Inspection Report

Date of Inspection: 13 March 2012
Purpose of inspection: Interim inspection of treatment and storage licence
Length of inspection: 7 hours
Inspectors: Chris Hall and Dave Gibbon

Inspection details:
The report covers the pre-inspection analysis, the visit and information received from the centre between 11 March 2010 and 17 May 2012.

Date of Executive Licensing Panel: 1 June 2012

Purpose of the Inspection report
The purpose of the inspection is to assess whether centres are complying with the Human Fertilisation and Embryology (HF&E) Act 1990 (as amended), the HF&E Act 2008 and the Code of Practice (CoP), to ensure that centres are providing a quality service for patients. The report summarises the findings of the licence interim inspection highlighting areas of good practice, as well as areas where further improvement is required to improve patient services and meet regulatory requirements. It is primarily written for the Authority's Executive Licensing Panel (ELP) which makes the decision about the continuation of the centre's licence.

Centre details

Centre Name	Leicester Fertility Centre
Centre Number	0068
Licence Number	L0068-15-C
Centre Address	Assisted Conception Unit, Women's Hospital, Leicester royal Infirmary, Leicester, LE1 5WW
Person Responsible	Mrs Jane Blower
Licence Holder	Mr Tarek Gelbaya
Date Licence issued	01/10/2010
Licence expiry date	30/09/2014
Additional conditions applied to this licence	None

Contents

Report to Executive Licensing Panel

Brief description of the centre and its licensing history:

The Leicester Fertility Centre has held an uninterrupted active HFEA licence since 1997. The centre has a good record of compliance with no previous conditions on its licence.

The centre is a self-contained facility based at the University Hospitals of Leicester NHS Trust and provides a range of fertility services to both NHS and privately funded patients. Fertility services are provided under contract on behalf of two strategic health authorities, four primary care trusts as well as privately funded patients. Eligibility criteria for patients vary between commissioning authorities although the centre has common standard operating procedures for all patients.

The facility comprises: a waiting and reception area; a fully equipped theatre; consulting and treatment rooms; counselling room; embryology and andrology laboratories, cryostorage room, sperm production rooms and staff facilities.

Activities of the Centre:

Type of treatment	Treatment cycles, Jan 2011 to 31 Dec 2011*
In vitro fertilisation (IVF) & Intracytoplasmic sperm injection (ICSI)	330
Frozen embryo transfer (FET)	167
Donor insemination (DI)	72
Partner insemination (IUIP)	225
Egg share provider (sharer)	4
Egg share recipient	3
Egg donation (non-egg share)	7

Other licensable activities	✓ or Not applicable (N/A)
Storage of eggs	✓
Storage of sperm	✓
Storage of embryos	✓
Research	N/A

Outcomes*
For fresh IVF/ICSI cycles and FET, HFEA register data for 1 January 2011 to 31 December 2011 show the centre's success rates are comparable to national averages. In 2010, the centre reported 225 cycles of partner insemination with 25 pregnancies. This equates to an 11% pregnancy rate which is in line with sector averages.

*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.

Summary for licensing decision :

In considering overall compliance, the inspection team considers that they have sufficient information drawn from documentation submitted by the centre prior to inspection and from observations and interviews conducted during the inspection visit, to draw a conclusion on the continuation of the centre's licence.

The Executive Licensing Panel is asked to note that at the time of the inspection there were a number of areas of practice that required improvement, including two major areas of non-compliance and one other areas of non-compliance.

Major areas of non compliance:

- The PR should ensure all critical equipment is validated.

- The PR should ensure diagnostic semen analyses are performed by a laboratory accredited by Clinical Pathology Accreditation (CPA) (UK) Ltd

Other areas of practice that require improvement:

- The PR should ensure fees for treatment cycles are paid no later than 28 days from the date on the Authority's invoice.

Since the inspection, the Person Responsible (PR) has responded to the recommendations regarding validation of critical equipment and treatment cycle fees The Executive is satisfied with the response and no further action is required. In addition the PR has committed to keep the Executive informed regarding CPA accreditation of the centre's laboratory performing diagnostic semen analyses.

