HFEA Executive Licensing Panel Meeting

13 June 2014

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

Minutes – Item 1

Centre 0153 – (Homerton Fertility Centre) – Renewal Treatment & Storage Inspection Report

Members of the Panel:	**Committee Secretary:**
Juliet Tizzard – Interim Director of Strategy (Chair)	Lauren Crawford
Paula Robinson – Head of Business Planning	**Also in attendance:**
Nick Jones – Director of Compliance & Information	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, an update report from the centre 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 large centre.

3. The Panel noted that the centre has been licensed by the HFEA since 1995 and is on a four-year licence due to expire on 31 August 2014.

4. The Panel noted that in the 12 months to 31 January 2014 the centre provided 1,307 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 except for:
    - success rates following IVF treatment in women under 38 years old, which are lower than average at a statistically significant level;
    - success rates following ICSI treatment in women under 38 years old, which are lower than average at a statistically significant level.

6. The Panel noted that in 2013, the centre reported 204 cycles of partner insemination with 32 pregnancies. HFEA analysis of results for the sector for 2013 had not been performed; therefore a comparison of the centre's results against the national average cannot be made at this time.

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 19%: 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 25 and 26 March 2014, the Inspectorate identified two 'major' and seven 'other' areas of non-compliance.

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

10. The Panel noted that the centre has responded to the Inspectorate in regards to the outstanding recommendations.

11. The Panel noted that the centre has been issued with seven performance alerts within the last 12 months, five of which were about success rates.

12. The Panel noted that the success rates for IVF and ICSI in women under 38 years old are below the national average, and that the Inspectorate recommends that the PR should ensure that the quality management system (QMS) is used to best effect to monitor and improve the centre's success rates so as to improve the quality of the service offered to patients. The centre's success rates will continue to be a focus of on-going monitoring by the Inspectorate. The ELP will be provided with an update in relation to the centre's success rates in March 2015, or sooner if there is a significant downward trend in success rates before that time.

13. The Panel acknowledged the positive comments made by patients in relation to their experience of the centre.

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 this report being fully implemented within the prescribed timescales.

Decision

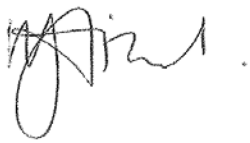
15. The Panel had regard to its decision tree. It was satisfied that the appropriate application and fee had been submitted and that the application contained the supporting information required by General Directions 0008.

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 he has discharged his 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 urged the Inspectorate to continue to work with the centre to monitor and address the success rates that are below average.

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



Signed: Date: 26 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: 25 and 26 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: Sara Parlett (lead), Lisa Beaumont, Jason Kasraie, Cathy Hodgson, Zakia Ezzouyar and Eileen Graham (observer)

Date of Executive Licensing Panel: 13 June 2014

Centre name	Homerton Fertility Centre
Centre number	0153
Licence number	L/0153/14/d
Centre address	Homerton University Hospital NHS Trust, Homerton Row, London, E9 6SR
Person Responsible	Mr Anil Gudi
Licence Holder	Ms Tracey Fletcher
Date licence issued	1 September 2010
Licence expiry date	31 August 2014
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:
The Homerton Fertility Centre is located in London and has held a treatment and storage licence with the HFEA since 1995. The centre 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 1307 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 January 2014. In relation to activity levels this is a large centre.

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

The centre has a satellite arrangement with one clinic in London.

In January 2014, an ELP approved the centre's application to relocate its cryostore. The change of premises was approved following a desk-based assessment. The relocation occurred in February 2014 and the centre provided confirmation that the dewars and associated alarms were tested and validated immediately following relocation. This inspection represents the first visit to the centre's new cryostore and the inspection team considered that the new room was suitable.

A change of Licence Holder (LH) from Ms Nancy Hallett to Ms Tracey Fletcher was approved by an ELP in January 2013.

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 with the following exceptions:

- success rates following IVF treatment in women under 38 years old are lower than average at a statistically significant level;
- success rates following ICSI treatment in women under 38 years old are lower than average at a statistically significant level.

