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
22 May 2015

Minutes – item no. 1

Centre 0341 (The Fertility & Gynaecology Academy) – Initial Treatment (including embryo testing) & Storage application

Members of the Panel:	Juliet Tizzard Director of Strategy & Corporate Affairs (Chair) Joanne Anton Policy Manager Paula Robinson Head of Business Planning
Members of the Executive in attendance:	Sam Hartley Head of Governance & Licensing 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 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)
- 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 directions 0000 – 0012
- guide to licensing
- compliance and enforcement policy
- policy on the publication of Authority and committee papers.

Background

1. The Fertility & Gynaecology Academy submitted an initial treatment (including embryo testing) and storage licence application for premises located at 57A Wimpole Street, London W1G 8YP.

2. The application was received by the Inspectorate in October 2014. The Inspectorate carried out a desk-based assessment, followed by an inspection on 19 January 2015.

3. A Licence Committee (LC) considered the centre's application on 15 March 2015 and noted that there was insufficient information available to recommend that a treatment (including embryo testing) and storage licence be granted and agreed to adjourn its decision until the inspectorate was able to reassess the centre's application.

4. The LC noted that this initial application could be considered by the Executive Licensing Panel once all evidence was provided by the centre and reassessed, providing the Inspectorate had no significant concerns.

Consideration

5. The panel considered the papers which included an application form, inspection report, CV of proposed Person Responsible (PR) and Licence Holder (LH) and licensing minutes for the past three years.

6. The panel noted that the proposed PR, Dr Amin Gorgy, holds academic qualifications in the field of medicine. The proposed PR also has more than two years' practical experience which is directly relevant to the activity to be authorised by the licence as required by the HFE Act 1990 (as amended) section 16(2)(c)(i) and (ii) (including acting in the capacity of PR). The proposed PR has successfully completed the HFEA PR Entry Programme.

7. The panel noted the suitability of the proposed Licence Holder (LH), Dr Adel Aziz Eskander.

8. The panel noted that at the time of the subsequent inspection on 7 April 2015 two critical, four major and two other areas of non-compliance were identified. The panel noted in particular the non-compliances relating to staff training and consent to parenthood. The panel noted that since the inspection the PR has provided evidence that some of the recommendations have been implemented including one critical, two major and one other area of non-compliance. The panel noted that the PR has committed to implement the outstanding recommendations within the prescribed timescales.

9. The panel noted the Inspectorate's recommendation to grant the centre's licence for a two-year period without additional conditions and to appoint the proposed PR and LH.

Decision

10. The panel referred to its decision tree.

11. The panel was satisfied that the appropriate application form was submitted. Initially, a treatment and storage application form was submitted by the centre, but this was followed by an inspection for a treatment (including embryo testing) and storage licence, which clarified that the application made by the centre was for a licence including embryo testing.

12. The panel noted that the Inspectorate had received the supporting information required by General Directions 0008 and was satisfied that the fee had been paid.

13. The panel was satisfied that the proposed PR, Dr Amin Gorgy, is suitable and will discharge his duty under section 17 of the HFE Act 1990 (as amended).

14. The panel agreed to appoint Dr Amin Gorgy as the Person Responsible when the new licence comes into effect, in accordance with section 18A of the HFE Act 1990 (as amended).

15. The panel was satisfied with the suitability of the proposed Licence Holder (LH), Dr Adel Aziz Eskander and agreed to appoint him as the Licence Holder when the new licence comes into effect.

16. The panel was satisfied that premises to be licensed (and those of relevant third parties) are suitable for the conduct of licensed activities based on evidence provided within the report.

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

18. The panel was concerned about the critical non-compliance regarding obtaining effective consent to legal parenthood. The panel noted the Inspectorate's recommendation that the PR should not provide treatment using donor sperm until satisfactory evidence of full compliance with the consent to parenthood requirements has been provided to the Inspectorate.

19. Given its concern, the panel considered making this recommendation a non-standard condition. However, given the commitment of the PR in relation to this aspect the panel was reassured that he would adhere to the Inspectorate's recommendation and that no treatment using donor sperm would be provided until satisfactory evidence of compliance had been provided. The panel asked that the Inspectorate revert immediately to a licensing committee should this commitment be broken. On balance, and notwithstanding its concern, the panel agreed that it would not be proportionate to add a non-standard condition to the centre's licence.

20. The panel agreed that copies of standard operating procedures and patient information which are revised should be provided to the Inspectorate prior to providing relevant treatment or by 7 July 2015 at the latest.

21. The panel further agreed that the PR should provide assurance to the Inspectorate that all the relevant staff referred to in the report are suitably trained and requested that the Inspectorate provide an update report within three months to provide evidence that the recommendations made in the report have been addressed. The update report will also provide confirmation of when the centre commenced donor conception treatment.

22. The panel referred to 'Guidance on periods for which new or renewed licences can be granted'. The panel noted paragraph 4.2 of the guidance which states that an initial treatment/storage/non-medical fertility services licence would normally be granted 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.

