New Premises Licence Inspection Report

Date of Inspection: 28 June 2011
Length of inspection: 5 hours
Inspectors: Paula Nolan, Vicki Lamb, Claudia Lally (observing)

Inspection details:
The report covers the pre-inspection analysis, the visit and information received from the centre between 13 January 2011 and 15 July 2011.

Date of Licence Committee: 28 July 2011

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, to ensure that centres are providing a quality service for patients. The report summarises the findings of the licence renewal 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	NewLife Fertility Centre
Centre number	0321
Centre address	The Pines, 2 The Parade, Epsom, Surrey, KT18 5DH
Proposed Person Responsible	Dr Amin Gafar
Proposed Licence Holder	Miss Viji Kakumani
Date of proposed licence issue	28 July 2011

Contents

Report to Licence Committee

Brief description of the centre and its licensing history:

An initial enquiry form was received by the HFEA from the NewLife Fertility Centre (private healthcare provider), in January 2011, regarding licensing requirements for an IVF centre, which they plan to have operational by June/July 2011.

The NewLife fertility centre is situated within a converted three story grade two listed building. As well as licenced fertility treatments the centre is also planning to offer a well woman service, male urology service, fetal medicine consultations, and alternative therapies including acupuncture and massage therapy. The centre is registered with the Care Quality Commission (CQC) having undergone a CQC inspection on 1 June 2011.

Proposed activities of the centre:
The centre will provide treatment to privately funded patients. The proposed Person Responsible (PR) has stated that the centre hopes, in the first year, to provide treatment to 100 patients and has the capacity to eventually provide 1500 treatment cycles. The proposed activities will include: procurement and distribution of gametes and embryos, processing of gametes and embryos, insemination, In Vitro Fertilisation (IVF), Intra Cytoplasmic Sperm Injection (ICSI), storage of eggs, storage of sperm, and storage of embryos. The centre will not be recruiting sperm or egg donors or offer a surrogacy service

The proposed PR initially applied for preimplantation genetic diagnosis and preimplantation genetic screening to be included on the centre's licence. However, following discussions with the proposed PR during the inspection visit, the proposed PR stated that he would like to withdraw the application to provide these services and that they would apply at a future date for these two activities to be added.

Recommendation to the Licence Committee

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 as he is a consultant gynecologist and obstetrician with over 16 years experience working in the field of assisted reproductive technology. The proposed PR is registered with the General Medical Council and has a licence to practice with no restrictions or conditions. The proposed PR's references raised no concerns and gave testimony to his suitability and good character. Though interviewing the proposed PR, during the inspection visit, and through the successful completion of the PR Entry programme it is the opinion of the inspectorate that the proposed PR will discharge their duty under section 17 of the HF&E Act 1990 (as amended).
- The proposed premises are suitable - from the submitted floor plan and a tour of the premises during the inspection visit it is the opinion of the inspectorate that the premises are suitable to carry out licensed treatment. The centre has the required facilities and equipment to ensure the safety of patients, gametes and embryos. The centre is secure and the dewars that will be used to store patient's gametes and embryos are almared.
- The proposed practices are suitable - from the submitted information and findings of the inspection visit it is the opinion of the inspectorate that the proposed practices are suitable to carry out licensed treatment. The centre has provided evidence that all the practices to be used in the course of licensed treatment have been validated.
- 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 are no areas of practice that require improvement.

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. Further to this the inspectorate recommends the appointment of the proposed Person Responsible and the appointment of the proposed Licence Holder.

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 appropriately

▶ **Witnessing and assuring patient and donor identification** (Guidance Note 18)
Evidence of how the centre demonstrates potential future compliance with this Guidance Note. The proposed PR provided copies of Standard Operating Procedures (SOPs) relating to witnessing. These were seen to cover all the required witnessing points. The centre will be using electronic witnessing, and additional manual witnessing is included in the SOP at the points of mixing eggs and sperm, injecting sperm into eggs and placing gametes/embryos into or removing from storage. Additionally, the action to be taken in the case of power failure or server failure is covered in the SOP. Thus ensuring that the centre will double check the identification of gametes and embryos and the patient or donor to whom they relate at all critical points of the clinical and laboratory process. Ensuring that patients receive treatment using the correct gametes or embryos (Standard Licence Condition (SLC) T71). The centre has set quality indicators relating to witnessing and plans to conduct regular audits of the practice (SLC T35).
What the centre could do better. No areas were identified as part of this inspection process.

