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
21 August 2015

Minutes – item no. 3

Centre 0035 (Oxford Fertility Unit) – Interim Inspection Report

Members of the Panel:	Juliet Tizzard Director of Strategy & Corporate Affairs (Chair) Joanne Anton Policy Manager Ian Peacock Analyst Programmer
Members of the Executive in attendance:	Dee Knoyle Committee Secretary

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 Oxford Fertility Unit, centre 0035, has held a licence with the HFEA 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 30 September 2017.

3. The panel noted that the inspection took place on 9 June 2015.

4. The panel noted that in the 12 months to 31 March 2015, the centre provided 2550 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 December 2014 showed the centre's success rates were in line with the national average.

6. The panel noted that in 2014, the centre reported 12 cycles of partner insemination with no pregnancies. This was consistent with the national average.

7. For the year ending December 2014, the centre's multiple pregnancy rate for all IVF, ICSI and frozen embryo transfer (FET) cycles for all age groups was 16%. This means that the centre's live birth rate was likely to be consistent with the 10% maximum multiple live birth rate target.

8. The panel noted that at the time of the interim inspection on 9 June 2015, three major and one other area of non-compliance was identified. The panel noted that since the inspection the Person Responsible (PR) has fully implemented one of the recommendations and has committed to fully implementing all of the recommendations within the prescribed timescales.

9. The panel noted that the Inspectorate recommends the continuation of the centre's treatment and storage 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 licence continued.

Signed: Date: 24 August 2015
Juliet Tizzard (Chair)

Interim Licensing Report

Centre name: Oxford Fertility Unit
Centre number: 0035
Date licence issued: 1 October 2013
Licence expiry date: 30 September 2017
Additional conditions applied to this licence: None
Date of inspection: 9 June 2015
Inspectors: Sara Parlett (Lead) and Gill Walsh
Date of Executive Licensing Panel: 21 August 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. For 2015-2017 the focus of an interim inspection is:

- **Quality of care:** the quality of care provided by a centre is defined by positive healthcare outcomes and a positive patient experience delivered via safe and effective care.
- **Patient safety:** patient safety is a fundamental and essential attribute to quality healthcare: without safety there cannot be high quality. Improving safety is an ethical imperative for healthcare providers and the individuals who deliver that care.
- **Patient experience:** understanding what matters to patients and improving the patient experience is crucial in delivering high quality care.

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 Executive Licensing Panel is asked to note that at the time of the inspection, there were four recommendations for improvement in relation to three major and one 'other' area of practice that required improvement.

The PR has implemented the following recommendation:

'Other' areas of practice that require improvement:

- The PR should ensure that the disposal of the unused portion of each ampoule of controlled drugs dispensed is recorded.

The PR has given a commitment to fully implement the following recommendations in the prescribed timescales:

Major areas of non compliance:

- The PR should ensure that infection control and medicine management procedures are audited against compliance with regulatory requirements and their own approved protocols and quality indicators.
- The PR should ensure that CE marked medical devices are used wherever possible.
- The PR should ensure that all licensed treatment activity is reported to the HFEA within the timeframes required.

Information about the centre

Oxford Fertility Unit has held a licence with the HFEA since 1992.

The centre provides a full range of licensed treatments.

The centre provided 2550 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 March 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 as they are important indicators of a centre's ability to provide high quality patient care and to meet the requirements of the law.

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the year ending December 2014 show the centre's success rates are in line with the national average.

In 2014 the centre reported 12 cycles of partner insemination with no pregnancies. This is consistent with the national average.

Multiple births[2]

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

For the year ending December 2014, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 16%. This means that the centre's live birth rate is likely to be consistent with the 10% multiple live birth rate target.

Witnessing

Good witnessing processes are vital in ensuring there are no mismatches of gametes or embryos, and that identification errors do not occur. Witnessing was observed being carried out using an electronic witnessing system during egg retrieval, sperm preparation and embryo thawing. The procedures were witnessed in accordance with HFEA guidance.

Consent to the storage of cryopreserved material

The storage of gametes and embryos is an important service offered by fertility clinics as it can enable patients to preserve their fertility prior to undergoing other medical treatment such as radiotherapy. The storage of embryos not required for immediate use also means that women can undergo further fertility treatment without further invasive procedures being performed. The centre's procedures for ensuring gametes and embryos are stored in accordance with the consent of the gamete providers are compliant with HFEA requirements. There is effective consent for all gametes and embryos being stored.

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[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%.

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.

Quality Management System (QMS)

It is important that clinics audit all of their practices at least every two years to ensure they are delivering the expected quality of service, that standard operating procedures are followed and that the centre's processes meet regulatory requirements. It is also important that these audits are robust and that any changes that are identified as required are implemented as this helps ensure that clinics continuously improve.

The effectiveness of the centre's QMS was assessed by evaluating a sample of the centre's audits. The inspection team also considered whether the clinic's processes for implementing learning are effective

The following audit reports were reviewed: witnessing; storage of gametes and embryos; confidentiality. The inspection team considered that the centre's audit practices are broadly compliant with requirements for the following reasons:

- infection control and medicines management procedures have not been audited in the last two years (see recommendation 1).

In the course of the inspection, the centre's actions with respect to implementation of HFEA guidance in relation to the following were discussed; use of revised HFEA consent forms released on 1 April 2015; learning from adverse incidents throughout the sector including failures of laboratory alarms; acting upon a field safety notice issued in relation to a piece of laboratory equipment used by the centre. The centre is effective in implementing learning from guidance from the HFEA.

