Executive Licensing Panel - minutes

Centre 0341 (The Fertility & Gynaecology Academy) Interim

Friday, 29 July 2016

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Paula Robinson (Chair) Joanne Anton Anjeli Kara	Head of Business Planning Head of Regulatory Policy Regulatory Policy Manager
Members of the Executive	Dee Knoyle Ian Brown	Secretary Head of Corporate Governance
External adviser		
Observers		

Declarations of interest

- Members of the panel declared that they had no conflicts of interest in relation to this item.

The panel had before it:

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

1. Consideration of application

1.1. The panel considered the papers, which included an inspection report and licensing minutes for the last three years.

1.2. The panel noted that The Fertility & Gynaecology Academy, centre 0341, has held a licence with the HFEA since May 2015. The centre provides a full range of fertility services including embryo testing.

1.3. The panel noted that the centre's current licence is due to expire on 21 May 2017.

1.4. The panel noted that this is the centre's initial licence which was granted for two years without any additional conditions. Prior to the centre's application for its initial licence, the centre operated as a satellite centre to Boston Place (centre 0327).

1.5. The panel noted that the inspection took place on 27 April 2016.

1.6. The panel noted that from the licence coming into force on 22 May 2015 to 29 February 2016, the centre provided 67 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is currently a small centre. However, the centre's initial licence application stated that the centre has capacity for up to 450 cycles per annum. It is therefore anticipated that activity and staffing will progressively increase as the centre becomes more established.

1.7. The panel noted that the centre does not yet have a full year of data for IVF and ICSI, therefore no comparison can be made with national averages.

1.8. The panel noted that in 2015 the centre reported three cycles of partner insemination with no pregnancies. This represents performance that is likely to be consistent with the national average.

1.9. The centre does not yet have a full year's worth of data required to compare their multiple pregnancy rate (MPR) with the maximum multiple live birth rate target for this period.

1.10. The panel noted that at the time of the interim inspection on 27 April 2016, three major areas of non-compliance were identified. In particular, the panel noted the non-compliance relating to taking donor consent. In light of the fact that the centre had experienced previous issues concerning taking consent to legal parenthood the panel had some concerns. The panel noted that since the inspection, the Person Responsible (PR) has implemented all of the recommendations to address the non-compliances and has committed to providing a summary of follow up audits of practice where required, to ensure the effectiveness of corrective actions taken.

1.11. The panel noted that the inspectorate recommends the continuation of the centre's treatment (including embryo testing) and storage licence without additional conditions.

2. Decision

2.1. The panel had regard to its decision tree.

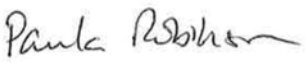
2.2. The panel had some concern about the non-compliance relating to donor consent. However the panel was pleased to see that the PR is engaging with the inspectorate to fully implement the recommendations.

2.3. The panel was satisfied that the centre was fit to have its treatment (including embryo testing) and storage licence continued.

3. Chair's signature

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

Signature



Name

Paula Robinson

Date

2 August 2016

Interim Inspection Report

Centre name: The Fertility & Gynaecology Academy
Centre number: 0341
Date licence issued: 22 May 2015
Licence expiry date: 21 May 2017
Additional conditions applied to this licence: None
Date of inspection: 27 April 2016
Inspectors: Polly Todd (Lead), Sara Parlett
Date of Executive Licensing Panel: 29 July 2016

Purpose of the report

This centre was first licenced by the HFEA in May 2015. This is a report of an inspection, carried out to assess whether the centre complies with essential requirements in providing safe and high quality care to patients and donors. The inspection was scheduled (rather than unannounced) and the report provides information on the centre's performance and level of compliance since this licence was granted.

This inspection visit also provides an opportunity for staff at a newly established centre to discuss any areas of concern they may have, enables the inspection team to assess the level of compliance with requirements in practice and provide support and advice at an earlier stage if required, and provides an opportunity for areas requiring improvement to be addressed at a much earlier point than the licence renewal inspection.