▶ **Patient selection criteria and laboratory tests** (Guidance Note 11)
Evidence of how the centre demonstrates potential future compliance with this Guidance Note. The proposed PR explained that patients will be provided with treatment according to their medical history and therapeutic indications and justification for treatment will be noted in the patient's medical records (SLC T49). The proposed PR provided copies of SOPs for all licenced activities as well as for other activities that will be carried out in the course of

providing treatment services (SLC T33 b).

The proposed PR provided evidence that patient screening/tests will be carried out in an accredited laboratory (SLC T 51).

The SOPs for sperm and embryo cryopreservation include the requirement to check that appropriate screening has been performed before the samples are placed in storage (SLC T50).

What the centre could do better.

No areas were identified as part of this inspection process.

Donor recruitment, assessment and screening (Guidance Note 11)
Donor assisted conception (Guidance Note 20)
Only applicable to centres licensed to carry out treatment using donor gametes and / or embryos

Evidence of how the centre demonstrates potential future compliance with this Guidance Note.
This section is not applicable to this centre at this time as they do not propose to provide donor assisted conception.

What the centre could do better.
N/A

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 with these Guidance Notes.

The centre has a quality manager and a quality management system. The centre has established quality indicators for clinical, laboratory and administration procedures. These will be measured and assessed at regular intervals (SLC T32, T33, T34, T35, and T36).

The centre has written procedures in place to ensure the traceability of all gametes and embryos and any equipment or material that will come into contact with the gametes and embryos from their procurement to their use in treatment or disposal. The SOP for traceability was reviewed at inspection and is compliant with the HFEA Code of Practice, 8TH edition (CoP) requirements.

The proposed PR provided the scientific inspector with documents evidencing that the centre's processes and equipment has been validated (SLC T72).

The premises appeared appropriate for the centre's proposed activities and should provide a safe, clean and private environment for patients and centre staff. The centre has undergone the necessary health & safety and fire inspections and documented evidence was provided by the proposed PR of the completed processes.
The air quality of the laboratory has been tested, and the results for this were provided to the scientific inspector. The air quality was seen to meet the requirements of Licence Condition T20.

The centre will be able to comply with the CoP requirements for reporting all adverse incidents to the HFEA (SLC T106). There are plans for regular team meetings where incidents and complaints will be discussed and HFEA alerts will be disseminated to all staff.

The centre has established third party written agreements with all suppliers who provide or will provide goods or services that influence the quality and safety of gametes and embryos (SLC T99). One of the centre's third party agreements was reviewed on inspection and found to be compliant with CoP requirements (SLC T102).

What the centre could do better.
No areas were identified as part of this inspection process.

Multiple Births (Guidance Note 7)

Evidence of how the centre demonstrates potential future compliance with this Guidance Note.

The centre has a multiple birth minimisation strategy in accordance with HFEA General Direction 0003. The centre will maintain a summary log of cases in which multiple embryos have been transferred to any patient who meets the criteria for a single embryo transfer as set out in its multiple birth minimisation strategy. The centre has a plan to audit its strategy on a quarterly basis.

What the centre could better

No areas were identified as part of this inspection process.

Staff engaged in licensed activity

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

Evidence of how the centre demonstrates potential future compliance with these Guidance Notes.

The proposed PR is registered with the General Medical Council and has a licence to practice with no restrictions or conditions. He is also a Fellow of the Royal College of Obstetricians and Gynaecologists. He has over sixteen years of experience within the field of assisted conception. He has successfully completed the Person Responsible Entry

Programme.

The proposed Licence Holder is registered with the General Medical Council and has a licence to practice with no restrictions or conditions. She has over 20 years experience within the field of assisted conception. The proposed Licence Holder is also on the Specialist Register for Obstetrics and Gynaecology.

The lead scientist is registered with the Health Professions Council and evidence of this was seen by the scientific inspector.
The lead nurse is registered with the Nursing and Midwifery council and has a licence to practise with no restrictions or conditions.

The two counsellors are both accredited members of the British Infertility Counselling Association.

What the centre could do better.

No areas were identified as part of this inspection process.

Welfare of the Child (Guidance Note 8)

Evidence of how the centre demonstrates potential future compliance with this Guidance Note.

The centre has a SOP for assessing welfare of the child (SLC T33b). The proposed PR and lead nurse described the process for evaluating the welfare of the child (SLC T56). Any issues would be raised and discussed at the proposed team meetings before any final decision was made. The proposed PR also explained that the counsellors, if required, would be involved in the assessment process.

