Executive Licensing Panel - minutes

Centre 0086 (BMI Chelsfield Park ACU) – Interim Inspection report

Friday, 18 September 2015

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

Panel members	Paula Robinson (Chair) Hannah Verdin Ian Peacock	Head of Business Planning Head of Regulatory Policy Analyst Programmer
Members of the Executive	Dee Knoyle	Secretary
External adviser	None	
Observers	None	

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 BMI Chelsfield Park ACU, centre 0086, has held a licence with the HFEA since 1992 and provides a full range of fertility services.

1.2. The panel noted that the centre's licence is due to expire on 30 September 2017.

1.3. The panel noted that the inspection took place on 9 June 2015.

1.4. The panel noted that in the 12 months to 30 April 2015, the centre provided 232 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a small centre.

1.5. The panel noted that HFEA-held register data for the year ending 30 November 2014 showed the centre's success rates, in terms of clinical pregnancy, were in line with national averages.

1.6. The panel noted that for the year 2014, the centre reported 12 cycles of partner insemination with one pregnancy. This represented performance which was in line with the national average.

1.7. Between March 2014 and February 2015, the centre's multiple clinical pregnancy rate for all IVF, ICSI and frozen embryo transfer (FET) cycles for all age groups was 22%. This means that the centre's multiple live birth rate is likely to meet the 10% maximum multiple live birth rate target.

1.8. The panel noted that at the time of the interim inspection on 9 June 2015, three major and two other areas of non-compliance were identified. The panel noted that since the inspection the Person Responsible (PR) has committed to fully implementing all of the recommendations within the prescribed timescales.

1.9. The panel noted that there were positive comments made by patients.

1.10. 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 and was satisfied that the centre was fit to have its treatment and storage licence continued. The panel urged the PR to fully implement the recommendations made in the interim inspection report within the prescribed timescales.

3. Chair's signature

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

Signature

Name

Paula Robinson

Date

29 September 2015

Interim Licensing Report

Centre name: Chelsfield Park ACU
Centre number: 0086
Date licence issued: 01 October 2013
Licence expiry date: 30 September 2017
Additional conditions applied to this licence: None
Date of inspection: 9 June 2015
Inspectors: Shanaz Pasha (lead) Karen Conyers, Susan Jolliffe
Date of Executive Licensing Panel: 18 September 2015

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. In particular we note the positive comments made by patients.

The ELP is asked to note that there were six recommendations for improvement in relation to three major and two 'other' areas of non compliance or poor practice.

'Major' areas of non compliance:

- The PR should ensure that the laboratory undertaking diagnostic semen analyses is accredited by Clinical Pathology Accreditation (CPA) UK Ltd or equivalent.
- The PR should review the efficacy of the Quality Management System (QMS).
- The PR should ensure witnessing is carried out in accordance with guidance.

'Other' areas of practice that require improvement:

- The PR should ensure that the withdrawal of consent and 'cooling off' period for storage are accurately recorded in the centre's bring forward system.
- The PR should ensure that suitable practices are in place for the storage and use of controlled drugs.

In responding to this report the PR has given a full commitment to implement the recommendations within the prescribed timeframes.

Information about the centre

The BMI Chelsfield Park Assisted Conception Unit (ACU) has held a licence with the HFEA since 1992. The centre provides a full range of fertility services.

A building project was completed in April 2015 at Chelsfield Park Hospital. The ACU in its entirety was affected by this work, and moved to temporary premises in August 2014 for the work to take place. The ACU re-opened as planned on 11 May 2015. The variation of the centre's licence was approved by a Licensing Committee on 22 August 2014 and again, on 1 May 2015 to reflect the changes of premises.

The centre provided 232 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 30 April 2015. In relation to activity levels this is a small 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 30 November 2014 show the centre's success rates in terms of clinical pregnancy rates are in line with national averages.

For the year 2014 the centre reported 12 cycles of partner insemination with one pregnancy. This represents a performance which is in line with national average.

Multiple births[2]

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

Between March 2014 and February 2015, the centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 22%: this means that the centre's multiple live birth rate is likely to meet the 10% multiple live birth rate target.

