HFEA Executive Licensing Panel Meeting

22 August 2014

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

Minutes – Item 1

Centre 0007 – (Hewitt Fertility Centre) – Interim Inspection Report

Members of the Panel: Juliet Tizzard – Director of Strategy & Corporate Affairs (Chair) Hannah Verdin – Head of Regulatory Policy David Moysen – Head of IT	Committee Secretary: Dee Knoyle Observing: 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

1. The Panel noted that the Hewitt Fertility Centre is located in Liverpool and has held an HFEA licence since 1992. The centre provides a full range of fertility services.

2. The Panel noted that the centre's licence is due to expire on 31 October 2016.

3. The Panel noted that the inspection took place on 28 May 2014.

4. The Panel noted that in the 12 months to 31 March 2014, the centre provided 2,264 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a large centre.

5. The Panel noted that in 2013, the centre reported 60 cycles of partner insemination with 12 pregnancies. This equates to a 20% clinical pregnancy rate which is consistent with the national average.

6. The Panel noted that for IVF and ICSI, HFEA-held register data for the period February 2013 to January 2014 show that the centre's success rates are in line with national averages.

7. Between October 2012 and September 2013, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 9%. This represents performance that is not likely to be statistically different from the 10% maximum multiple live birth rate target for this period.

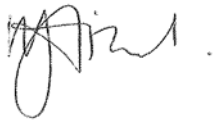
8. The Panel noted the recommendations made at the renewal inspection in 2013 and was pleased to see notable improvement had been made since then. The Panel urged the centre to continue making improvements to fully implement the outstanding recommendations.

9. The Panel noted that at the time of the interim inspection in May 2014, two major areas of non-compliance were identified. The Panel noted that the Person Responsible is committed to fully implement the recommendations made by the Inspectorate.

10. The Panel noted that the Inspectorate recommended the continuation of the centre's licence.

Decision

11. The Panel had regard to its decision tree and was satisfied that the centre was fit to have its treatment and storage licence continued.



Signed: Date: 5 September 2014
Juliet Tizzard (Chair)

Interim Licensing Report

Centre name: Hewitt Fertility Centre
Centre number: 0007
Date licence issued: 01/11/2013
Licence expiry date: 31/10/2016
Additional conditions applied to this licence: None
Date of inspection: 28/05/2014
Inspectors: Janet Kirkland (Lead),Chris Hall, Neil McComb, Sam Hartley (observing)
Date of Executive Licensing Panel: 22/08/2014.

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).

Following a renewal inspection in 2013 the inspection team recommended renewal of the centre's licence for a period of three years which is less than the normal term of four years. This was primarily due to persistent non-compliance in the accuracy and timeliness of the centre's reporting of treatment data to the HFEA register.

The Executive Licensing Panel (ELP) endorsed this recommendation on 16 August 2013. The minutes of that meeting state that non compliances first identified during the centre's 2011 interim inspection remained unresolved, notably the critical non-compliance relating to concerns about the reliability of data submissions and the centre's systems for submitting information to the HFEA register. The ELP agreed that a focused interim inspection should be performed within a year of licence renewal.

The HFEA register team monitored the data submissions by the centre carefully for several months. No evidence of improvement was seen so the PR was invited to the HFEA in January 2014 to discuss the non-compliance and to identify an action plan to correct it.

At the time of the 2013 licence renewal inspection, the HFEA information team were concerned about the reliability of historic treatment records provided to the HFEA for audit purposes. Since this time the centre has conducted a significant piece of work to review all licensed activity, which has provided assurance to the HFEA register team regarding the completeness of the reporting of licensed activity. The HFEA register team are satisfied that there had been a significant improvement in the quality of data submitted by the centre by the time of this focused inspection.

This report of an inspection is primarily focused on the centre's data submissions to the HFEA register, in addition to our assessment of the centre's performance based on other information.

- **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 ELP 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 progress made by the centre in addressing the non-compliances detailed in the report of the renewal inspection in May 2013.

The Executive Licensing Panel is asked to note that there a two recommendations for improvement in relation to two major areas of non-compliance. Since the inspection, the Person Responsible (PR) has given a commitment to fully implement these recommendations.

'Major' areas of non compliance:

- the PR should ensure that no gametes or embryos are stored beyond the consented storage period;
- the PR should ensure that patient and partner disclosure consent information supplied to the Authority accurately reflects that given and recorded on completed disclosure consent forms.

Information about the centre

The Hewitt Fertility Centre is located in Liverpool and has held a licence with the HFEA since 21 May 1992.

The centre provides a full range of fertility services.