Refer to section three of this report for further details.

In 2012, the centre reported 340 cycles of partner insemination with 47 pregnancies. This equates to a 14% clinical pregnancy rate which is consistent with the national average.

In 2013, the centre reported 204 cycles of partner insemination with 32 pregnancies. This equates to a 16% clinical pregnancy rate. 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 January and 31 December 2013, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 19%. This represents performance that is not likely to be statistically different from 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 10% multiple live birth rate (MLBR) target to a multiple pregnancy rate (MPR) target of 13%.

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 his 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 two major areas of non-compliance and seven 'other' areas of non-compliance.

Since the inspection visit, the centre has provided evidence that the following recommendation has been fully implemented:

Major areas of non compliance:

- The PR should establish a third party agreement (TPA) with the day surgery unit performing egg collections and surgical sperm retrievals.

The PR has provided a commitment to fully implement the following recommendations:

Major areas of non compliance:

- The PR should ensure that welfare of the child (WoC) assessments are performed and clearly documented within the patient record.

'Other' areas that require improvement:

- The PR should ensure the theatre's arrangements for documenting the disposal of controlled drug wastage and the drug dosage on prescriptions are reviewed.
- The PR should ensure written confirmation, satisfying all relevant requirements of General Directions 0006, is obtained for donor sperm samples prior to import.
- The PR should consider the risks of not labelling the containers used during egg collection.
- The PR should develop the two standard operating procedures (SOPs) referenced in this report.
- The PR should ensure the success rates published on the centre's website reflect the requirements of Chair's letter CH(11)02 and ensure that the satellite clinic's website complies with HFEA guidance. The PR should also review and revise the other areas of concern in the centre's patient information noted by the inspection team.

- The PR should ensure that the centre submits accurate information to the Register regarding consent to disclosure to researchers.
- The PR should ensure treatment outcomes are reported to the HFEA within the required timeframes.

Recommendation to the Executive Licensing Panel

The centre has no critical areas of concern but does have two major areas of concern.

The inspection team also notes the success rates for IVF and ICSI in women under 38 years old are below the national average. The PR should ensure that the quality management system (QMS) is used to best effect to monitor and improve the centre's success rates so as to improve the quality of the service offered to patients. The centre's success rates will continue to be a focus of on-going monitoring by the Executive. The ELP will be provided with an update in relation to the centre's success rates in March 2015 or sooner if there is a significant downward trend in success rates before that time.

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 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 non-identifying 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 requirements 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 premises of the centre's satellite facilities and laboratories conducting tests that impact on the quality and safety of gametes and embryos are suitable.

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

Laboratory accreditation (Guidance note 25)
The centre's laboratories and third party laboratories which undertake the diagnosis and investigation of patients, patients' partners or donors, or their gametes, embryos or any material removed from them, are compliant with HFEA requirements for accreditation by CPA (UK) Ltd or another body accrediting to an equivalent standard. 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.

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; General 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 for 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 note 15)
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;
- if 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; General 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 note 15)
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.

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;
- identify any person who has carried out any activity in relation to particular gametes or embryos; and
- 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 (Guidance note 23)
The centre has a QMS in place that is compliant with HFEA requirements. The establishment and use of a QMS is important to ensure continuous improvement in the quality of treatments and services.

Transport and satellite agreements (Guidance note 24; General Directions 0010)
The centre has systems in place to manage satellite activities that are compliant with HFEA requirements. This is important to ensure that activities performed by the satellite clinic on behalf of the licensed centre are suitable and meet the HFEA requirements.

Equipment and materials (Guidance note 26)
The centre uses equipment and materials that are compliant with HFEA requirements, with one exception detailed below. 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, with one exception detailed below.

