Human Fertilisation and Embryology Authority

Minutes of the Executive Licensing Panel

Meeting held at HFEA, Finsbury Tower, 103-105 Bunhill Row, London, EC1Y 8HF on
5 June 2015

Minutes – item no. 6

Centre 0102 (Guy's Hospital) – Interim Report

Members of the Panel:	**Juliet Tizzard** Director of Strategy & Corporate Affairs (Chair) **David Moysen** Head of IT **Hannah Verdin** Head of Regulatory Policy
Members of the Executive in attendance:	**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 the 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 the 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 the publication of Authority and committee papers

Consideration of Application

1. The panel noted that Guy's Hospital has held a licence with the HFEA since 1992. The centre provides a full range of fertility services including a pre-implantation genetic diagnosis service.

2. The panel noted that the centre's licence is due to expire on 30 June 2017.

3. The panel noted that the inspection took place on 10 March 2015.

4. The panel noted that in the 12 months to 31 January 2015, the centre provided 2,391 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a large centre.

5. The panel noted that for IVF and ICSI, HFEA-held register data for the year ending October 2014 showed the centre's success rates were in line with national averages.

6. The panel noted that in 2014, the centre performed 99 cycles of IUI with 13 pregnancies. This is consistent with the national average.

7. Between 1 December 2013 and 30 November 2014, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 15%. This represented performance that was not likely to be statistically different from the 10% maximum multiple live birth rate target for this period.

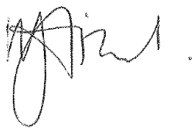
8. The panel noted that at the time of the interim inspection on 10 March 2015, three major areas of non-compliance were identified. The panel noted that since the inspection the Person Responsible (PR) has committed to fully implementing the outstanding recommendations within the prescribed timescales.

9. The panel noted that the inspection team recommended the continuation of the centre's licence.

Decision

10. The panel had regard to its decision tree and was satisfied that the centre was fit to have its treatment and storage (including embryo testing) licence continued.

Signed: Date: 15 June 2015



Juliet Tizzard (Chair)

Interim Licensing Report

Centre name: Guys Hospital
Centre number: 0102
Date licence issued: 01/07/2013
Licence expiry date: 30/06/2017
Additional conditions applied to this licence: none
Date of inspection: 10/03/2015
Inspectors: Louise Winstone (Lead), Janet Kirkland Machattie, Stephanie Gadd and Lesley Brown (observer)
Date of Executive Licensing Panel: 05/06/2015

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 an unannounced 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. Currently, 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

The inspection team recommends the continuation of the centre's licence.

The ELP is asked to note that there are recommendations for improvement in relation to three 'major' areas of non-compliance:

Major area of non-compliance:

- The Person Responsible (PR) should ensure that patient/partner consents to disclosure of identifying information to researchers are accurately recorded on the HFEA register.
- The PR should review procedures for submitting licensed treatment data to the HFEA to ensure that it is accurate and is provided within the timeframes specified in Directions.
- The PR should ensure that the legal parenthood audit that all centres were asked to perform in 2014 is performed according to the method specified by the HFEA, by documenting whether counselling was offered prior to obtaining consent.

The PR has provided a commitment to implement the recommendations within the required time frame.

Information about the centre

The centre is part of Guy's and St Thomas' Hospitals Foundation Trust and has held a HFEA licence since 1992. The centre provides a full range of licensed fertility treatments including a pre-implantation genetic diagnosis (PGD) service to NHS and self-funded patients. It is the primary centre in a satellite agreement for patients requiring PGD with The Leeds Centre for Reproductive Medicine (centre 0314), Jessop Fertility, Sheffield (centre 0196) and Spire Healthcare Limited, Dorset Rise, London.

The centre has an active research programme for which there is a separate HFEA research licence in place.

The centre provided 2391 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 January 2015. 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]

HFEA held register data for the year ending October 2014 show the centre's success rates in terms of clinical pregnancy rates are in line with national averages.

For the year 2014, the centre reported 99 cycles of partner insemination with 13 pregnancies. This pregnancy rate is consistent with the national average.

Multiple births[2]

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

Between 1 November 2013 and 31 October 2014, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 15%: this means that the centre's multiple live birth rate is not likely to be statistically different from the 10% multiple live birth rate target.

[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.

Witnessing

Good witnessing processes are vital in ensuring there are no mismatches of gametes or embryos and that identification errors do not occur. The following laboratory activities were observed during the course of the inspection: egg collection and the thawing of embryos. All of the procedures observed were witnessed in accordance with HFEA requirements using manual and electronic witnessing. The inspection team was also able to discuss the process of sperm preparation and witnessing procedures with staff.

The inspection team reviewed laboratory records in five sets of patient notes and concluded that records of manual and electronic 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) system. It is important that the reporting of such consent decisions through the EDI system is accurate, so that patient information is not disclosed without consent.

The records of consent to disclosure to researchers given by 10 patients were reviewed in the course of the inspection. Two discrepancies were found where the patients had not consented to contact research but the data submitted by the centre to the HFEA indicated that the patients had. This consent decision does not accurately reflect the consent provider's wishes (see recommendation 1).