The centre provided 2,264 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 March 2014. In relation to activity levels this is a large centre.

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.

Pregnancy outcomes[1]

IVF and ICSI, HFEA held register data for the period February 2013 to January 2014 show the centre's success rates are in line with national averages.

In 2013 the centre reported 60 cycles of partner insemination with 12 pregnancies .This equates to a 20% clinical pregnancy rate which is consistent with the national average.

Multiple births[2]

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

For treatments performed between October 2012 and September 2013, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 9%; this represents performance that is not likely to be statistically different from the 10% multiple live birth rate target for this period.

Witnessing

This area of practice was reviewed in May 2013 when the scientific inspector was satisfied that the centre's procedures for double checking the identification of gametes and embryos and the patients or donors to whom they relate, were broadly compliant with HFEA requirements. For this reason the inspection team performed only a limited review of witnessing procedures on this inspection.

In the previous inspection report the PR was asked to ensure that witness signatures are recorded at the time that witnessing is carried out. The PR was also asked to provide the inspector with the results of their own witnessing audit by August 2013 as evidence that corrective action to ensure that signatures are recorded was effective.

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[1] [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. Centre success rates are considered statistically different from the national averages, and multiple pregnancy rates are considered statistically different from the 10% multiple live birth rate target, when $p \leq 0.002$.

[2]The HFEA use a conversion factor of 1.27 to convert the 10% multiple live birth rate (MLBR) target to a multiple pregnancy rate (MPR) target of 13%.

The inspector had the opportunity on this inspection to observe the centre's most recent audits which further demonstrated that the centre has fully implemented the recommendations from the previous inspection in May 2013 and that corrective actions were effective.

Consent: Disclosure to researchers

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 12 patients were reviewed in the course of this inspection. The consents were completed and reported to the HFEA accurately in six of the records reviewed. The issues with the remaining consent decisions were as follows:

- in two of the records reviewed the consent decisions had not been reported to the HFEA;
- in two cases the patients consent recorded in the records indicated that the patients had given consent to disclosure while the consent reported to the HFEA recorded that consent had not been given;
- in two of the records reviewed the patient had not consented to disclosure to researchers however the entry on the register at the HFEA indicated that they had consented. For this reason this has been categorised as a major non-compliance due to the risk that the patient's consent may be breached.

See recommendation 2.

Consent: To the storage of cryopreserved material

The centre's database was not reviewed on this inspection; however the laboratory manager confirmed that at the time of the inspection, sperm samples from two providers and embryos from one patient couple, were being stored beyond their consented storage periods.

The PR explained the circumstances regarding these samples and the inspector was satisfied that PR was taking satisfactory action to resolve this matter and to ensure that gametes and embryos are stored within the terms of the storage consent.
See recommendation 1

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 three patients who provided feedback on their experiences. We also observed interactions between centre staff and patients. A further 16 patients had provided feedback directly to the HFEA in the time since the last inspection. Feedback was mixed with comments ranging from "exceptional treatment" to concerns regarding waiting times for scheduled appointments.

The inspector discussed the patient feedback with the laboratory manager who took note of the compliments and concerns and confirmed that the centre team will address them accordingly.

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 additional non-compliance to those documented in this report.

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in 2013, recommendations for improvement were made in relation to two areas of critical non-compliance, five areas of major non-compliance and seven 'other' areas of non-compliance.

The PR provided information and evidence that twelve of the fourteen recommendations were fully implemented. The following two recommendations relating to 'critical' areas of non-compliance have not been fully implemented:

- **the PR should ensure that no gametes or embryos are kept in storage for longer than the consented period;**
- **the PR must ensure compliance with the data submission requirements detailed in General Direction 0005.**

On-going monitoring of centre success rates

In 2013, the centre received two alerts regarding success rates for the following treatments:

- IVF/ ICSI for patients under 38 years of age
- IVF for patients over the age of 38 years.

The PR responded to the request to review the treatment results and during discussions at the time of the inspection, provided a commitment to keep success rates in this group of patients under review.

Provision of information to the HFEA

The HFEA has a legal responsibility to maintain a register containing information about all licensed activities including information on donors and on any children conceived as a

result of their donation. In order to maintain this register, clinics are required by law to provide information to the HFEA about all licensed fertility treatments they carry out. The primary purpose for keeping this information is to allow the donor-conceived and their parents to access information about the donor and about any donor-conceived genetic siblings.