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 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

Medicines management
The centre has arrangements in place for obtaining, recording, handling, using, keeping, dispensing, administering and disposing of medicines that are broadly compliant with guidance. The controlled drugs log is the responsibility of the theatre team, and is kept in the adjacent day surgery unit, where egg collections and sperm retrievals are undertaken. In multiple cases, the log did not record the drug wastage when only part of an ampoule was administered. Five sets of HFEA records were inspected against the controlled drug log and in two records drug wastage had not been documented. A further brief look at the

rest of the log demonstrated that this was consistent practice by the anaesthetists.

It was also noted that two prescription charts did not have the drug dosage clearly documented.

The Trust's 'controlled drugs policy' sets out prescribing requirements, including documenting/witnessing drug wastage and documenting drug dosage. This policy is not being followed. It is important to adhere to the Trust policy to ensure the legal requirements, as per the Medicines Act 1968 and the Misuse of Drugs Act 1971 and their associated regulations, are complied with (SLC T2) (see recommendation 3).

Imports and exports (Guidance note 16; General Directions 0006)
The centre's procedures for import and export of gametes and embryos are broadly compliant with HFEA requirements. The centre has imported gametes in the time since the last inspection. General Directions 0006 sets out the requirements under which a centre may import gametes from within and outside the European Economic Area (EEA) and Gibraltar and requires that written confirmation is obtained that the supplying centre meets these requirements before import, as is described in centre SOPs. However, the centre could not provide written confirmation to demonstrate compliance with all of these requirements for two sets of sperm imported (see recommendation 4).

Traceability (Guidance note 19)
At egg collection, not all containers used during the procurement of eggs are labelled with the patient's/donor's full name and a further unique identifier or a uniquely identifying donor code (SLC T101) (see recommendation 5).

Third party agreements (Guidance note 24)
The centre's TPAs are compliant with HFEA requirements with one exception. Egg collection and surgical sperm retrieval is performed at the hospital's day surgery unit which is not within the centre's licensed premises. A TPA to cover these procuring activities at third party premises is not in place (SLC T111). Post inspection, the centre submitted a TPA compliant with HFEA requirements (see recommendation 1).

Equipment and materials (Guidance note 26)
The centre does not have an SOP documenting the requirement and procedure for the revalidation of equipment following repair (SLC T33b) (see recommendation 6).

At the time of the inspection, the centre was using a non CE marked culture medium (SLC T30). The HFEA has since received information that this media has been withdrawn from the market and therefore no recommendation has been made in relation to this non-compliance.

Staff engaged in licensed activity
Person Responsible (PR)
Staff

What the centre does well

Person Responsible (Guidance note 1)
The PR has complied with HFEA requirements.

The PR has academic qualifications in the field of medicine 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/1053/7).

Staff (Guidance note 2)
The centre is compliant with HFEA requirements. 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 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 are partially compliant with HFEA requirements.

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

What the centre could do better

Welfare of the child (Guidance note 8)
In seven out of 10 patient records reviewed in the course of the inspection, there was no evidence that the WoC information provided by the patients had been assessed by a member of staff (SLC T46 and T56). Whilst the inspection team had no concerns that WoC issues would not be taken into consideration by the centre, it is difficult to be fully assured without the appropriate records being maintained.

A WoC audit was performed recently by the centre and the audit findings were similar to those of the inspection team. Corrective action was identified and implemented, including re-training of centre staff responsible for the assessments (see recommendation 2).

Embryo testing

Preimplantation genetic screening
Embryo testing and sex selection

What the centre does well

Preimplantation genetic screening (Guidance note 9); Embryo testing and sex selection (Guidance note 10)
The centre does not perform embryo testing and therefore this area of practice is not applicable to this inspection.

What the centre could do better

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 experience. A further 26 patients also provided feedback directly to the HFEA in the time since the last inspection. Feedback was positive, with 15 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 and sperm 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 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 and sperm sharing arrangements (Guidance note 12; General Directions 0001)
The centre does not treat patients in sperm or egg sharing arrangements, therefore this area of practice is not applicable to this inspection.

