HFEA Executive Licensing Panel Meeting

27 June 2014

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

Minutes – Item 1

Centre 0068 – (Leicester Fertility Centre) – Renewal Treatment & Storage Inspection Report

Members of the Panel:	**Committee Secretary:**
Juliet Tizzard – Interim Director of Strategy (Chair) Joanne Anton – Policy Manager Ian Peacock – Analyst Programmer	Sam Hartley – Head of Governance & Licensing

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:

- 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 considered the papers, which included a completed application form, an inspection report and licensing minutes for the past three years.

2. The Panel noted that this is a treatment and storage centre which provides a full range of licensed treatments. The Panel noted that in relation to activity levels this is a small centre.

3. The Panel noted that the centre has been licensed by the HFEA since 1997 and is on a four-year licence due to expire on 30 September 2014.

4. The Panel noted that in the 12 months to 31 January 2014 the centre provided 480 cycles of treatment (excluding partner intrauterine insemination).

5. The Panel noted that for IVF and ICSI, HFEA-held register data for the period November 2012 to October 2013 show the centre's success rates are in line with national averages.

6. The Panel noted that in 2013, the centre reported 196 cycles of partner insemination with 24 pregnancies, one of which resulted in a multiple pregnancy. This equates to a 12% clinical pregnancy rate. HFEA analysis of results for the sector for 2013 had not been performed at the time of the inspection; therefore a comparison of the centre's results against the national average could not be made.

7. Between 1 January and 31 December 2013, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 12%; this represented performance that was not likely to be statistically different from the 10% maximum multiple live birth rate target for this period.

8. The Panel noted that at the time of the inspection on 18 and 19 March 2014, the Inspectorate identified one 'major' and nine 'other' areas of non-compliance.

9. The Panel noted that since the inspection the PR (Person Responsible) has completed the one recommendation relating to a 'major' area of non-compliance, and five of the recommendations relating to the 'other' areas of non-compliance.

10. The Panel noted that the PR has given a commitment to fully implementing the four outstanding recommendations relating to the 'other' areas of non-compliance.

11. The Panel noted that the centre awaits CPA accreditation for its laboratory, and that the Inspectorate will continue to work with the PR on this issue in order to be assured that the semen diagnostics on which the centre relies are carried out by a suitably accredited laboratory. The Panel urged the centre to

continue to work towards accreditation, and noted that the Inspectorate will consider referring the matter to a licensing committee should they not be reassured in relation to this matter.

12. The Panel also noted that fees for treatment cycles were not being paid within the 28 day limit set by the Authority. The Panel acknowledged the work the PR had done in addressing this issue and noted that the Inspectorate will continue to closely monitor the payment of fees through the Risk-Based Assessment Tool (RBAT).

13. The Panel acknowledged the positive comments made by patients in relation to their experience of the centre, and the steps taken by the PR in addressing the non-compliances.

14. The Panel noted the Inspectorate's recommendation for the renewal of the centre's Treatment and Storage licence for a period of four years without additional conditions, subject to compliance with the recommendations made in the report being fully implemented within the prescribed timescales.

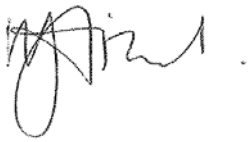
Decision

15. The Panel had regard to its decision tree. It was satisfied that the appropriate application and fee had been submitted and that the application contained the supporting information required by General Directions 0008.

16. The Panel was satisfied that the qualifications and character of the PR are such as is required for the supervision of licenced activities, and that she has discharged her duty under section 17 of the HF&E Act 1990 (as amended).

17. The Panel noted that the premises to be licensed are suitable for the conduct of the licensed activities.

18. The Panel endorsed the Inspectorate's recommendation to renew the centre's Treatment and Storage licence for four years, without additional conditions.



Signed: Date: 30 June 2014
Juliet Tizzard (Chair)

Inspection Report

Purpose of the Inspection Report

This is a report of an inspection, carried out to assess whether this 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 application for a renewal of its existing licence. Licences are usually granted for a period of four years. The Authority's Executive Licensing Panel (ELP) uses the application and this report to decide whether to grant a new licence and, if so, whether any additional conditions should be applied to the licence.

Date of inspection: 18 and 19 March 2014.

Purpose of inspection: Renewal of a licence to carry out treatment and storage.

