Executive Licensing Panel - minutes

Centre 0026 (BMI The Priory) Progress Update Further to Renewal Inspection Report

Thursday, 6 April 2017

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Juliet Tizzard (Chair) Ian Peacock Joanne Anton	Director of Strategy & Corporate Affairs Systems Manager Head of Regulatory Policy
Members of the Executive	Bernice Ash Siobhain Kelly	Secretary Senior Governance Manager
External adviser		
Observers	Anna Quinn	Scientific Policy Manager

Declarations of interest

- Members of the panel declared that they had no conflicts of interest in relation to this item.

The panel had before it:

- 8th edition of the HFEA Code of Practice
- Standard licensing and approvals pack for committee members.

1. Background

1.1. The BMI The Priory, centre 0026 is located in Birmingham. The centre is privately owned and offers a full range of fertility treatment to both self-funding and NHS funded patients. The centre has been licensed by the HFEA since 1992.

1.2. The Executive Licensing Panel considered the centre's application to renew the Treatment and Storage licence at its meeting on 10 February 2017. The panel noted that at the time of the renewal inspection on 8 and 9 November 2016, there were a number of areas of practice that required improvement, including one critical, six major and five 'other' areas of non-compliance.

1.3. The Executive Licensing Panel was particularly concerned about the one critical area of non-compliance concerning legal parenthood. The panel noted that the Person Responsible (PR) had committed to fully implementing all the recommendations. However, a number of recommendations, including a repeat audit and root-cause analysis regarding the critical non-compliance, had been due by 9 February 2017, a day before the panel meeting.

1.4. The Executive Licensing Panel had therefore decided to defer the decision to renew the centre's Treatment and Storage licence, pending an update from the inspectorate on receipt of the repeat audit and root cause analysis.

2. Consideration of application

2.1. The panel considered the papers, which included an executive update, inspection report and licensing minutes up to the last licence renewal.

2.2. The panel noted that the Executive had confirmed that the audit and root cause analysis in relation to consent to legal parenthood were provided by 9 February 2017. The Executive had sought further information in relation to the root cause analysis and this was provided within the requested timescale.

2.3. The panel noted that all but one of the actions (for an 'other' non-compliance), due by 9 February 2017, had been completed within the timescales requested. The panel noted that the outstanding actions had now been completed and the Executive will continue to follow up with the PR on the implementation of the remaining recommended actions due later in 2017.

2.4. The panel noted the inspectorate's recommendation to renew 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.

2.5. The panel noted the inspectorate's recommendation, to issue a Special Direction to the PR under Section 24 (5A)(b) of the HF&E Act 1990 (as amended) to permit the continuation of the centre's Treatment and Storage licence from 1 May to 30 June 2017. This will allow time for the administrative process of licence renewal to be completed within the usual timeframe.

3. Decision

3.1. The panel considered the update from the inspectorate and was pleased to see that the critical non-compliance had been addressed according to the prescribed timescales.

3.2. The panel endorsed the inspectorate's recommendation to renew 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.

3.3. The panel endorsed the inspectorate's recommendation to issue a Special Direction to the PR under Section 24 (5A)(b) of the HF&E Act 1990 (as amended), to permit the continuation of the

centre's Treatment and Storage licence from 1 May 2017 to 30 June 2017, to allow time for the administrative process of licence renewal to be completed within the usual timeframe.

4. Chair's signature

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

Signature

Name

Juliet Tizzard

Date

13 April 2017

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: 8 and 9 November 2016

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: Karen Conyers, Sara Parlett and Grace Lyndon.

Date of Executive Licensing Panel: 10 February 2017

Centre name	BMI The Priory Hospital
Centre number	0026
Licence number	L/0026/15/c
Centre address	The Fertility Centre, BMI Priory Hospital, Priory Road, Edgbaston, Birmingham, B5 7UG, United Kingdom
Person Responsible	Mrs Jane Cuthbert
Licence Holder	Mrs Lesley Ryan
Date licence issued	01 May 2013
Licence expiry date	30 April 2017
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history

BMI The Priory Hospital has been licensed by the HFEA since 1992. The centre is privately owned and offers licensed treatment to both self-funding and NHS funded patients.

The current licence has been varied to reflect the following changes:

- July 2015; a change of Licence Holder (LH) to Mrs Lesley Ryan.
- May 2013; a change of Person Responsible (PR) to Mrs Jane Cuthbert.
- May 2013; a change of LH to Mrs Carol Gulliver.
- April 2013; a change of name to BMI The Priory Hospital.

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

The centre provided 510 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 30 September 2016. In relation to activity levels this is a medium sized centre.

