Initial Application for a Licence Inspection Report

Date of Inspection: 20 December 2011
Length of inspection: 3.5 hours
Inspectors: Vicki Lamb
Paula Nolan

Inspection details:
The report covers the pre-inspection analysis, the visit and information received from the centre between 7 September 2011 and 14 January 2012.

Date of Licence Committee: 26 January 2012

Purpose of the Inspection Report
The purpose of the inspection is to assess whether centres are complying with the Human Fertilisation and Embryology (HF&E) Act 1990 (as amended), the Human Fertilisation and Embryology (HF&E) Act 2008 and the Code of Practice (CoP), to ensure that centres are providing a quality service for patients. The report summarises the findings of the initial inspection highlighting areas of good practice, as well as areas where further improvement is required to improve patient services and meet regulatory requirements. It is primarily written for the Authority's Licence Committee which makes the decision about the centre's licence application.

Centre details

Centre name	Brighton Fertility Associates
Centre number	0322
Centre address	Lower ground floor, Olivier House, 18 Marine Parade, Brighton, BN2 1TL
Proposed Person Responsible	Suzy Duffy
Proposed Licence Holder	Carolyn Croucher
Proposed date for issue of licence	1 February 2012

Contents

Report to Licence Committee

Brief description of the centre and its licensing history:

An initial enquiry was received by the HFEA from Brighton Fertility Associates in November 2010, regarding licensing requirements for a donor sperm storage and insemination centre.

The Brighton Fertility Associates centre is situated within a converted grade two listed building. The centre is in the process of becoming registered with the Care Quality Commission (CQC), and was inspected on 22 December 2011.

Activities of the Centre:

The proposed Person Responsible (PR) initially applied for a treatment (insemination) and storage licence. However, the proposed PR has now decided to recruit sperm donors and store donor sperm only at present, in order to build up a bank of donor sperm, and intends to apply for a variation to include use of gametes at a later date if she wishes to provide this service.

The application is for a licence to undertake the following activities:
Procuring gametes
Processing gametes
Distribution of gametes
Storage of gametes

Summary for licensing decision

In considering overall compliance, the inspection team considers that they have sufficient information drawn from documentation submitted by the centre prior to inspection and from observations and interviews conducted during the inspection visit to conclude that:

- the proposed PR is suitable and will be able to discharge her duty under section 17 of the HF&E Act 1990 (as amended)
- the premises are suitable
- the practices are suitable
- the centre has submitted appropriately completed documentation in accordance with General Direction 0008, in application for the new licence
- the centre has submitted an application fee to the HFEA in accordance with requirements

The Licence Committee is asked to note that at the time of the inspection there were a number of areas of practice that required improvement, including three other areas of non-compliance or areas of poor practice.

Since the inspection visit the PR has confirmed that the following recommendations have been fully implemented.

Other areas of practice that require improvement:

- The witnessing standard operating procedure (SOP) should be updated to include the requirement to cross check information against patient records.

- The complaints poster should be updated to include the new address for the HFEA.

- The information sheets should be amended to reflect the requirements of General Directions 0001, CoP Guidance Note 11.24d and CoP Guidance Note 11.24k.

The Licence Committee is asked to note that there are no areas of practice that still require improvement.

Recommendation to the Licence Committee

The inspectorate considers that overall there is sufficient information available to recommend the granting of the centre's licence for a period of two years without additional conditions. In making this recommendation it is noted that the PR has responded to all recommendations made in this inspection report. Further to this the inspectorate recommends the appointment of the proposed PR and the appointment of the proposed Licence Holder (LH).

Details of inspection findings

1. Protection of patients and children born following treatment

Focus

The purpose of the inspection was to assess whether the centre:

- conducts all licensed activities with skill and care and in an appropriate environment, in line with good clinical practice, to ensure optimum outcomes and minimum risk for patients, donors and offspring
- takes into account the welfare of any child who may be born as a result of the licensed treatment provided by the centre, and of any other child who may be affected by that birth
- ensures that all premises, equipment, processes and procedures used in the conduct of licensed activities are safe, secure and suitable for the purpose
- reports all adverse incidents (including serious adverse events and reactions) to the HFEA, investigates all adverse incidents and shares lessons learned.

