Interim Inspection Report

Date of Inspection: 8 September 2010
Length of inspection: 4 hours
Inspectors: Bhavna Mehta
Vicki Lamb (Observing)

Inspection details:
The report covers the pre-inspection analysis, the visit and information received between 7 October 2008 and 3 December 2010.

Date of Executive Licensing Panel: 3 December 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 make the decision about the continuation of the centre's licence.

Centre details

Centre Name	Andrology Unit, Hammersmith Hospital
Centre Number	0080
Licence Number	L0080-13-b
Centre Address	South Corridor, Area C/FR30, Hammersmith Hospital, Du Cane Road, London, W12 0HS
Telephone Number	020 8383 1039
Person Responsible	Dr Kevin Lindsay
Licence Holder	Dr Richard Chapman
Date Licence issued	1 March 2009
Licence expiry date	28 February 2014
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 years.

The inspector also recommends that the Executive Licensing Panel requires that the Person Responsible (PR) complies with the following recommendation within the prescribed timeframe set out in the inspection report:

- Validation of critical equipment and processes:
  The centre must to continue with the planned validation of critical equipment and processes.

Details of Inspection findings

Brief description of the centre and its licensing history:

The Andrology Unit at the Hammersmith Hospital is a part of the Imperial College NHS Trust and provides storage of sperm for patients who are undergoing treatment that may impair their fertility. The centre also occasionally provides the same service to patients seeking short-term storage of sperm when undergoing fertility treatment. The laboratory is also contracted to carry out a sperm processing service to two HFEA licensed intrauterine (IUI) centres, St Mary's Hospital Trust (centre 0292) and West Middlesex University Hospital (centre 0302) under satellite arrangements.

The centre is open five days a week between the hours of 09:00 – 12:00 or by appointment for urgent sperm cryopreservation.

The PR has been in post since 1995. He is suitably qualified and experienced to carry out the role of PR. He is registered with the Health Professions Council.

Activities of the Centre:

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

Updated actions since the centre was inspected on 8 September 2010:

The PR has added, to the witnessing protocol and practice, a step to cross-check the information marked on dishes and tubes against the patient's or donor's records (see page 15 of this report).

1. Focus of inspections for 2010-12

Providing information to patients in relation to costed treatment plans and parenthood
What the centre does well. This theme is not applicable to this centre as the centre offers the storage service to NHS patients only.
What they could do better. N/A

Consent - particularly consent to disclosure to researchers and consent to storage
What the centre does well. The consent to treatment, for patients' whose sperm is processed by the centre for use in IUI treatment is taken by the transport centres where the treatment is provided. For patients undergoing treatment that may impair their fertility, the consent to store, in the first instance, is obtained on the centre's own consent form. This form allows diagnostic tests to be conducted to confirm that the sample is suitable for freezing and for the sample to be stored temporarily pending completion of the HFEA consent forms. At inspection, an audit of five patient records provided evidence that the correct HFEA consent forms are used. The PR explained that the centre has in storage a few hundred samples from patients who have not provided effective written consent to store their gametes. These samples are all from patients who stored sperm before the HF&E Act was implemented, when there was no requirement for patients to provide effective written consent. The PR explained he has attempted to contact these patients to obtain effective written consent since the HF&E Act has been implemented but that these patients have not been traceable. The PR explained that these patients may qualify for an extension to storage under Schedule 3, paragraph 9 (3) HF&E Act. The CoP states that if sperm was in storage on 1 August 1991, storage may legally continue without the written consent of the individual who provided the sperm. However, the centre is not obliged to continue to store sperm in the absence of a written agreement to do so. As a storage only centre, the consent to disclosure of information to researchers requirements do not apply to this centre.
What they could do better. None identified at this inspection.

Multiple births
What the centre does well. This theme is not applicable to this centre.
What they could do better. N/A

Validation of critical equipment and processes
What the centre does well. All technical devices, such as the thermometer, are identified and validated, regularly inspected and maintained in accordance with the manufacturer's instructions. Where equipment or materials affect critical processing or storage parameters, these are also identified and appropriately monitored, and any necessary corrective action is taken (T24). The validation and service records reviewed at inspection demonstrated evidence in compliance of this requirement.
What they could do better. The centre must continue with the planned validation of all laboratory equipment and processes and to complete the validation of all critical processing procedures. To assist with completion of the validation requirements, the centre staff may wish to use the Association of Clinical Embryologists validation templates.