Witnessing

Good witnessing processes are vital in ensuring there are no mismatches of gametes or embryos, and that identification errors do not occur. The inspection team were not able to observe any laboratory activities but centre staff were able to describe the witnessing procedures that would be undertaken during an egg collection, thawing of gametes/embryos and sperm preparation.

During the inspection, we assessed the centre's witnessing procedures and considered that they are partially compliant. The following non-compliances were noted:

[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%.

- Dishes and tubes used for gamete and embryo processing are labelled with only with the patient's initial, surname and hospital number (see recommendation 3).
- Tubes used during egg collection are not labelled. The inspection team note that checks of the procedure room and critical laboratory work areas are made before setting up for, and immediately after, each egg collection to remove all tubes, so only tubes for a single patient are present during their egg collection. These checks are not documented in the patient records and the risks of these labelling practices used have not been formally assessed (see recommendation 3).
- Centre staff advised that at the time of embryo transfer a witness checks the identity of the embryos to be transferred by checking the details on the lid of the dish but not the dish itself (see recommendation 3).

Consent: To the storage of cryopreserved material

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. 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 centre's processes for storing gametes and embryos were considered to be broadly compliant with HFEA requirements. The centre has a bring-forward system to ensure that all samples are stored in line with the gamete provider's consent. All patients with stored gametes and/or embryos are contacted annually. During the inspection it was noted that one withdrawal of consent to storage had been received by the centre which resulted in the initiation of a 'cooling off' period; however the database recording consent expiry has not been updated to reflect the reduced consent storage period (see recommendation 5).

Staffing

Having the right numbers of staff, competent to carry out highly technical work in a non-pressured environment is important in infertility services.

Staffing levels observed in the course of the on-site inspection appeared to be suitable for the activities being carried out: patients were seen promptly on arrival; the atmosphere in the clinic appeared calm at all times.

Quality Management System (QMS)

It is important that clinics 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 changes that are identified as required are made as this helps ensure that clinics continuously improve.

The effectiveness of the centre's QMS was assessed by evaluating a sample of the centre's audits. We also considered whether the clinic's processes for implementing learning are effective.

The centre's audits of documentation of witnessing, consent to storage and medicines' management were reviewed during the inspection. The inspection team considered that the centre's audit practices are partially compliant with requirements for the following reasons:

- The centre's audit of consent identified three non-conformances. These were; a missing signature on the last page of a treatment and storage consent form, incorrect dates of signing, and a missing signature on a consent to disclosure (CD) form. The inspection team were concerned the findings identified in the audit did not prompt action to identify the root causes of the non-conformances (so mitigating the risk that the same errors may recur) and in particular, action had not been taken in relation to the incomplete consent forms (see recommendation 2).
- The centre had not conducted an audit of processes to ensure that all information is kept confidential in the last two years (see recommendation 2).
- The observations documented above with respect to non-compliance with witnessing guidance suggest that the centre's audit of witnessing had failed to assess compliance with the regulatory requirements effectively (see recommendation 2).

The centre is partially effective in implementing learning from their audits and from guidance from the HFEA. The centre undertakes diagnostic semen analyses however the laboratory is not accredited by CPA or equivalent: this indicates that centre has not taken action to implement advice on CPA accreditation issued by the HFEA in a Clinic Focus article issued in June 2011 (see recommendation 1). In addition, the centre had not extracted learning from the findings of their own audit of consent (see recommendation 2).

Medicines Management

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

During the inspection the centre's processes for medicines management and the safe storage disposal and administration of medicines were reviewed and found to be broadly compliant with guidance. The following non-compliance was noted:

- The ACU theatre does not have a controlled drugs cupboard. In the course of the inspection conflicting accounts were provided about how controlled drugs are transferred from the cupboard in the main theatre to the ACU theatre: in one account it was reported that all the controlled drugs required for a list are transferred to the ACU theatre at the same time. The inspectors did not consider this to be a safe system of working (see recommendation 4).

Infection Control

Having suitable arrangements in place to ensure that patients experience care in a clean environment is important, as well as ensuring that both patients and staff are protected from acquiring infections.

During the inspection, we assessed compliance with infection control guidance by observation, and found that the centre's procedures are compliant with guidance.

Equipment and Materials

It is important that products (known as medical devices) that come into contact with gametes and/or embryos are approved for use in treatment to ensure the safety of gametes and embryos and patients. Approval of such products is denoted by the issue of a 'CE mark'.