The inspection team recommend the continuation of the centre's licence without additional conditions subject to compliance with the recommendations made in this report being implemented within the prescribed timescales.

Details of Inspection findings

1. Focus of inspections for 2010-12

Providing information to patients in relation to costed treatment plans and parenthood
What the centre does well. The centre has a documented protocol for the provision of information to patients, partners and donors and has developed a relevant quality indicator (QI) against which it conducts audits (Standard Licence Condition (SLC) T33b; T35; and T36). **Costed treatment plans** The centre provides a range of fertility services to both NHS and private/self-funding patients. The latter are provided with personalised costed treatment plan prior to treatment (CoP Guidance 4.3). The Nurse Co-ordinator explained that private/self-funding patients are provided with a price list on which indicative cost of treatments, drugs and blood tests are detailed. The price list is used to provide patients with an estimate of the full cost of treatment by identifying relevant costs. The circumstances in which both the patient may be required to meet additional costs and in which refunds will be made are outlined. Patients are given the opportunity to discuss the treatment plan and costs prior to treatment commencing. The files of three self-funding patients were reviewed at the time of inspection. Copies of completed cost of treatment plans were found on each file. **Legal parenthood** The Nurse Co-ordinator demonstrated an understanding of the legal parenthood provisions. Parenthood issues are discussed with patients and partners by both nursing staff and counsellors (SLC T60 & T61). A file of a patient who had undergone treatment with donor sperm was selected and reviewed; consent to legal parenthood was found to have been appropriately obtained. **Website** The centre publishes data on its treatment activity and pregnancy and live birth rates on its website. This data is broken down by maternal age and treatment type and a link to the HFEA's fertility clinic success rate website page is also provided (Chair's Letter CH(11)02).
What they could do better. Nothing noted at the time of inspection.

Consent - particularly consent to disclosure to researchers and consent to storage

What the centre does well.

Consent to disclosure of identifying information to researchers
The centre seeks patient and partner consent to the disclosure of identifying information in the HFEA register to researchers. Registry information demonstrates that 65% of patients and partners who have been registered at the centre since October 2009 have opted to disclose some information to researchers.

The consents for disclosure of identifying information to researchers held on five patient files were reviewed against the disclosure information submitted by the centre for inclusion on the HFEA's statutory register; no discrepancies were found (General Direction 0007 (5)).

Consent to storage
The centre has a documented standard operating procedure (SOP) in place for the storage of patient gametes and embryos (SLC T33b). Documentary evidence was seen of the audit of procedures for the taking patient consent in the last two years and relevant QIs are in place. An audit of all cryopreserved gametes and embryos is undertaken biennially to ensure there is written and effective consent for all material held (HF&E Act Schedule 3, 8(2)). The latest audit was completed during March 2011 (SLC T36; T35).

The senior embryologist demonstrated a good understanding of the 'statutory cooling-off period' to be invoked in the event that there is a dispute between gamete providers regarding the continued storage of their embryos (HF&E Act Schedule 3, 4A(4)).

What they could do better.
Nothing noted at the time of inspection.

Multiple births

For the 9 month period 01 April 2011- 31 December 2011, the centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 11%.[1]

The centre's multiple clinical pregnancy rate for 2010/11 represents performance likely to be better than target performance at a statistically significant level, and which is unlikely to be due to random variation.

What the centre does well.
On-going monitoring of the centres multiple clinical pregnancy rate suggests that the centre is not likely to exceed the 2011/12 multiple birth rate target of 15% (SLC T123).

The PR has provided sufficient evidence to demonstrate compliance with HFEA Directions

[1] A multiple clinical pregnancy rate of 25% is calculated as likely to result in a multiple live birth rate of 20%.