▶ **Witnessing and assuring patient and donor identification** (Guidance Note 18)
Evidence of how the centre demonstrates potential future compliance The proposed PR provided a copy of the SOP for witnessing (Standard Licence Condition (SLC) T33b). This covers all critical points where witnessing is required, but some amendments are needed (see below). Witnessing, and the documentation of witnessing, will take place at the time the relevant procedure takes place and will be recorded in the donor's notes (SLC T71). The centre has set quality indicators (QIs) relating to witnessing, and plans to audit against these QIs by December 2012 (SLC T35 and T36). Donors will be required to provide photographic identification each time they attend the centre (CoP Guidance Note 18.17).
What the centre could do better. The witnessing SOP should include the requirement to cross check information against patient records (CoP Guidance Note 18.4).

Patient selection criteria and laboratory tests

- Procuring, processing and transporting gametes and embryos (Guidance Note 15)
- Counselling (Guidance Note 3)

Evidence of how the centre demonstrates potential future compliance

The proposed PR gave the inspection team access to SOPs for licensed activities as well as for other activities that will be carried out (SLC T33b). The centre will only be recruiting sperm donors and storing donor sperm. No donors will produce sperm off-site.

Critical processing procedures have been validated (SLC T72) and evidence of this was seen during the inspection.

All donors will be offered counselling (HF&E Act 1990 (as amended) schedule 3, 3(1a)). Donors can be seen for counselling at the centre or at the counsellor's premises if preferred. Counselling notes will be kept in a locked filing cabinet at the counsellor's premises. The counsellor is able to refer donors to genetic or oncology counsellors if necessary.

What the centre could do better

Nothing noted

Donor recruitment, assessment and screening (Guidance Note 11)
Payments for Donors (Guidance Note 13)
Donor assisted conception (Guidance Note 20)

Evidence of how the centre demonstrates potential future compliance

There is a SOP for the process to be followed when selecting and recruiting sperm donors (SLC T33b). This documents that donors will be selected on the basis of their age, health and medical history and screening results (SLC T52).

Arrangements for appropriate screening are in place, including screening for additional conditions when required (SLC T52). Screening will be performed in a laboratory which holds Clinical Pathology Accreditation (CPA accreditation) (SLC T53a).

Donor sperm samples will be quarantined for a minimum of 180 days (SLC T53c).

QIs relevant to the selection and recruitment of donors have been established (SLC T35).

The centre will be able to provide donors with information on the number of children born as a result of donation, the sex of those children and their year of birth if requested (HF&E Act 1990 (as amended) 31ZD(3)).

Sperm donors will be reimbursed in line with General Direction 0001. The amount reimbursed will be recorded and receipts provided by the donor will be retained.

No treatment will be provided at this centre.

What the centre could do better

Nothing noted

Good clinical practice

- Quality management system (Guidance Note 23)
- Traceability (Guidance Note 19)
- Validation (Guidance Note 15)
- Equipment and materials (Guidance Note 26)
- Premises – suitability of the premises and air quality (Guidance Note 25)
- Adverse incidents (Guidance Notes 27)
- Third party agreements (Guidance Note 24)

Evidence of how the centre demonstrates potential future compliance

The centre has a quality management system (SLC T32), including a quality manual and SOPs (SLC T33) and has established QIs for its procedures (SLC T35). These QIs are due to be assessed by December 2012. Documents were seen to be subject to document control, with version numbers and review dates (SLC T34). There will be an annual directors' review, which will review the effectiveness of the quality management system (CoP Guidance Note 23.3g).

The centre has written procedures in place to ensure the traceability of all gametes, and any equipment or material that will come into contact with them, from their procurement to their distribution (SLC T99).