Inspection details: The report covers the performance of the centre since the last inspection, findings from the inspection visit and communications received from the centre.

Inspectors: Janet Kirkland MacHattie, Lisa Beaumont, Karen Conyers, Douglas Gray, Chris Hall and Roup Kaur.

Date of Executive Licensing Panel: 27 June 2014

Centre name	Leicester Fertility Centre
Centre number	0068
Licence number	L/0068/15/c
Centre address	Assisted Conception Unit, Women's Hospital, Leicester Royal Infirmary, Leicester, LE1 5WW, UK
Person Responsible	Mrs Jane Blower
Licence Holder	Mr Tarek Gelbaya
Date licence issued	01/10/2011
Licence expiry date	30/09/2014
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:

The Leicester Fertility Centre has held a Treatment and Storage Licence with the HFEA since 1997 and provides a full range of fertility services. The inspection team is satisfied that the activities carried out at the centre are necessary or desirable in order to provide licensed treatment services.

The centre provided 480 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31/01/2014. In relation to activity levels this is a small centre.

Other licensed activities of the centre included storage of gametes and embryos.

This current licence was varied in 2011 to reflect a change in licence holder.

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period November 2012 to October 2013 show the centre's success rates are in line with national averages.

In 2013, the centre reported 196 cycles of partner insemination with 24 pregnancies one of which resulted in a multiple pregnancy. This equates to a 12% clinical pregnancy rate. The HFEA analysis of the sector's results for 2013 has not yet been performed; therefore a comparison of the centre's 2013 results against the national average cannot be made yet.

Multiple births[2]

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

Between 1 April 2010 and 31 March 2011, the centre's multiple live birth rate for all IVF, ICSI and FET cycles for all age groups was 7%: this represented performance that was statistically lower than the 20% multiple live birth rate target for this period.

Between 1 April 2011 and 30 September 2012, the centre's multiple live birth rate for all IVF, ICSI and FET cycles for all age groups was 7%: this represented performance that was not statistically different from the 15% multiple live birth rate target for this period.

Between 1 January 2013 and 31 December 2013, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was12%: this represents performance that is not likely to be statistically different than the 10% multiple live birth rate target for this period.

[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. The HFEA considers differences in a centre's success rates and multiple pregnancy rates from the national averages are only statistically significant if they occur at a significance level of $P \leq 0.002$.

[2]The HFEA use a conversion factor of 1.27 to convert the multiple live birth rate (MLBR) target to a multiple clinical pregnancy rate (MCPR) target. The 2011/12 MLBR target of 15% is calculated as equivalent to a 19% MCPR. The MLBR target of 10% (from October 2012) is calculated as equivalent to a 13% MCPR.

Summary for licensing decision.

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

- the application has been submitted in the form required;
- the application has designated an individual to act as the Person Responsible (PR);
- the PR's qualifications and experience comply with section 16 (2) (c) of the HF&E Act 1990 (as amended);
- the PR has discharged her duty under section 17 of the HF&E Act 1990 (as amended);
- the premises (including those of relevant third parties) are suitable;
- the centre's practices are suitable;
- the application contains the supporting information required by General Direction 0008, in application for renewal of their licence;
- the centre has submitted an application fee to the HFEA in accordance with requirements.

The ELP is asked to note that at the time of the inspection there were a number of areas of practice that required improvement, including no critical, one major and nine 'other' areas of non-compliance.

Since the inspection visit, the following recommendations have been fully implemented:

Major areas of non compliance:

- The PR should ensure that no gametes or embryos are kept in storage for longer than the consented storage period.

'Other' areas of non-compliance:

- the PR should ensure that either the tubes used during egg collection are labelled or that the risks of the current practice are assessed and appropriate risk control measures are documented and implemented during each treatment process;
- the PR should ensure that all relevant data relating to products and materials coming in to contact with gametes and embryos is traceable;
- the PR should ensure that documented procedures adequately describe when additional testing is required depending on a patient's travel and exposure history and the characteristics of the tissue or cells donated;
- the PR should ensure that patient information regarding the use of embryos in training includes the requirements of Standard Licence Conditions;
- the PR should ensure that fees for treatment cycles are paid no later than 28 days from the date on the Authority's invoice.

