HFEA Executive Licensing Panel Meeting

24 January 2014

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

Minutes – Item 4

Centre 0151 – (Gloucestershire Hospitals NHS Trust) – Interim Inspection Report

Members of the Panel:	**Committee Secretary:**
Juliet Tizzard – Interim Director of Strategy (Chair)	Dee Knoyle
Paula Robinson – Head of Business Planning	**Observing:**
David Moysen – Head of IT	Sam Hartley – Head of Governance and 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 considered the papers, which included an inspection report and licensing minutes.

2. The Panel noted that this is a storage centre, licensed by the HFEA since 1995. The Panel noted that the centre is part of Gloucestershire Hospitals NHS Trust and is located in Gloucester and offers a sperm storage service for the preservation of fertility to oncology patients in the Gloucestershire, Herefordshire and Worcestershire area.

3. The Panel noted that the centre is currently on a four-year licence, due to expire on 31 October 2015.

4. The Panel noted that the inspection took place on 7 November 2013.

5. The Panel noted that the inspection theme relating to outcomes is not relevant as the centre does not offer treatment services.

6. The Panel noted that there were no areas of non-compliance or poor practice identified and commended the centre.

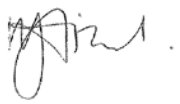
7. The Panel acknowledged the positive comments made by patients in relation to their experience of the centre.

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

Decision

9. The Panel had regard to its decision tree and was satisfied that the centre was fit to have its Storage licence continued.

10. The Panel approved the Inspectorate's recommendation to continue the centre's licence with no additional conditions.



Signed: Date: 4 February 2014
Juliet Tizzard (Chair)

Interim Licensing Report

Centre name: Gloucestershire Hospitals NHS Trust
Centre number: 0151
Date licence issued: 01/11/2011
Licence expiry date: 31/10/2015
Additional conditions applied to this licence: None
Date of inspection: 07/11/2013
Inspector: Parvez Qureshi
Date of Executive Licensing Panel: 24/01/2014

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 (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 inspector to form a conclusion on the continuation of the centre's licence. The inspector recommends the continuation of the centre's licence. In particular the inspector notes the implementation of recommendations made at the time of the last inspection and the positive comments made by patients in feedback provided directly to the centre in relation to their experiences.

The ELP is asked to note that there are no recommendations for improvement resulting from this inspection.

Information about the centre

The centre is part of Gloucestershire Hospitals NHS Trust and is located in Gloucester and has held a storage only licence since 1995. The centre offers a sperm storage service for the preservation of fertility to oncology patients in the Gloucestershire, Herefordshire and Worcestershire area.

Details of Inspection findings

The ELP is asked to note that not all interim inspection themes were relevant to the inspection of this storage only centre.

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[1]

This inspection theme is not relevant as the centre does not offer treatment services.

Multiple births[2]

This inspection theme is not relevant as the centre does not offer treatment services.

Witnessing

Good witnessing processes are vital in ensuring there are no mismatches of gametes or embryos and identification errors do not occur. At the time of this inspection no laboratory procedures were taking place therefore no witnessing activities were observed in the course of the inspection. However, a discussion held with the laboratory staff and a review of the centre's witnessing standard operating procedure showed that the centre has a robust witnessing procedure in place in accordance with HFEA requirements.

The inspector was able to review five sets of patient notes and concluded that appropriate records of manual witnessing are maintained.

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)

[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.

system. It is important that the reporting through EDI is accurate so that patient information is not disclosed without consent.

The HFEA does not hold information, including records of intentions relating to consent to disclosure, about patients storing sperm. Therefore the centre is not required to collect and report consents for disclosure to researchers. A review of notes on inspection confirmed that consent to disclosure to researchers was not being taken. The PR is aware that these consents should be taken and reported to the HFEA if the gametes are used in treatment at a later stage.

Consent: To the storage of cryopreserved material

Patients notes reviewed on inspection contained appropriate and effective consent for storage of sperm. A review of the centre's database indicated that gametes currently in store are being stored within their consented storage period. The storage periods for three sets of sperm samples as recorded on the centre's database were cross checked against the consent given by the gamete providers. In the three sets of records checked, the sperm samples were being stored in accordance with those consenting decisions.

All stored samples are within their statutory storage period and the centre operates a robust bring-forward system to ensure that samples are not stored beyond their 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: A discussion held with staff confirmed that staff in the laboratory are able to carry out their activities without distraction and are available to carry out witnessing activities when required.

Patient experience

No patients were available to speak with the inspector to provide feedback on their experiences at the centre on inspection. However, a discussion held with staff and a review of the centre's recent patient questionnaire results showed that patients were complimentary about the service, including general attitude of staff and the respect for their privacy and dignity.

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 were identified.

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in August 2011 recommendations for improvement were made in relation to four areas of major non-compliance and two 'other' areas of non-compliance.

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

On-going monitoring of centre success rates

This inspection theme is not relevant as the centre does not offer treatment services

Provision of information to the HFEA

This inspection theme is not relevant as the centre does not offer treatment services for which HFEA collects information.

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
None noted.			

Additional information from the Person Responsible