23. The panel agreed to grant the licence for treatment (including embryo testing) and storage for a period of two years with no additional conditions.

Signed: Date: 3 June 2015

Juliet Tizzard (Chair)

Inspection Report

Purpose of the Inspection Report

This is a report of an assessment and inspection, carried out to determine whether an application for a new licence will meet essential requirements. The Authority's Executive Licensing Panel (ELP) uses the application and this report to decide whether to grant a new licence and, if so, whether any additional conditions should be applied to the licence.

Date of inspection: 7 April 2015

Purpose of inspection: Issue of a licence to carry out Treatment (including embryo testing) and Storage.

Inspection details: The report covers the findings from a desk based assessment of submitted documentation, two inspection visits and communications received from the centre.

Inspectors: Sara Parlett and Gill Walsh

Date of Executive Licensing Panel: 22 May 2015

Centre name	The Fertility & Gynaecology Academy
Centre number	0341
Centre address	57A Wimpole Street London W1G 8YP
Proposed Person Responsible	Dr Amin Gorgy
Proposed Licence Holder	Dr Adel Eskander

Contents

Section 1: Summary report

Brief description of the centre:

The Fertility & Gynaecology Academy is a private clinic in London. The proposed Person Responsible (PR) has applied for a treatment (including embryo testing) and storage licence. The centre proposes providing a full range of fertility services. The inspection team is satisfied that the activities to be carried out at the centre are necessary or desirable in order to provide licensed treatment services.

The clinic currently operates as a satellite of Boston Place (centre 0327). The centre is registered with the CQC for diagnostic and screening procedures and treatment of disease, disorder or injury.

An initial licence application was received by the HFEA in October 2014. A full desk based assessment was followed by an inspection visit on 19 January 2015. On the basis of the information provided in support of the application, the on-site inspection of the premises to be licensed and interviews conducted on the day of the inspection with staff, the inspection team considered that there was insufficient information available to be able to recommend that a licence be granted.

A Licence Committee (LC) considered the centre's application on 15 March 2015 and agreed to adjourn its decision until the inspectorate was able to reassess the centre's application.

The committee also noted that the application could be considered by ELP once all evidence was provided. However, the committee also reminded the inspectorate that, if concerns still exist, the application should be returned to the LC for consideration.

Centre's anticipated activity levels:

Type of treatment	Maximum number of proposed treatment cycles
In vitro fertilisation (IVF)	450
Intracytoplasmic sperm injection (ICSI)	
Frozen embryo transfer (FET)	
Donor insemination (DI) and Partner insemination (IUI)	50

Other licensable activities	✓ or Not applicable (N/A)
Storage of gametes	✓
Storage of embryos	✓
Embryo testing	✓

Summary for licensing decision

Taking into account the essential requirements set out in the Human Fertilisation and Embryology (HF&E) Act 1990 (as amended), the HF&E Act 2008 and the HFEA Code of Practice (CoP), the inspection team considers that it has sufficient information to conclude that:

- the application has been submitted in the form required;
- the application has been submitted by the individual designated to act as the PR;
- the PR's qualifications and experience comply with section 16 (2) (c) of the HF&E Act 1990 (as amended);
- subject to the PR implementing the recommendations made in this report, it is considered likely that the PR will discharge his duty under section 17 of the HF&E Act 1990 (as amended)
- the centre's premises (including those of relevant third parties) are considered likely to be suitable subject to the implementation of recommendations in this report;
- the centre's practices are considered likely to be suitable subject to the implementation of recommendations in this report;
- the application contains the supporting information required by General Direction 0008, in application for an initial licence;
- the centre has submitted an application fee to the HFEA in accordance with requirements.

The ELP is asked to note that at the time of the inspection, there were a number of areas of practice that required improvement including two critical, four major and two 'other' areas of non-compliance.

The PR has provided evidence that the following recommendations have been implemented:

Critical areas of non compliance:

- **The PR should ensure that the management of surgical procedures at the centre is compliant with all relevant regulatory requirements and guidance.**

Major areas of non compliance:

- The PR should ensure that procedures for screening donors are compliant with all relevant regulatory requirements and guidance.
- The PR should ensure that clinical waste management procedures are effective and occupational health screening is performed for all members of staff.

'Other' areas that requires improvement:

- The PR should ensure that the premises are suitable for conducting licensed treatment.

The PR has provided a commitment to implement the following recommendations:

Critical areas of non compliance:

- **The PR should ensure that effective consent to legal parenthood is obtained where relevant prior to treatment.**

Major areas of non compliance:

- The PR should ensure that all medicines held in the procedure room are stored in a locked cupboard.
- The PR should ensure that all centre staff have undertaken the required mandatory training.

'Other' areas that requires improvement:

- The PR should review and revise the centre's website to ensure it is compliant with the guidance of the Chair's letter on presentation of success rates.