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period 1 July 2015 to 30 June 2016 show the centre's success rates are in line with national averages.

In 2015, the centre reported nine cycles of partner insemination with two pregnancies. This represents a clinical pregnancy rate which is in line with the national average.

Multiple births[2]

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

Between 1 July 2015 and 30 June 2016 the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 16%: this represents performance that is not likely to be statistically different from the 10% multiple live birth rate target.

[1]The data in the Register may be subject to change as errors are notified to us by clinics, or picked up through our quality management systems. Centre success rates are considered statistically different from the national averages, and multiple pregnancy rates are considered statistically different from the 10% multiple live birth rate target, when $p \leq 0.002$.

[2]The HFEA use a conversion factor of 1.27 to convert the 10% multiple live birth rate (MLBR) target to a multiple pregnancy rate (MPR) target of 13%.

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, Statutory Licence Conditions (SLC) 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 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 one critical, six major and five 'other' areas of non-compliance.

Since the inspection visit the PR has confirmed that the following recommendation has been fully implemented:

'Other' areas that require improvement:

- The PR should ensure that all patients are safely assessed and cared for pre, peri and post operatively.

Since the inspection visit the PR has given a commitment to implementing the following recommendations in the prescribed timescales:

Critical areas of non-compliance:

- **The PR should ensure that effective consent to legal parenthood is obtained.**

Major areas of non-compliance:

- The PR should ensure that all gamete donors are screened in accordance with regulatory requirements and professional guidelines.
- The PR should ensure compliance with medicines management regulations and best practice guidance.
- The PR should ensure that all relevant data about anything coming into contact with gametes or embryos is traceable.
- The PR should ensure that the centre's quality management system (QMS) and auditing processes are effective, that they include an audit against regulatory requirements and professional guidance, and that audits, including proposed corrective actions, are consistently documented.
- The PR should ensure that all critical processes are validated.
- The PR should ensure that all consents are clear and readable, and protected from unauthorised amendment.

'Other' areas that require improvement:

- The PR should ensure that the time at which all witnessing checks take place is recorded.
- The PR should ensure infection control and prevention practices comply with statutory requirements and best practice guidance.
- The PR should ensure that the identity of a patient is reliably confirmed and documented, and that all patient records are accurately completed.
- The PR should ensure that all licensed treatment activity is reported to the Authority within the timeframe required by General Direction 0005.

Recommendation to the Executive Licensing Panel

The centre has one critical and six major areas of concern.

The inspection team notes that the centre's success rates are consistent with the national averages and their multiple clinical pregnancy rate meets the target. Significant improvement is required in order for the centre to reflect suitable practices. The PR is encouraged to use the QMS to best effect to monitor and improve the service provided.

Since the inspection, the inspection team considers that the PR has engaged fully with the HFEA in addressing the areas of concern identified, notably the critical non-compliance concerning consent to legal parenthood. The PR has kept the centre's inspector updated on the actions taken to address this matter and has initiated a re-audit of all relevant records to ensure that no further unidentified anomalies remain. The PR is also taking appropriate actions to address the cases identified as having anomalous legal parenthood consents and will be offering support and guidance to all couples affected that is in line with HFEA guidance. Further progress with these actions will be followed up by the centre's inspector.

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. The inspector will continue to monitor the centre's performance.

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)
It is important that patients receive treatment using the correct gametes or embryos. The centre's procedures for double checking the identification of gametes and embryos and the patient or donor to whom they relate are broadly compliant with HFEA requirements.

What the centre could do better

Witnessing (Guidance note 18)
The centre does not record the time at which any of the witnessing steps are undertaken during the sperm preparation and insemination procedures used during intrauterine insemination treatment (recommendation 8, SLC T71 and CoP 18.8). The inspection team note that this is not the case for other laboratory activities and that the centre's audit of witnessing practice did not identify this issue (see 'Quality Management System' section below).

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)
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. The centre's procedures for screening donors are partially compliant with HFEA requirements.

Payments for donors (Guidance note 13; General Direction 0001)
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. 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 with the exception noted below.

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 requirements which ensure the donor-conceived and their parents will be able to receive all required donor-related information.

What the centre could do better

Screening of donors (Guidance note 11)
The centre does not screen egg donors for syphilis at the time of donation. Egg donors are screened for syphilis as part of the donor recruitment process but this test is not repeated at the time of donation (recommendation 2, SLC T52b and T53b). The centre carries out treatments with donor eggs infrequently, therefore the inspection team was not able to audit records. However, discussions with centre staff assured the inspection team that, in practice, screening of egg donors is carried out at the time of donation, although this does not include testing for syphilis, as discussed above.

