Licence Committee - minutes

Thursday, 5 November 2015

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

Centre 0324 (City Fertility) – variation of licensed activities

Committee members	Andy Greenfield (Chair) Anita Bharucha Kate Brian Margaret Gilmore	
Members of the Executive	Sam Hartley	Head of Governance and Licensing
Legal Adviser	Graham Miles	Blake Morgan

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:

- 8th edition of the HFEA Code of Practice
- Standard licensing and approvals pack for committee members

The following papers were considered by the committee:

- Licence variation application report to include embryo testing as an activity on the licence
- Licence variation application form
- Licence Committee minutes for the past three years:
  - 07-08-2015 change of person responsible
  - 07-05-2015 up-date report
  - 12-03-2015 up-date report
  - 15-03-2015 change of person responsible
  - 25-09-2014 licence renewal
  - 18-10-2013 change of licence holder
  - 29-11-2012 initial inspection report

1. Consideration of application

1.1. The committee noted that City Fertility, centre 0324, has held a licence with the HFEA since November 2012 and provides a full range of fertility services. The centre's licence is due to expire on 28 November 2016. The interim inspection took place on 11 August 2015.

1.2. The panel noted that the centre was currently operating under a two-year licence (rather than the usual four) due to the number and severity of non-compliances identified at its renewal inspection in 2014. Because of its concerns at renewal in 2014, the Licence Committee had requested progress reports and a further interim inspection to be conducted by September 2015 in order to ensure that the centre was addressing the non-compliances. The committee further noted that since the licence was renewed, the centre's licence has been varied twice to change the person responsible (PR). The centre has now applied to vary its licence to allow embryo testing.

1.3. The committee further noted that it had considered the interim inspection report at the same meeting as the consideration of this variation application. Minutes of its consideration of that inspection are available separately. While it would take the decision on the variation of the licence based on the evidence before it, the committee agreed it could not be blind to the non-compliances raised at the recent interim inspection, and the renewal inspection prior to that.

1.4. The committee noted that the recommendation from the inspectorate was that the centre's licence be varied to allow embryo testing because all requirements of general direction 0008 had been provided, and there were no non-compliances related to embryo testing identified at the interim inspection.

2. Decision

2.1. The committee had raised its serious concerns about the operation of this centre when it considered the interim inspection report (minutes available separately). Those concerns were equally valid in relation to the decision to allow the centre to conduct embryo testing. When considering the interim inspection the committee decided, on balance, for the centre's licence to continue. It is expected to urgently address the non-compliances in early 2016, and at the very least before the next renewal inspection.

2.2. The committee noted the recommendation from the inspectorate before it to vary the centre's licence, and the evidence provided that the centre had supplied all information necessary by General Direction 0008. The premises and practices were, in the inspectorate's view, suitable to carrying out embryo testing, and there was evidence provided by the centre that a multidisciplinary team with the appropriate skills will be involved in the embryo testing service. There were no areas of practice relating to embryo testing that required improvement.

2.3. In light of those factors, the committee agreed to vary the licence to allow embryo testing. The committee noted that, because of the concerns with the operation of this centre raised at the renewal and interim inspections, the inspectorate would be monitoring the centre's practices closely, and was confident that such monitoring would be extended to include the embryo testing provision.

3. Chair's signature

3.1. I confirm this is a true and accurate record of the meeting.

Signature

Name

Andy Greenfield

Date

13 November 2015

Licence Variation Application Report

Inspector: Louise Winstone

Date of Assessment: 24/06/2015

Date of Executive Licensing Panel: 24/07/2015

Purpose of report: Desk based assessment of the centre's application to vary their licence to include embryo testing.

Centre details

Centre name	City Fertility
Centre number	0324
Licence number	L/0324/3/a
Centre address	16, St John Street, London, EC1M 4NT, UK
Person Responsible	Shaun Rogers
Licence Holder	Mr Matej Stejskal
Date licence issued	25/03/2015
Licence expiry date	28/11/2016
Additional conditions applied to this licence	None

Contents

Report to the Executive Licensing Panel

Brief description of the centre and its licensing history:

City Fertility has been licensed by the HFEA for treatment and storage since November 2012 and provides licensed treatment to self-funded patients.

Following a renewal inspection in June 2014, a licence was granted for two years (rather than the usual four) due to the number and severity of non compliances identified. The Licence Committee requested that a further inspection should take place by September 2015 and that prior to this the executive provide it with an update on the centre's progress with implementing the recommendations made in the report. Progress reports were considered by Licence Committee in March and May 2015, and In summary the executive were assured that the recommendations made during the 2014 renewal inspection had been implemented. The report of an interim inspection in August 2015 is presented alongside this report.

Since the renewal inspection, the centre's licence has been varied twice to change the person responsible (PR). The centre is now applying to have their licence varied to allow embryo testing.