Recommendation to the Executive Licensing Panel

The inspection team considers that there is sufficient information available to recommend:

- the appointment of the proposed Licence Holder;
- the appointment of the proposed Person Responsible;
- the grant of a treatment (including embryo testing) and storage licence for a period of two years. It is further recommended however, that the PR should be directed not to provide treatment using donor sperm until satisfactory evidence of full compliance with the consent to parenthood requirements has been provided to the executive.

Section 2: Inspection findings

This section details what the centre does well and which areas need to be improved to meet essential requirements. We break this down in to four areas covering all the activities of a licensed centre:

1. The protection of the patient, and children born following treatment at this centre
2. The experience of patients at this centre
3. The protection of gametes (sperm and eggs) and embryos at this centre
4. How this centre looks after important information

1. Protection of the patient and children born following treatment

Witnessing and assuring patient and donor identification

What the centre does well

Witnessing (Guidance note 18)
The centre's proposed procedures for double checking the identification of gametes and embryos and the patient or donor to whom they relate are compliant with HFEA requirements. This will ensure that patients receive treatment using the correct gametes or embryos.

What the centre can do better

Nothing identified at this inspection.

Donor selection criteria and laboratory tests

Screening of donors
Donor assisted conception

What the centre does well

Screening of donors (Guidance note 11)
The centre's proposed procedures for screening donors are broadly compliant with HFEA requirements. It is important that donors are appropriately screened to minimise the risks of cross infection during treatment, processing and storage of gametes and embryos.

Payments for donors (Guidance note 13; Directions 0001)
The centre's proposed procedures are compliant with HFEA requirements for giving and receiving money or other benefits in respect to any supply of gametes or embryos. It is important that the principle of altruistic donation be upheld but at the same time donors receive appropriate compensation for their time and any inconvenience caused.

Donor assisted conception (Guidance note 20)
A donor-conceived person is entitled to know details of their donor and any donor-conceived genetic siblings they may have. Parents of a donor-conceived child are able to access information on their child's donor (and about any donor-conceived genetic siblings) from the HFEA or the clinic where they received treatment.

Therefore it is important that centres use donated gametes or embryos from identifiable donors. The centre's proposed procedures are compliant with HFEA requirements to ensure the donor conceived will be able to receive this information.

What the centre could do better

Screening of donors (Guidance note 11)
The centre's standard operating procedure (SOP) for embryo donation does not describe additional testing that may be required depending on the donor's history, for example sickle cell disease. The centre has developed an SOP to direct surrogacy treatment but it does not cover all required screening test requirements (SLC T52; recommendation 3).

Suitable premises and suitable practices

Safety and suitability of premises and facilities
Laboratory accreditation
Infection control
Medicines management
Pre-operative assessment and the surgical pathway
Multiple births
Procuring gametes and embryos
Transport and distribution of gametes and embryos
Receipt of gametes and embryos
Imports and exports
Traceability
Quality management system
Third party agreements
Transports and satellite agreements
Equipment and materials
Process validation
Adverse incidents

What the centre does well

Safety and suitability of premises and facilities (Guidance note 25)
The centre's premises are broadly suitable. This is important to ensure that all licensed activity will be conducted in a suitable environment that is fit for purpose.

The premises of the laboratories conducting tests that impact on the quality and safety of gametes and embryos (relevant third parties) are suitable.

The centre is compliant with HFEA requirements to ensure gametes and embryos will be processed in an environment of appropriate air quality.

Laboratory accreditation (Guidance note 25)

The third party laboratories which will undertake the diagnosis and investigation of patients, patients' partners or donors, or their gametes, embryos or any material removed from them, are compliant with HFEA requirements for accreditation by CPA (UK) Ltd or another body accrediting to an equivalent standard. This is important to assure the quality of the services provided.

Infection control
The centre's proposed systems to manage and monitor the prevention and control of infection are partially compliant with guidance.

Medicines management
The centre's proposed arrangements for obtaining, recording, handling, using, keeping, dispensing, administering and disposing of medicines are broadly compliant with guidance. The centre has provision in place for the management of controlled drugs and has been assessed by the Home Office for a licence to keep, prescribe and administer controlled drugs.

Multiple births (Guidance note 7; Directions 0003)
The centre's proposed procedures are compliant with HFEA multiple births minimisation strategy requirements. The single biggest risk of fertility treatment is a multiple pregnancy and implementation of a suitable strategy is expected to minimise the incidence of multiple births.

Procurement of gametes and embryos (Guidance note 15)
The centre's proposed procedures are compliant with HFEA requirements to:

- document the justification for the use of the patient's gametes (or embryos created with their gametes) in treatment, based on the patient's medical history and therapeutic indications;
- where the sperm is procured at home, to keep a record of this in the gamete provider's records.