The PR has given a commitment to fully implementing the following recommendations:

'Other' areas of non-compliance:

- the PR should ensure that following audits of licensed activities corrective actions are implemented and the outcomes are appropriately documented;
- the PR should ensure that where possible only CE marked medical devices are used;

- the PR should ensure that diagnostic semen analysis is performed by a laboratory accredited by the CPA;
- the PR should ensure that the patient and partner consent to disclosure to researchers supplied to the Authority accurately reflects that given and recorded on completed disclosure consent forms;

Recommendation to the Executive Licensing Panel.

The centre has no critical areas of concern but does have one major area of concern, and nine 'other' areas that require improvement.

The inspection team notes that the success rates are consistent with the national average and their multiple clinical pregnancy and live birth rates meet or are below the target. The PR is encouraged to continue to use the Quality Management System (QMS) to best effect to monitor their success rates and to improve the quality of the service offered to patients.

Some improvement is required in order for the centre to demonstrate suitability of their practices. The centre has a QMS in place and the PR is encouraged to use this to best effect to monitor and improve the service provided.

The inspector will continue to monitor the centre's performance. Failure to implement the recommendations relating to the areas of non-compliance within the prescribed timescales will result in the submission of a further report to the ELP with the recommendation that regulatory action be taken in accordance with the Authority's Compliance and Enforcement Policy.

The inspection team recommends the renewal of the centre's Treatment and Storage licence for a period of four years without additional conditions subject to the recommendations made in this report being implemented within the prescribed timescales.

Section 2: Inspection findings

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

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

1. Protection of the patient and children born following treatment

Witnessing and assuring patient and donor identification

What the centre does well

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

What the centre could do better

Nothing identified at this inspection.

Donor selection criteria and laboratory tests

Screening of donors prior to procuring, processing gametes and embryos
Payments for donors
Donor assisted conception

What the centre does well

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

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

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

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

What the centre could do better

Nothing identified at this inspection.

Suitable premises and suitable practices

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

What the centre does well

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

The centre has procedures in place that are compliant with requirements to ensure that risks are taken into account to ensure patients and staff are in safe surroundings that prevent harm.

The centre is compliant with HFEA requirements to processes gametes and/or embryos in an environment of appropriate air quality.

Laboratory accreditation(Guidance note 25)
Third party laboratories which undertake the screening of blood samples taken from patients, patients' partners or donors, are accredited by Clinical Pathology Association (CPA) Ltd. This is important to assure the quality of the services provided.

Infection control
The centre has systems in place to manage and monitor the prevention and control of infection that are compliant with guidance.

Medicines management
The centre has arrangements in place for obtaining, recording, handling, using, keeping, dispensing, administering and disposing of medicines that are compliant with guidance.

Pre-operative assessment and the surgical pathway
The centre has policies and procedures in place that are compliant with professional body guidelines for pre-operative assessment and management of the surgical pathway. This is important to ensure that all patients are safely assessed and cared for pre-, peri- and post-operatively.

Multiple births (Guidance note 7; Directions 0003)
The single biggest risk of fertility treatment is a multiple pregnancy. The centre's procedures are compliant with HFEA multiple births minimisation strategy requirements, keeping a summary log of cases in which multiple embryos have been transferred and conducting regular audits and evaluations of the progress and effectiveness of the strategy.

Procurement of gametes and embryos (Guidance note15)
The centre's procedures are compliant with HFEA requirements to:

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

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

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

Receipt of gametes and embryos (Guidance note15)
The centre's procedures for the receipt of gametes and embryos are compliant with HFEA requirements. This is important to ensure that the centre only accepts gametes and embryos from other centres if the gametes and embryos are appropriately labelled and has enough information to permit the gametes and embryos be stored or used in treatment in a way that does not compromise their quality and safety.

Imports and exports (Guidance note 16; Directions 0006)
The centre has not imported or exported gametes or embryos since the time of the last inspection.

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

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

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

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

Transport and satellite agreements (Guidance note 24; Directions 0010)
The centre has no transport or satellite agreements.

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

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

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

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

Adverse incidents (Guidance note 27)
The centre's procedures for reporting adverse incidents are compliant with HFEA requirements. The centre reports all adverse incidents (including serious adverse events and reactions) to the HFEA. The centre investigates all adverse incidents that have occurred. Reporting and investigation of adverse incidents is important to ensure that centres share the lessons learned from incidents and continuously improve the services it offers.