This is a report of a targeted, scheduled, interim inspection together with our assessment of the centre's performance based on other information. The inspection focused on legal parenthood, consent and donor assessment and screening; these are key areas of risk in the sector. Other areas of focus included:

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

The inspection team also take into account the progress made in implementing the actions identified at the last inspection, and on-going monitoring of the centre's performance.

The report represents a mid-term evaluation of the centre's performance based on the above. The aim is to provide the Authority's Executive Licensing Panel (ELP) with information on which to make a decision about the continuation of the licence.

Summary for the Executive Licensing Panel

The inspection team recommends the continuation of the centre's licence without additional conditions.

The ELP is asked to note that there were recommendations for improvement in relation to three major areas of non-compliance.

Since the inspection visit the PR has provided assurance that the following recommendations have been fully implemented:

Major' areas of non-compliance:

- the PR should ensure that all entries in the controlled drugs register are compliant with statutory, regulatory and best practice guidance;
- the PR should ensure that donor screening is performed within the timeframes specified by the Authority;
- the PR should review the procedures for taking consent and the use of appropriate consent forms for patients and donors.

Since the inspection visit the PR has provided assurance that all recommendations have been fully implemented. Where required, and by the dates specified, the PR will provide an update or summary of audits conducted to ensure the corrective actions taken are effective.

Information about the centre

The Fertility & Gynaecology Academy is located in central London and has held a Treatment (including embryo testing) and Storage licence with the HFEA since May 2015. This initial licence was granted for two years without any additional conditions.

Prior to the centre's application for its initial licence the centre operated as a satellite centre to Boston Place (centre 0327).

Initially, concerns relating to taking legal parenthood consent resulted in 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 had been provided. This recommendation was fully implemented and the centre started providing treatment with donor sperm in August 2015.

From the licence coming in to force on 22 May 2015 to 29 February 2016, the centre provided 67 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is currently a very small centre; however, the centre's initial licence application stated that the centre has activity capacity for up to 450 cycles per annum. It is therefore anticipated that activity and staffing will progressively increase as the centre becomes more established.

Details of Inspection findings

Quality of Service

Each interim inspection focuses on the following themes: they are important indicators of a centre's ability to provide high quality patient care and to meet the requirements of the law.

Pregnancy outcomes[1]

The centre does not yet have a full year of data for IVF and ICSI, therefore no comparison can be made with national averages.

In 2015 the centre reported three cycles of partner insemination with no pregnancies. National data has yet to be analysed but this is likely to be consistent with the national average.

Multiple births[2]

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

The centre does not yet have a full year's worth of data required to compare their multiple pregnancy rate (MPR) with the current live birth rate target.

Witnessing

Good witnessing processes are vital in ensuring there are no mismatches of gametes or embryos and that identification error does not occur. The inspection team was not able to observe any laboratory activities during the inspection but was able to discuss witnessing with staff and review witnessing procedures in five patient records. This discussion and review indicated that witnessing procedures are compliant with HFEA requirements.

Consent: To the storage of cryopreserved material

The storage of gametes and embryos is an important service offered by fertility clinics. It enables patients to undergo further fertility treatment without additional invasive procedures and to preserve their fertility prior to undergoing other medical treatment such as radiotherapy. It is important that the centre has measures in place to ensure that gametes and embryos are stored in accordance with the consent of the gamete providers.

The inspection team reviewed the accuracy of storage logs and consent records, reports of audits of all stored gametes and embryos, and discussed the 'bring forward' system with staff. These activities indicate that the centre's processes for storing gametes and embryos in line with the consent of the gamete providers are effective.

Staffing

Having the right numbers of staff, competent to carry out highly technical work in a non-pressured environment is important in infertility services.
The inspection team considered that staffing levels in the clinic appeared suitable for the activities being carried out. The atmosphere in the clinic appeared calm at all times; and

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[1] The data in the Register may be subject to change as errors are notified to us by clinics, or picked up through our quality management systems. Centre success rates are considered statistically different from the national averages, and multiple pregnancy rates are considered statistically different from the 10% multiple live birth rate target, when $p \leq 0.002$.