0003 in that:

- staff were able to describe their progress towards reducing their multiple pregnancy rates and subsequent multiple birth rates;
- staff at the centre have audited their strategy and protocols as part of the quality management audit programme;
- staff have maintained a log of women receiving double and triple embryo transfers who meet the criteria for single embryo transfer;
- staff have maintained a log which indicates the reasons for variation from the single embryo transfer policy and outcomes which are also recorded in the patients records.

The PR explained that that the centre's multiple birth minimisation strategy is reviewed annually and that the process involved doctors, embryologists and nursing staff.

The centre's Primary Care Trust (PCT) commissioners have implemented a single embryo transfer (SET) policy for all patients irrespective of age, clinical indications or previous successful or failed cycles. As a result only self-funding patients eligible for single embryo transfer can opt to have more than a single embryo transferred. The PR reports that since 2009 only one patient has done so. The PR explained that the risks are explained to the patient and are documented in the patient's file.

What they could do better.
Nothing noted at the time of inspection.

Validation of critical equipment and processes

What the centre does well.

Process validation
The senior embryologist explained that the centre's critical processes have been validated using supporting evidence in the form of SOPs, records of audited compliance and related validation data. Validation records for 14 processes were observed on inspection (including sperm preparation; egg collection; and cryopreservation) (SLC T72).

Equipment validation
With the exception of the two items detailed below, critical equipment has been validated (SLC T24). Validation records for a selection of equipment (including an incubator, class II cabinet and fridge) were reviewed on inspection.

The centre has processes in place for revalidation of equipment following repair and the documented revalidation of an ICSI rig following repair was reviewed on inspection (SLC T25).

Instruments and devices used for procurement for gamete and/or embryos are regularly maintained (SLC T28). Maintenance files were reviewed on inspection and maintenance certificates were produced on request for three items of equipment to confirm they had been serviced in the last 12 months (i.e. ICSI microscope, Galaxy mini-incubator and flow-

hood). Service reports for prior years were found to be complete.

The senior embryologist explained that the centre has a validated cleaning and sterilisation procedure for removing infectious agents (SLC T29).

What they could do better.

Equipment validation
Not all critical equipment was found to have been validated on inspection (SLC T24):

- the centrifuge has been calibrated, serviced and pattern tested but not validated;
- Gilson pipettes are calibrated yearly but not validated.

Witnessing

What the centre does well.
The senior embryologist explained that a double check of the identification of gametes and embryos the patient or donor to whom they relate is carried out at all critical points of the clinical and laboratory processes (SLC T71).

There is a documented SOP describing the witnessing procedure for all critical points specified in CoP Guidance 18.4. A copy was reviewed at inspection (SLC T33b). Witnessing steps observed during the inspection were performed in accordance with CoP requirements. A QI has been established for witnessing and was observed on inspection (SLC T35).

Monthly audits of ten sets of records and full annual audits of how far witnessing procedures comply with the approved protocols, regulatory requirements and QIs are undertaken (SLC T36). The most recent audit report date 11 January 2012 was reviewed on inspection. No corrective actions were required.

Six sets of patients notes audited on inspection were found to include records of all required witnessing steps.

Evidence of staff competence in witness is documented (SLC T15a). Appropriately completed competency assessment records of all embryologists were reviewed on inspection.

What they could do better.
Nothing noted at the time of inspection.

Gamete and embryo donation – reimbursement, information provision and screening

What the centre does well.

Information provision
A comprehensive 'Provision of Information' protocol is in place that includes donation and information to be provided to support the donor recruitment, assessment and selection process (SLC T33b). An information booklet has been produced for prospective donors and all donors receive counselling (HF&E Act 1990 (as amended), Schedule 3, 3(1)a and 3(1)b).

QIs relevant to the provision of information have been established (SLC T35) and audits are conducted by way of patient survey to determine the extent to which information provided meets user needs (SLC T36).

The centre maintains a record of all births resulting from donated gametes which facilitates the provision of information concerning the number, gender and birth year of offspring resulting from their donation, if and when requested (HFE Act 1990 (as amended), Schedule 3, 31ZD(3)).