Consent: To the storage of cryopreserved material

A review of the centre's database indicated that gametes and embryos currently in store are being stored within 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: 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 there were no patients available to talk to the inspection team regarding their experience at the centre, however we were provided with the centre's analysis of feedback from the Trust wide patient questionnaire that is completed by the centre's patients. The feedback from this was positive with 92% of patients rating the care that they received as good.

A further 13 patients have provided feedback directly to the HFEA in the time since the last inspection. Feedback was mixed with three individuals commenting that they had compliments, five individuals commenting that they had complaints and five individuals commenting that they had both compliments and complaints about the care that they received. Some patients fed back that they felt that they had been rushed during appointments, that they had no choice about the number of embryos that were being transferred and that they had difficulties contacting the centre by telephone.

The negative feedback was discussed with the PR and he assured the inspection team that actions will be taken to address these matters. These include the recent appointment of a patient experience coordinator to help to improve the patient pathway.

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 non-compliance.

Compliance with recommendations made at the time of the last inspection

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

The PR provided information and evidence that all of the recommendations were fully implemented before the report was considered by a licensing committee.

On-going monitoring of centre success rates

In the last year the centre has received two risk tool alerts relating to multiple birth rates and was asked to review procedures. The PR responded fully to the requests.

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 has a large number of data submission errors that have not been addressed which are primarily due to treatment information being submitted prior to patients being registered. In addition the centre has recently had an increase in missing and late data submission forms (see recommendation 2).

Legal parenthood audit

The partners of women treated with donated gametes or embryos, where the couple are not married or in a civil partnership, must give written consent in order to become the legal parent of any child born. If this consent is not documented properly or if proper information is not provided or counselling offered prior to both parties giving consent there may be doubt about the effectiveness of the consent and in some cases it may be necessary for a patient couple to obtain a court declaration to establish legal parenthood. In February 2014, the HFEA asked all centres to audit their practices in this area to ensure they are suitable, to report the findings of the audit to the HFEA and to respond to those findings. The centre sent the report of the audit to the HFEA within the required timeframe.

On this inspection we reviewed the centre's audit and found that it had not been performed according to the method specified by the HFEA. Whilst it was documented that counselling had been offered, there was no date recorded. It was therefore unclear if this counselling had been offered prior to obtaining consent to legal parenthood (see recommendation 3).

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 areas 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;
- which can comprise 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. In two of the ten patient consent to disclosure forms reviewed, the patients had not consented to contact research but the data submitted by the centre to the HFEA indicated that the patients had. General Direction 0007. It is noted that contact research would not be initiated by the HFEA and it would be expected that if the clinic was asked to initiate contact research, consent forms would be reviewed before patients are contacted.	The PR should correct the submissions that were identified as incorrect and review the procedures for checking and submitting consent to disclosure decisions to the HFEA to ensure that consent to disclosure decisions made by patients are accurately reported to the HFEA. A summary of the findings and any corrective actions identified should be submitted to the centre’s inspector by 10 June 2015. It is also recommended that the clinic undertakes a further sample audit of the records of 100 patients who have been reported as having given consent to non-contact disclosure of their	The PR has responded to the report by email stating that he is happy with the report and will implement the recommendations in the stated time frame.	The Executive acknowledges the PR’s response and commitment to implement the recommendations within the required time frame.

	information to researchers on the HFEA register. The purpose of this audit is to identify whether the observation made on inspection represents a systemic failure of the recording of this consent in cases where there is a risk that information could be disclosed if the consent is not reported accurately. The PR should advise the HFEA of the findings of this audit by 10 June 2015. On completion of the audit it is recommended that the PR should liaise with the HFEA's register team to consider the most proportionate way to implement corrective actions to mitigate any risks identified by the audit.		
2. The centre does not submit licensed treatment data to the HFEA within the timeframes specified in Directions. The centre also has a large number of data errors that have not been addressed. General Direction 0005.	The PR should review the centre's data submission processes and should take corrective actions to prevent late or absent data reporting. A summary of the review and corrective actions required should be provided to the HFEA by 10 June 2015. The PR should also review information on the clinic portal related to the centre's HFEA Register data errors and should ensure that data submission errors are cleared by 10 June 2015.	The PR has responded to the report by email stating that he is happy with the report and will implement the recommendations in the stated time frame.	The Executive acknowledges the PR's response and commitment to implement the recommendations within the required time frame.

	Three months after the implementation of corrective actions, the centre should perform an audit to ensure that these corrective actions have been effective. This audit should be submitted by 10 September 2015. It is also recommended that the PR reviews error reports on a weekly basis to prevent a build up of unresolved data issues which may affect the quality of the data held by the HFEA.		
3. The legal parenthood audit conducted by the centre did not record if counselling had been offered prior to obtaining consent to legal parenthood. CE (14)01 and CE (14)02	The PR should review the legal parenthood audit conducted by the centre and document whether there is evidence that counselling was offered prior to obtaining consent to legal parenthood. The PR should inform the HFEA of the audit results by 10 June 2015.	The PR has responded to the report by email stating that he is happy with the report and will implement the recommendations in the stated time frame.	The Executive acknowledges the PR's response and commitment to implement the recommendations within the required time frame.

‘Other’ areas of practice that requires improvement

Areas of practice that require improvement are any area of practice in which failings occur, which cannot be classified as either a critical or major area of non compliance, but which indicate 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