[2] The HFEA use a conversion factor of 1.27 to convert the 10% multiple live birth rate (MLBR) target to a multiple pregnancy rate (MPR) target of 13%.

whilst there were no witnessing activities taking place during the inspection the atmosphere within the laboratory was calm and relaxed allowing staff to be available to carry out their activities without distraction when required.

Quality Management System (QMS)

It is important that centres audit all of their practices at least every two years to ensure they are delivering the expected quality of service, that staff are following prescribed standard operating procedures and that the centre's processes meet the HFEA's regulatory requirements. It is also important that these audits are robust and that any necessary changes that are identified are made, as this supports continuous improvement.

Whilst the centre has not been open for two years it has conducted a number of audits and is closely monitoring key performance indicators in the laboratory. The effectiveness of the centre's QMS was assessed by reviewing the reports of the following audits: witnessing, consent to storage, medicines management and infection control.
The centre's procedures for auditing and acting on the findings of audits are compliant with requirements.

The inspection team also considered whether the clinic's processes for implementing learning are effective. If a clinic is to achieve continuous improvement and encourage a learning culture then it is important that they act to review their practices when guidance is issued by the HFEA or other bodies. The clinic's procedures for acting on guidance from the HFEA were evaluated with reference to the following:

- the centre's audits of witnessing, consent to storage, medicines management and infection control;
- the use of CE marked medical devices;
- the use of the most recently issued HFEA consent form versions;
- the HFEA reports of adverse incidents from 2010-2012 and 2013;
- HFEA Clinic Focus articles regarding screening requirements and equipment failures.

With the exception of donor screening, the centre has been effective in ensuring compliance with guidance issued by the HFEA. See recommendation 2.

Medicines management

It is important that clinics follow best practice for medicines management both to protect patients and ensure that medicines are stored, administered and disposed of in the correct way.

During the inspection, the clinic's processes for medicines management and the safe storage, disposal and administration of medicines were reviewed and were found to be partially compliant with guidance because;

- the centre does not have a Controlled Drugs Accountable Officer (CDAO) or a certificate of exemption;
- following a review of the controlled drugs register a number of areas of concern were noted:
    - the name, strength and volume of each drug is not always recorded on the top of each page;
    - some entries are illegible;

- it is unclear in some entries the amount of drug that has been administered to the patient and how much has been discarded;
- mistakes in the register are not amended in accordance with regulatory and best practice requirements. Changes should be corrected in a margin note or footnote and specify the date a correction is made and by whom;
- the recording of the 'carry over' of stock has not been witnessed by a second person or recorded in the appropriate place.

See recommendation 1.

Infection Control

It is important that clinics have suitable arrangements in place so that patients experience care in a clean environment and to prevent patients and staff acquiring infections.

During the inspection, the inspection team reviewed infection control practices and found them to be compliant with guidance.

Equipment and Materials

It is important that products (known as medical devices) that come into contact with gametes and embryos are approved for the provision of fertility treatment, to ensure the safety of gametes, embryos and patients. The approval of such products is denoted by the issue of a 'CE mark'.

The CE mark status of medical devices in the centre was reviewed in the course of the inspection. The centre is compliant with HFEA requirements to use CE marked medical devices wherever possible.

Patient experience

During the inspection, there were no patients available to speak with the inspectors about their experiences at the centre and, to date, no patients have provided feedback directly to the HFEA in the time since the last inspection. The inspection team was able to review some patient feedback provided directly to the centre which was mostly positive.

On the basis of this feedback and observations made in the course of the inspection, it was possible to assess that the centre:

- has respect for the privacy and confidentiality of patients in the clinic;
- provides a clean and well organised environment for patient treatment;
- has staff who are supportive and professional;
- maintains an effective system for responding to patient feedback and complaints.

Monitoring of the centre's performance

In addition to commenting on evidence gathered on the inspection it is important to report on the centre's performance since the granting of the licence based on other evidence available to us.

Compliance with HFEA standard licence conditions

As previously stated, donor assessment and screening and consent were a particular focus for this inspection as new centres can experience difficulties with these areas of practice.

