# Interim Licensing Report

**Centre name:** Andrology Unit, Hammersmith Hospital
**Centre number:** 0080
**Date licence issued:** 01/10/2011
**Licence expiry date:** 28/02/2014
**Additional conditions applied to this licence:** None
**Date of inspection:** 6 September 2012
**Inspectors:** Bhavna Mehta (Lead); Chris O'Toole; (Gemma Hobcraft - observer)
**Date of Executive Licensing Panel:** 2 November 2012

## Purpose of the report

The Human Fertilisation and Embryology Authority (HFEA) is the UK's independent regulator of the fertility sector. The HFEA licenses centres providing in vitro fertilisation (IVF) and other fertility treatments and those carrying out human embryo research.

Licensed centres usually receive a licence to operate for up to four years and must, by law, be inspected every two years. The full inspection prior to a licence being granted or renewed assesses a centre's compliance with the law and the HFEA's Code of Practice (CoP) and Standard Licence Conditions (SLC).

This is a report of an interim inspection together with our assessment of the centre's performance based on other information. We do this at the mid-point of the licence period. For 2012-14 the focus of an interim inspection is:

- **Quality of service**: the quality of service provided by a centre, including its success rates and performance in reducing multiple births – the biggest single risk of IVF.
- **Patient experience**: it is considered crucial that the experiences of service users feed into any evaluation of a centre's performance.

We also take into account the centre's own assessment of its service; the progress made in implementing the actions identified at the last inspection; and our on-going monitoring of the centre's performance.

The report represents a mid-term evaluation of a centre's performance based on the above. The aim is to provide the Authority's Executive Licensing Panel with information on which to make a decision about the continuation of the licence.

## Summary for the Executive Licensing Panel

This report has enabled the inspection team to form a conclusion on the continuation of the centre's licence.

The inspection team recommends the continuation of the centre's licence.

The team has made recommendations for improvement and these should be implemented within the time specified.

There is one recommendation relating to a **'critical'** area of improvement. The Executive Licensing Panel is asked to note that there are recommendations for improvement in relation one 'other' area of non-compliance as follows:

**'Critical' areas of non compliance:**

- **The Person Responsible (PR) should ensure that all samples of gametes and embryos are stored with effective written consent.**

**'Other' areas of practice that require improvement:**

- The PR should ensure that personnel in the centre are available in sufficient number and are qualified and competent for the tasks they perform.

## Information about the centre

The Andrology Unit is located within the Hammersmith Hospital, London, and has held a licence with the HFEA since 1992.

The centre is part of 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 NHS Trust (centre 0292) and West Middlesex University Hospital (centre 0302) under satellite arrangements.

## Details of Inspection findings

## Quality of Service

Each interim inspection focuses on the following themes: they are very important indicators of centres' ability to provide high quality patient care and to meet the requirements of the law.

### Outcomes

This does not apply to this centre as it holds a storage only licence.

### Multiple births

This theme does not apply to this centre.

### Witnessing

Good witnessing processes are vital in ensuring there are no mismatches of gametes or embryos and that identification errors do not occur. Witnessing checks for sperm preparation were observed at the inspection. The procedures observed were witnessed in accordance with HFEA requirements using a manual system. The inspection team was able to review records and concluded that records of witnessing are maintained.

### Consent: Disclosure to researchers

This theme does not apply to this centre.

### Consent: To the storage of cryopreserved material

The PR's responses to the self assessment questionnaire and discussions at inspection found that there are a number of sperm samples in storage that are being stored without consent and may be outside the statutory consent time. The PR explained that these are historic samples and they are under constant review. See recommendation 1.

A review of a sample of the centre's records of consent to storage of gametes showed that the samples put in storage more recently, are being stored in accordance with the consent of the gamete providers and are within the consented storage period.

## Staffing

Having the right numbers of staff, competent to carry out highly technical work in a non-pressured environment is important in infertility services.

Staffing levels observed in the course of the on-site inspection appeared to be suitable for the activities being carried out: patients were seen promptly on arrival, staff in the laboratory were able to carry out their activities without distraction and were available to carry out witnessing activities when required.

However, the PR stated at inspection and in response to the self assessment questionnaire that the centre is not operating with a full staff complement. This has had an impact on service delivery as the PR stated that at times the centre has to stop carrying out routine semen analysis in order to prioritise licensed treatment. See recommendation 2.

## Patient experience

It was not possible to speak with patients on the day of inspection. Only one patient provided feedback directly to the HFEA in the time since the last inspection. This written feedback to the HFEA was complimentary about the care that they received.

On the basis of this feedback and observations made in the course of the inspection it was possible to assess that the centre:

- has respect for the privacy and confidentiality of patients in the clinic;
- gives prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions;

maintains an effective system for responding to patient phone calls

## Monitoring of the centre's performance

In addition to commenting on evidence gathered on the inspection it is important to report on the centre's performance since the granting of the licence based on other evidence available to us.

## Compliance with HFEA standard licence conditions

From the information submitted by the centre in their self assessment questionnaire and from observations during the visit to the centre, the inspection team did not identify any non-compliances further to those already covered in the body of this report.

## Compliance with recommendations made at the time of the last inspection

Following the interim inspection in 2010 recommendations for improvement were made in relation to one major area of non-compliance and one 'other' area of non-compliance.

The PR provided information and evidence that all of the recommendations were fully implemented within the prescribed timescales.

**Annex 1**

# 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 required are given, as well as the timescales in which these improvements should be carried out.

