Executive Licensing Panel - minutes

Centre 0019 (Aberdeen Fertility Centre) Interim Inspection Report

Friday, 23 September 2016

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Juliet Tizzard (Chair) Joanne Anton Anna Rajakumar	Director of Strategy & Corporate Affairs Head of Regulatory Policy Scientific Policy Manager
Members of the Executive	Dee Knoyle	Secretary
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 noted that Aberdeen Fertility Centre has held a licence with the HFEA since 1992. The centre provides a full range of fertility services.

1.2. The panel noted that the centre's licence is due to expire on 31 January 2019.

1.3. The panel noted that the inspection took place on 9 August 2016.

1.4. The panel noted that in the 12 months to 30 June 2016, the centre provided 864 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a medium-sized centre.

1.5. The panel noted that for the year ending March 2016, HFEA-held register data showed the centre's success rates in terms of clinical pregnancy rates, were in line with national averages.

1.6. The panel noted that for the year ending March 2016, HFEA-held register data showed the centre's multiple pregnancy rate for all IVF, ICSI and frozen embryo transfer (FET) cycles for all age groups was 10%. This represented performance that is not likely to be significantly different from the 10% maximum multiple live birth rate target for this period.

1.7. The panel noted that at the time of the inspection on 9 August 2016, one major and two other areas of non-compliance were identified. The panel noted that the PR has committed to implementing only two of the recommendations within the prescribed timescales. The PR had expressed concern about her ability to implement the recommendation relating to outpatient services. The panel noted in particular that the Executive acknowledges that this area of non-compliance will be addressed on completion of a new hospital build, however does not consider a four-year timescale for compliance acceptable and requires this recommendation to be implemented within the prescribed timescales. The panel noted that the Executive will continue to liaise with the centre to resolve this non-compliance and that the PR is engaged with finding a solution.

1.8. The panel noted that the inspectorate recommends the continuation of the centre's treatment and storage licence.

2. Decision

2.1. The panel had regard to its decision tree.

2.2. The panel urged the PR to work with NHS Grampian to address the non-compliance relating to outpatient services.

2.3. The panel was satisfied that the centre was fit to have its treatment and storage licence continued.

3. Chair's signature

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

Signature

Name

Juliet Tizzard

Date

5 October 2016

Interim Licensing Report

Centre name: Aberdeen Fertility Centre
Centre number: 0019
Date licence issued: 01 February 2015
Licence expiry date: 31 January 2019
Additional conditions applied to this licence: None
Date of inspection: 09 August 2016
Inspectors: Lesley Brown, Grace Lyndon
Date of Executive Licensing Panel: 23 September 2016

Purpose of the report

The Human Fertilisation and Embryology Authority (HFEA) is the UK's independent regulator of the fertility sector. The HFEA licenses centres providing in vitro fertilisation (IVF) and other fertility treatments and those carrying out human embryo research.

Licensed centres usually receive a licence to operate for up to four years and must, by law, be inspected every two years. The full inspection prior to a licence being granted or renewed assesses a centre's compliance with the law and the HFEA's Code of Practice (CoP) and Standard Licence Conditions (SLC).

This is a report of an unannounced interim inspection together with our assessment of the centre's performance based on other information. We do this at the mid-point of the licence period. For 2015-2017 the focus of an interim inspection is:

- **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.

We also take into account the centre's own assessment of its service; the progress made in implementing the actions identified at the last inspection; and our on-going monitoring of the centre's performance.

The report represents a mid-term evaluation of a 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.

The ELP is asked to note that at the time of inspection there were recommendations for improvement in relation to one major and two 'other' areas of non compliance or poor practice.

In responding to the report, the PR has given a commitment to fully implement the following recommendations within the required timescales:

'Major' areas of non compliance:

- The PR should ensure gas cylinders and liquid nitrogen vessels are stored safely and securely at all times.

'Other' areas of practice that require improvement:

- The PR should ensure medicines management procedures comply with relevant regulations and guidance.

The PR has expressed concern about the ability to implement the following recommendation:

'Other' areas of practice that require improvement:

- The PR should ensure: sinks with taps for 'hands free' use are available in all areas where clinical procedures take place; clinical areas where there is a risk of body fluid spillage have sealed floors; and clinical waste is stored securely and disposed of effectively.

The Executive will continue to liaise with the centre to resolve this non-compliance. The PR is engaged with finding a solution.

Information about the centre

The Aberdeen Fertility Centre has held a licence with the HFEA since 1992. The centre provides a full range of fertility services.

The centre provided 864 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 30 June 2016. In relation to activity levels this is a medium centre.

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]

HFEA held register data for the year ending March 2016 show the centre's success rates in terms of clinical pregnancy rates are in line with national averages.