Since the licence was granted, the centre has recruited and assessed one egg donor. The centre is partially compliant with HFEA requirements in these areas because a review of this donor's record showed

- Donor screening was not performed within the timescales specified by the Authority. The donor was screened over a year before the egg collection took place in March 2016. The centre's standard operating procedure (SOP) correctly states that donor screening should take place at the time of donation but this procedure has not been followed. It is important that donors are screened in a timely manner to minimise the risk of cross infection to the recipient following donation. See recommendation 2.
- The egg donor has completed a WD HFEA 'consent to donating eggs' form on the day of egg collection. From further discussion with staff and review of the donor's records, it was clarified that the egg donor had previously completed a WD form, but it had contained an error. A new consent form was then completed. The centre subsequently shredded the donor's original consent form. Such information should not be removed from the patient's records. See recommendation 3.
- The egg donor has also completed a WT HFEA 'consent to treatment' form. The WT form is designed solely for women who are consenting to having fertility treatment and storage of embryos created in vitro using their own eggs. The inspection team is concerned that asking an altruistic egg donor to complete this form could result in her having inaccurate information and may cast doubt as to whether fully informed consent has been given. See recommendation 3.

Compliance with recommendations made at the time of the last inspection

Following the inspection in April 2015, recommendations for improvement were made in relation to two critical, four major and two 'other' areas of non-compliance.

The PR subsequently provided information and evidence that all of the recommendations were fully implemented within the required timescales.

On-going monitoring of centre success rates

Since the grant of the licence in May 2015 the centre has not received any performance related risk tool alerts.

Provision of information to the HFEA

Clinics are required by law to provide information to the HFEA about all licensed fertility treatments they carry out. This information is held in the HFEA Register. There are no significant data submission issues at this centre. The clinic is therefore compliant with requirements to submit information to the HFEA.

Legal Parenthood

Where a couple to be treated with donated gametes or embryos are not married or in a civil partnership, both the woman and her partner must give written consent in order for the partner to become the legal parent of any child born. If this consent is not documented

properly or if proper information is not provided, or counselling offered prior to both parties giving consent, there may be doubt about the effectiveness of the consent and in some cases it may be necessary for a patient couple to obtain a court declaration to establish legal parenthood.

In October 2015, the HFEA's Chief Inspector asked all newly licensed centres to audit their practices in this area to ensure they are suitable, to report the findings of the audit to the HFEA and to respond to those findings. The centre provided evidence that an audit had been conducted and submitted a report to the HFEA. The audit found that since undertaking donor treatment cycles, only three cycles of treatment had been completed, all of which were with single female patients. To date, the centre has not undertaken any treatments using donated gametes or embryos with couples who are not married or not in a civil partnership, so the inspection team has no primary evidence of the effectiveness of the centre's procedures. However, discussions during the inspection and review of the centre's original audit provided assurance that the current procedures for obtaining consent to legal parenthood are robust.

To provide further assurance of the effectiveness of the centre's procedures, four patient records, where donated gametes or embryos had been used, were crossed referenced with the information held by the HFEA. All of the records reviewed were either single women being treated without a partner or married couples; therefore consent to legal parenthood does not apply in these cases.

Areas of practice that require the attention of the Person Responsible

The section sets out matters which the Inspection Team considers may constitute areas of non-compliance. These have been classified into critical, major and others. Each area of non-compliance is referenced to the relevant sections of the Acts, Regulations, Standard Licence Conditions, Directions or the Code of Practice, and the recommended improvement actions required are given, as well as the timescales in which these improvements should be carried out.

Critical areas of non-compliance

A critical area of non-compliance is an area of practice which poses a significant risk of causing harm to a patient, donor, embryo or child who may be born as a result of treatment services. A critical area of non-compliance requires immediate action to be taken by the Person Responsible.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team's response to the PR's statement
None identified at this inspection.			

