HFEA Executive Licensing Panel Meeting

27 June 2014

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

Minutes – Item 3

Centre 0294 – (Craigavon Area Hospital) – Interim Inspection Report

Members of the Panel:	**Committee Secretary:**
Juliet Tizzard – Interim Director of Strategy (Chair) Joanne Anton – Policy Manager Ian Peacock – Analyst Programmer	Sam Hartley – Head of Governance & Licensing

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

The Panel 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 Craigavon Area Hospital has held a licence with the HFEA since 2007. The centre holds a Treatment (Insemination using partner sperm) licence.

2. The Panel noted that the centre is currently on a four-year licence, due to expire on 31 August 2016. The Panel noted that the inspection took place on 6 March 2014.

3. The Panel noted that for the year 2013 the centre provided 208 cycles of partner IUI treatment with 25 pregnancies, which equates to a 12% clinical pregnancy rate. This is consistent with the national average pregnancy rate.

4. The Panel noted that no multiple pregnancies were reported in 2013.

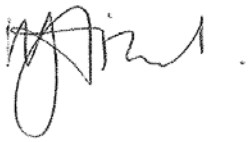
5. The Panel noted that at the time of inspection one recommendation for improvement was made regarding an 'other' area of non-compliance. Since the inspection, the PR has given a commitment to fully implement this recommendation within the prescribed timescale.

6. The Panel noted the generally positive patient feedback received. The Panel also noted the areas of concern raised by the Inspector in relation to the location of the treatment rooms and the possible distress caused to patients. However, the Panel acknowledged the consideration the centre's team gives to their patients to try to reduce any distress caused.

7. The Panel noted that the Inspectorate recommends the continuation of the centre's licence.

Decision

8. The Panel had regard to its decision tree and was satisfied that the centre was fit to have its Treatment (Insemination using partner sperm) licence continued, and approved the Inspectorate's recommendation to continue the centre's licence with no additional conditions.



Signed: Date: 30 June 2014
Juliet Tizzard (Chair)

Interim Licensing Report

Centre name: Craigavon Area Hospital
Centre number: 0294
Date licence issued: 01/09/2012
Licence expiry date: 31/08/2016
Additional conditions applied to this licence: None
Date of inspection: 06/03/2014
Inspectors: Ms Janet Kirkland (Lead), Mr Andrew Glew
Date of Executive Licensing Panel: 27/06/2014

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 a short notice 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. In particular we note the implementation of the actions identified at the last inspection and the positive comments written by patients in relation to their experiences. The inspection team also acknowledges the consideration that the centre team gives to their patients to try to reduce any distress due to the sharing of facilities and waiting areas with the antenatal clinic and early assessment unit.

The Executive Licensing Panel is asked to note that there is a recommendation for improvement in relation to one 'other' area of non-compliance. Since the inspection, the Person Responsible (PR) has given a commitment to fully implement this recommendation.

'Other' areas of practice that require improvement:

- The PR should either ensure that all sperm providers are screened before their sperm is processed, or should provide a summary report to the HFEA outlining how the risks of cross contamination and staff exposure resulting from the centre's screening practices, are mitigated by the use of good laboratory and clinical practice.

Information about the centre

The centre is located within the general gynaecology service of the Craigavon Area Hospital and shares resources with the general gynaecology and maternity outpatient department. The centre has held a licence with the HFEA since 01/09/2007.

The centre is licensed for Treatment (Insemination using Partner Sperm).

Details of Inspection findings

Quality of Service

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

Outcomes

For the year 2013 the centre reported 208 cycles of partner IUI with 25 pregnancies, this equates to a 12% clinical pregnancy rate which is consistent with the national average pregnancy rate.

Multiple births

The single biggest risk of fertility treatment is a multiple pregnancy.

The centre provides only partner IUI treatment. However, no multiple pregnancies were reported in 2013.

Witnessing

Good witnessing processes are vital in ensuring there are no mismatches of gametes and that identification errors do not occur. The laboratory procedure of preparation of sperm was observed by the scientific inspector in the course of the inspection; the inspector also observed the active identification of the sperm provider. The procedure was witnessed in accordance with HFEA requirements using a manual system.
The inspection team was able to review records that were present in the laboratory and concluded that records of manual witnessing are accurately maintained.

Consent: Disclosure to researchers

No treatments requiring consent to disclosure to researchers are undertaken at this centre; therefore this theme was not relevant at this inspection.

Consent: To the storage of cryopreserved material

No gamete or embryo storage occurs at this centre; therefore this theme was not relevant at this inspection.

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; the atmosphere in the clinic appeared calm at all times; staff in the laboratory were able to carry out their activities without distraction and were available to carry out witnessing activities when required.

