Interim Licensing Report

Centre name: Shropshire and Mid-Wales Fertility Centre

Centre number: 0148

Date licence issued: 1 December 2008

Licence expiry date: 30 November 2013

Additional conditions of licence: None

Date of Inspection: 30 May 2012

Inspectors: Dr Vicki Lamb (lead), Mrs Sara Parlett

Date of Executive Licensing Panel: 10 August 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 centres 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. In particular we note the positive comments expressed by the patients who were interviewed during the inspection.

At the time of the inspection, the team made one recommendation for improvement in relation to 'other' areas of non-compliance. The Person Responsible (PR) has provided evidence that the following recommendation has been acted upon:

'Other' areas of practice that require improvement:

- The time of some procedures, specifically sperm preparation, frozen embryo transfer and removal of embryos from storage, is not recorded in the patient records, which is not compliant with guidance note 18.7(b) in the Code of Practice.

Information about the centre

The Shropshire and Mid-Wales Fertility Centre is part of The Shrewsbury and Telford Hospital NHS Trust and is located in Shrewsbury. It has held a licence with the HFEA since 1994.

The centre provides a wide range of fertility services.

The centre provided 513 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 30 April 2012. In relation to activity levels this is a medium-sized centre.

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[1]

HFEA held register data for the year ending February 2012 show the centre's success rates in terms of clinical pregnancy rates are in line with national averages.

Multiple births[2] (SLC T123)

The single biggest risk of fertility treatment is multiple pregnancy. In 2010/11 the centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 25%: this represented performance that was not likely to be statistically different from the 20% live birth rate target.

For the time period April 2011 to March 2012 the centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 22%: this also represents performance that is not likely to be statistically different from the 15% live birth rate target.

The progress in reducing the clinical multiple pregnancy rates from 2010/11 to 2011/12 suggests that the centre is being proactive and effective in adapting their strategy to meet the HFEA's multiple birth rate target. The inspection team congratulates the centre on this achievement.

[1] 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.
[2] The HFEA use a conversion factor of 1.27 to convert the multiple live birth rate (MLBR) target to a multiple clinical pregnancy rate (MCPR) target. The 2010/11 MLBR target of 20% is calculated as equivalent to a MCPR of 25%: the 2011/12 MLBR target of 15% is calculated as equivalent to a 19% MCPR.

Witnessing (SLC T71)
Good witnessing processes are vital in ensuring there are no mismatches of gametes or embryos and that identification errors do not occur. No laboratory activities were being performed on the day of the inspection, therefore no laboratory procedures were observed in the course of the inspection.

The inspection team was able to review ten sets of patient records and concluded that records of witnessing are maintained. It was noted that the time of some procedures, specifically sperm preparation, frozen embryo transfer and removal of embryos from storage, is not recorded in the patient records, which is not compliant with guidance note 18.7(b) in the Code of Practice.

Consent: Disclosure to researchers (Direction 0007)
A patient providing informed consent is one of the most important principles in healthcare. Since 1 October 2009, the HFEA has been able to release patient-identifying information held by the HFEA to researchers if patients give their permission. Patients are asked to give their consent to the disclosure of this information and this is recorded in their records and the HFEA is notified of their decision through the electronic data interface (EDI) system. It is important that the reporting through EDI is accurate so that patient information is not disclosed without consent.

The records of consent to disclosure to researchers given by 14 patients were reviewed in the course of the inspection. The consents were completed and reported to the HFEA accurately in all of the records reviewed.

Consent: To the storage of cryopreserved material (Human Fertilisation and Embryology (HFE) Act 1990 (as amended), Schedule 3, 2 (2))
A review of the centre's records of consent to storage of gametes and embryos showed that all gametes and embryos currently in storage are being stored in accordance with the consent of the gamete providers and are within the consented storage period.

Staffing (SLC T12)
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 and the atmosphere in the clinic appeared calm at all times. However, no theatre or laboratory activities were being performed on the day of the inspection.