‘Major’ area of non-compliance

A major area of non-compliance is a non-critical area of non-compliance:

- which poses an indirect risk to the safety of a patient, donor, embryo or child who may be born as a result of treatment services;
- which indicates a major shortcoming from the statutory requirements;
- which indicates a failure of the Person Responsible to carry out his/her legal duties;
- which can comprise a combination of several ‘other’ areas of non-compliance, none of which on their own may be major but which together may represent a major area of non-compliance.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team’s response to the PR’s statement
1. Medicines management: The following issues were noted on inspection: • the centre does not have a registered CDAO or a certificate of exemption. Controlled Drugs (Supervision of management and use) Regulations (2013). Review of the controlled drugs register identified a number of areas of concern;	The inspection team acknowledges that an application has been made to the Care Quality Commission (CQC) by the centre for an exemption from having a CDAO. The PR should provide the centre’s inspector with evidence of an exemption or registration of a CDAO by 27 October 2016 at the latest. The PR should ensure that all entries in the controlled drugs register are compliant with statutory,	The registration with the CQC for a CDAO is complete. entry shown as: 1-109580499The Fertility & Gynaecology Academy; Adel Eskander 0781 0796135. a.eskander@fertility-academy.co.uk London W1G 8YP (http://www.cqc.org.uk/content/controlled-drugs-accountable-officers) The Nurse Manager has implemented a system to ensure that entries in the controlled drugs register are compliant	The inspection team acknowledge and confirm that the centre now have a CQC registered CDAO. The inspection team acknowledge receipt of the centre’s medicines management review.

• the name, strength and volume of each drug is not always recorded on the top of each page; Misuse of Drugs Regulations (2001) Regulation 20(a). • some entries are illegible; • it is unclear in some entries, the amount of drug that has been administered to the patient and how much has been discarded; Misuse of Drugs Regulations (2001) Regulation 27 and Controlled Drugs in Perioperative Care (2006) section 4(ii). • mistakes in the register are not amended in accordance with regulatory and best practice requirements. Changes should be corrected in a margin	regulatory and best practice guidance. The PR should conduct a review of the centre's medicines management procedures; this should include staff training requirements. The findings of the review, including corrective actions and timescales for implementation of the corrective actions should be provided to the centre's inspector by 27 July 2016. Three months after the implementation of corrective actions the PR should perform an audit to ensure that these actions have been effective. The PR should ensure that this audit is sufficient in scope to identify any issues with the management of controlled drugs as outlined in this report. A summary report of this audit should be provided	with requirements, including the NMC Standards noted here. The medicines management procedures have been reviewed. Staff training was provided to all staff on 20 June 2016. The summary report of the review is sent to the centre's inspector with this response. An audit of controlled drugs was done on 21 June 2016 to check the above actions. The next controlled drugs audit is scheduled for August and we will review implementation of corrective actions as part of that audit. We will provide a summary report of the audit to the centre's inspector by 27 October 2016.	The recommendation requires an audit to be completed three months after corrective actions have been implemented, therefore the audit submitted in October should include at least three months' worth of data. No further action required beyond submission of the medicines management audit by 27 October 2016.

note or footnote and specify the date a correction is made and by whom; Misuse of Drugs Regulations (2001) Regulation 19, 20(c) and 27; NMC 'Standards for medicines management' Standard 8, (2010). • the recording of 'carry over' of stock has not been witnessed by a second person or recorded in the appropriate places. DH (2007) 'Safer Management of Controlled Drugs: A guide to good practice in secondary care (England)' Section 4.7.1.3. SLC T2.	to the centre's inspector by 27 October 2016.		
2. Donor screening The centre has recruited and assessed one egg donor since the licence was granted. A review of this record showed,	The PR should ensure that donor screening is performed within the timeframes specified by the Authority.	The centre's procedures do ensure that donor screening is performed within the timeframes specified by the Authority.	The inspection team acknowledge the PR's response, actions and commitment to implement this recommendation.

screening was performed over a year before the egg collection. The centre's SOP correctly states that donor screening should take place at the time of donation but this procedure has not been followed. SLC T53b.	The PR should assess the risk to the recipient of this donor's eggs and consider re-testing the egg donor. The PR should inform the centre's inspector of his decision regarding this when responding to this report. The PR should also provide the following information when responding to this report: • the number of recipients from this donation; • confirmation that any remaining gametes or embryos created from this donor's gametes are appropriately stored and/or quarantined until her viral status is confirmed; • confirmation that this is the only egg donor cycle performed to date at the centre.	The PR has assessed the risk to the recipient of this donor's eggs. The egg donor is to be re-tested and is attending the clinic next week. As requested: there is one recipient from this donation. there are no gametes or embryos created from this donor's gametes in storage. this is the only egg donor cycle performed to date at this centre.	The PR should provide an update once the donor screening is complete.