The standard operating procedure (SOP) for recruitment and screening of egg donors does not describe the requirement to screen at the time of donation or the tests required (see 'Quality Management System' section below). The inspection team also noted that the SOP for sperm donor screening does not fully reflect professional guidance with regard to post quarantine screening tests but this has not led to a non-compliance as the centre does not currently recruit sperm donors. This is discussed further in the 'Quality Management System' section below.

Payments for donors (Guidance note 13; General Direction 0001)
The SOP describing the payments that are allowed for sperm donors does not reflect current regulatory requirements in that it refers to an out-of-date version of General Direction 0001 and states: 'The law does not allow centres to pay donors a flat fee for donation and requires proof of expenses.' This inaccuracy has not led to non-compliant donor payment because the centre does not currently recruit sperm donors, it is however discussed further in the 'Quality Management System' section below. The allowed payments for egg donors is not described in the egg donor or egg sharing SOPs.

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 process gametes and/or embryos in an environment of appropriate air quality.

Laboratory accreditation (Guidance note 25)
The centre's laboratories and/or 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 Clinical Pathology Accreditation (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 broadly 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 partially compliant with guidance.

Prescription of intralipid 'off label'
The centre does not prescribe intralipid therefore the associated requirement was not relevant at this inspection.

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

Multiple births (Guidance note 7; General Direction 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;
- 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; General Direction 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 and/or 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; and
- the container/package is secure and ensures that the gametes or embryos are maintained in the specified conditions. All containers and packages are validated as fit for purpose.

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 are accompanied by enough information to permit them to be stored or used in treatment in a way that does not compromise their quality and safety.

Imports and exports (Guidance note 16; General Direction 0006)
The centre's procedures for the import and export of gametes and embryos are compliant with HFEA requirements.

Traceability (Guidance note 19)
The centre's procedures are partially 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 (QMS) (Guidance note 23)
The establishment and use of a QMS is important to ensure continuous improvement in the quality of treatments and services. The centre has a QMS in place that is partially compliant with HFEA requirements.

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

Transport and satellite agreements (Guidance note 24; General Direction 0010)
The centre does not have any transport and satellite arrangements.

Equipment and materials (Guidance note 26)
The centre uses equipment and materials that are 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 partially 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

Infection control
The sink in the treatment room does not have 'hands-free' taps and not all the chairs in the scan room have an impermeable cover and are 'wipe clean' (recommendation 9, SLC T17 and Health Building Note 00-09: Infection control in the built environment document, 2013).

The centre's hand hygiene audit (October 2016) documented that staff did not wash their hands with soap and water after the removal of gloves, but failed to highlight this as a contravention of the centre's SOP, or to document appropriate corrective actions (see the 'Quality Management System' section below).

Medicines management
The controlled drugs required for each day's treatments are taken out of the controlled drugs cupboard in the main hospital's recovery area, along the corridor, in a lift to the next floor up, and along the corridor to the centre's procedure room. During the procedures the controlled drugs and the controlled drugs book are kept in the non-controlled drugs cupboard in the centre's procedure room, and when staff take the patient back to the

recovery area after each case, the key to this cupboard is kept in the embryology lab. The inspectors considered this was not a safe system of working and that the cupboard in the procedure room was not suitable as a controlled drugs cupboard because it was not suitably secure (recommendation 3, SLC T2, The misuse of drugs (safe custody) regulations 1973, regulation 4, and the National Institute for Health and Care Excellence (NICE) guidance: 'Controlled drugs: safe use and management April 2016', sections 1.1.14-1.1.15). The inspection team also noted that this practice is not compliant with the BMI's SOP relating to the controlled drugs cupboard which states: 'The cupboard must be dedicated to the storage of Controlled Drugs. No other medicines or items may be stocked in the Controlled Drug cupboard.'

There was a medicine stored in the controlled drugs cupboard (in the main hospital's recovery area) which was past its expiry date (recommendation 3, SLC T2). Drugs from this cupboard are used for the centre's patients. The controlled drugs book had been signed since the expiry date of this drug to say that the contents had been checked, but this check had not identified the expired drug. Staff were informed and they immediately removed the drug from the cupboard.

Pre-operative assessment and the surgical pathway
In the record of a patient who had undergone an egg collection, the section documenting allergies in the centre's equivalent to the World Health Organisation (WHO) surgical safety checklist was left blank, therefore it is not known if she did not have any allergies or if this check was missed (recommendation 10, WHO Patient Safety Implementation Manual WHO surgical safety checklist 2009).