Multiple births[2]

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

HFEA held register data for the year ending March 2016 show the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 10%. This represents performance that is not likely to be significantly different to the 10% multiple live birth rate target for this period.

Witnessing

Good witnessing processes are vital to ensure there are no mismatches of gametes or embryos and that identification errors do not occur. The following laboratory activity was observed in the course of the inspection: preparation for frozen embryo transfer. The procedure observed was witnessed using an electronic witnessing system in accordance 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.

On inspection, reports of audits of all stored gametes and embryos were reviewed and the accuracy of storage logs, consent records and the 'bring-forward' system was discussed 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.

---

[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%.

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; staff in the laboratory were able to carry out their activities without distraction and were available to carry out witnessing activities 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 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.

The effectiveness of the centre's QMS was assessed by reviewing the reports of the following audits: witnessing, consent, storage and controlled drugs.

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 use of CE marked medical devices;
- the use of the most recently issued HFEA consent form versions;
- the centre's audit and management of legal parenthood;
- the follow-up actions taken following a recent incident reported to the HFEA;
- HFEA Clinic Focus articles regarding: supporting patients with legal parenthood issues, Ebola and Zika advice and changes to storage periods for gametes and embryos.

The centre has been generally effective in ensuring compliance with guidance issued by the HFEA, notwithstanding the use of a non CE marked medical device discussed below.

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 broadly compliant with guidance because: a review of the controlled drugs register showed that on one occasion an alteration had been made, without being accompanied by an asterisk and footnote explanation (SLC T2; recommendation 3).

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 broadly compliant with guidance because taps in some consultation and treatment rooms are not suitable for hands-free operation and the floors in the male production room and some clinical areas are not sealed. In addition, on the day of inspection clinical waste bags were being stored in an unlocked yellow bin and black bagged waste was being stored in an open trolley, both in a patient accessible corridor (SLC T17; recommendation 2).

Equipment and Materials

It is important that products (known as medical devices) that come into contact with gametes and/or 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 the following medical devices was reviewed in the course of the inspection: IVF/ICSI dishes, serological pipettes, denuding pipettes, centre well dishes, four well dishes, six well repro plate, conical bottom tubes, round bottom tubes, stripper tips, syringes, catheters, sperm wash, ICSI media, vitrification kit, IVF media and embryo glue. The inspection team found the centre to be compliant with HFEA requirements to use CE marked medical devices wherever possible.

If nitrogen gas is produced using a nitrogen generator, it is important to be assured that the gas produced is of an appropriate specification. On the day of inspection the centre could not locate paperwork to demonstrate the nitrogen generator had been fully validated and could not provide evidence of the specification of gas being produced. Evidence of compliance has since been provided.

Patient experience

During the inspection, no patients were available to speak with the inspectors about their experiences at the centre. Twelve patients provided feedback directly to the HFEA in the time since the last inspection. Feedback was positive, with three of the individuals providing written feedback giving compliments about the care received.

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;
- gives prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions;
- is taking measures to improve the system for responding to patient phone calls.

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

Information submitted by the centre in their self assessment questionnaire, the pre-inspection assessment and observations during the visit to the centre, indicate that the centre is broadly compliant with the following HFEA requirements:

Premises and Facilities

The outside gas storage area appeared accessible to the public. On the day of inspection, 12 gas cylinders were observed in the area but only three were securely chained; the remainder were unsecured. Centre staff also described liquid nitrogen being stored, unsecured overnight on occasion. These practices may constitute a safety risk (SLC T17; recommendation 1).

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in 2014 recommendations for improvement were made in relation to three major and four '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 last renewal inspection in August 2014 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.

The clinic is compliant with requirements to submit information to the HFEA. There are currently no data submission issues at this clinic. This conclusion is based on a review of the clinic's register submissions conducted on 27 July 2016.

Legal parenthood

Where a couple to be treated with donated gametes or embryos is 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 February 2014, the HFEA asked all 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 submitted the report of the audit to the HFEA within the required timeframe. The audit showed that four couples were initially believed to be affected by legal parenthood consent anomalies.

A copy of the centre's audit was submitted to the HFEA in May 2014 for review, and found to have been performed according to the method specified by the HFEA. Actions had been taken in response to the audit findings.

As part of the HFEA's ongoing activities relating to legal parenthood consenting, in October 2015 all PRs were asked to confirm that specific actions had been undertaken; that there are effective methods for assessing the on-going competence of staff to take this consent; and that effective audit procedures are in place to ensure on-going compliance with consent taking requirements. The PR provided the required reassurances to the satisfaction of the Executive during a telephone interview in October 2015. The PR confirmed that the centre had one case known to be affected by legal parenthood consent anomalies, and one case where the civil partnership status of the couple at the time of treatment was still to be established.