The proposed PR provided documents evidencing that the centre's processes and equipment have been validated (SLC T24 and T72).

The fridge is continuously monitored using a data logger, and additional manual temperature measurements will also be taken. The storage dewars will be monitored and are fitted with alarms that are connected to an autodialler (SLC T24). Where measurements are outside the centre's specified parameters, corrective actions will be recorded and implemented. There is a low oxygen monitor in place in the laboratory.

Pipettors and thermometers will be calibrated against a traceable standard and certified (SLC T24).

Where possible, medical devices will be CE marked (SLC T30).

The premises appeared appropriate for the centre's proposed activities and should provide a safe, clean and private environment for donors and centre staff. There are locks on the laboratory and consulting room doors and a lockable cabinet in the consulting room for donor notes The centre was inspected by the CQC on 22 December 2011 and is awaiting registration.

The air quality of the laboratory has been tested, and meets the requirements of SLC T20.

The centre will be able to comply with requirements for investigating and reporting all adverse incidents to the HFEA, and the SOP for this was provided to the inspection team (SLC T118, T119, T120 and T121).

The centre has established third party written agreements with suppliers who provide or will provide goods or services that influence the quality and safety of gametes (SLC T111). One of the centre's third party agreements was reviewed on inspection and found to be compliant with SLC T114.

What the centre could do better

Nothing noted

Multiple Births (Guidance Note 7)

Evidence of how the centre demonstrates potential future compliance

This is not relevant as no treatment services will be provided at the centre.

What the centre could better

N/A

Staff engaged in licensed activity

- Person Responsible (Guidance Note 1)
- Staff (Guidance Note 2)

Evidence of how the centre demonstrates potential future compliance

The proposed PR has academic qualifications in the field of biological sciences and has more than two years of practical experience which is directly relevant to the activity to be authorised by the licence as required by the HF&E Act 1990 (as amended) section 16(2)(c)(i) and (ii) . She is registered with the Health Professions Council (SLC T14) and is also the lead scientist at the centre. The proposed PR has successfully completed the HFEA PR Entry Programme (certificate number T/1196/8). Two satisfactory references, as to the character and experience of the proposed PR, have been received.

The proposed LH is registered with the General Medical Council (SLC T14 and T16), has a licence to practice and is also on the Specialist Register for Obstetrics and Gynaecology. She has indicated her willingness to become LH at this centre.

The other clinical and scientific staff at the centre are registered with the relevant professional bodies (SLC T14).

The counsellor has over 19 years' experience within the field of infertility and has been the

lead counsellor at centre 0254 for the last five years. He has been a member of the UK Council for Psychotherapy since 2000 and a member of the British Association for Counselling and Psychotherapy since 1996.

There is an organisational chart for the centre which was provided to the inspection team (SLC T11).

The proposed PR provided the inspection team with a list of competence assessments that staff will need to complete to ensure they are competent in performing their tasks (SLC T15).

What the centre could do better

Nothing noted

Welfare of the Child (Guidance Note 8)

Evidence of how the centre demonstrates potential future compliance

This is not relevant as no treatment is offered at the centre.

What the centre could do better.

N/A

2. Patient Experience

Focus

The purpose of the inspection visit was to assess whether the centre:

- treats prospective and current patients and donors fairly, and ensures that all licensed activities are conducted in a non-discriminatory way
- has respect for the privacy, confidentiality, dignity, comfort and well being of prospective and current patients and donors
- gives prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions
- ensures that patients and donors have provided all relevant consents before carrying out any licensed activity

Treating donors fairly • Confidentiality and privacy (Guidance Note 30) • Complaints (Guidance Note 28)
Evidence of how the centre demonstrates potential future compliance The laboratory and consulting room have lockable doors, and there is a lockable cabinet in the consulting room to keep donor records in, thereby ensuring confidentiality (SLC T43). The centre has a complaints procedure and a complaints poster is displayed in the reception area, detailing who to contact in the event of a complaint.
What the centre could do better. The complaints poster displayed in the reception area needs to be updated to include the new address for the HFEA.

