# Interim Inspection Report

**Date of Inspection:** 18 March 2010
**Length of inspection:** 5 hours
**Inspectors:** Bhavna Mehta
Wil Lenton

**Inspection details:**
The report covers the pre-inspection analysis, the visit and information received between the date of the last inspection on the 4 March 2008 and 18 March 2010.

**Date of Executive Licensing Panel:** 15 June 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 (CoP) 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

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| **Centre Name** | Hull IVF Unit |
| **Centre Number** | 0021 |
| **Licence Number** | L0021-12-B |
| **Centre Address** | Hull and East Yorkshire Women and Children's Hospital, Hull Royal Infirmary, Anlaby Road, Hull, HU3 2JZ |
| **Telephone Number** | 01482 382 648 |
| **Person Responsible** | Mr Stephen Maguiness |
| **Licence Holder** | Dr John Robinson |
| **Date Licence issued** | 1 October 2008 |
| **Licence expiry date** | 30 September 2013 |
| **Additional conditions applied to this licence** | None |

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# Report to Executive Licensing Panel

**Recommendation to the Executive Licensing Panel:**

The inspection team considers that, overall there is sufficient information available to recommend the continuation of the centre's licence.

The inspection team has no other recommendations to make arising from this inspection.

# Details of Inspection findings

**Brief description of the centre and its licensing history:**
The Hull IVF Centre has been licensed since 1986 and offers treatment to both NHS and private patients. The Person Responsible (PR), Stephen Maguiness, is a Consultant Obstetrician and Gynaecologist and has been in post since the inception of the Centre. He has completed the PR entry programme which was assessed as being satisfactory.

The Centre is custom built and located within the Hull and East Yorkshire (HEY) Women and Children's Hospital and therefore benefits from facilities offered by the hospital including:

- Pharmaceutical services
- Resuscitation services
- Infection control
- Maintenance
- Laundry services
- Clinical governance arrangements

Since the last renewal inspection in 2008, the centre has acquired an andrology laboratory that is used, at present, for non-licensable processing. However, the PR explained that, he may use this laboratory for licensable activities in the future and that he is considering a variation to the existing licence to include this room.

**Activities of the Centre:**

| Type of treatment | Number of treatment cycles for the period Jan 2008 to Dec 2008 |
|---|---|
| DI | 0 |
| IVF | 222 |
| ICSI | 122 |

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

*These data were extracted from the HFEA register for the period January 2008 to December 2008. 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.

**Updated actions since the centre was inspected on 18 March 2010.**

None required.

## 1. Focus of inspections for 2010-12

| Witnessing |
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| Evidence of how the centre demonstrates compliance with the requirement to double check the identification of samples and the patients or donors to whom they relate at all critical points of the clinical and laboratory process.<br><br>The centre has in place a written standard operating procedure (SOP) to be followed for both manual and electronic witnessing practice. This SOP specifies the witnessing steps to be carried out, both for the clinical and laboratory practice (T33 b). The electronic witnessing system (RFID) was trialled by the staff at the centre for approximately twelve months prior to its implementation in order, to ensure that they were all comfortable with it, appropriately trained and to both risk assess and validate the new system.<br><br>Witnessing checks are carried out by two members of staff and are recorded in patient/donor medical records. These records include the status and signature of both the person performing the activity and the person who witnesses the procedure. Each patient is issued with an electronic identity card which holds an identical record of the manual witnessing record. This card is kept in the patient's notes. Recently, the centre has introduced a policy of placing a copy of the printout of the electronic witnessing in the patient files. The electronic data on the identity card is backed up on each computer in the centre and on the main centre server. At inspection, the inspection team reviewed a sample of patient records for patients treated after 1 October 2009, when the new Act and Licence conditions came into force. The patient files reviewed, provided evidence that the centre has in place a double witness system, which meets Licence Condition T71. The PR has stated that the centre has always has a system of double witnessing.<br><br>The centre has established quality indicators and objectives relevant to witnessing (T35). Evidence in support of this was seen in the patient satisfaction survey and in the equipment service and maintenance records.<br><br>Annual audits of patient records are conducted by the staff to verify that witnessing checks are recorded. Any errors or omissions are documented and corrective actions taken. The witnessing procedures were audited in March 2010 against compliance with the protocols, the regulatory requirements and quality indicators (Schedule 3A (10) 2006/86/EC, Appendix 1 F and T36). The witnessing audit report was reviewed at inspection.<br><br>The inspection team conducted an audit of the centre's witnessing and patient identification practice by reviewing a sample of patient files. All the files reviewed appeared to be compliant with requirements.<br><br>A review of the staff training folder demonstrated that the staff carrying out the witnessing checks, have been trained and their competency assessed and recorded. (T15 (a)). |

What the centre does well.

All areas of practice are risk assessed.

What they could do better.

No areas for improvement were identified.

## Parenthood

Evidence of how the centre demonstrates compliance with the requirements in relation to legal parenthood

The centre has a written SOP in place for the process to be followed when obtaining the relevant written records of consent to parenthood, when a woman is to be treated with donor sperm or embryos (T33 b). The SOP was reviewed pre inspection and is compliant with requirements.

The centre has a written SOP for the process to be followed to ensure that treatment is not provided when a person who has consented to be the second parent of a child born has withdrawn their consent to parenthood, before the woman being treated has been advised of the withdrawal of consent (T64(b)).

The centre has another written SOP for the process to be followed to ensure that if a woman withdraws her consent to her nominated second parent being treated as the legal parent, or consents to a different person being the legal parent of any child resulting from treatment, the original nominated second parent is notified in writing of this (T65). However, the staff explained that these procedures have not yet been needed.