What the centre could do better

Laboratory accreditation
SLC T21 requires that laboratories used for diagnostic semen analysis are accredited by CPA (UK) Ltd or another body accrediting to an equivalent standard. The andrology laboratory used by the centre for diagnostic semen analysis is not accredited (see recommendation 8). The PR provided evidence to the inspection team confirming that the andrology department is currently awaiting inspection by an accrediting body.

Traceability

- SLC T101 requires that all containers used in the course of procurement of gametes are labelled with the patients/donors full name and a further identifier. During the inspection staff confirmed that tubes used during egg collection to transfer follicular fluid containing eggs to the laboratory were not labelled. There is a risk of misidentification if unmarked tubes from one patient are inadvertently left in a critical work area when a second egg collection commences. Whilst measures were in place to mitigate such a risk, these were not documented and there were no records in patient files to confirm that measures had been taken.
  See recommendation 2.

- SLC T99 requires a centre to ensure that all relevant data relating to anything coming into contact with gametes, including critical equipment, are traceable. Whilst it was possible to trace most critical equipment used in any given treatment cycle, it was not possible to trace which centrifuge had been used during the preparation of sperm.
  See recommendation 3.

Quality management system

- Staff could describe aspects of the quality management system including audits. However in some instances it was difficult to ascertain if corrective actions identified as a result of the audits had been implemented and whether the subsequent impact had been reviewed (SLC T36).
  See recommendation 4.

- SLC T33a requires that there are SOPs for all activities authorised by the licence. Whilst the PR assured inspectors that patients are screened, when appropriate, in accordance with SLC T50(c) & (d) there was no documented procedure in place to describe when this should be done.
  See recommendation 6.

Equipment and materials
The following medical devices used by the centre are not CE marked: one type of specimen container, 5 ml tubes, pipettes, micro centrifuge tubes (SLC T30).
See recommendation 5.

Staff engaged in licensed activity
Person Responsible (PR)
Staff

What the centre does well

Person Responsible (Guidance note 1)
The PR has academic qualifications in the field of biological sciences and has more than two years of practical experience which is directly relevant to the activity to be authorised by the licence. The PR has successfully completed the HFEA PR Entry Programme (PREP number T/1041/7).

Staff (Guidance note 2)

The centre has suitably qualified and competent staff, in sufficient number**,** to carry out the licensed activities and associated services. The centre has an organisational chart which clearly defines accountability and reporting relationships.

The centre has access to a nominated registered medical practitioner and scientist, within the UK, to advise on and oversee medical and scientific activities respectively.

What the centre could do better

Nothing identified at this inspection.

Welfare of the child and safeguarding

What the centre does well

Welfare of the child (Guidance note 8)
The centre's procedures for taking into account the welfare of the child are compliant with HFEA requirements. This is important to ensure that the centre takes into account the welfare of any child who may be born as a result of the licensed treatment, and of any other child who may be affected by that birth before treatment is provided.

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

What the centre could do better

Nothing identified at this inspection.

Embryo testing

Preimplantation genetic screening

Embryo testing and sex selection

The centre does not perform treatments involving embryo testing, therefore this area of practice is not applicable to this inspection.

2. The experience of patients

Patient feedback

What the centre does well

During the inspection visit the inspectors spoke to one couple who provided feedback on their experiences. A further 31 patients also provided feedback directly to the HFEA in the time since the last inspection. Feedback was predominantly positive with 24 of the individuals providing written feedback to the HFEA commenting that they have compliments about the care that they 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;
- gives patients sufficient, accessible and up-to-date information to enable them to make informed decisions;
- provides patients with satisfactory facilities for their care.

What the centre could do better

Nothing identified at this inspection.

Treating patients fairly

Counselling
Egg sharing arrangements
Surrogacy
Complaints
Confidentiality and privacy

What the centre does well

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

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

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

Egg sharing arrangements (Guidance note 12; Direction 0001)
The centre's procedures for egg sharing arrangements are compliant with HFEA requirements. This is important to ensure that:

- care is taken when selecting egg and/or sperm providers donating for benefits in kind
- egg and/or sperm providers are fully assessed and medically suitable, and
- the benefit offered is the most suitable for the egg or sperm provider and recipient(s) (where relevant).

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

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

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

What the centre could do better

Nothing identified at this inspection.