Witnessing
What the centre does well. Witnessing checks are recorded in the patient medical records (T71). At inspection, an audit of a sample of patient records demonstrated compliance with this licence condition. Discussion with laboratory staff and a review of individual training records, demonstrated compliance with the witnessing competence assessment requirements. The centre conducts an audit of recorded witnessing steps in ten patient records every month. Any errors or omissions are documented and corrective actions taken (T36).

The centre has a documented system in place that ensures the identification of all gametes from procurement to use or disposal (T70).
What they could do better. The centre has a witnessing protocol that describes double-checking the identification of samples and the patients to whom they relate at most critical points of the laboratory processes. The centre does not witness the transferring gametes or embryos between tubes or dishes. The requirement in the CoP is to cross-check information marked on dishes and tubes against the patient's records, and the information marked on the dishes and tubes that the gametes or embryos are being transferred from. The centre staff explained that the centre has a policy of processing only one sample at any one time.

Gamete and embryo donation – reimbursement, information provision and screening
What the centre does well. This theme is not applicable to this centre.
What they could do better. N/A

Welfare of the Child (in relation to basic partner treatment services only)
What the centre does well. This theme is not applicable to this centre.
What they could do better. N/A

Embryo testing (if applicable)
What the centre does well. This theme is not applicable to this centre.
What they could do better. N/A

2. Changes / improvements since the last inspection on 7 October 2008

Area for improvement	Action required	Action taken as evidence during this inspection
The centre took 92 days to pay the HFEA renewal fee. This is a breach of the **Licence Condition A.16.3** (In consideration of the grant of the licence (or its variation to designate the individual named in this licence as PR), the Person Responsible agrees that 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. **A.16.3)**	The PR should 1. review whether there are barriers to the prompt payment of HFEA invoices 2. take steps to ensure the fees are paid within 28 days.	Not applicable at this interim inspection. To be followed up at the next renewal of licence application.
Some policy documents and procedures are reviewed on a 24 month cycle. This is a breach of **S.5.2.5 (a).** (The Centre shall establish a Documented Procedure to control all documents (internally generated and from external sources) required by the Quality Management System(QMS). This procedure shall ensure that **S.5.2.5 (a)** documents are regularly reviewed, revised as required, dated and re-approved promptly by authorised personnel. NOTE: Review, revision and re-approval should be conducted at a frequency that ensures that they remain 'fit for purpose'. The maximum interval between reviews should be twelve	The PR and Quality Manager to ensure that 1. all documents are reviewed every 12 months. 2. all Standard Operating Procedures (SOP) to have effective document control and be subject to regular review in accordance with S.5.2.5 (a).	The action required at the last inspection, is in the 8 CoP, recommended as best practice. The PR has reported that the centre is currently transferring the QMS to the recently acquired Q-Pulse system. This system will electronically monitor review dates and document control. The PR explained the progress to date and a review of the QMS demonstrated that the centre's documents and SOPs are to be reviewed in compliance with licence condition T34 and best practice guidance in the CoP. No further action required.

Area for improvement	Action required	Action taken as evidence during this inspection
months.		
Training files were reviewed at inspection and found to be in order except for one file where the log did not show how the individual had demonstrated confidence in the performance of their designated tasks. This is a breach of **A 10.11.**	The PR should ensure that it is documented that each individual has demonstrated confidence in the performance of their designated tasks.	Action taken. Training files were reviewed at inspection and found to be in order. The log shows how the individual demonstrates confidence in the performance of their designated tasks. No further action required.
The batch numbers for freezing media had not been recorded in some patient records reviewed in the course of the inspection.	The PR should ensure traceability of any materials that come in contact with gametes or embryos are implemented in compliance with S.6.4.3.	Action taken. The centre has changed its process to ensure that the centre records such information as is necessary to facilitate the traceability of any information relating to the quality or safety of gametes. A review of patient records demonstrated compliance with licence condition T101. No further action required.
Witnessing was not carried out contemporaneously.	The PR should ensure that staff comply with the centres own witnessing standard operating procedures to ensure that the checking of identification of samples and patients/donors, and witnessing of these checks, should be recorded at the time the clinical and laboratory procedures) take place in compliance with the requirements of G.13.2.1.	Action taken. The centre has reviewed and revised the witnessing SOP. The centre's witnessing protocol is in place to double check the identification of samples and the patient to whom the sample relates, at all critical points of the clinical and laboratory process. These checks are completed and recorded at the time the relevant laboratory process takes place. A record is kept in each patient's medical records. These records