	The PR should conduct a review of the centre's donor screening procedures; this should include staff training requirements and a root cause analysis to include why a documented SOP was not followed. The findings of the review, including further corrective actions with timescales for implementation, should be submitted to the centre's inspector by 27 July 2016. Three months after the implementation of corrective actions, the centre should perform an audit to ensure that these actions have been effective. A summary report of the audit should be submitted to the centre's inspector by 27 October 2016.	The PR has conducted a review of the centre's donor screening procedures,and staff training was provided on 20 June 2016. A root cause analsis (RCA) has been conducted. A summary report of the RCA, including corrective actions with a timeline for actions is sent to the centre's inspector with this response. An audit is scheduled for August and we will review implementation of the corrective actions as part of that audit. We will provide a summary report of the audit to the centre's inspector by 27 October 2016.	The inspection team confirm the receipt of the centre's screening procedures and root cause analysis summary report. The recommendation requires an audit to be completed three months after corrective actions have been implemented, therefore the audit submitted in October should include at least three months' worth of data. No further action beyond submission of the audit report by 27 October 2016.
3. Donor consents	The PR should review the procedures for taking	The procedures for taking consent and the use of appropriate consent forms	Since the inspection the PR has informed the

On review of a donor record the following issues were noted; • the egg donor has completed the WD consent form on the day of donation. From discussion with staff and review of the patient records, it was clarified that the egg donor had previously completed a WD form, but it had contained an error. A new consent form was then completed. The centre subsequently shredded the donor's original consent form. Such information should not be removed from the patient's records; • the egg donor has completed WT and WD HFEA consent forms. The WT form is designed solely for women who are consenting to having fertility treatment and storage of embryos	consent and the use of appropriate consent forms for patients and donors, this should include staff training requirements. The findings of the review, including corrective actions with timescales for implementation, should be submitted to the centre's inspector by 27 July 2016. Three months after the implementation of corrective actions, the centre should perform an audit to ensure that these corrective actions have been effective. A summary report of the audit should be submitted to the centre's inspector by 27 October 2016. The PR should ensure that information is not removed from any records maintained in pursuance of the licence before the expiry of such period as may be specified in Directions.	have been reviewed. Staff training was provided on 20 June 2016. The report of the review is sent to the centre's inspector with this response. An audit of donor consents is on our Audit schedule for August and we will review implementation of the corrective actions as part of that audit. We will provide a summary report of the audit to the centre's inspector by 27 October 2016. The PR has reminded all staff that patient information is not to be removed from patient records. We are not sure why the final column for this section has already been completed	centre's inspector of the intended actions and timescales for their implementation to achieve compliance with this recommendation. The inspection team acknowledge receipt of the centre's consent procedures review. The recommendation requires an audit to be completed three months after corrective actions have been implemented, therefore the audit submitted in October should include at least three months' worth of data. No further action required beyond submission of the screening audit by October 2016. In response to the PR's final comment, the

created in vitro using their own eggs. The inspection team is concerned that asking an altruistic egg donor to complete this form, could result in her having inaccurate information and may cast doubt as to whether fully informed consent has been given. SLC T40, T57, CoP 5.8, General Directions 0012.		by the inspector - may have been in error? Please confirm.	inspection team received an email from the centre in relation to this recommendation which identified intended actions and timescales for their implementation.

‘Other’ areas of practice that requires improvement

Areas of practice that require improvement are any area of practice in which failings occur, which cannot be classified as either a critical or major area of non-compliance, but which indicate a departure from statutory requirements or good practice.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team’s response to the PR’s statement
None identified at this inspection.			

Additional information from the Person Responsible