Information

What the centre does well

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

What the centre could do better

See recommendation 7 (see use of embryos for training staff guidance note 22)

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

What the centre does well

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

Disclosure of information, held on the HFEA Register, for use in research (Directions 0005)
The centre's procedures for taking consent to disclosure to researchers are broadly compliant with HFEA requirements.

This is important to ensure that the HFEA holds an accurate record of patients' consent, so that it only releases the patients identifying information, to researchers, with their consent. Information can be used by researchers to improve the knowledge about the health of patients undergoing ART and those born following ART treatment.

What the centre could do better

Consent (Guidance note 5)
On the day of the inspection the centre did not have written effective consent for the storage of embryos for one couple (Schedule 3, 8(1) HF&E Act).
See recommendation 1 (see storage of gametes and embryos guidance note 17)

Disclosure of information, held on the HFEA Register, for use in research (Directions 0005)
From 16 cases reviewed one discrepancy was found between a patient's consent to disclosure and the related consent data submitted for inclusion on the HFEA register. In this case the register records that consent has been withheld but the consent records consent for the disclosure of identifying register data for generic, non-contact and contact research purposes (Directions 0005).
See recommendation 9

3. The protection of gametes and embryos

Respect for the special status of the embryo

What the centre does well

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

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

What the centre could do better

Nothing identified at this inspection.

Screening of patients
Storage of gametes and embryos

What the centre does well

Screening of patients (Guidance note 17)
The centre's procedures for screening patients are broadly compliant with HFEA requirements. It is important that gamete providers are appropriately screened to minimise the risks of cross infection during treatment, processing and storage of gametes and/or embryos.

Storage of gametes and embryos (Guidance note 17)
The centre's procedures for storing gametes and embryos are broadly compliant with HFEA requirements. These measures ensure that the gametes and embryos are stored appropriately to maintain their quality and safety. The storage of gametes and embryos is an important service offered by fertility clinics, as it can enable patients to preserve their fertility prior to undergoing other medical treatment such as radiotherapy. The storage of embryos not required for immediate use also means that women can undergo further fertility treatment without further invasive procedures being performed.

What the centre could do better

Storage of gametes and embryos(Guidance note 17)
On the day of the inspection the centre had in storage embryos for one couple whose consents to storage had recently expired. The circumstances surrounding these embryos in storage were discussed in detail during the inspection. The inspection team are satisfied

that the centre has in place a robust bring-forward system and that staff are suitably aware of consented storage periods that are coming to an end. Centre staff ensure that necessary actions are taken to seek the intentions of patients well in advance of the consents expiring. The PR assured the inspection team that the wishes of the patients would be carried out soon after our inspection (HF&E Act 1990 (as amended), Schedule 3, 8(1)).
See recommendation 1.

Use of embryos for training staff (Guidance note 22)

What the centre does well

Use of embryos for training staff (Guidance note 22)
The centre's procedures for using embryos for training staff are broadly compliant with HFEA requirements. Embryos are only used for the purpose of training staff in those activities expressly authorised by the Authority.

The PR informed the inspection team that a log of embryos used for training was kept, but this was not viewed at the time of inspection.

What the centre could do better

Use of embryos for training staff (Guidance note 22)
Written information provided to patients does not contain all necessary information regarding the use of embryos for training. The information for patients does not include the following (SLC T97);

- that the decision to donate will not affect their treatment in any way;
- that they can vary or withdraw their consent up until such times as they are used in training;
- whether any information will be fed back to them.

See recommendation 7

4. Information management

Record keeping
Obligations and reporting requirements

What the centre does well

Record keeping and document control (Guidance note 31)
The centre's procedures for keeping records are compliant with HFEA requirements to ensure that accurate medical records are maintained. Good medical records are essential for the continuity of the patient's care.

Obligations and reporting requirements (Guidance note 32 ; Directions 0005)
The centre's procedures for submitting information, about licensed activities to the Authority are compliant with HFEA requirements This is important to ensure the HFEA can supply accurate information to a donor-conceived person and their parents or donors.

The HFEA register audit team found no evidence of problems with the timeliness and accuracy of the centre's submission of data to the Register.

What the centre could do better

Nothing identified at this inspection.

Section 3: Monitoring of the centre's performance

Following the interim inspection in 2012 recommendations for improvement were made in relation to, two areas of major non-compliance and one 'other' area of non-compliance.

The PR provided information and evidence that one of the recommendations was fully implemented within the prescribed timescales.