Medicines Management

It is important that a clinic follows best practice for medicines management both to protect patients and ensure that medicines are stored, administered and disposed of in the correct way. The centre's processes for medicines management and the safe storage, disposal and administration of medicines were reviewed and were considered broadly compliant with guidance. The following non compliance was noted

- the disposal of the portion of each ampoule of controlled drugs dispensed but not used is not recorded (see recommendation 4).

Infection Control

Having suitable procedures in place to ensure that patients experience care in a clean environment is important, as well as ensuring that both patients and staff are protected from acquiring infections. During the inspection, we assessed the ACU's infection control procedures by observation and found that they were compliant with guidance.

Equipment and Materials

It is important that products (known as medical devices) that come into contact with gametes and/or embryos are approved for use in treatment to ensure the safety of gametes and embryos and patients. The approval of such products is denoted by the issue of a 'CE mark'. The CE mark status of the following medical devices was reviewed in the course of

the inspection: embryo culture media, reagents and consumables. The centre is broadly compliant with requirements to use CE marked medical devices wherever possible. The following consumable is not CE marked: 14ml tubes used at egg collection (see recommendation 2).

Patient experience

During the inspection visit we did not have the opportunity to speak to any patients. Sixteen patients have provided feedback directly to the HFEA in the time since the last inspection. Feedback was mixed with nine compliments and seven complaints. There were no trends in the negative feedback.

The centre's own patient satisfaction survey results were discussed on inspection. They have a good response rate to these surveys and take corrective action based on any negative trends. The results of these surveys are carefully considered and demonstrated a learning culture at the centre.

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, the inspection team identified no further area of practice that could be improved.

Compliance with recommendations made at the time of the last inspection

At the centre's renewal inspection in May 2013, there were two major and eleven 'other' areas of non-compliances.

Evidence was provided that all but the following recommendation in relation to an 'other' non-compliance have been implemented effectively:

- submission of data to the HFEA within the required timescales (refer to 'provision of information to the HFEA' section of this report).

On-going monitoring of centre success rates and risk tool alerts

In the last year, the centre has received four alerts relating to multiple pregnancy rates. The centre responded appropriately to these alerts on all occasions.

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. This information is held in the HFEA Register. The clinic is partially compliant with requirements to submit information to the HFEA. The centre has recurrent issues with duplicate treatment form submission, substantial missing outcomes and a considerable proportion of records submitted late. This was an issue at the previous inspection.

The centre audits data submission regularly and is aware of the issues. Further corrective action in the form of staff refresher training, re-organisation of staff responsible for data submission and SOP reviews has recently been taken (see recommendation 3).

Legal parenthood

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, HFEA asked all centres to audit their procedures for giving patients an opportunity to consent to legal parenthood to ensure they are suitable, to report the findings of the audit to us and to respond to those findings. A report of the audit was submitted

within the required timeframe and the clinic have acted on their findings. The centre's audit was performed according to the method specified by the HFEA.

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	Executive review
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;
- 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	Executive Review
1. Quality management system Infection control and medicine management procedures have not been audited in the last two years. SLC T36.	The PR should ensure that infection control and medicine management procedures are audited against compliance with regulatory requirements and their own approved protocols and quality indicators. A summary report of these audits, including any corrective action identified, should be forwarded to the centre's inspector by 9 September 2015.	Audits of infection control and medicine management procedures have been planned and added to the annual audit plan. Summary reports of the findings, including any corrective actions, will be sent to our inspector by 9th September.	The Executive acknowledges the PR's response and his commitment to fully implementing the recommendation. Further action is required.
2. CE marked consumables 14ml tubes used during egg collection are not CE marked. SLC T30.	The PR should ensure that CE marked medical devices are used wherever possible. The PR should advise the centre's inspector by 9 December 2015, of the action that has been taken to ensure compliance.	The laboratory manager is currently away however, on her return, we will discuss the findings of the report and consider the alternative products available. We will advise the HFEA of the action we have taken by the 9th December.	The Executive acknowledges the PR's response and his commitment to fully implementing the recommendation. Further action is required.

3. Data submission The centre has repeated issues with duplicate treatment form submission, substantial missing outcomes and a considerable proportion of records submitted late. Data reporting was an issue at the previous inspection and as a result has been upgraded to a major non-compliance. SLC T9e, SLC T41 and General Direction 0005.	The PR should ensure that all licensed treatment activity is reported to the HFEA within the timeframes required. The centre is aware of this issue and has already taken corrective action. Within three months, the centre should carry out an audit of its data submission procedures to ensure that the corrective actions have been effective in ensuring compliance. A summary report of the audit should be submitted to the centre's inspector by 9 September 2015.	As discussed on the day of inspection, all staff responsible for data submission have been retrained and we are monitoring the timing and quality of our data submission as a key objective. We will audit our data submission times and procedures since implementing the corrective actions and submit the summary reports to the HFEA by 9th September.	The Executive acknowledges the PR's response and his commitment to fully implementing the recommendation. Further action is required.

► '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	Executive Review
4. Medicines management The disposal of the portion of each ampoule of controlled drugs dispensed but not used is not recorded. Section 27, The Misuse of Drugs Regulations, 2001.	The PR should ensure that the disposal of the portion of each ampoule of controlled drugs dispensed is recorded. The PR should provide confirmation of this at the time of responding to the inspection report.	I will ensure that where controlled drugs are dispensed but not used the discarded portion is recorded appropriately.	The Executive acknowledges the PR's response. No further action is required.

Additional information from the Person Responsible
I would like to thank the Inspectors for the way that they successfully fitted around a busy clinic schedule on the day of this unannounced inspection and for the constructive feedback which, where negative, will be acted upon as described above.