What the centre could do better.

No areas were identified as part of this inspection process.

Embryo Testing – *only applicable to centres licensed to carry out preimplantation genetic diagnosis and screening)*

- Preimplantation genetic screening (Guidance Note 9)
- Embryo testing and sex selection (Guidance Note 10)

Evidence of how the centre demonstrates potential future compliance with these Guidance Notes.

This section is not applicable to this 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 patients fairly • Treating patients fairly (Guidance Note 29) • Confidentiality and privacy (Guidance Note 30) • Complaints (Guidance Note 28) • Provision of a costed treatment plans (Guidance Note 4)
Evidence of how the centre demonstrates potential future compliance with these Guidance Notes. This could not be assessed at this was an initial inspection. However, the centre does have a complaints policy and an audit of patient satisfaction is planned for each quarter. The proposed PR explained that the centre has an anti-discrimination policy and that equality and diversity training will be part of the staff induction programme. The proposed PR explained that before treatment is offered the centre will provide the person seeking treatment, and their partner (if applicable) with a personalised costed treatment plan (Guidance Note 4.3).
What the centre could do better. No areas were identified as part of this inspection process.

Information • Information to be provided prior to consent (Guidance Note 4) • Information about storage of embryos (including cooling off periods) • Information about Intracytroplasmic sperm injection (Guidance Note 21)
Evidence of how the centre demonstrates potential future compliance with these Guidance Notes. Patient information sheets were submitted pre-inspection and were found to provide information about the nature of treatment, consequences and risks, analytical tests, confidentiality, consent and the availability of counselling (SLC T58).
What the centre could do better.

No areas were identified as part of this inspection process.

Consent • Consent to treatment, storage, donation, training and disclosure of information (Guidance Note 5) • Consent to legal parenthood (Guidance Note 6)
Evidence of how the centre demonstrates potential future compliance with these Guidance Notes. The centre provided the inspection team with the SOPs for obtaining consent, and these were considered to be fit for purpose (SLC T33b). Quality indicators relating to consent have been set and these were seen by the team (SLC T35).
What the centre could do better. No areas were identified as part of this inspection process.

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
- Only permitted embryos are used in the provision of treatment services
- Embryos are not selected for use in treatment for social reasons
- Embryos are not created by embryo splitting
- Embryos are only created where there is a specific reason to do so which is in connection with the provision of treatment services for a particular woman
- Embryos are only stored if those embryos where created for a woman receiving treatment services or from whom a third party agreement applies
- Embryos which are or have been stored are not given to a person, other than in the course of providing treatment services, unless that person is a person to whom a licence applies
- 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 with the legal requirements.
As this was a new premises inspection, and therefore no work had taken place and no embryos were in store, it was not possible to inspect against these areas.

What the centre could do better.

No areas were identified as part of this inspection process.

Storage of gametes and embryos

- Storage of gametes and embryos (Guidance Note 17) – *only applicable for centres licensed to store gametes and / or embryos*

Evidence of how the centre demonstrates potential future compliance with this Guidance Note.

There are SOPs in place for the procedure for storing gametes and embryos (SLC T33b). These include the requirement to screen patients prior to their material being placed in store (SLC T50).

The laboratory manager described the bring forward system the centre will implement to ensure that gametes and embryos are not storage beyond the statutory storage period.

The centre has set quality indicators relating to material that will be held in storage and evidence of this was provided to the inspection team (SLC T35).

What the centre could do better. No areas were identified as part of this inspection process.

▶ **Use of embryos for training staff** (Guidance Note 22) – *only applicable for centres which use embryos to train staff*
Evidence of how the centre demonstrates potential future compliance with this Guidance Note. No embryos have been used for training and the staff have no intention of doing this at present.
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 with this Guidance Note. The centre has a quality manager who is further developing the quality management system (SLC T32, T33b and T35). The centre is working towards ISO 9001:2000 accreditation. The proposed PR demonstrated a good understanding of the requirements of maintaining accurate records and information in accordance with the CoP, including those specified by the Authority in Directions.
What the centre could do better. No areas were identified as part of this inspection process.

▶ **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 with this Guidance Note. The centre has submitted all necessary information to support its application for a treatment and storage licence. They are aware of the requirement to submit treatment data to the HFEA.
What the centre could do better. No areas were identified as part of this inspection process.

Disclosure of information

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

Evidence of how the centre demonstrates potential future compliance with this Guidance Note.