Transport and distribution of gametes and embryos (Guidance note 15; Directions 0009)
The centre's procedures for the transport, distribution and recall of gametes and embryos are compliant with HFEA requirements. This is important to ensure that all gametes/embryos sent to other licensed centres within or outside the UK are:

- packaged and transported in a manner that minimises the risk of contamination and preserves the characteristics and biological functions of the gametes or embryos;
- shipped in a container that is designed for the transport of biological materials and that maintains the safety and quality of the gametes or embryos;
- appropriately labelled with the transport conditions, including temperature and time limit being specified;
- the container/package is secure and ensures that the gametes or embryos are maintained in the specified conditions.

Receipt of gametes and embryos (Guidance note 15)
The centre's proposed procedures for the receipt of gametes and embryos are compliant with HFEA requirements. This is important to ensure that the centre only accepts gametes and embryos from other centres if the gametes and embryos are appropriately

labelled and has enough information to permit the gametes and embryos be stored or used in treatment in a way that does not compromise their quality and safety.

Imports and exports (Guidance note 16; Directions 0006)
The centre's proposed procedures for imports and exports of gametes and embryos are compliant with HFEA requirements.

Traceability (Guidance note 19)
The centre's proposed procedures are compliant with HFEA traceability requirements. These requirements are important to ensure that the centre has the ability:

- to identify and locate gametes and embryos during any step from procurement to use for human application or disposal;
- to identify the donor and recipient of particular gametes or embryos;
- to identify any person who has carried out any activity in relation to particular gametes or embryos; and
- to identify and locate all relevant data relating to products and materials coming into contact with particular gametes or embryos and which can affect their quality or safety.

Quality management system (QMS) (Guidance note 23)
The centre has a QMS in place that is compliant with HFEA requirements. The establishment and use of a QMS is important to ensure continuous improvement in the quality of treatments and services.

Third party agreements (Guidance note 24)
The centre's third party agreements are compliant with HFEA requirements.

Transport and satellite agreements (Guidance note 24; Directions 0010)
This section is not applicable as the centre is not intending to undertake any satellite or transport arrangements if they are licensed.

Equipment and materials (Guidance note 26)
The centre will use equipment and materials that are compliant with HFEA requirements. All of the equipment and materials to be used in licensed activity are designated for the purpose and will be appropriately maintained in order to minimise any hazard to patients and/or staff.

The centre is compliant with HFEA requirements to validate critical equipment.

The centre has documented procedures for the operation of critical equipment and procedures to follow if equipment malfunctions.

Process validation (Guidance note 15)
The centre's proposed procedures are compliant with HFEA requirements to validate critical processes. This ensures that these processes are effective and do not render the gametes or embryos clinically ineffective or harmful to the recipient.

Adverse incidents (Guidance note 27)
The centre's proposed procedures for reporting adverse incidents are compliant with HFEA requirements. The centre will report all adverse incidents (including serious adverse events and reactions) to the HFEA. The centre has processes in place to

investigate all adverse incidents that may occur. Reporting and investigation of adverse incidents is important to ensure that centres share the lessons learned from incidents and continuously improve the services it offers.

What the centre could do better

Safety and suitability of premises and facilities (Guidance note 25)
Building work has now been completed at the centre, but a small number of issues were noted during the tour of the premises on inspection; the surgical scrub sink in the theatre has not been sealed to the wall; a soap dispenser had been fixed to the wall by this sink, but had fallen down and there was a small leak in the sink in the staff/patient toilet in the basement. These could pose infection control risks (SLC T17; recommendation 7).

Infection control
Refer to the safety and suitability of premises and facilities section above for details.

Patients are currently being seen at the centre for non-licensed treatment under the terms of its satellite arrangement with Boston Place. On the day of inspection, clinical waste bins were present in the room that had been offered to the inspection team for their use. These bins contained used intra venous (IV) cannulas, IV giving sets and other clinical waste. As there had been no clinical activity at the centre for four days over the Easter holiday period, it appears that the clinical waste had not been cleared during this time. Centre staff explained that the procedure for clinical waste management had recently been changed. This was being managed by their cleaning service, but a new cleaning company had been employed and clinical waste is not part of their remit. Centre staff are now responsible for clinical waste management (SLC T2 and Health and Social Care Act 2008: CoP on the prevention and control of infection; recommendation 4).

The centre has protocols in place to perform pre employment occupational health screening, but this has not yet been carried out for all members of staff (SLC T2 and Health and Social Care Act 2008: CoP on the prevention and control of infection; recommendation 4).

Medicines management
The cupboard in the procedure room intended for the storage of routine IV theatre drugs and intravenous fluids is not lockable (CoP Guidance 25.22a; recommendation 5).

Pre-operative assessment and the surgical pathway
The centre has not determined its pathway for the provision of conscious sedation during operative procedures. The proposed PR is currently considering employing the services of an external company specialising in providing conscious sedation in small medical and dental practices. Protocols to be followed have also not been agreed and therefore these processes, including the suitability of personnel, could not be assessed by the inspection team (SLC T2, T12 and T14; recommendation 1).