In the course of the inspection the CE mark status of a sample of the medical devices used by the clinic was reviewed. The centre is compliant with the HFEA requirement to use CE marked medical devices wherever possible.

Patient experience

During the inspection visit there was not any clinical activity and it was therefore not possible to speak to any patients. 16 patients provided feedback directly to the HFEA in the time since the last inspection. Feedback was positive, with 12 of the individuals commenting that they had compliments about the care that they received.

On the basis of this feedback it was possible to assess that the centre:

- has respect for the privacy and confidentiality of patients in the clinic;
- gives prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions;
- maintains an effective 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

From the information submitted by the centre in their self assessment questionnaire, pre-inspection assessments and from observations during the visit to the centre, the inspection team identified the following non-compliance:

- The centre undertakes diagnostic semen analyses however the laboratory is not accredited by CPA or equivalent (recommendation 1).

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in 2013 recommendations for improvement were made in relation to six 'other' areas of non-compliance.

The PR provided information and evidence that all of the recommendations were fully implemented.

On-going monitoring of centre success rates and risk tool alerts

Since the last inspection in April 2013 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. The centre is compliant with data submission requirements.

The partners of women treated with donated gametes or embryos, where the couple are not married or in a civil partnership, must give written consent in order 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 completed a legal parenthood audit in May 2014 in response to recommendations from their renewal inspection and meeting the requirements of the audit requested by the HFEA in February 2014. No actions were identified as necessary as a result of the findings.

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	Executive review
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	Executive review
1. The centre undertakes diagnostic semen analyses however the laboratory is not accredited by CPA or equivalent. SLC T21	The PR should ensure that the laboratory which undertakes diagnostic semen analysis is accredited by CPA, or provide evidence to support a status equivalent to accreditation. Evidence of CPA accreditation, or equivalent should be forwarded to the centre’s inspector by 9 December 2015.	As a result of a recent building project the ACU now has an andrology lab. It is our intention to gain CPA accreditation and offer a full diagnostic semen analysis service, but the accreditation process will take time. In the interim, in order to comply with current requirements in relation to the embryology laboratory, evidence of CPA equivalence will be supplied within the timeframe requested	The Executive acknowledge the PR’s response and her commitment to implementing the recommendation. Further action required.
2. The centre’s audit of consent including consent to storage identified three non-conformances. The inspection team were concerned the findings identified in the audit did not prompt action to identify	The PR should review the efficacy of the centre’s QMS with regard to the process of ensuring audits include an assessment of compliance with regulatory requirements; effective root cause analysis where non-	Audits of consent are conducted regularly and results are presented at monthly meetings. Non- conformances are highlighted and discussed, the discussion including root causes and preventative actions	The Executive acknowledge the PR’s response and her commitment to implementing the recommendations.

the root causes of the non-conformances (so mitigating the risk that the same errors may recur) and in particular, action had not been taken in relation to the incomplete consent forms. . The centre had not conducted an audit of processes to ensure that all information is kept confidential in the last two years. Inspection observations suggest that the centre's witnessing audit failed to assess compliance with the regulatory requirements effectively. SLC T36 and Code of Practice 23.19 & 23.27	conformances are identified and implementation of corrective actions. The centre's inspector should be provided with a summary report of the findings of this review including any changes in practice identified as required by 9 September 2015. Within three months of implementing changes, the centre should carry out review of audits conducted since the implementation of corrective actions to identify whether the changes have been effective. A summary report of the review should be supplied to the centre's inspector by 9 December 2015. The PR should also review the findings of audits performed since the last inspection to ensure that any corrective actions identified have been fully implemented. Confirmation that this action has been taken should be provided to the centre's inspector by 9 December 2015.	(CAPAs). The CAPAs are fully documented. It is accepted however that the incomplete consent forms identified during the inspection had not been re-addressed, This practice will be reviewed An audit to ensure information is kept confidential will be performed and such an audit added to the annual audit schedule. A review of previous audits will be conducted as required	Further action required.