Surrogacy (Guidance note 14)
The centre does not provide a surrogacy service therefore this area of practice is not

applicable to this inspection.

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)
Procedures for providing information to patients and donors ensures that centres give prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions. The centre's procedures for providing information to patients and donors are broadly compliant with HFEA requirements.

What the centre could do better

Information (Guidance note 4; CH(11)02)
The website of the centre's satellite clinic does not comply with the requirements of the HFEA's Chief Executive's letter CE(10)05. For example, it does not explain that satellite patients can only receive licensed treatment at an HFEA licensed centre.

The centre's website was reviewed prior to inspection and the presentation of success rates was not considered to be compliant with the guidance of the HFEA Chair's letter (CH(11)02). For example the centre's 2010 clinical pregnancy rates are presented, alongside national data from 2008. This comparison is not like for like and suggests that the centre's success rates are above the national average. This raises concerns that the presentation of success rates on the website is misleading to patients.

Further patient information available on the centre's website was reviewed and several leaflets were out of date, being last reviewed in 2010. The following concerns were also noted:

- The centre's 'assisted conception leaflet', available on the centre's website, documents a live birth rate of 30% for ICSI and IVF. This does not reflect current centre success rates and is considered to be misleading to patients.

- The centre's 'investigations' patient information leaflet, available on the centre's website, documents that screening for syphilis and chlamydia is an HFEA mandatory requirement. This is only a requirement for donors (SLC T52).

On inspection, centre staff explained that this website is managed by the Trust and centre staff do not have direct access to update it. This has been recognised as an issue and has been resolved by developing their own website which is due to be launched mid-April.

The centre's patient information leaflets were reviewed on inspection and the following concerns were noted:

- the centre's 'breast cancer booklet' advises patients that ovarian tissue freezing is not an option because it is not allowed under European law at present in clinical practice. This is not accurate and could potentially mislead patients researching treatment options.
- The centre's 'IUI patient information' documents that virology screening for the female patient is an HFEA mandatory requirement. Virology testing is only a requirement when a patient's gametes/embryos are to be processed and in the case of IUI treatment, the female partner's gametes are not collected or processed.

See recommendation 7.

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

What the centre does well

Consent (Guidance note 5; 6)
The centre's procedures for obtaining consent are 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 (General 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

Disclosure of information, held on the HFEA Register, for use in research (General Directions 0005)
Four discrepancies were found amongst 12 completed patient/partner disclosure consents examined on patient files and the related consent data submitted for inclusion on the HFEA register (General Directions 0005).

A consent to disclosure audit was performed recently by the centre and discrepancies were also noted. Corrective action was identified and implemented (see recommendation 8).

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 or relevant third party 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 TPA 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 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 embryos.

Storage of gametes and embryos (Guidance note 17)
The centre's procedures for storing gametes and embryos are compliant with HFEA requirements. These measures ensure that the gametes and embryos are stored appropriately to maintain their quality and safety. Furthermore, the centre only stores gametes and embryos in accordance with the consent of the gamete providers. 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

Nothing identified at this inspection.

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.

What the centre could do better

The centre's training SOP does not document all of the procedures that are in place to manage the use of embryos in training, for example to ensure that there is no actual or perceived conflict of interest between the use of embryos in training and the use of embryos in the provision of treatment services (SLC T95) (see recommendation 6).

The patient information regarding the use of embryos for the purpose of training staff does not include:

- information that the gamete provider can vary or withdraw the terms of their consent until the point the embryos are used in training (SLC T97c); and
- details of whether any information will be fed back to them (SLC T97d) (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, with the exception detailed below. Good medical records are essential for the continuity of the patient's care.

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

What the centre could do better

Record keeping and document control (Guidance note 31)
Refer to the welfare of the child section of the report and recommendation 2.

Obligations and reporting requirements (Guidance note 32; General Directions 0005)
Ten per cent of audited treatments were not submitted within the timeframe specified by General Directions 0005. There have been considerable delays in the reporting of pregnancy outcomes (see recommendation 9).