A sample of patient records reviewed at inspection contained consent to legal parenthood. The centre's egg donor protocol includes a requirement to discuss the issue of the legal parents of a child born as a result of egg donation and is compliant with licence condition T58. It is the centre's policy that prospective donors are offered counselling. Discussions with the staff at the centre demonstrated that the staff have an understanding of the counselling requirements of the CoP.

Annual audits of patient records are conducted by the staff to verify that both patients and/or donors give consent, including consent to legal parenthood. The centre's last audit report was reviewed at inspection; the findings were clearly documented and corrective actions taken (T36).

The centre's information for patients was reviewed pre-inspection. This contains information about parenthood laws for those having treatment with donor gametes or embryos (T60).

What the centre does well.

All areas of practice are risk assessed.

| What they could do better. |
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| No areas for improvement were identified. |

| **Information about the cost of treatment** |
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| Evidence of how the centre demonstrates that it has introduced personalised costed treatment plans for all patients<br><br>A copy of a personalised costed treatment plan provided to patients was seen and discussed at inspection. The plan detailed the main elements of treatment proposed and the cost of that treatment. The centre provides written general information on the cost of treatments to patients following initial consultation. Once a course of treatment has been agreed, a personalised costed treatment plan is provided in writing to the patient (Guidance Note 4.3). |
| What the centre does well.<br><br>All areas of practice are risk assessed. |
| What they could do better.<br><br>No areas for improvement were identified. |

| **Patient consent to the disclosure of information, held on the HFEA Register, for use in Research** |
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Evidence of how the centre demonstrates that it provides information to patients about the use of information, held on the HFEA Register, for use in research.

The centre has a written SOP for the process to be followed when obtaining consent (T33(b)).

A sample of patient records reviewed at inspection included consent to the disclosure of identifying information for use in research. The staff demonstrated an awareness and understanding of the CoP requirements related to disclosure of information for use in research. HFEA consent forms and patient information sheets are accessible to all staff on the centre's electronic document management system and are provided to patients at initial consultation.

The last audit report reviewed at inspection demonstrated that annual audits of patient records are conducted by staff to verify that patient consents, including consent to disclose identifying information, is accurately documented. Any errors or omissions are documented and corrective actions taken (T36).

In addition to the verbal explanation by the staff, the centre has a patient information leaflet to explain the consent to disclosure requirements of the data held on the HFEA Register.

What the centre does well.

All areas of practice are risk assessed.

What they could do better.

No areas for improvement were identified.

**Consent issues in relation to the storage of embryos (including cooling off period)**

Evidence of how the centre demonstrates compliance with the requirements relating to the withdrawal of consent to storage of embryos intended for use in treatment.

Centre staff demonstrated an awareness of the requirements relating to the withdrawal of consent to storage of embryos intended for use in treatment, including the cooling off period. The centre's protocols have been updated to include the new requirements of the CoP.

Annual audits of patient records are conducted by staff to verify that patient consent, including consent to the storage of embryos, is accurately documented. Any errors or omissions are documented and corrective actions taken (T36).

What the centre does well.

All areas of practice are risk assessed.

What they could do better.

No areas for improvement were identified.

## Multiple Births

Evidence of how the centre demonstrates compliance with Guidance Note 7 of the Code of Practice relating to multiple births:

In compliance with Direction 0003, the centre has a documented strategy to minimise multiple births and conducts regular audits to assess progress in reducing the centre's multiple birth rate. The centre maintains a summary log of all cases where more than one embryo was transferred to a patient who met the single embryo transfer criteria outlined in the centre's strategy. In accordance with the Directions, the reason for the deviation from the policy was seen to be written up in the patient's note, together with note of a further warning having been given about the risks associated with multiple births.

A dedicated member of the embryology team undertakes regular audits that assess progress in the reduction of multiple pregnancies and help evaluate the effectiveness of the centre's strategy. The centre appeared very determined to lower their multiple birth rates and is looking at ways to increase the uptake of elective single embryo transfers (eSET). At the time of the initial consultation, patients are provided with written and verbal information on the risks of multiple births and are given sufficient time to consider the information prior to treatment. Clinical staff members discuss eSET with patients following egg collection and patients who are likely to meet the eSET criteria.

The staff at the centre reported that 31.7% of patients (111/350) had a single embryo transferred and the multiple birth rate for 2009 was 19.2% (as at the date of inspection). The centre has revised their multiple births strategy in accordance with revised Direction 0003 (version 2), setting the target at 20% for 2010. This policy is to be introduced in April 2010. The policy is to be reviewed in October 2010 to ensure sustained commitment to meeting the centre's Quality Policy Objectives and HFEA target reduction in multiple births.

What the centre does well:

N/A

What they could do better:

No areas for improvement were identified.

## 2. Changes / improvements since the last inspection on 4 March 2008

| Area for improvement | Action required | Action taken as evidenced during this inspection |
|---|---|---|
| None | None | None |

## 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 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 | None | 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 identified at the time of this inspection. | | None | None | | None |

## Major area of non compliance

A major are of non compliance is a non critical are 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 |
|---|---|---|---|---|---|
| None identified at the time of this inspection. | | None | None | | 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 good practice.

| Area of practice | Reference | Action required | Timescale for action | PR Response | Executive Review |
|---|---|---|---|---|---|
| None identified at the time of this inspection. | | None | None | | None |

| Additional Information from the Person Responsible |
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