The centre has basic resuscitation equipment which includes an automated defibrillator. It was noted that the single use disposable pads required to deliver an electric shock in the event that defibrillation is required were significantly out of date. There was no evidence that the equipment had been subject to routine testing, maintenance or portable appliance testing (PAT). This may compromise the effectiveness of the equipment and the safety of patients and staff (SLC T23 and T26; recommendation 1).

Further equipment is in the process of being obtained before licensed activity is provided. The senior nurse is planning to discuss resuscitation requirements and the drugs to be held to support this with the conscious sedation provider once the agreed service provider is identified (SLC T2 and CoP Guidance 25.14 (b); recommendation 1).

Staff engaged in licensed activity

Person Responsible (PR)
Staff

What the centre does well

Person Responsible (Guidance note 1)
The proposed PR has academic qualifications in the field of medicine and has more than two years of practical experience which is directly relevant to the activity to be authorised by the licence. The PR has successfully completed the HFEA PR Entry Programme (PREP number T/1267/82).

Staff (Guidance note 2)
The centre has an organisational chart that clearly defines accountability and reporting relationships.

The centre has access to a nominated registered medical practitioner and scientist, within the UK, to advise on and oversee medical and scientific activities respectively. The centre's staff are registered in accordance with the appropriate professional and/or statutory bodies.

What the centre could do better

Staff (Guidance note 2)
The centre has not yet recruited all staff that it considers necessary to provide licensed activity. For example, the recruitment of a second embryologist is in progress. However, arrangements for locum staff to be employed as an interim arrangement are in place and appear to be suitable.

The PR has not completed the centre's mandatory training programme including for fire safety, health and safety, infection control and safeguarding (SLC T15; recommendation 6).

The required level of life support training of centre staff necessary to support the sedation service provided has not been considered (refer to the pre-operative assessment and the surgical pathway section of this report and recommendation 1).

Also refer to the legal parenthood section of this report and recommendation 2.

Welfare of the child and safeguarding

What the centre does well

Welfare of the child (Guidance note 8)
The centre's proposed procedures for taking into account the welfare of the child are

compliant with HFEA requirements. This is important to ensure that the centre takes into account the welfare of any child who may be born as a result of the licensed treatment, and of any other child who may be affected by that birth before treatment is provided.

Safeguarding
The centre's proposed procedures are broadly compliant with safeguarding guidance. This guidance ensures that the centre's patients and staff are protected from harm where possible.

What the centre could do better

Safeguarding
The PR has not received safeguarding training (SLC T15; recommendation 6).

Embryo testing

Preimplantation genetic screening
Embryo testing and sex selection

What the centre does well

Preimplantation genetic screening (Guidance note 9); Embryo testing and sex selection (Guidance note 10)
The centre's proposed procedures for performing embryo testing will be compliant with HFEA requirements. This ensures that:

- no embryo is transferred to a woman where that embryo or material removed from it, or the gametes that produced it, has been subject to genetic testing unless expressly authorised by the HFEA;
- no information derived from tests conducted is used to select embryos of a particular sex for social reasons;
- no embryo is tested unless the statutory tests are met i.e. that the embryos is at a significant risk of having a serious genetic condition.

The centre will ensure that people seeking embryo testing are given suitable information, and have access to advice from a clinical geneticist and a counsellor.

What the centre could do better

Nothing identified at this inspection.

2. The experience of patients

Treating patients fairly
Counselling
Egg sharing arrangements (Guidance note 12; Direction 0001)
Complaints
Confidentiality and privacy

What the centre does well

Treating patients fairly (Guidance note 29)
The centre's proposed procedures are compliant with the HF&E Act 1990 (as amended) to ensure that staff members understand the requirements for a conscientious objection to providing a particular licensed activity governed by the Act.

The centre's proposed procedures appeared compliant with requirements to ensure that prospective and current patients and donors are treated fairly and that all licensed activities are conducted in a non-discriminatory way.

Counselling (Guidance note 3)
The centre's proposed counselling procedures are compliant with HFEA requirements. This is important to ensure that counselling support is offered to patients and donors providing relevant consent and prior to consenting to legal parenthood.

Egg sharing arrangements (Guidance note 12; Direction 0001)
The centre will not recruit egg sharers.

Surrogacy (Guidance note 14)
The centre's proposed procedures for treatment involving surrogacy are partially compliant with HFEA requirements. This is important to protect the surrogate and any children born as a result of the treatment.

Complaints (Guidance note 28)
The centre's proposed procedures are compliant with HFEA requirements to seek patient feedback and to be responsive to patient complaints. This is important to ensure that the centre uses patient feedback and any complaints as an opportunity to learn and improve their services.

Confidentiality and privacy (Guidance note 30)
The centre's proposed procedures are compliant with HFEA requirements to ensure it has respect for the privacy, confidentiality, dignity, comfort and wellbeing of prospective and current patients and donors.