Some minor data quality issues were identified via a review of data submissions and source documentation. They have been reported separately to the centre for review and correction. The findings are not significant enough in number to require a recommendation to be made.

Section 3: Monitoring of the centre's performance

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

The PR provided evidence that all of the recommendations were fully implemented, with the following exception:

- the PR should ensure that the data provided to the HFEA regarding consent to the disclosure of identifying information to researchers is accurate.

Refer to the 'consent and disclosure of information, held on the HFEA Register, for use in research' section of this report for further details.

On-going monitoring of centre success rates

In the last twelve months, the centre has been issued with seven performance alerts:

- three alerts in relation to IVF success rates in women under 38 years;
- two alerts in relation to ICSI success rates in women under 38 years; and
- two alerts in relation to multiple pregnancy rates.

The centre has taken action to reduce its multiple pregnancy rate (refer to the multiple births section at page four of this report).

The centre has investigated thoroughly the low success rates for IVF and ICSI in women under 38 years and has kept the Executive informed of the findings. Investigations have included a review of patient demographics and both laboratory and clinical processes. The PR considers that the centre's open acceptance policy for patients who are predicted to have a poor response to stimulation is a critical factor in the centre's poor success rates. The PR confirmed that these patients are advised about the realistic chances of success but are currently treating them if that is the patient's wish. However, on inspection, the PR explained that the centre's policy on treating those likely to be very poor responders will change in April. The centre has also implemented several other changes to address the success rate issues in the last few months, these include the introduction of time-lapse monitoring of embryos and changes to stimulation regimes.

In consideration of the information provided by the centre documenting the implementation of changes anticipated to improve success rates, it is concluded that the PR has taken steps to ensure the use of suitable practices in compliance with the HF&E Act 1990 (as amended), Section 17 (1d). The inspection team considers that no further regulatory action in relation to success rates would be proportionate at this time. The effectiveness of the recently implemented changes will continue to be the subject of on-going monitoring.

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 identified.			

Major area of non compliance

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

- which poses an indirect risk to the safety of a patient, donor, embryo or 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. Egg collection and surgical sperm retrieval is performed at the hospital's day surgery unit which is not within the centre's licensed premises. A TPA to cover these procuring activities at third party premises is not in place. SLC T111.	The PR must ensure that TPAs are established with all third parties who provide goods or services that influence the quality and safety of gametes and embryos. Post inspection, the centre submitted a TPA with the day surgery unit compliant with HFEA requirements. No further action is required.	N/A.	N/A.
2. In seven of the 10 patient records reviewed in the course of the inspection, there was no evidence that the WoC information provided by the patients	The PR should ensure that WoC assessments are performed and clearly documented within the patient record.	The centre is conducting a training program with the nurses and the doctors to adress this area.We have taken the HFEA advice and will be asking the nursing team	The lead inspector acknowledges the PR's response and this will be subject to on-going monitoring.

had been assessed by a member of staff. SLC T46 and T56.	The inspection team recognises that this non-compliance has been identified by the centre's own QMS. Three months after the implementation of the corrective action already identified by the centre, the centre should perform an audit of a random representative sample of patient records to ensure that these corrective actions are effective. This audit should be submitted to the HFEA by 26 June 2014.	to introduce a 2nd check before starting treatment . The process has already started and we aim to audit this by the middle of June	