Screening
The donor screening records in six donor files were reviewed on inspection. The sample of records provided evidence that:

- donors are selected on the basis of age, health and medical history, facilitated by interview, examination by a consultant and completion of a medical history questionnaire (SLC T52(a));
- donors are selected in accordance with the screening requirements of SLC T52 and relevant professional bodies and additional screening is undertaken if indicated;
- Donor sperm is quarantined for a minimum of 180 days, followed by repeat testing in accordance with SLC T53(c).

Donor screening is compliant with the requirements SLC T52 and screening tests are performed within laboratories that have been accredited by the CPA (SLC T 53(a)).

Reimbursement of donors
The Nurse Co-ordinator explained that any compensatory payments made to donors are restricted to donation related expenses incurred in the UK and loss of earnings. A record is maintained of the loss of earnings and expenses, with supporting evidence, such as receipts, tickets and other documentation, and of all reimbursements paid (General Directions 001).

What they could do better.
Nothing noted at the time of inspection.

Welfare of the Child (in relation to basic partner treatment services only)
What the centre does well. The Nurse Co-ordinator explained that before any woman is provided with treatment services the welfare of any child who may be born as a result of treatment and of any other child who may be affected is taken into account (SLC T56). There is a Welfare of the Child (WoC) protocol in place; an electronic copy was observed on inspection (SLC T33(b)). Monthly notes audits are conducted. The audit checklist includes in addition to an assessment of the extent to which the consent and recording keeping QIs are being met (SLC 36), whether: • WoC assessment has been carried out; • clinic staff have completed the relevant section of the WoC form; and • any WoC issues have been followed-up Five patient files were reviewed on inspection including patients receiving basic partner treatment services. All contained completed patient and partner WoC assessment forms that bore evidence of review by centre staff. In each instance the assessment had taken place prior to treatment. In no instances was further information sought and the assessment question responses were found to support this decision.
What they could do better. Nothing noted at the time of inspection.

2. Changes/improvements since the previous inspection on 11 March 2010

Area for improvement	Action required	Action taken as evidenced during this inspection
Staff interviewed could not provide evidence of the evaluation of their competencies being carried out at appropriate intervals and the results documented. Licence Condition T12	At the time of inspection the PR was aware of this non-compliance, had completed the pre inspection self-assessment questionnaire accordingly and provided an action plan and timetable for introduction of documented competency assessments to begin in spring 2010. The PR should ensure that the competency of the personnel at the centre is evaluated at appropriate intervals and the results documented as described in the action plan and timetable.	Competency documentation was submitted 31 August 2010: No further action is required.
Not all critical equipment (technical devices) and critical processing procedures have been validated. Licence Conditions T24 and T72	At the time of inspection the PR was aware of this non-compliance, had completed the pre inspection self-assessment questionnaire accordingly and provided evidence of a detailed action plan for all critical procurement, processing procedures and equipment to be validated The PR should ensure that all critical equipment (technical devices) and critical processing procedures have been validated.	Validation/Qualification matrix & validation schedule submitted 31 August 2010. On this inspection, processes were seen to be validated, but two pieces of equipment were found not to have been validated. Further action is required.
The laboratory that the centre uses for some diagnostic semen	The PR must ensure that diagnostic laboratory tests are carried out by a	On this inspection, it was found that a CPA audit visit had been conducted during

Area for improvement	Action required	Action taken as evidenced during this inspection
evaluations is not CPA (UK) accredited. Licence Condition T21 & T51	laboratory which has suitable accreditation (for example by CPA (UK) Ltd or another body accrediting to an equivalent standard.	February 2012. An application for CPA accreditation is scheduled for June 2012. Further action is required. The inspectorate have asked for quarterly progress updates.
The centre has a third party agreement (TPA) with a courier company for the transport of gametes and embryos. This third party agreement does not define the transport conditions nor has the requirement for their maintenance been documented. Licence Condition T107	The PR should ensure that all transport conditions, such as temperature and time limit are defined and maintained during distribution.	TPA submitted 25 August 2010: now compliant. No further action required

3. Areas of concern

The analysis of the centre's self assessment questionnaire and the information the centre has submitted to the HFEA e.g. staff changes and the treatment cycles carried out at the centre, have identified that the following areas needed to be looked during the inspection visit to this centre.