What the centre could do better

Surrogacy (Guidance note 14)
Refer to screening of donors and legal parenthood sections of this report and recommendations 2 and 3.

Information

What the centre does well

Information (Guidance note 4; CH(11)02)
The centre's proposed procedures for providing information to patients are broadly compliant with HFEA requirements. This is important to ensure that the centre will give prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions.

What the centre could do better

The centre currently operates as a satellite of Boston Place. Prior to this, the centre had a satellite arrangement with City Fertility (centre 0324) which terminated in November 2014.

The centre's website was reviewed prior to inspection. Information included details of the satellite arrangement with City Fertility but the presentation of success rates was not considered to be compliant with the guidance of the HFEA Chair's letter (CH(11)02). For example, the website does not provide raw numbers, it only provides success rates as percentages. This is particularly important where only small numbers of treatment cycles are provided. For example it quotes a success rate of 100% for DI treatment in patients under 35 years old. It also does not provide details of what the '100% success rate' relates to (e.g. clinical pregnancy rate or live birth rate, per cycle started or insemination or the time period). This raises concerns that the presentation of success rates on the website could be misleading to patients (recommendation 8).

Consent and Disclosure of information, held on the HFEA Register, for use in research

What the centre does well

Consent (Guidance note 5) and legal parenthood (Guidance note 6)
The centre's proposed procedures for obtaining consent are partially compliant with HFEA requirements. This ensures that patients and donors have provided all relevant consents before carrying out any licensed activity.

What the centre could do better

Legal parenthood (Guidance note 6)
The centre has documented procedures for providing information and obtaining consent to legal parenthood. However, the inspection team noted several areas of concern as follows.

- The centre's consent SOP documents that legal parenthood consent should be obtained from a couple using donor eggs in treatment with the partner's own sperm. Legal parenthood consent is only relevant when donor sperm is used in treatment.
- It is a requirement that patients are given information on the difference in law between legal parenthood and parental responsibility; on inspection centre staff

were not clear on the difference (CoP Guidance 6.2).

- There is inconsistency between the centre's SOPs and patient information regarding the consent forms to be completed when donor sperm is used and patients are not married or in a civil partnership.
- The centre's embryo donation SOP does not reference the importance of providing information on the uncertain legal status of men donating embryos when the embryos are used in the treatment of a single woman (CoP Guidance 5.21).
- The centre's legal parenthood SOP directs centre staff to obtain consent for legal parenthood in surrogacy cases using consent forms intended where the patient's partner is receiving treatment using donor sperm rather than in surrogacy treatment. There is a risk that legal parenthood may not be legally recognised in such cases. This was discussed with centre staff on inspection and a revised SOP has since been submitted (SLC T60 and T61).

The inspection team was not assured that all relevant staff had suitable training and experience to provide appropriate information and seek consent to legal parenthood (SLC T12; recommendation 2).

3. The protection of gametes and embryos

Respect for the special status of the embryo

What the centre does well

The centre's proposed procedures are compliant with the requirements of the HF&E Act 1990 (as amended). This ensures that the centre will have respect for the special status of the embryo when conducting licensed activities.

- licensed activities will only take place on licensed premises;
- only permitted embryos will be used in the provision of treatment services;
- embryos will not be selected for use in treatment for social reasons;
- embryos will not be created by embryo splitting;
- embryos will only be created where there is a specific reason to do so which is in connection with the provision of treatment services for a particular woman; and
- embryos will only be stored if those embryos were created for a woman receiving treatment services or from whom a third party agreement applies.

What the centre could do better

Nothing identified at this inspection.

Screening of patients
Storage of gametes and embryos

What the centre does well

Screening of patients (Guidance note 17)
The centre's proposed procedures for screening patients are compliant with HFEA requirements.

It is important that gamete providers are appropriately screened to minimise the risks of cross infection during treatment, processing and storage of gametes and/or embryos.

Storage of gametes and embryos (Guidance note 17)
The centre's proposed procedures for storing gametes and embryos are compliant with HFEA requirements. These measures ensure that the gametes and embryos are stored appropriately to maintain their quality and safety. Furthermore, the centre will only store gametes and embryos in accordance with the consent of the gamete providers. 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.

What the centre could do better

Nothing identified at this inspection.

Use of embryos for training staff (Guidance note 22)
What the centre does well **Use of embryos for training staff (Guidance note 22)** The centre's proposed procedures for using embryos for training staff are compliant with HFEA requirements. Embryos will only be used for the purpose of training staff in those activities expressly authorised by the Authority.
What the centre could do better Nothing identified at this inspection.