The following recommendations have not been implemented:

- the PR should ensure that diagnostic semen analysis are performed by a laboratory accredited by the CPA.
  The PR has been in regular correspondence with the inspector regarding this issue and has applied for accreditation for the Andrology services, evidence was provided on inspection to support this.
  See recommendation 8.

- the PR should ensure that fees for treatment cycles are paid no later than 28 days from the date on the Authorities invoice.
  See recommendation 10.

On-going monitoring of centre success rates

In 2013 the centre did not receive any performance related alerts with regards to treatment outcomes.

Areas of practice requiring action

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

Critical area of non compliance

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
None noted			

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
1. On the day of the inspection the centre did not have written effective consent for the storage of embryos for one couple (Schedule 3, 8(1) HF&E Act).	The PR should ensure that no embryos remain in storage contrary to Schedule 3, 8(1) of the HF&E Act. The PR is reminded of guidance issued by the HFEA in CH(03)03 (http://www.hfea.gov.uk/2687.html) in relation to the timely disposal of cryopreserved material where there is consent to do so and actions should there be a possibility of legal challenge to the disposal of cryopreserved material. We acknowledge the PR's commitment given on inspection to process the embryos identified in accordance with the patient's wishes. The PR should up-date	The patients wishes in respect of these embryos have now been carried out and the embryos are no longer in store	No further action is required.

	the inspection team in relation to these embryos by the time she responds to this report.		

Other areas of practice that requires improvement

Areas of practice that requires improvement is any area of practice, which cannot be classified as either a critical or major area of non compliance, but which indicates a departure from statutory requirements or good practice.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
2. The tubes used during egg collection to transfer follicular fluid to the laboratory are not labelled, so the transfer of oocytes from those tubes to dishes cannot be witnessed (SLC T101).	The PR should ensure that either the tubes used during egg collection are labelled or that the risks of the current practice are assessed and appropriate risk control measures are documented and implemented during each treatment process. This action should be implemented with immediate effect and confirmation of the implementation received by the time the PR responds to the report.	A risk assessment has been carried out and documentation updated to accomadate a signature by laboratory and nursing staff post egg collection, to check disposal of all material from the preceeding egg collection. This risk assessment was emailed to the HFEA on 21st March 2014 and implemented the same day	The risk assessment has been received. No further action is required.
3. The centre does not ensure that relevant data about the centrifuge used in preparation of the sperm samples is traceable (SLC T99).	The PR should ensure that all relevant data relating to products and materials coming in to contact with gametes and embryos is traceable. The PR has assured the inspection team that the relevant data will now be	The use of equipment is now recorded on the laboratory patient sheets	No further action is required.

	documented on the laboratory records. No further action		
4. Whilst the centre could provide evidence of regular audits of licensed activities it was difficult to ascertain in some instances if corrective actions had been implemented and subsequent impact reviewed (SLCT36).	The PR should ensure that the findings of audits for which corrective actions have been identified are implemented. The PR should perform an audit to determine whether corrective actions identified as required in the course of audits have been implemented six months after the inspection. The PR should provide the HFEA with a summary of the audit results. By 18 September 2014	We will audit implementation of the corrective actions and ensure the action taken on the weekly and monthly audit results are clearer. A summary of the audit results will be provided by the 18th September	The inspector looks forward to receiving the summary of the audit results by 18 September 2014. Further action is required.
5. The following medical devices used by the centre are not CE marked: one type of specimen container, 5 ml tubes, pipettes, micro centrifuge tubes (SLC T30).	The PR should ensure that where possible CE marked medical devices are used. The PR should inform the HFEA of actions that will be taken by 18 June 2014.	We have now sourced the Vitrolife CE marked pipettes as discussed with at the inspection and these are now in use, we have been unable to source CE marked & MEA tested 5ml sterile tubes or sterile Eppendorff tubes. Our action plan has been updated after contacting the	The action plan has been received at the HFEA. No further action is required.