3. Dishes and tubes used for gamete and embryo processing are labelled with the patient's initial, surname and hospital number only, rather than with the full name and a unique identifier. Tubes used during egg collection are not labelled. The inspection team note that checks of the procedure room and critical laboratory work areas are made before setting up for, and immediately after, each egg collection to remove all tubes, so only tubes for single patient should be present during the egg collection. These checks are not documented in the patient records however, and the risks of not labelling the tubes have not been formally assessed. Centre staff advised that at the time of embryo transfer a witness checks the identity of the embryos to be transferred by checking the details on the lid of the dish but not the dish itself.	The PR should take immediate action to ensure witnessing is carried out in accordance with guidance. The PR should advise what action has been taken when responding to this report. The PR should also undertake a review of witnessing practices to ensure that they are compliant with regulatory requirements and guidance. It is acknowledged that only one egg collection takes place at a time, but the PR should consider the risks of not labelling the tubes used during egg collection and should take appropriate action to mitigate any risks identified. A summary of the findings of the review including corrective actions and the timescales for implementation should be provided to the centre's inspector by 9 September 2015. Within three months, the centre should carry out an audit of witnessing practices, including compliance with regulatory requirements, to ensure that the proposed corrective actions have been effective in ensuring	At the time of the inspection, tubes were labelled with the full name and (unique) hospital number as were the tops of dishes. It was the bottom of the dishes only that had just the initial, surname and hospital number. Since the inspection the practice has changed and the bottoms of the dishes are now also fully labelled. As the inspectors have stated tubes used in the collection of follicular fluid are not labelled. However it is acknowledged that tubes for egg collection are brought into theatre one case at a time and at the end of that egg collection all tubes, used and unused, are disposed of so that no tube remains from the end of one case to the start of the next. It is felt therefore that the process itself is robust but since the inspection a signature has been added to the lab sheet formally documenting the cleared tube check. Al review will be conducted by the PR, as requested.	The Executive acknowledge the PR's response and her commitment to fully implementing the recommendations. Further action required.

SLC T101, SLCT71 and Code of Practice 18.28	compliance. A summary report of the audit findings should be supplied to the centre's inspector by 9 December 2015.	Prior to embryo transfer, embryos are moved from the culture dish into a transfer dish. The transfer dish is labelled top and bottom and the transfer witnessed by a second embryologist who confirms the correct labelling top and bottom. The configuration of our laboratory and theatre means that direct communication is via a hatch and a nurse cannot easliy walk between the two rooms. The top of the dish is shown to the nurse through the hatch immediately before the embryos are loaded to confirm patient identity but it is not possible for the base of the dish to be seen from the hatch nor practical for the nurse to leave the patient and walk around . Since the dish has already been fully checked it is felt the system is robust but a further review will be conducted by the PR as requested.	

‘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	Executive review
4. A withdrawal of consent to storage had been received by the centre which resulted in the initiation of a ‘cooling off’ period; however the database recording consent expiry has not been updated to reflect the reduced consent storage period. SLC T46(f)	The PR should provide assurance that the database has been corrected when responding to the report. The PR should review processes for recording withdrawal of consent and ensuring that their bring forward systems are accurate. A summary of the findings of the review including corrective actions and the timescales for implementation should be provided to the centre’s inspector by 9 September 2015.	The Unit has a database to monitor storage periods for cryopreserved material. At the time of the insprection one set of data had not been updated to reflect the reduced consent to storage period. This has now been corrected.	The Executive acknowledge the PR’s response and her commitment to implementing the recommendation. Further action is required.
5. The ACU theatre currently does not have a controlled drugs cupboard and therefore any controlled drugs required for patients being treated in the ACU theatre are brought in from the main theatre’s controlled drugs cupboards.	The PR should review the centre’s processes for safe handling of controlled drugs. A summary of the findings of the review including corrective actions and the timescales for implementation should be provided to the centre’s inspector by 9 September 2015	Since the inspection, a new CD cupboard has been delivered and fittied into the ACU theatre. Once stocked, the ACU theatre will maintain its own stock of CDs and CD log book which will be managed in line with the hospital's Safe Management of Controlled Drugs Policy	The Executive acknowledge the PR’s response and her commitment to implementing the recommendation. Further action required.

On the day of the inspection, centre staff advised that a controlled drugs cupboard has been ordered. SLC T2		Confirmation of this will be provided in the timescale requested	

Additional information from the Person Responsible