4. Information management

Record keeping **Obligations and reporting requirements**
What the centre does well **Record keeping and document control (Guidance note 31)** The centre's proposed procedures for keeping records are compliant with HFEA requirements to ensure that accurate medical records are maintained. Good medical records are essential for the continuity of the patient's care. **Obligations and reporting requirements (Guidance note 32; Direction 0005)** The centre's proposed procedures for submitting information, about licensed activities to the Authority, are compliant with HFEA requirements. This is important to ensure the HFEA can supply accurate information to a donor-conceived person and their parents or donors.
What the centre could do better Nothing identified at this inspection.

Areas of practice requiring action

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, or a significant shortcoming from the statutory requirements. 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
1. Surgical procedures The centre has not determined its pathway for the provision of conscious sedation during operative procedures. The centre had basic resuscitation equipment in place on the day of inspection which includes an automated defibrillator. It was noted that the single use disposable pads were significantly out of date.	The PR should ensure that the management of surgical procedures at the centre are compliant with all relevant regulatory requirements and guidance. When responding to this report, the PR should provide detail of the protocols to be followed for the conscious sedation of patients undergoing surgical procedures. The PR should also provide detail of who will provide this service and of how they are	At the time of the inspection we were in advanced discussion with a third party company for the provision of sedation and a TPA was in place. The first draft of SOPs were shown to the inspection team. Since the inspection we have worked with the sedation company to revise the SOPs to meet FGA's requirements. The final version of SOPs are available to the Executive along with the response to this report.	The executive acknowledges the PR's response. **No further action is required.**

There was no evidence that the equipment had been subject to routine testing, maintenance or PAT testing. Resuscitation requirements and the drugs to be held to support this have not been determined. The required level of life support training necessary to support the sedation service has not been considered. SLC T2, T12, T14, T23 and T26.	qualified to do so. The PR should provide detail of the agreed drugs and other equipment to be held on the resuscitation trolley. The PR should also provide evidence that the automated defibrillator is fit for use and is regularly tested and that consumables necessary for its use are in date. The centre should review the level of life support training required and provide details of the training to be provided, if required, when responding to this report.	The third party company has provided the CVs, GMC Registration numbers, life support qualification and expiry dates, medical malpractice indeminity insurance details of the five practitioners who will provide sedation at FGA. Please see SEDSOP06 for details of qualifications, experience and training of those providing sedation. FGA has worked with the third party company to agree the list of drugs, equipment and consumables required for sedation. Please see SEDSOP04. All the equiments in the procedure room had already been tested and certified by an engineer at the time of perchase in Jan 2015. The cetificate has been available since. However all theatre equipments and leads are booked for a PAT testing on 8 May 2015. The dates on the single use disposable pads for the defibrellator have been checked	

		with the provider who advised that this is the manifacturing date, however new consumables have been ordered and will be in place prior to treatment being provided. The sedation SOPs require FGA to ensure the availability of at least one member of staff who is BLS trained. All staff are BLS trained (the PR's training is booked for 12 May) and in addition the Senior Nurse Manager is ILS trained.	
2. Legal parenthood The centre has documented processes for providing information and obtaining consent to legal parenthood. However, the inspection team noted several areas of concern. The inspection team was not assured that all relevant staff had suitable training and experience to provide appropriate information and seek consent to legal parenthood.	The PR should ensure that staff have the appropriate training and competence to provide information and obtain consent to legal parenthood in all situations where this is required. The PR should ensure that procedures for obtaining consent to legal parenthood are compliant with all relevant regulatory requirements and guidance. When responding to this report, the PR should provide a robust	As was recommended by the Inspectors, FGA's Senior Nurse Manager is arranging a training session to be performed by the Senior Nurse of another centre to cover parental responsibility and legal parenthood. The training session will be attended by the Person Responsible, the Senior Nurse Manager and the Nurse. The Consent SOP and Patient Information were revised on 08/04/15 in light of the errors identified on inspection.	The executive acknowledges the PR's response. The centre has provided revised SOPs but the executive is concerned to note that the centre's consent SOP does not capture the process by which posthumous consent to parenthood is obtained. The PR should provide evidence to the executive that staff training has been completed and competence

SLC T12.	plan for staff training and the evaluation of competence in this area to be completed prior to the report being considered by an ELP. Copies of SOPs and patient information which are revised as a result of this should be provided to the HFEA prior to providing relevant treatment or by 7 July 2015 at the latest.	The HFEA algorithms for legal parenthood are in place in the Doctor and Nurse Consulting Rooms as reference tools in cases where legal parenthood provision is relevant.	in taking consent has been assessed. The centre's protocols should then be further reviewed and revised with respect to obtaining posthumous consent and copies provided to the HFEA. Treatment should not be provided using donor sperm until satisfactory evidence of this has been provided to the executive. **Further action is required.**