Information • Information to be provided prior to consent (Guidance Note 4) • Information about legal parenthood (Guidance Note 6)
Evidence of how the centre demonstrates potential future compliance Sperm donor information sheets were submitted pre-inspection and were found to provide information about the consequences of donation, analytical tests, confidentiality, consent and the availability of counselling (SLC T58). Donors are also informed of their legal responsibility and what information can be disclosed to donor-conceived people and their parents. Information about legal parenthood was not inspected as no treatment will be provided at the centre.
What the centre could do better. On one sheet, information on reimbursement for donors needs to be amended to reflect the requirements of General Directions 0001. The other information sheet that includes

information on reimbursement meets the requirements of General Directions 0001.

Donor information needs to be amended to include that they should tell the centre of any medical information that comes to light after donation that may have health implications for any woman who receives treatment with the gametes or for any child born as a result of treatment (CoP Guidance Note 11.24d).

Donor information needs to be amended to include the importance of supplying up-to-date contact information so they can be informed if and when disclosure of identifying information will be made (CoP Guidance Note 11.24k).

Consent

- Consent to treatment, storage, donation, training and disclosure of information (Guidance Note 5)

Evidence of how the centre demonstrates potential future compliance

Centre-specific sperm donor consent forms were submitted pre-inspection along with the SOP for taking consent (SLC T57 and T33b), and these were considered to be fit for purpose. The centre will also ensure that HFEA consents are completed.

What the centre could do better

Nothing noted

3. Protection of gametes and embryos

Focus

The purpose of the inspection was to assess whether the centre has respect for the special status of the embryo when conducting licensed activities

Legal Requirements [Human Fertilisation and Embryology Act 1990 (as amended)] • Licensed activities only take place on licensed premises • No money or other benefit is given or received in respect of the supply of gametes or embryos unless authorised by the Authority
Evidence of how the centre demonstrates potential future compliance The proposed PR confirmed that licensed activities will only take place on licensed premises. Sperm donors will be reimbursed in line with General Directions 0001. The amount reimbursed will be recorded and receipts provided by the donor will be retained.
What the centre could do better Nothing noted

Storage of gametes • Storage of gametes (Guidance Note 17)
Evidence of how the centre demonstrates potential future compliance There are SOPs in place for the procedure for storing gametes (SLC T33b). These include the requirement to screen donors prior to their material being placed in store (SLC T52). Gametes from unscreened donors will not be stored. The proposed PR described the bring-forward system the centre will implement to ensure that gametes are not storage beyond the statutory storage period.
What the centre could do better Nothing noted

Distribution and / or receipt of gametes and embryos

- Distribution of gametes and embryos (Guidance Note 15)

Evidence of how the centre demonstrates potential future compliance

Donor sperm will be distributed from the centre to other centres within the UK. SOPs for these procedures were provided to the inspection team and contained requirements to package the gametes appropriately (SLC T105), use an appropriate shipping container (SLC T106), label the container appropriately (SLC T107) and gave information on when a shipping container is unsuitable for use (SLC T108). There is a SOP for the recall procedure when a sample has been distributed, and this includes the requirement to report this recall to the HFEA as an incident (SLC T122).

What the centre could do better

Nothing noted

Use of embryos for training staff (Guidance Note 22)

Evidence of how the centre demonstrates potential future compliance

No embryos will be kept or used at this centre and therefore no embryos will be used in training.