Patient experience

During the inspection visit we spoke to patients who provided feedback on their experiences and observed interactions between centre staff and patients. A further 24 patients also provided feedback directly to the HFEA in the time since the last inspection. Feedback was very positive with 19 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:

- 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, no non-compliances with standard licence conditions were identified. However, it was noted that the time of some procedures, specifically sperm preparation, frozen embryo transfer and removal of embryos from storage, is not recorded in the patient records, which is not compliant with guidance note 18.7(b) in the Code of Practice.

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 two major non-compliances and six 'other' areas of non-compliance.

The interim report included the following recommendations:

- The PR should ensure that HFEA treatment fees are paid within 28 days.
- The PR should ensure that all relevant data relating to anything coming into contact with gametes or embryos is traceable from procurement of gametes to patient treatment or disposal and vice versa.
- The PR should ensure that the third party agreement states the requirement for the procuring establishment to produce a report to the licensed centre.
- The centre should provide a safe working environment for all staff.

- The PR should obtain accreditation by CPA (UK) Ltd or another body accrediting to an equivalent standard as required.
- The PR should revise the witnessing standard operating procedure.
- The PR should review the process to be followed 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, and should audit this.
- The PR should review the requirements of the CoP and continue with the progress of the patient information.

In responding to the report immediately after the inspection the PR provided assurance that all of these recommendations would be implemented. Evidence provided by the PR after the report was considered by the Executive Licensing Panel along with information and evidence gathered in the course of the inspection has enabled the inspector to assess that the centre is now compliant with these regulatory requirements and no further action is required.

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 is responsive and generally acts promptly in relation to data submission and when alerted to data validation and verification issues. There are no outstanding forms in relation to donor treatments with missing patient registration forms, donor treatments with missing outcomes or treatments with unregistered donors.

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			

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
The time of some procedures, specifically sperm preparation, frozen embryo transfer and removal of embryos from storage, is not recorded in the patient records, which is not compliant with guidance note 18.7(b) in the Code of Practice.	The PR should consider review of the record sheets to include the time of all procedures. If the PR amends the record sheets to include this information he should submit a copy of the amended sheet to the HFEA by 31 August 2012. If the PR decides not to amend the record sheet he should submit an explanation of his reasons to the HFEA by 31 August 2012.	Thank you for your comments. Time of FET is recorded on the back of our FET record sheet- I have enclosed a copy. This will be updated to add time of transfer to the front also. Time of sperm preparation and time of removal of embryos from storage will be added to the appropriate record sheets and forwarded to you by the 31st August.	The Executive considers that this is an appropriate response. The PR submitted copies of the amended sheets to the Executive on 16 July 2012. No further action required.

Additional information from the Person Responsible
The new inspection process seemed to work well and caused little or no interruption to clinical work in the department.

HFEA Executive Licensing Panel Meeting

10 August 2012

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

Minutes – Item 2

Centre 0148 – (Shropshire and Mid-Wales Fertility Centre) – Interim Inspection Report

Members of the Panel:	Committee Secretary:
Juliet Tizzard, Head of Policy & Communications (Chair) Danielle Hamm, Senior Policy Manager David Moysen, Head of Information Technology	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 has been licensed since 1994, and provides a wide range of fertility services.

2. The Panel noted that the centre provided 513 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 30 April 2012 and is a medium-sized centre.

3. The Panel noted that at the time of the inspection the Inspectorate identified one other area of practice that required improvement.

4. The Panel noted that since the inspection the Inspectorate is satisfied that the Person Responsible has addressed this area of practice that required improvement.

5. The Panel noted that the centre's multiple clinical pregnancy rate for IVF, ICSI and FET cycles for all age groups was 25% for 2010/2011 and 22% for 2011/12. This represents performance that was not likely to be statistically different from the live birth rate target in each year.

6. The Panel noted the positive comments from patients that were made at the time of the Inspection.

7. The Panel noted that the Inspectorate recommends the continuation of the centre's licence without additional conditions.

8. The Panel noted the positive progress that has been made at the centre since the last inspection, and commended the PR on this. The Panel encouraged the PR to continue the good work.

Decision

9. The Panel endorsed the Inspectorate's recommendation to continue the centre's licence, with no additional conditions.

Signed: Date: 20/8/12

Juliet Tizzard (Chair)