Traceability (Guidance note 19)
One of six items currently in use in the laboratory was not correctly documented in the centre's traceability records (recommendation 4, SLC T99). The centre's recent audits of traceability have identified this issue but corrective actions have not been effective in ensuring compliance (see 'Quality Management System' section below).

Quality management system (QMS) (Guidance note 23)
The QMS is not effective because the centre has not effectively audited their processes against regulatory requirements, and a number of audits failed to identify regulatory issues which were subsequently identified by the inspection team, or they identified issues which have not then been properly addressed to ensure on-going compliance (recommendation 5, SLC T33b, T34, and T36).

The centre has not effectively audited these processes against regulatory requirements:

- the SOP for egg donor screening does not describe the requirement to screen at the time of donation, or the screening tests required;
- the SOP for sperm donor screening does not fully reflect professional guidance with regard to post quarantine screening tests,
- the SOP describing the allowed payments to sperm donors does not include the requirements of General Direction 0001 and refers to a previous version of General Direction 0001, and
- the consent SOP refers to recording consent for research in the HFEA WT and MT consent forms, which is no longer possible in the current versions of these forms.

The inspection team noted the following:

- The audit of consent to legal parenthood did not identify the anomaly and alterations in consent forms noted by the inspection team (see 'Legal parenthood'

section below).

- The audit of donor screening did not identify that the process for screening egg donors is not compliant with regulatory requirements.
- The audit of witnessing practice did not identify that witnessing records used during the preparation of samples for intrauterine insemination did not include the requirement to record the time the witnessing steps took place.
- The corrective actions taken in response to audits of traceability have not been effective in ensuing compliance with the requirement to ensure all items are traceable.
- The audit of data submission to the HFEA did not identify any issues with the reporting of treatment cycles, yet unreported donor insemination cycles were subsequently found by centre staff when preparing notes for archiving.
- The inspection team noted that an old version of a patient information leaflet regarding sperm banking was present in the laboratory and that an old version of an audit template was used for one audit. The audit of version control did not identify these issues.
- The audit of hand hygiene recorded that staff sometimes failed to wash their hands after removing gloves, but did not document that this was non-compliant with the centre's SOP for hand washing, or recommend appropriate corrective actions.
- The audit of stored gametes and embryos found some anomalies but did not document any corrective actions or timescales for implementation.

Process validation (Guidance note 15)
The process validation for the use of 'EmbryoGlue®' was not specific to the product and did not include evidence from studies performed by the centre, reference to data from published studies or retrospective evaluation of the centre's own results (recommendation 6, SLC T72).

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.

Staff (Guidance note 2)
The centre is compliant with HFEA requirements to have 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 before treatment is provided, 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, are 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
Nothing identified at this inspection.

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 carry out embryo testing and therefore this area of practice is not relevant to this inspection.

What the centre could do better
Nothing identified at this inspection.

2. The experience of patients

Patient feedback

What the centre does well

During the inspection visit the inspector spoke to one patient who provided feedback on their experiences. A further 12 patients also provided feedback directly to the HFEA in the time since the last inspection. Feedback was positive, with seven of the eight individuals who provided additional written responses including compliments about the staff and 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 a 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.

Egg sharing arrangements (Guidance note 12; General Direction 0001)

For centres providing egg sharing arrangements it is important to ensure that:

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

relevant).
The centre's procedures for egg sharing arrangements are partially compliant with HFEA requirements.

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

Egg sharing arrangements (Guidance note 12; General Direction 0001)
The SOP for the screening of egg donors, which also applies to egg sharers, does not reflect the requirements for screening as per standard licence conditions and professional body guidance. This non-compliance is described in the 'Screening of Donors' and 'Quality Management System' sections above.

Information

What the centre does well

Information (Guidance note 4; Chair's Letter CH(11)02)
The centre's procedures for providing information to patients and/or donors are 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
Nothing identified at this inspection.

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

What the centre does well

Consent (Guidance note 5;6)
It is important that patients and donors have provided all relevant consents before

carrying out any licensed activity. The centre's procedures for obtaining consent are partially compliant with HFEA requirements.

Legal parenthood (Guidance note 6)
Where a couple to be treated with donated gametes or embryos is not married or in a civil partnership, both the woman and her partner must give written consent in order for the partner to become the legal parent of any child born. If this consent is not documented properly, or if proper information is not provided, or counselling offered prior to both parties giving consent, there may be doubt about its effectiveness and, in some cases, it may be necessary for a partner to obtain a court declaration to establish legal parenthood.