		following companies on 4.4.14: Hunter, Biotipp, Fisher, SLS, VWR, Sarstedt, Vitrolife (see attached).	
6. SLC T33b requires that SOPs are documented for all activities authorised by the licence. Whilst the PR assured inspectors that patients are screened, when appropriate, in accordance with SLCT50(c,d), there was no documented procedure in place to describe when this should be done.	The PR should ensure that the SLC requirements to screen patients prior to treatment are documented in SOPs. The HFEA should be advised of the measures taken to ensure that this happens by the time that the she responds to the report.	The clinical and nursing SOPs have now been updated to include this as a documented procedure -See attached	The updated documents have been received. No further action is required.
7. Written information provided to patients did not contain necessary information regarding the use of embryos for training Subsequent to the inspection, the PR submitted updated patient information, however this does not fully comply with the requirements as set out in SLC T97.	The PR should review the patient information against the requirements of the relevant SLC. Updated patient information should be submitted to the inspector by 18 June 2014	The patient information has been reviewed and updated - see attached	The updated patient information has been received. No further action is required.

8. The Andrology laboratory used by the centre for diagnostic semen analysis is not CPA accredited (SLCT21).	The PR should ensure that diagnostic semen analysis is performed by a laboratory accredited by the CPA. The PR provided evidence to the inspection team showing that the Andrology department is currently awaiting inspection by an accrediting body. The PR should keep the HFEA informed regarding progress towards accreditation.	The UHL andrology laboratory is located within the LFC premises. However it is not used by the centre to undertake diagnostic semen analyses for LFC patients undergoing licenced treatment at the centre. The andrology laboratory provides a service on behalf of UHL to GP's and other service users, such as patients undergoing treatment in other fertility centres within the East Midlands. Patients undergoing treatment at the LFC undergo an assessment and 'dummy' run sperm preparation purely to inform treatment options, not for diagnostic purposes. The HFEA are aware that an application for CPA accreditation was submitted in March 2013, however as CPA accreditation has now been superceeded by UKAS and ISO 15189 accreditation then the application was required to be revised and resubmitted accordingly. This application was submitted in November 2013 and we are still awaiting confirmation of inspection	The PR's response suggests that the CPA status of the andrology laboratory is not relevant as this laboratory does not carry out diagnostic semen analysis for the centre. This is the first time that this has been clarified. Further action is therefore required by the PR to provide assurance that the diagnostic semen analysis on which the centre relies is carried out by a laboratory accredited by CPA or equivalent. The Executive recognises that many centres consider that their own laboratories have status equivalent to that conferred by CPA where they have an HFEA approved QMS, staff suitably qualified to interpret semen diagnostics and where they participate in NEQAS. The Executive will continue to work with the centre to be assured that the semen diagnostics on which they rely are carried out by a suitably accredited laboratory.

		dates. The HFEA has been informed of the progress towards accreditation on a regular basis.	If the PR cannot provide this reassurance then the Executive will consider referring the matter to a Licensing Committee for further consideration.
9. During an audit of 16 cases for patient consent to disclosure for research it was noted that one discrepancy was found between a patient completed disclosure and the related consent data submitted for inclusion on the HFEA register.	The PR should ensure that the patient and partner disclosure consent to researchers supplied to the Authority accurately reflects that given and recorded on completed disclosure consent forms; The PR should: • correct the submissions that have been identified as being incorrect • review systems and processes to ensure that, the patient and partner disclosure consent information supplied to the Authority accurately reflects that given and recorded on completed disclosure consent forms; • the PR should ensure that their audit schedule includes the recording and submission of patient	The submission that was incorrect has been corrected and resubmitted via EDI. We have reviewed our systems and procedures for checking the consent to disclosure forms before submission to the HFEA. this will be included in our audit schedule and in our SOPs. We will carry out an audit and submitt the findings in the timescale required.	The inspector looks forward to receiving the audit summary by 18 September 2014.

	consent to disclosure decisions to the HFEA; • the PR should provide the HFEA with a summary of the audit findings six months after the review of the process and implementation of corrective actions where applicable. By 18 September 2014		
10. The centre took on average of 57 days to pay invoices between April 2013 and February 2014 (SLC T9(d)).	The PR should ensure that fees for treatment cycles are paid no later than 28 days from the date on the Authorities invoice.	I believe there have been problems with inputting the relevant purchase order numbers and invoice numbers both at UHL and the HFEA. I understand this has now been resolved and a system is operating where invoice numbers generated by the HFEA now reference the correct purchase orders. NHS standard T&C of payment are 30 days from receipt of invoice.	The payment of treatment fees will continue to be monitored through the Risk Based Assessment tool (RBAT).

Responses from the Person Responsible to this inspection report