At the time of the 2013 licence renewal inspection we found that:

- not all licensed treatment activity had been reported to the HFEA in accordance with General Direction 0005. The records provided to the HFEA for audit purposes were not considered complete or reliable enough for an assessment to be made of the extent of any outstanding licensed activity reporting in relation to pre 2012 treatments;
- compliance with data submission requirements had not been audited by the centre in the previous two years ;
- register data submission error rates were high. A significant proportion of the errors were the result of data on treatments and outcomes being submitted for patients that had not previously been registered with the HFEA.

At the time of our interim inspection we found that:

- the centre's 'HFEA Reporting Data' SOP had been updated and clearly detailed the requirement to register all new patients following their first appointment;
- there was documentary evidence of data submission competence assessment of 27 members of staff;
- patient file checklists were in use to indicate when patients have been registered with the HFEA;
- weekly monitoring of unsubmitted register forms was being undertaken and the results reviewed at the centre's monthly Quality Management meeting;
- audits of data submission had been conducted and corrective actions had been followed-up.

At the time of the interim inspection, we reviewed evidence of the work the centre had undertaken to assess the quality of the reporting to the HFEA register of historic licensed activity. This work had identified some information technology (IT)-related issues at the centre but no significant outstanding licensed treatment activity reporting. It was concluded therefore that the outstanding reporting identified and the submission errors arising from register forms being submitted to the register out of sequence has been addressed.

The inspector from the HFEA register information team noted that the patient information management software used by the centre was significantly less responsive than had been observed in other centres that use the same software. Concern was expressed that this may impact on both the quality and completeness of data submission with busy staff needing to attend to other matters before they can complete a particular data submission task.

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
1. The Laboratory Manager informed the inspection team that at the time of the inspection, sperm samples from two providers and embryos from one patient couple, were being stored beyond their consented storage periods (HF&E Act, Schedule 3, 8(1)).	The PR explained the circumstances regarding these samples and the inspector was satisfied that the PR was taking satisfactory action to resolve this matter. The PR is reminded of guidance issued by the HFEA in CH(03)03 (http://www.hfea.gov.uk/2687.html) in relation to the timely disposal of cryopreserved material where there is consent to do so and actions should there be a possibility of legal challenge to the disposal of cryopreserved material. We acknowledge the PR’s commitment, given on inspection, to process the gametes and	Please replace title of Laboratory Manager with Head of Laboratories. The PR can confirm that these issues continue to be proactively addressed. At the time of this response, the Hewitt Fertility Centre has only one patient's material in storage beyond the consented period. Attempts continue to be made to make contact with the patient in question. The PR has instructed that the patient be informed that unless effective consent is obtained by 15th August 2014 the samples will be removed from storage.	The inspector notes the request to refer to replace the title of Laboratory Manager with Head of Laboratories. The inspector looks forward to receiving an update on the situation regarding this issue.

	embryos at issue in accordance with the patients' wishes. The PR should up-date the inspection team in relation to these gametes and embryos by the time he responds to this report. Thereafter the PR should keep the inspector informed as to progress towards compliance regarding the material in store beyond the consented period.		
2. The records of consent to disclosure to researchers given by 12 patients were reviewed The consents were completed and reported to the HFEA accurately in six of the records reviewed. Issues note included: • in two of the records reviewed the consent decisions had not been reported to the HFEA; • in two cases the patients consent recorded in the records indicated that the patients had given	The PR should ensure that patient and partner disclosure consent information supplied to the Authority accurately reflects that given and recorded on completed disclosure consent forms. The PR should review the processes by which the completion of consent to disclosure forms are explained to patients and checked by staff, to ensure that the forms are completed effectively and that the consent decisions are clear. The PR should in addition review the process for submitting the	The PR can confirm that the CD for researchers has been added to the centre's audit schedule. In addition, the process for obtaining CD for researchers is under review with a view of ensuring future compliance. The PR acknowledges the requirement to provide the HFEA with the results of the appropriate audit by 15th February 2015.	The inspector looks forward to receiving the audit results by February 2015.

consent to disclosure while the consent reported to the HFEA recorded that consent had not been given • in two of the records reviewed the patient had not consented to disclosure to researchers however the entry on the register at the HFEA indicated that they had consented. For this reason this non-compliance has been considered as a major non-compliance due to the perceived risk that the patient's consent may be breached. (Chair's Letter CH(10)05 and General Direction 0007)	consent to disclosure decisions to the HFEA to ensure that they accurately reflect the consents recorded by the patients. The PR should perform an audit of the completion of the consents and subsequent submissions to the HFEA six months after any changes to the process have been made. The PR should provide the inspector with the results of this audit by 25 February 2015.		

‘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
None			

Additional information from the Person Responsible
The PR would like to thank the HFEA for their constructive and encouraging advice during the inspection process.