## Critical area of non compliance

A critical area of non compliance is an area of practice which poses a significant risk of causing harm to a patient, donor, embryo or child who may be born as a result of treatment services. A critical area of non-compliance requires immediate action to be taken by the Person Responsible.

| Area of practice and reference | Action required and timescale for action | PR Response | Inspection team's response to the PRs statement |
|---|---|---|---|
| 1. There are a number of sperm samples in storage that are being stored without consent and may be outside the statutory consent period. These are historic samples, some stored before the HF&E Act 1990. (HF&E Act 1990 (as amended), Schedule 3, 8 (2)) and Chair's letter CH(03)03: Withdrawal of | The PR must ensure that all samples in storage have appropriate consent and are within the statutory storage period.<br><br>The PR should give an update and an action plan **when responding to this report** to include:<br>• the number of samples<br>• the current position and timeline for resolution | It has been accepted by Trust managers that the centre requires additional clerical help to progress these patients. We have identified 58 of 302 patients awaiting sample disposal after pervious attempts to resolve the lack of consent. Additional clerical assistance will be drafted in to trace the remaining 244 patients. Any that cannot be traced will be subject to a | The PR's commitment to resolve this issue is noted.<br><br>The inspection team acknowledges that resolution of this action will take time and therefore extend the time to 31 March 2013.<br><br>The PR must ensure compliance with requirements (that all sperm samples being stored have effective consent |

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| Consent to Storage). | with regard to each of the samples stored without effective written consent to ensure that compliance with requirements is met **within 3 months of the date of this report (6 December 2012).**<br><br>The PR should provide **monthly updates** on progress **until the matter is resolved**. | individual clinical risk assessment taking into account the potential degree of fertility impairment in addition to age and length of time in storage.<br><br>The PR will provide progress reports between December and March 2013. | to storage), by **31 March 2013**, failing which this matter will be referred back to ELP. |

## 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, embryo or child who may be born as a result of treatment services
- 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 and reference | Action required and timescale for action | PR Response | Inspection team's response to the PR's statement |
|---|---|---|---|
| None | | | |

## 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 statutory requirements or good practice.

| Area of practice and reference | Action required and timescale for action | PR Response | Inspection team's response to the PR's statement |
|---|---|---|---|
| 2. Staffing levels<br><br>Personnel in the centre must be available in sufficient number and be qualified and competent for the tasks they perform.<br>SLC T12 | The PR should ensure that personnel in the centre are available in sufficient number and are qualified and competent for the tasks they perform.<br><br>The PR should assess how many treatment cycles can be safely accommodated taking into account the number of staff available; their skills mix | The PR has decided to change the current walk-in clinic to a 5x outpatient booked clinic each working day. The expected consequence will be to produce a waiting list for diagnostic testing but will provide a more manageable workload and assure the appropriate skill mix. | The PR's comments are noted and accepted.<br><br>The PR is requested to keep the centre's inspector informed if any further issues arise with regard to staffing levels.<br><br>To be monitored at the next inspection. |

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| | and experience; the equipment and premises. The PR should ensure that activity levels are maintained within the identified limits and a copy of the assessment should be provided to the lead inspector by 6 December 2012. | | |

| Additional information from the Person Responsible |
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| The current PR will be taking early retirement at the end of the financial year that is March 2013. Currently an options appraisal is in progress to consider the implications and appropriate updates will be provided along with the above reports. |

# HFEA Executive Licensing Panel Meeting

**2 November 2012**

Finsbury Tower, 103-105 Bunhill Row, London, EC1Y 8HF

**Minutes – Item 2**

**Centre 0080 – (Andrology Unit, Hammersmith Hospital) – Interim Inspection Report**

| Members of the Panel: | Committee Secretary: |
|---|---|
| Mark Bennett, Director of Finance & Facilities (Chair)<br>Nick Jones, Director of Compliance<br>Joanne Anton, Policy Manager | 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 Report

1. The Panel noted that this centre has held a licence with the HFEA since 1992, is part of Imperial College NHS Trust, and provides storage for patients who are undergoing treatment that may impair their fertility.

2. The Panel noted that the Inspectorate identified one critical and one other area of non-compliance or poor practice that required improvement at the time of the inspection.

3. The Panel noted that the critical area related to a significant number of sperm samples in storage without effective consent and which may be outside the statutory consent period.

4. The Panel noted that 58 of 302 patients have samples awaiting disposal. The Panel also noted that additional clerical assistance will be drafted in to trace the remaining 244 patients. The samples relating to those who cannot be traced will be subject to individual clinical risk assessment.

5. The Panel noted that the Person Responsible (PR) will provide monthly progress reports between December and March 2013 until this has been resolved. The Panel requested the Inspectorate report to it should adequate progress not be made. In doing so it is expected to take into account a non-compliance relating to adequate resourcing. The Panel made the observation that effective consent and adequate resource are vital components of a licensed storage centre.

6. The Panel noted that the current PR is due to retire in March 2013. Therefore, the Panel urged the centre to apply to change the PR in good time to ensure a smooth transition and managed implementation of the non-compliances.

7. The Panel requested the Inspectorate, with the PR, to identify how many of the 244 patients reactivate or extend consent (and how many do not) as this could provide valuable intelligence to the centre and to the Inspectorate.

8. The Panel noted that the Inspectorate recommends that the centre's licence continues without additional conditions.

## Decision

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

Signed: Date: 14 November 2012
Mark Bennett (Chair)