Area of concern	Inspection findings	Assessment of whether the findings meet the requirement or whether any further action is required
The laboratory that the centre uses for some diagnostic semen analyses is not accredited by CPA (UK) Ltd or another body accrediting to an equivalent standard (SLC T21).	The PR explained that CPA had conducted an audit visit during February 2012 and that the centre planned to apply for CPA accreditation in June 2012 based on the auditor's view of the readiness of the centre to do so.	Further action is required.
HFEA invoices are not paid within the required 28 day timeframe (Chairs Letter CH(10)02).	At the time of inspection the average invoice payment period was 30 days.	Further action is required.

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 require are given as well as the timescales in which these improvements should be carried out.

Critical area of non compliance

A critical are of non compliance is an area of practice which poses a significant direct risk of causing harm to a patient, donor, embryo or to a 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.			

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
Guidance Note 26 Equipment and materials All critical equipment has not been validated (SLC T24): • the centrifuge has been calibrated, serviced and pattern tested but not validated; and • Gilson pipettes are calibrated yearly but not validated.	The PR should ensure all critical equipment is validated by 15 June 2012.	The centre has undertaken a comprehensive assessment of equipment to determine critical and non critical equipment and equipment with direct and indirect impact on gametes and embryos. All critical equipment is validated- please see attached documents for assessments of equipment and categorisation of critical/non critical equipment. The pieces of equipment mentioned have been assessed as non-critical with an indirect impact on gametes and embryos and therefore, calibrated	Pipettes are considered to have a critical measuring function: if reagent volumes are not measured accurately then this could have a direct impact on gametes and or embryos. Similarly the speed with which samples are centrifuged can have a direct impact on gamete quality. For this reason, the executive do not agree with the PRs comments however, the executive do consider that the servicing and calibration of these pieces of equipment does ensure that it is fit

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
		and serviced, but not validated. See supporting documentation	for the purpose for which it is used and when this information is considered in combination with monitoring of quality indicators (fertilisation rates following sperm preparation using the centrifuge for example) then the activities carried out by the centre are equivalent to validation. No further action is required
Guidance Note 25 Premises and facilities The laboratory that the centre uses for some diagnostic semen evaluation is not accredited by CPA (UK) Ltd or another body accrediting to an equivalent standard (SLC T21). The PR explained that CPA had conducted an audit visit during February 2012 and that the centre planned to	The PR should ensure quarterly updates on progress towards CPA accreditation are made to the inspectorate on a quarterly basis. The first progress report should be provided by 15 June 2012.	The centre has a clear ISO objective and timeline in place for achievement of CPA accreditation for the diagnostic andrology service. The PR discussed this during the inspection. The diagnostic andrology service is offered to GP patients across the county and includes patients undergoing vasectomy. Semen samples for fertility assessment and treatment evaluation are processed in the fertility centre laboratory not the	The PR states that 'semen samples for fertility assessment and evaluation are processed in the fertility centre laboratory.' Such semen testing is diagnostic and will influence the treatment pathway. Therefore in order to be compliant with SLC T21, the laboratory in the fertility centre performing such tests should be accredited by CPA or another body accrediting to an equivalent standard.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
apply for CPA accreditation in June 2012 based on the auditor's view of the readiness of the centre to do so.		diagnostic andrology laboratory. The service offered to fertility patients is used as a tool to establish treatment options Although the diagnostic andrology service is located in the fertility centre it does not analyse samples for ACU fertility patients prior to treatment. Samples processed in the diagnostic laboratory are on behalf of GP practices across the city and county therefore it is not clear what remit the HFEA have over this service.	It is acknowledged that the activities carried out in relation to analysis of semen samples for GPs do not fall within the remit of the HFEA. It remains the case however that the diagnostic testing of semen samples for fertility assessment must be performed in a CPA accredited laboratory, as stated above.