Area for improvement	Action required	Action taken as evidence during this inspection
		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. No further action required.

3. Areas of concern

The analysis of the centre's self assessment questionnaire 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 at 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
None		

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
None					

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
Validation of equipment and processes: The centre is encouraged to progress the planned validation of all equipment and processes.	T72 T24	Complete the validation of all critical equipment and processes The centre staff may wish to use the Association of Clinical Embryologists validation templates. The PR should submit a detailed plan, including a list of all critical processes to be validated and quarterly reports to the centre's inspector regarding the progress of implementation of this plan until it is completed.	8 December 2010	A new validation document is being prepared and an interim document attached. Ket elements in terms of process validation have been fundemental to the unit, however the current documents fail to meet the transparency. This is also being addressed as older style documentation is being reviewed as	The PR has submitted various revised SOPs but the interim document referred to in the PR response was not attached. The PR should submit a detailed action plan, as soon as possible, for the validation of all critical equipment and processes. The validation should be completed by 8 December 2010.

Area of practice	Reference	Action required	Timescale for action	PR Response	Executive Review
				migration to an electronic document control system is being implemented.	Further action required.

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
Witnessing: The centre does not witness the transferring gametes or embryos between tubes or dishes.	GN 18 (4 e)	The PR should ensure that the following step is added to the witnessing protocol and practice: cross-check information marked on dishes and tubes against the patient's or donor's records, and the information marked on the dishes and tubes that the gametes or embryos are being transferred from.	By the time the PR responds to this report.	Policies and procedures have been reviewed and re-formatted to improve transparency of process. Copies are attached for reference.	A review of the revised policies and the laboratory witnessing sheets submitted, demonstrate that the PR acted on the action required and the centre is compliant with this requirement. No further action required.

Additional Information from the Person Responsible
None.

HFEA Executive Licence Panel Meeting

3 December 2010

21 Bloomsbury Street London WC1B 3HF

Minutes – Item 1

Centre 0080 (Andrology Unit, Hammersmith Hospital) – Interim Inspection Report (Treatment and Storage)

Members of the Panel:	Committee Secretary:
Peter Thompson, Director of Strategy & Information (Chair) Nick Jones, Director of Compliance Mark Bennett – Director of Finance & Facilities	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 Directions 0000 – 0012
- Guide to Licensing
- Compliance and Enforcement Policy
- Policy on Publication of Authority and Committee Papers

Consideration of Application

1. The Panel noted that the centre is part of the Imperial College NHS Trust and provides storage of sperm from patients who are undergoing treatment that may impair their fertility.

2. The Panel noted that the centre also has a contract agreement with St Mary's Hospital Trust (centre 0292) and West Middlesex University Hospital (centre 0302) under satellite arrangements.

3. The Panel noted that the Person Responsible (PR) has been in post since 1995, and is suitably qualified and experienced to carry out the role of PR and is registered with the Health Professions Council.

4. The Panel noted that the centre is currently operating under a five year licence.

5. The Panel noted that the centre has complied with the recommendations identified on the previous inspection, and that there were no critical areas of non compliance identified on this inspection.

6. The Panel noted that the Inspectorate have recommended that the centre's licence be continued with no additional conditions.

7. The Panel noted that the Inspectorate have recommended that the PR complies with the validation of critical equipment and processes, as identified in the report.

Decision

8. The Panel was satisfied that the centre is largely compliant and noted and endorsed the recommendations made by the Inspectorate in the report.

9. The Panel agreed to the continuation of the centre's licence, with no additional conditions.

Signed: Peter Thompson Date: 22/12/10.

Peter Thompson (Chair)