Patient records will be stored in locked filing cabinets in a room specifically allocated for this purpose. The room can only be accessed by centre staff via a secure corridor that is not accessible to patients or members of the public. The proposed PR explained that the room will always be locked and assess provided by one of two members of staff who hold the keys (SLC T43).

The centre has various SOPs to ensure that all information is kept confidential and only disclosed in circumstances permitted by law (SLC T43 and T33b).

What the centre could do better.
No areas were identified as part of this inspection process.

Areas of proposed practice that require the attention of the proposed 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.

Areas of potential non compliance in the proposed activities and practices at the new centre

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
Nil noted at time of inspection.			

Additional information from the Person Responsible
I have reviewed the report, and I am happy with the contents and have no comments to add.

HFEA Licence Committee Meeting
28 July 2011

21 Bloomsbury Street London WC1B 3HF

Minutes – Item 3

Centre 0321 – New Treatment and Storage Licence Application

Members of the Committee: David Archard (lay) – Chair Anna Carragher (lay) Sue Price (Professional)	Committee Secretary: Terence Dourado Legal Adviser: Sarah Ellson, Field Fisher

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:

- New Premises Report
- New Treatment and Storage Licence Application
- CV and references for the proposed Person Responsible – Dr Amin Gafar
- CV for the proposed Licence Holder – Miss Viji Kakumani

The Committee also had before it:

- HFEA Protocol for 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)
- 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

Tabled Documents

- General Direction 0008 bundle

Consideration of Application

1. The Committee had regard to its Decision Tree. The Committee was satisfied that the application was submitted by the proposed Person Responsible (PR) in the form required, and contained all the supporting information required by General Direction 0008. The Committee was also satisfied that the appropriate fee had been paid.

2. The Committee was satisfied that the application designated Dr Amin Gafar to act as the Person Responsible (PR).

3. The Committee was satisfied that the licence application concerns treatment and storage services which relate to gametes or embryos intended for human application.

4. The Committee was satisfied that the proposed PR possesses the formal qualifications required because he is registered with the General Medical Council and has a licence to practice with no restrictions or conditions. He has over sixteen years experience of working in the field of assisted reproductive technology including acting as PR for the Lister Fertility Clinic (centre 0006). The Committee was also satisfied that the proposed Licence Holder was a suitable person to hold the licence based upon the information contained within her CV.

5. The Committee was satisfied that the licence application did not concern storage of gametes and embryos not intended for human application.

6. The Committee noted that although the proposed PR initially applied for preimplementation genetic diagnosis and preimplementation genetic screening to be included on the licence he had since withdrawn the application to provide these services for the time being.

7. The Committee was satisfied that the character of the PR is such as is required for supervision of the licensed activities and that the PR will discharge the duties under section 17 of the HF&E Act 1990 (as amended): The proposed PR had appropriately completed the PR entry programme (PREP) based both on the HFEA Code of Practice (CoP), 8th edition. Furthermore, two referees provided by the proposed PR attested to his suitability of character for the post. The Executive are satisfied that the proposed practices are suitable based on the

submitted information and findings of the inspection visit. There were no identified areas of practice that require improvement.

8. The Committee was satisfied that the premises to be licensed are suitable for the conduct of licensed activities there and noted that the premises appeared to the Executive at inspection, appropriate for the proposed licensable activities. The Executive was satisfied from the submitted floor plan and inspection tour that the premises are suitable to carry out licensed treatment; the Centre has the required facilities and equipment to ensure the safety of patients, gametes and embryos, it is secure, and the dewars that will be used to store patient's gametes are alarmed.

Decision

9. The Committee had regard to the 'Guidance on Periods for which New or Renewed Licences Should be Granted'. The Committee noted paragraph 4.2 of the guidance which states the '[Licence Committee] will normally grant an initial treatment/ storage/ non-medical fertility services licence for up to two years. This is because in granting an initial licence, there will be no history of compliance to support a longer licence'.

10. The Committee granted the Centre a treatment and storage licence of two years with no additional conditions placed upon the licence.

11. The Committee agreed to the appointment of the proposed Person Responsible and the proposed Licence Holder. However, it noted the absence within the application of any reference to a Senior Andrologist. It was unclear whether one would be appointed. The Committee noted that a Quality Manager and Senior Counsellor are yet to be appointed. The Committee requested that this outstanding information (names and CVs) be provided to the Executive as soon as practicable.

Signed: Date: 03/08/2011

David Archard (Chair)