What the centre could do better

N/A

4. Good governance and record keeping

Focus

The purpose of the inspection was to assess whether the centre:

- maintains accurate records and information about all licensed activities
- conducts all licensed activities with regard for the regulatory framework governing treatment involving gametes and embryos within the UK, including
    - maintaining up-to-date awareness and understanding of legal obligations
    - responding promptly to requests for information and documents from the HFEA
    - co-operates fully with inspections and investigations by the HFEA or other agencies responsible for law enforcement or regulation of healthcare

▶ **Record keeping** • Record keeping and document control (Guidance Note 31)
Evidence of how the centre demonstrates potential future compliance The proposed PR demonstrated a good understanding of the requirements for maintaining accurate records and information in accordance with the CoP, including those specified by the Authority in Directions. Donor forms will be submitted securely to the HFEA via the electronic data interchange (EDI) system.
What the centre could do better Nothing noted

▶ **Legal requirements** [Human Fertilisation and Embryology Authority 1990 (as amended)] • Obligations and reporting requirements of centres (Guidance Note 32)
Evidence of how the centre demonstrates potential future compliance The centre has submitted all necessary information to support its application for a licence. The proposed PR is aware of the requirement to submit data to the HFEA within the appropriate timelines.
What the centre could do better Nothing noted

Disclosure of information

- Confidentiality and privacy (Guidance Note 30)
- Disclosure of information, held on the HFEA Register, for use in research

Evidence of how the centre demonstrates potential future compliance

Sperm donor records will be stored in a locked cabinet in a lockable consulting room (SLC T43). Donors will be informed of what information may be disclosed to donor-conceived people and their parents.

At present, information held about donors on the HFEA register is not available for disclosure to researchers. Therefore, this aspect was not inspected.

What the centre could do better

Nothing noted

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 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
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 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
None			

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
The witnessing SOP should include the requirement to cross check information against patient records (CoP Guidance Note 18.4).	The witnessing SOP should be updated to include the requirement to cross check information against patient records. This should be updated prior to sperm donors being recruited.	The SOP has been amended to strengthen this aspect of witnessing.	The inspectorate considers this to be an acceptable response.
The complaints poster displayed in the reception area needs to be updated to include the new address for the HFEA.	The complaints poster should be updated to include the new address for the HFEA. This should be updated prior to sperm donors being recruited.	This has already been actioned and the new address is displayed at reception.	The inspectorate considers this to be an acceptable response.
Donor information needs to be amended to include correct information on reimbursement for donors (Directions 0001), that donors should tell the centre of any medical information that comes to light after donation (CoP Guidance Note 11.24d) and that donors should supply up-to-date	The information sheets should be amended to reflect the requirements of Directions 0001, CoP Guidance Note 11.24d and CoP Guidance Note 11.24k. This should be updated prior to sperm donors being recruited.	This has been amended to be general, in case of further changes in reimbursements. All written information and the website have been amended. The initial donor interview has been amended to include the statement that donors are aware that they should provide	The inspectorate considers this to be an acceptable response.

contact information (CoP Guidance Note 11.24k).		any medical information if any future changes that may be relevant.	

Additional information from the Person Responsible
All suggestions for improvement have been actioned and now in place. Recruitment is now taking place using these amended documents. All amendments have also been applied to the website which was changed before going live.

HFEA Licence Committee Meeting

26 January 2012

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

Minutes – Item 1

Centre 0322 (Brighton Fertility Associates) – Initial Inspection Report

Members of the Committee: David Archard (lay) Chair Anna Carragher (lay) Rebekah Dundas (lay) (videoconference) Sue Price (professional) Debbie Barber (professional) Jane Dibblin (lay)	Committee Secretary: Lauren Crawford Legal Adviser: Graham Miles, Morgan Cole

Declarations of Interest: members of the Committee declared that they had no conflicts of interest in relation to this item.

The following papers were considered by the Committee

- Cover sheet
- Initial inspection report
- Completed application form
- CV of proposed PR
- References (x2) for proposed PR
- CV of proposed LH

The Committee also had before it

- HFEA Protocol for the Conduct of Licence Committee Meetings and Hearings
- 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); and
- 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 Directions 0000 – 0012

- Guide to Licensing
- Compliance and Enforcement Policy
- Policy on Publication of Authority and Committee Papers

Background

1. The Committee noted that an initial enquiry was received by the HFEA from Brighton Fertility Associates in November 2010, regarding licensing requirements for a donor sperm storage and insemination centre.