Patient experience

During the inspection visit we spoke to one patient who provided feedback on their experience and we observed interactions between centre staff and patients. A further 14 patients also provided feedback directly to the HFEA in the time since the last inspection. Feedback was primarily positive with 13 of the individuals providing written feedback to the HFEA commenting that they have compliments 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:

- gives prospective and current patients sufficient, accessible and up-to-date information to enable them to make informed decisions;
- maintains an effective system for responding to patient phone calls.

There were however two areas of concern observed by the inspection team. These had also been highlighted in patient questionnaire responses to the centre and to the HFEA.

- The nurse's offices and consultation rooms are located on the first floor of the hospital. The scan rooms are on the lower floor and shared with the ante-natal clinics. It is recognised within the field of infertility that it can be distressing for patients with fertility problems to share facilities and waiting areas with patients who are obviously pregnant. The centre team do take this in to account by offering early scan appointments to their patients; often as early as 0700hrs, however, it is not always possible for patients to attend at this time. During a tour of the premises the inspection team walked through an assessment unit for patients in the early stages of labour and it was considered that this could be particularly distressing for patients attending the fertility centre.

- The majority of male partners produce their semen samples at home, however, those who choose to attend the centre are asked to produce their samples in the treatment room where the actual insemination procedures occur.

Whilst it is acknowledged that these observations did not amount to a non-compliance as such it was considered by both the inspection team and the centre staff that these issues had a negative impact on the patient experience and that the location of some of the treatment rooms did cause a degree of distress to some of their patients.

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 identified the following non-compliance:

- Prior to the processing of sperm intended for use in treatment, the centre does not test all sperm providers for HIV1 and 2, hepatitis B and hepatitis C, nor is an assessment made of the need for HTLV testing or testing for pathogens which may be risks dependent on the sperm provider's medical history and recent travel history. See recommendation 1.

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in 2012 recommendations for improvement were made in relation to one major area of non-compliance and two 'other' areas of non-compliance. The PR provided information and evidence that the recommendations had been fully implemented before the report was considered by a licensing committee.

On-going monitoring of centre success rates

The HFEA risk tool is used to monitor the success rates of centres providing IVF and ICSI treatments. This IUI centre is not subject to on-going monitoring through the HFEA risk tool and has not therefore been issued with any performance alerts.

Provision of information to the HFEA

Clinics are required by law to provide information to the HFEA about all licensed fertility treatments they carry out.

The centre provided its annual IUI treatment return for 2013 within the required 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 PR’s statement
None noted			

‘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 noted			

‘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
1. Prior to the processing of sperm intended for use in treatment, the centre does not test sperm providers for HIV1 and 2, hepatitis B and hepatitis C, nor is an assessment made of the need for HTLV testing or testing for pathogens which may be risks dependent on the sperm provider’s medical history and recent travel history (SLC T50).	EC Directive 2006/17/EC, from which the screening requirements of SLC T50 are derived, stipulates that biological testing may not be required if sperm is processed for partner insemination only and a tissue establishment can demonstrate that the risk of cross contamination and staff exposure has been addressed through the use of validated systems and processes. The PR should therefore either ensure that all sperm providers are screened before their sperm is processed, or should provide a summary report to the HFEA outlining how the risks of cross contamination and staff exposure resulting from the centre’s screening practices, are mitigated by the use of good laboratory and clinical practice. The PR should also provide the HFEA with a summary report explaining the justification for the different degrees of viral testing evidenced on inspection. By 16 May 2014.	E-mail response provided by PR and copied below.	The inspector is satisfied that this centre in now fully compliant with the requirements. No further action is required.

Additional information from the Person Responsible

1) The clinic will no longer universally screen female patient blood samples for blood borne viruses.

2) The clinic will continue to apply a blood borne virus and infection exposure risk evaluation tool to all female patients participating in licensed treatments, and selectively screen blood and urine samples from those found to be at increased risk.

3) The clinic will not institute universal male patient blood sampling for blood borne viruses.

4) The clinic will immediately introduce a blood borne virus exposure risk evaluation tool to all male patients participating in licensed treatments, and selectively screen blood samples for those found to be at increased risk.

5) If either the female or male partner is suspected to be at increased risk of blood borne virus exposure or other infection, both partners will be subject to blood sample viral screening and/or appropriate antimicrobial investigation.

6) The provision and testing of a blood sample will be subject to routine policies in respect of patient consent.

7) If consent for blood sampling is with-held in high risk cases, then all samples are to be treated as potentially infected, and handling practices adjusted in line with local infection control policies. In such circumstances, the requirement for the licensed treatment will be reviewed by a HFEA licensed medical officer, and treatment continued if clinically appropriate.

8) This process will be subject to regular audit and review.

9) Patients with proven infections will be informed, and arrangements made for referral to appropriate specialist management teams. Patients will be made aware that such management may delay their licensed treatment.

10) Patient confidentiality will be maintained in line with local policy and HFEA regulation.