The PR confirmed in May 2016 that both couples had been successfully contacted by the centre. One couple was able to confirm that they were in a civil partnership at the time of treatment, thus legal parenthood consents were not required.

During the inspection visit the PR discussed the one case affected by legal parenthood consent anomalies. The centre has taken independent legal advice, has offered full support to the affected couple and has identified a specialist legal representative should the couple choose to pursue a legal declaration of parenthood.

To provide further assurance of the effectiveness of the centre's procedures, the inspection team reviewed 10 sets of records where treatment with donor sperm had recently been provided in circumstances where consent to legal parenthood was required. Effective consent to legal parenthood and the offer of counselling was in place prior to consent and treatment in all cases.

A robust consent taking staff training program was discussed, which included staff seminars, a presentation by a prominent specialist legal expert, one-to-one staff supervision and a detailed consent taking competency record.

In summary, the inspection team considers the processes used to collect legal parenthood consent at this centre to be compliant with HFEA requirements.

Annex 1

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			

‘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. **Premises and Facilities** The outside gas storage area appeared accessible to the public. On the day of inspection 12 gas cylinders were observed in the area but only three were securely chained; the remainder were unsecured. Centre staff also described liquid nitrogen being stored, unsecured overnight on occasion. These practices may cause a safety risk (SLC T17).	The PR should ensure gas cylinders and liquid nitrogen vessels are stored safely and securely at all times. Evidence confirming the implementation of this recommendation should be submitted to the centre’s inspector by 9 November 2016.	NHS facilities maintenance team visited the area and a report had been put and recommendations have been agreed by them (attached). The work will follow in due course.	The Executive acknowledges the PR’s response and her commitment to fully implementing the recommendation. Further action required.

‘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
2. **Infection Control** • Taps in some consultation and treatment rooms are not suitable for hands-free operation. • The floors in the male production room and some clinical areas are not sealed. • Clinical waste bags were being stored in an unlocked yellow bin, and black bagged waste in an open trolley, in a patient accessible corridor (SLC T17).	The PR should ensure that: • sinks with taps for hands-free use are available in all areas where clinical procedures take place; • clinical areas, where there is a risk of body fluid spillage, have sealed floors; • clinical waste is stored securely and disposed of effectively. Evidence confirming the implementation of this recommendation should be submitted to the centre’s inspector by 9 February 2017.	We were fully aware of this, and reasons for non-compliance explained by the SCN at the time of the inspection. The Inspector was also provided with copy of our last HAI audit and completed action plan. Non- compliant sinks/taps and waste segregation areas are already listed on the NHS Grampian 'risk register' and the Organisation is reluctant to invest in minor works within out-patient facilities prior to completion of the new hospital in 2020 where out-patient facilities will meet standard for in-patient facilities in accordance with SHPN 04-01). We have since had our 2016 HAI environmental audit (31st Aug) and we did not receive non-conformance for the	The Executive acknowledges the PR’s response. The PR is reminded that centres must be fully compliant with HFEA licence conditions. The Executive accepts the NHS Grampian Infection Control team’s assessment of the suitability of flooring within the male production room. No further action is required for this aspect of the recommendation. The Executive acknowledges that the remaining non-compliances will be addressed on completion of a new hospital build, however does not consider a four year timescale for compliance acceptable. The Executive requires the recommendations to be

		flooring in the men's rooms for reasond already listed above. This inspection was carried out by our Infection Control Team and we have also informed them of concerns raised in this report	implemented within the stated timescales. Further action required.
3. **Medicines Management.** A review of the controlled drugs register, showed that on one occasion an alteration had been made without being accompanied by an asterisk and footnote explanation (SLC T2).	The PR should identify suitable corrective actions. The PR should then conduct an audit of the controlled drugs register six months after implementing corrective actions, to confirm the actions have had the desired effect. A summary of the audit should be submitted to the centre's inspector by 9 February 2017.	We accept that this is a non-conformance and the medical and nursing teams have been made aware by team meetings and email communications. We have recently requested a Controlled Drugs audit following discussion at the July risk management meeting; a copy of which was given to the Inspectors on the day. This audit was carried out by the Lead Pharmacist from NHSG, who provided positive feedback. We have requested NHSG pharmacy to do another audit and will update HFEA of the outcome.	The Executive acknowledges the PR's response and her commitment to fully implementing the recommendation. Further action required.

Additional information from the Person Responsible
We thank HFEA inspectors for their time and positive comments. We will take on board on their recommendations to help maintain the high standard of patient care and further improve service provision.