Activities of the Centre:

Type of treatment	Number of treatment cycles performed 1/1/15-30/6/15
In vitro fertilisation (IVF)	36
Intracytoplasmic sperm injection (ICSI)	40
Frozen embryo transfer (FET)	34
Donor insemination (DI) and	5
Partner insemination IUI(P)	N/A

Other licensable activities	✓ or Not applicable (N/A)
Storage of eggs	✓
Storage of sperm	✓
Storage of embryos	✓
Research	N/A

Summary for licensing decision:

The inspector concludes that sufficient documentation and information in support of the application has been submitted by the centre to confirm that:

- the premises are suitable for carrying out embryo testing,
- the practices are suitable for carrying out embryo testing,
- the centre has submitted appropriately completed documentation in accordance with General Direction 0008, in application for variation of their licence.
- there is evidence that a multidisciplinary team including reproductive specialists, embryologists, clinical geneticists, genetic counsellor and cytogeneticists will be involved in the embryo testing service.

The Executive Licensing Panel is asked to note that at the time of the assessment there were no areas of practice that required improvement with respect to the proposed procedures for embryo testing.

Recommendation to the Executive Licensing Panel

The inspection team considers that, overall there is sufficient information available to recommend the variation of this centre’s licence to include embryo testing.

Details of assessment findings

The Licence variation application:

An application has been received to vary the centre's licence to add embryo testing as an additional licensable activity. Both pre-implantation genetic diagnosis (PGD) and pre-implantation genetic screening (PGS) services will be offered to patients. The centre has predicted they are likely to provide up to 20 PGS and five PGD cases per year.

The centre will perform biopsy procedures relating to PGS and PGD with genetic testing being completed at a third party laboratory.

The applicant has complied with the requirements of General Direction 0008 (paragraph 6), and has submitted the following:

- an application form;
- copies of information provided to patients relating to the new activity;
- evidence that the equipment and processes used in carrying out the new activity have been validated and;
- a schedule of the quality indicators, and reporting arrangements, established for this activity

Desk based assessment of the application:

An additional on-site inspection at the centre was considered unnecessary in relation to this application. This is because the centre had an interim inspection in September 2015.

Assessment findings:

Evidence provided by the centre was compared against the requirements of the Human Fertilisation and Embryology Act 1990 (as amended), Directions, Standard Licence Conditions (SLCs) and the Code of Practice (CoP), with the following findings

A. Staff

The centre has provided evidence that its has staff competent to carry out embryo biopsy. The centre has submitted documented evidence of the training provided to and the competence of the Laboratory Manager who will perform blastomere biopsy (SLC T15a).

Provisions are in place for patients to have access to a genetic counsellor (CoP Guidance 10.11).

B. Equipment

The centre has suitable equipment to carry out embryo testing.

The centre has submitted documentation demonstrating that the equipment and consumables that will be used for embryo biopsy, including the OCTAX NaviLase (laser) and the OCTAX EyeWare imaging software has been validated (SLC T24).

C. Processes

The centre has standard operating procedures (SOPs) for embryo biopsy processes and the preparation of samples for transport to the testing laboratory (SLC T33b).

The SOPs document that any information derived from tests will not be used to select embryos of a particular sex for social reasons (SLC T88b), that embryo testing can only be carried out for those genetic conditions that are expressly authorised by the Authority (SLC T89) and that embryos from which biopsies have been taken, or resulting from gametes from which biopsies have been taken, should not be transferred with any other (non-biopsied) embryos in the same treatment cycle.

Sufficient evidence has been provided to demonstrate that the procedures to be used for blastomere biopsy have been validated as required by SLC T72.

Quality indicators (QI's) for clinical pregnancy rates following embryo biopsy have been established, including Blastocyst biopsy degeneration rates (SLC T35).

D. Genetic testing

The genetic testing will be conducted by Genesis Genetics Ltd or by Reprogenetics UK Ltd. The Genesis Genetics Ltd laboratory and Reprogenetics UK Ltd are accredited by CPA (SLC T21). The decision on which genetic service that will be used will be decided by the clinical team on a case by case basis, taking advice from the clinical geneticist and genetic counsellor.

The centre has a third party agreement in place with both the testing laboratories which meet the requirements of SLC T114.

E. Patient information

Two information leaflets relating to PGS and PGD were submitted with the application. These were reviewed against relevant guidance in the Code of Practice. The information leaflets provide all relevant information and meet the requirements set out in the CoP.

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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, and embryo or to a 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
No critical non compliances were noted during this desk based evaluation.			

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 to a 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	Executive Review
No major non compliances were noted during this desk based evaluation.			

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	Executive Review
No ‘other’ non compliances were noted during this desk based evaluation.			

Additional information from the Person Responsible