Other areas of practice that require improvement

Other areas of practice that require 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
Guidance Note 1 Person Responsible HFEA invoices are not paid within the required 28 day timeframe (Chair's Letter CH(10)02)). At the time of inspection the average invoice payment period was 30 days.	The PR should ensure fees for treatment cycles are paid no later than 28 days from the date on the Authority's invoice immediately.	This issue was not raised on the day of inspection I have enquired from our financial directorate and we comply with the "NHS conditions of contract for the purchase of goods – September 2010", this stipulates the following: "The Authority or, as the case may be, any Beneficiary shall pay the Contract Price to the Contractor, by BACS (Bank Automated Clearing System) if the Authority or such beneficiary so chooses, within 30 days of the **receipt** of the Goods or a valid invoice (rendered in accordance with Clauses 4.3 and 5.1), whichever is later." So, based on this we pay within 30 days of receipt of invoice. The information the HFEA are quoting suggests we are compliant with our terms, on the assumption that invoices take at least 2 days to reach us from when they are produced. This difference in invoice date and receipt of invoice may account for the 2 days difference in payment receipt	The executive has reviewed the response and accepts the PR's comments. No further action is required.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
		There is conflict between the NHS invoice payment schedule of 30 days to which we comply and the HFEA requirement.	

Additional information from the Person Responsible

HFEA Executive Licence Panel Meeting

1 June 2012

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

Minutes – Item 5

Centre 0068 – (Leicester Fertility Centre) – Interim Inspection Report

Members of the Panel:	Committee Secretary:
Juliet Tizzard, Head of Policy & Communications (Chair) Mark Bennett, Director of Finance & Facilities Paula Robinson, Head of Business Planning	Joanne McAlpine

Declarations of Interest: members of the Panel declared that they had no conflicts of interest in relation to this item.

The Panel also had before it:

- HFEA Protocol for the Conduct of Meetings of Executive Licensing Panel
- 8th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- Decision trees for granting and renewing licences and considering requests to vary a licence (including the PGD decision tree)
- Guidance for members of Authority and Committees on the handling of conflicts of interest approved by the Authority on 21 January 2009.
- Guidance on periods for which new or renewed licences should be granted
- Standing Orders and Instrument of Delegation
- Indicative Sanctions Guidance
- HFEA Direction 0008 (where relevant), and any other relevant Directions issued by the Authority
- Guide to Licensing
- Compliance and Enforcement Policy
- Policy on Publication of Authority and Committee Papers

Consideration of Application

1. The Panel noted that this centre has been licensed since 1997 and offers IVF/ICSI and IUI treatment to NHS and privately funded patients.

2. The Panel noted that the centre carried out approximately 330 IVF/ICSI cycles last year and that the centre's success rates are in line with the national averages.

3. The Panel noted that, for the year 2010, the centre also reported 225 cycles of partner insemination with 25 pregnancies.

4. The Panel noted that at the time of the inspection there were two major areas of non-compliance and one other area of practice that required improvement.

5. The Panel noted that since the inspection visit the Person Responsible (PR) has addressed the recommendations regarding one of the major areas of non-compliance and the other area of practice that required improvement.

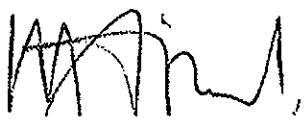
6. The Panel noted that the PR has committed to keep the Executive informed regarding the other major non-compliance (CPA accreditation of the centre's laboratory performing diagnostic semen analyses).

7. The Panel noted that the Inspectorate recommended the continuation of the centre's licence without additional conditions, subject to compliance with the recommendations made in the report being implemented within the prescribed timescales.

8. The Panel noted the progress that has been made at the centre since the last inspection, and encouraged the PR to continue to work with the Inspectorate to resolve the outstanding non-compliance as soon as possible.

Decision

9. The Panel endorsed the Inspectorate's recommendation to continue the centre's licence with no additional conditions.

Signed:  Date: 20/06/2012

Juliet Tizzard (Chair)