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
3. Donor screening The centre's SOPs for embryo donation and surrogacy do not describe all donor screening test requirements. SLC T52.	The PR should ensure that procedures for screening donors are compliant with all relevant regulatory requirements and guidance. Revised copies of the centre's SOPs for surrogacy and embryo donation should be submitted to the HFEA before treatment is provided with donor gametes or donor embryos or by 7 July 2015 at the latest.	SOPs for Surrogacy and Embryo Donation have been revised and are available to the Executive along with this response.	The centre has submitted revised copies of the SOPs for surrogacy and embryo donation. **No further action is required.**
4. Infection control Clinical waste bins containing clinical waste at the centre had not been disposed of for four days.	The PR should ensure that the centre's procedures for management of clinical waste are compliant with infection control guidance. The centre's procedures should	The cleaning company that has taken over the centre's cleaning services will empty all bins, including clinical waste and tag these with the clinic ID and place in the large yellow bin outside the building. During	The executive acknowledges the PR's response. **No further action is required.**

The centre has protocols in place to perform pre employment occupational health screening, but this has not yet been carried out for all members of staff. Health and Social Care Act 2008: CoP on the prevention and control of infection.	be reviewed and a summary report of the findings of the review including corrective actions taken should be submitted when responding to this report. The PR should ensure that occupational health screening is performed for all members of staff. Confirmation that this has been completed should be submitted to the HFEA by 7 July 2015.	the day bins that become three quarters full will be deposited there by the nursing team, tagged with the clinic ID tags. Senior nurse manager undertook an infection control audit as part of the monthly clinical review audits. This identified that the issues had been rectified following staff education. All staff have now been screened and all have the required immunity.	
5. Medicines management The cupboard in the procedure room intended for the storage of routine IV theatre drugs and intravenous fluids is not lockable. CoP Guidance 25.22a.	The PR should ensure that all drugs that are stored are secure. Evidence of this should be submitted before treatment commences.	We have also ordered a lock for one of the wall hung units and will be fitted as soon as it arrives.	The executive acknowledges the PR's response and his commitment to implement this recommendation. The PR should inform the executive when the lock has been fitted. This must be before treatment commences. **Further action is required.**
6. Staff The PR has not completed the centre's mandatory	The PR should undertake the required mandatory training. Evidence that this has been	The Person Responsible's mandatory training is booked for 12 May (booking confirmation is provided with	The executive acknowledges the PR's response and his commitment to implement this recommendation.

training programme. SLC T12 and T15.	completed should be submitted to the HFEA by 7 July 2015.	this response) covering: 1. Health and Safety at Work 2. Control of Substances Hazardous to Health 3. Caldicott Principles 4. Fire Safety Awareness 5. Infection Control 6. Food Hygiene 7. Manual Handling - (Includes Practical Session) 8. Basic Life Support including CPR - (Includes Practical Session) 9. Safeguarding Vulnerable Adults 10. Safeguarding Children 11. Conflict Management 12. Lone Working.	The PR should provide confirmation to the executive when the training has been completed. **Further action is required.**

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
7. Suitable premises All building work has now been completed at the centre, but a small number of issues were noted during the tour of the premises on inspection; the surgical scrub sink in the theatre has not been sealed to the wall; a soap dispenser had been fixed to the wall by this sink, but had fallen down and there was a small leak in the sink in the staff/patient toilet in the basement. SLC T17.	The PR should ensure that the premises are suitable for conducting licensed treatment. A full assessment of the premises should be conducted and a summary report of the findings of the assessment, including corrective actions and the timescale for implementation of the corrective actions should be submitted when responding to this report. This should include those areas noted in the inspection report.	The surgical scrub sink in the theatre has been sealed and the soap dispenser has been screwed to the wall on 30 April 2015. The leak in the downstairs small sink has already been fixed.	The executive acknowledges the PR's response. The centre has also submitted a report of an infection control audit of the centre's premises demonstrating that no further corrective actions were required. **No further action is required.**
8. Patient information The presentation of success rates on the centre's website was not considered to be compliant with the guidance of the HFEA Chair's letter (CH(11)02). For example, the website does not provide raw numbers; it only provides	The PR should review and revise the centre's website to ensure it is compliant with the guidance of the Chair's letter. The PR should inform the HFEA when this has been completed and by 7 July 2015 at the latest.	As previously explained the publishe results in our website were given to us by City Fertility as instructed by their HFEA inspectors at the time of their last inspection to put up in our web site without any alterations which we did.	The executive acknowledges the PR's response and his commitment to implement this recommendation. **Further action is required.**

success rates as percentages. This is particularly important where only small numbers of cycles are provided. For example it quotes a success rate of 100% for DI treatment in under 35 year olds. It also does not provide details of what the '100% success rate' relates to (e.g. clinical pregnancy rate or live birth rate, per cycle started or insemination or the year). This raises concerns that the presentation of success rates on the website could be misleading to patients.		Howevre we will replace them with our personal recent results as validated by City Fertility and Boston Place as soon as we can.	

Reponses from the Person Responsible to this inspection report
The FGA team would like to thank the HFEA Inspectors for their help and guidance throughout the inspection process. I would like to thank our team who have been working tirelessly to ensure we meet HFEA and other regulatory requirements.