Other areas of practice that require 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
3. Five sets of HFEA records were inspected against the theatre controlled drug log and in two records drug wastage had not been documented. It was also noted that two prescription charts did not have the drug dosage clearly documented. The Trust's 'controlled drugs policy' sets out prescribing requirements, including documenting/witnessing drug wastage and documenting drug dosage. This policy is not being followed. SLC T2.	The Trust's controlled drugs accountable officer is responsible for ensuring compliance with the Trust controlled drugs policy. The PR should liaise with her to ensure that the day surgery unit's procedures for documenting the disposal of controlled drugs and documenting drug dosage on prescriptions are reviewed. A summary report of the findings of the review including corrective actions and the timescale for implementation of the corrective actions should be submitted to the centre's inspector by 26 June 2014. Three months after the implementation of corrective actions, the centre should perform an audit to ensure that these corrective actions have	I have spoken to the controoled drug accountable officer and immedictae changes have been made 1) Email sent to all anaesthetists and ODPs /Anaesthetist and recovery nurses reminding them of their responsibilities and the accountability in relation to controlled drugs 2) Controlled Drug denature containers to be available in all areas where controlled drugs are administered 3) Accountable officer will ensure that controlled drug waste is captured in routine 3/12 checks undertaken by pharmacy 4) These reports will be made available in the July LIN meeting 5) Unannounced audit will be carried out by accountable	The lead inspector acknowledges the PR's response and this will be subject to on-going monitoring.

	been effective. This audit should be submitted by 26 September 2014.	officer in June 2014.	
4. The centre could not provide written confirmation that the requirements of General Directions 0006 were met before two sets of gametes were imported.	The PR should ensure that, prospectively, written confirmation to satisfy all points of General Directions 0006 is obtained prior to the import/export of any sample. The PR should report the action that has been taken to ensure that this is done at the time of responding to this report. The PR should ensure that the written confirmation required by General Directions 0006 is available for all donor sperm imported since the last inspection. This must be confirmed in writing, along with a sample of the written confirmation obtained, to the centre's inspector for review by 26 September 2014.	The changes regarding import of sperm have been made . A meeting with the embryologist was carried out and the protocol has been discussed . The required details from the clinic abroad will be requested and the yearly accreditation dcoumented We will send a report on all the samples imported following the inspection and audit it against the Direction 0006 and send it to the HFEA by September 2014,	The lead inspector acknowledges the PR's response and this will be subject to on-going monitoring.
5. At egg collection not all containers (dishes, vials, ampoules, tubes etc) used during the procurement of	While it is acknowledged that only one egg collection takes place at a time, the PR should consider the risks of not	We have already started labelling the dishes for each patient but are present are not labelling all the tubes .	The lead inspector acknowledges the PR's response and this will be subject to on-going monitoring.

eggs are labelled with the patient's/donor's full name and a further identifier or a uniquely identifying donor code. SLC T101.	labelling all containers used during egg collection. The centre's inspector should be informed of any actions taken to mitigate the risks of misidentification as a result of this practice by 26 June 2014.	We will perform a risk assesment and inform the HFEA with the details by the 26th of June	
6. **SOPs** • The centre's training SOP does not document all of the procedures in place to manage the use of embryos in training, for example to ensure that there is no actual or perceived conflict of interest between the use of embryos in the provision of treatment services. • The centre does not have an SOP documenting the requirement and procedure for revalidation of equipment following repair. SLC T33b.	The PR should ensure that the highlighted SOPs are developed to direct the relevant activities. Copies of the SOPs should be submitted to the centre's inspector by 26 September 2014.	The SOP for embryos in training has been changedto ensure that it clearly states that is are no conflicts in the use of embryos for treatemnt and training The SOP document for revalidation following repair has been amended	The lead inspector acknowledges the PR's response. The PR is asked to submit the revised SOPs by 26 June 2014.
7. The centre's website is not compliant with the	The PR should review and revise the patient information,	The patient information is being reveiwed and a new	The lead inspector acknowledges the PR's

