civil partnership with, at any age, and (v) information about the possibility of being related to the person they intend to enter into an intimate physical relationship with, from the age of 16.				
Adverse incidents (guidance note 27): During the inspection the Centre's incident log was matched against centre records during the inspection. It was	**Code of Practice guidance 27.5:** The centre's documented procedures should ensure that any adverse incident or near miss that may result in harm to the patient, patient's partner or donor is recorded and reviewed.	The PR should consider review of the centre's incident reporting standard operating procedure to include notification to the HFEA of less serious incidents and near misses as recommended by Code of Practice Guidance 27.5 and 27.6.	Recommendation only.		

Area of practice	Reference	Action required	Timescale for action	PR Response	Executive Review
found that while all serious adverse incidents had been reported to the HFEA in compliance with T120 several less serious incidents and near misses had not been reported as recommended by G27.5 and 27.6.	**Code of Practice Guidance 27.6:** If an adverse incident or near miss occurs, centres are expected to: (a) review relevant procedures to minimise the risk of the incident happening again, and (b) inform the HFEA of the revised procedures.				
Packaging, distribution and recall of gametes and embryos The transport of gametes/ embryos SOP needs to be revised to include guidance on: • Verification of patient, patient's partner and donor when gametes/ embryos are	**Code of Practice Guidance 15.10:** In addition to the requirements in licence conditions, the documented procedures against which each consignment of gametes and embryos is verified should include requirements for: (a) patient, patient's partner and donor verification (b) packaging and transport (c) labeling of	The PR should ensure that the transport of gametes/embryos SOP is reviewed and updated in accordance with Code of Practice 15.10 and 15.15d.	14 October 2010	will be updated by 14/10/10	The Executive considers this response to be acceptable.

Area of practice	Reference	Action required	Timescale for action	PR Response	Executive Review
received. • Recalling gametes and embryos	containers for procured gametes, and (d) labeling of shipping containers and any associated documents. **Code of Practice Guidance 15.15d:** The centre's documented procedures should ensure that the following are recorded: (a) packaging and labeling procured gametes for distribution (b) transporting gametes and embryos (c) labeling shipping containers, and (d) recalling gametes and embryos.				

Additional Information from the Person Responsible

HFEA Executive Licence Panel Meeting

7 October 2010

21 Bloomsbury Street London WC1B 3HF

Minutes – Item 3

Centre 0078 – (IVF Hammersmith) – Interim Inspection Report

Members of the Panel:	Committee Secretary:
Peter Thompson, Director of Strategy & Information (Chair) Mark Bennett, Director of Finance & Facilities Nick Jones, Director of Compliance	Joanne McAlpine

Declarations of Interest: members of the Panel declared that they had no conflicts of interest in relation to this item.

The Panel also had before it:

- HFEA Protocol for the Conduct of Meetings of Executive Licensing Panel
- 8th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- Decision trees for granting and renewing licences and considering requests to vary a licence (including the PGD decision tree)
- Guidance for members of Authority and Committees on the handling of conflicts of interest approved by the Authority on 21 January 2009.
- Guidance on periods for which new or renewed licences should be granted
- Standing Orders and Instrument of Delegation
- Indicative Sanctions Guidance
- HFEA Direction 0008 (where relevant), and any other relevant Directions issued by the Authority
- Guide to Licensing
- Compliance and Enforcement Policy
- Policy on Publication of Authority and Committee Papers

Consideration of Application

1. The Panel noted that this centre had been licensed since 1992 and provides treatment to NHS and privately funded patients.

2. The Panel noted that the centre's licence was last renewed in October 2007, and the centre was last inspected on 8 April 2009 and the Licence Committee that considered this report agreed that the centre's licence should continue without additional conditions.

3. The Panel noted that this is a large centre that has carried out over 2000 treatment cycles during the period of 2009/10.

4. The Panel noted that the centre had reported an overall multiple pregnancy rate at the time of the inspection 26%. The centre is likely to meet the 2009/10 24% target multiple live birth rate but progress may be required if the centre is to meet the 2010/11 multiple live birth rate of 20%.

5. The Panel noted that at the time of the inspection, there were a number of recommendations made by the Inspectorate including submitting of information to the HFEA, validation of critical laboratory procedures, and witnessing.

6. The Panel noted that, since the inspection, the Person Responsible (PR) has provided evidence to the Inspectorate which addresses some of the recommendations that have been highlighted in the report and has given commitment to fully address the other recommendations that remain outstanding.

7. The Panel noted that the PR has now addressed the submission of Electronic Data Information (EDI) forms and would urge the PR to continue to submit EDI forms to the register within the appropriate timescales.

8. The Panel noted that at the time of the inspection the PR was absent, which is not unusual for a random unannounced inspection. The Panel noted that the staff that were present on the day of the inspection acted confident and competently in the absence of the PR.

9. The Panel noted that the Inspectorate recommended that the centre's licence continue without additional conditions.

Decision

10. The Panel agreed with the Inspectorate's recommendations made in the report. The Panel agreed to the continuation of the centre's licence with no additional conditions.

Signed:  Date: 14/10/2010

Peter Thompson (Chair)