2. The Committee noted that The Brighton Associates Fertility centre is situated within a converted grade two listed building located at:

   Lower ground floor
   Olivier House
   18 Marine Parade
   Brighton
   BN2 1TL

3. The Committee noted that the application is for a licence to undertake the following activities:

   Procuring gametes
   Processing gametes
   Distribution of gametes
   Storage of gametes

4. The Committee noted that at the time of the inspection, the Inspectorate reported that there were a number of areas on practice that required improvement, including three other areas of non-compliance or poor practice

5. The Committee noted that since the inspection the Person Responsible (PR) has provided evidence to the Inspectorate that the three other areas of non-compliance have been fully implemented.

6. The Committee noted the Inspectorate's recommendation to grant the centre's licence for a two year period without additional conditions and to also appoint the proposed PR and Licence Holder (LH).

Discussion

7. The Committee referred to its decision tree. It was satisfied that the appropriate application and fee had been submitted, and contained the supporting information required by General Direction 0008.

8. The Committee was satisfied that the character of the proposed PR, Suzy Duffy, is such as required for the supervision of the licensed activities and

that the PR will discharge the duties under section 17 of the HF&E Act 1990 (as amended).

9. The Committee noted that the proposed PR has academic qualifications in the field of biological sciences and has more than 2 years of practical experience which is directly relevant to the activity to be authorised by the licence as required by the HF&E Act 1990 (as amended) section 16(2)(c)(i) and (ii). She is registered with the Health Professions Council (SLC T14) and is also the lead scientist at the centre. She has successfully completed the HFEA PR Entry Programme and has 2 satisfactory references.

10. The Committee noted the PR's commitment to the centre and the fact that all recommendations from the Inspectorate had been fully implemented.

11. The Committee was satisfied regarding the suitability of the proposed LH, Carolyn Croucher. She is registered with the General Medical Council (SLC T14 and T16), has a licence to practice and is also on the Specialist Register for Obstetrics and Gynaecology and she has indicated her willingness to become LH at this centre.

12. The Committee was satisfied that the licence application concerns treatment, storage or non-medical fertility services which relate to gametes or embryos intended for human application.

13. The Committee was satisfied that premises to be licensed are suitable for the conduct of licensed activities based on evidence provided within the report.

14. The Committee referred to 'Guidance on periods for which new or renewed licences can be granted'. The Panel took into account matters set out in paragraph 4.3 and noted paragraph 4.4 of the guidance which states [The Executive Licensing Panel] will normally only grant a renewal licence for treatments/ storage non-medical fertility services licence for a period of up to four years where the evidence before it reveals no concerns in the matters specified in paragraph 4.3.

15. The Committee noted PR initially applied for a treatment (insemination) and storage licence. However, the PR has now decided to recruit sperm donors and store donor sperm only at present, in order to build up a bank of donor sperm, and intends to apply for a variation to include use of gametes at a later date if she wishes to provide this service.

16. The Committee praised the PR and Inspectorate for working well together to produce the report.

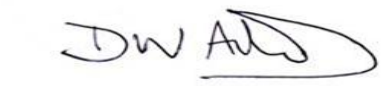
Decision

17. The Panel agreed to appoint Suzy Duffy as the Person Responsible for Brighton Associates Fertility Centre (Centre 0322) with immediate effect, in accordance with section 18A of the HFE Act 1990 (as amended).

18. The Panel agreed to appoint Carolyn Croucher as the Licence Holder for Brighton Associates Fertility Centre (Centre 0322) with immediate effect.

19. The Committee agreed to grant the centre's licence for a period of two years with no additional conditions.

Signed: Date: 20/02/2012



David Archard (Chair)