guidance of the HFEA Chair's letter (CH(11)02). This raises concerns that the presentation of success rates on the website could be misleading to patients. Several patient information leaflets available on the centre's website were out of date, being last reviewed in 2010. The website of the centre's satellite clinic does not comply with the requirements of the HFEA's Chief Executive's letter CE(10)05. The centre's patient information leaflets were reviewed on inspection and a small number of concerns were noted.	including success rate data, published on the centre's website. The PR should ensure that the satellite clinic's website complies with HFEA guidance. The PR should also review and revise the patient information leaflets highlighted in this inspection report. The PR should inform the HFEA when this has been completed. This should be by 26 June 2014 for success rate data on the website and by 26 September 2014 for all other areas.	website is going live in a few days. The success rates have been changed and a direct link to the HFEA has been given so that patient can access the HFEA website The satellite clinic has changed the details explaining on the PR's page explaining that all treatments are carried out at the Homerton The Spire Central site sis changing the details they put on their website since they have sold the 2nd satellite and this change should be completed by 26th of June The relevant patient information sheets will be updates within the next 6 weeks and sent to the HFEA	response. The centre's website has been updated to present pregnancy rates for 2013 and comparisons to national averages are no longer made. However, a link to the HFEA website commented on by the PR is not present on this webpage. The PR should further review the presentation of success rates on the website. The PR's webpage on the satellite clinic's website has been revised and is now compliant with HFEA guidance. The main IVF information webpage on the website has not yet been revised. This non-compliance will be subject to on-going monitoring.
8. Four discrepancies were found amongst 12 completed patient/partner disclosure consents examined on patient files	The PR should ensure that the centre submits accurate information to the Register regarding consent to disclosure to researchers.	We have reviewed the training to all our doctors and nursing about giving information to patient about consenting for research.	The lead inspector acknowledges the PR's response and this will be subject to on-going monitoring.

and the related data submitted for inclusion on the register. General Directions 0005. **This was an issue at the previous inspection.**	The inspection team recognises that this non-compliance has been identified by the centre's own QMS. Six months after the implementation of the corrective action already identified by the centre, the centre should perform an audit of a random representative sample of patient records to ensure that these corrective actions are effective. This audit should be submitted to the HFEA by 26 September 2014. The PR should ensure that the submissions that have been identified as being incorrect are corrected.	We will be conducting a training course in June and Plan to audit this in September.We have already identified this in our audit and have planned corrective measures and an audit	As of 20 May 2014, the four discrepancies noted have not been corrected by the centre. The PR is asked to ensure these are corrected immediately.
9. Ten per cent of audited treatments were not submitted within the timeframes specified. There have been considerable delays in the reporting of pregnancy outcomes.	The PR should review procedures for reporting on pregnancy outcomes to enable the reasons for delayed submissions to be identified and addressed. A summary report of the findings of the review including corrective actions and the timescale for	We realise that submitting data is extremely critial and due to some changes in the staffing realise that corrective measure are needed.We have already submitted a business case to the trust for an additional adminstrative person with Key responsibility for submitting	The lead inspector acknowledges the PR's response and this will be subject to on-going monitoring.

General Directions 0005, SLC T9e and T41.	implementation of the corrective actions should be submitted to the centre's inspector by 26 June 2014. Three months after the implementation of corrective actions, the centre should perform an audit to ensure that these corrective actions have been effective. This audit should be submitted by 26 September 2014.	data	

Reponses from the Person Responsible to this inspection report
We are working towards improving our Pregnancy rates and in the past 3 months have significantly increased our pregnancy rates . We treat a huge number of women with AMH levels less than 3 pmol/litre. NICE recomends that women with AMH under 5.4 Pmol /Litre may not respond to ovarian stimulation. This accounts for 30% pf our patients where Pregnancy rates are less than 10%. From The 1st of June we will not be offerring IVF treatments to women whose AMH is under 3 pmol/L on the NHS and Self funded . These new criteria will aloow us to offer a far more successful service We have succsfully reduced our Clinical Pregnancy rate with Twins and are planning to us the Embryoscope (Time lapse technology) to increase our single embryo transfer rate and encourage more patients to opt for single embryo . By offerring the time lapse technology to women having the 3 cycle , we hope to investigate the causes of failure and hopefully increase the pregnancy rates. Having looked at the past 3 months results we are certain that the pregnancy rates will be maintained around the national average with these changes We are continuuing to invest in staff and equipment to improve the service that we provide to our patients