In February 2014, the HFEA asked all centres to audit their practices in this area to ensure they are suitable, to report the findings of the audit to the HFEA and to respond to those findings. The centre provided a summary of the findings of the audit to the HFEA within the required timeframe. The audit showed that two couples could be affected as they had not completed the HFEA consent to legal parenthood but had completed the centre's own internal consent forms confirming that they would be the legal parents of any resulting child. Where anomalies were identified in audits, centres were strongly advised by the HFEA to seek legal advice, and that in the interests of transparency, couples affected should be informed of any anomalies so that they may decide how they wish to proceed. At the interim inspection in November 2014, the inspectors reviewed the centre's audit and found that it had been performed according to the methodology specified by the HFEA. In December 2014 the PR informed the HFEA that whilst acknowledging our advice, their legal advice was that as the patients had completed the centre's own consent forms they considered that there was a low risk of the partner being divested of legal parenthood. The PR informed the HFEA that the centre would not be taking any further action.

As part of the HFEA's ongoing activities relating to legal parenthood, in October 2015 the PR was asked to review all relevant cases, to ensure that the review was robust such that there was complete assurance that she had identified all cases where there were anomalies in consent to legal parenthood, to provide assurance that there are effective methods for assessing the on-going competence of staff to take this consent; and that effective audit procedures are in place to ensure on-going compliance with consent taking requirements. The PR responded to this communication confirming that she was assured that all cases had been identified and that procedures, staff competency and audit processes were robust.

A further communication from the HFEA in December 2015 asked the PR to review her decision not to contact the couples identified in the 2014 audit in light of the recent judgement handed down by the President of the Family Division of the High Court, Sir James Munby, as it is clear from the judgment that only a court can make a declaration of parenthood where parenthood is in doubt. The PR was also asked to consider her duty of candour with respect to her patients such that they should be informed of any anomalies, any potential impact these may have, and their options for seeking a declaration of parenthood. The PR responded to this communication and indicated that in light of the recent judgements she would consider contacting the patients in the new year.

Following further correspondence, the PR advised the HFEA that, on 13 May 2016, she had written to these two couples regarding the issues with their consents to legal parenthood. The PR further advised the HFEA in August 2016 that the patients had not

responded to the letters sent in May 2016 and that no further action had been taken. The HFEA advised the PR that, in the HFEA's view, further contact with both couples was necessary to ensure that they were well informed of the issues relating to their legal parenthood consents, any potential impact these may have, their options and potential consequences of seeking a declaration of parenthood, and to ask them to confirm if they have decided not to take any action. The PR wrote to the two couples again in September 2016. Following further correspondence and discussions during this inspection, the PR confirmed that the couples have not taken any actions in response to the letters and that she is assured that the couples are well informed of the issues and are aware of how to follow up if they wish to take any action. The inspection team is assured that the PR is offering appropriate support and guidance to these two couples should they wish to take any action. Any further progress with these actions will be followed up by the centre's inspector.

The inspection team reviewed three sets of records of patients who had had successful treatment with donor sperm in November 2014, April 2015 and October 2015. This review led the inspection team to have concerns, discussed below in 'what the centre could do better'.

To assess the effectiveness of the centre's current procedures, the inspection team reviewed the centre's processes for obtaining and checking consent to legal parenthood. The inspection team was assured that the centre's current processes to obtain legal parenthood consent are satisfactory and compliant with HFEA requirements. Two separate members of staff check the consent forms before treatment and audits of consent to legal parenthood are frequently performed.

Disclosure of information, held on the HFEA Register, for use in research (General Direction 0005)
It 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 Assisted Reproductive Techniques (ART) and those born following ART treatment.

The centre's procedures for taking consent to disclosure to researchers are compliant with HFEA requirements.

What the centre could do better

Consent (Guidance note 5;6)
Three consent forms had omissions, alterations or amendments that were not initialled; and the inspection team considered these could raise doubt over the patient's consent intentions (recommendation 7, SLC T57 and T47). These were in addition to the issues identified in consent to legal parenthood forms (see 'Legal parenthood' section below).

Two pairs of WT and MT consent form pairs had discrepancies in the number of years of embryo storage consented to by each partner. Neither couple stored embryos however there was no record whether this discrepancy had been discussed with the patients and thus whether their consents were fully informed (recommendation 7, Schedule 3 of the HF&E Act 1990 (as amended)).

In three records, a member of staff had signed the representative's section in the consent

form as a way of documenting their checking of the form (recommendation 7, SLC T57). The inspection team was concerned that using the patient's consent form in this way is not appropriate and that staff may not fully understand the purpose of this section.

Legal parenthood (Guidance note 6)
The inspection team reviewed three sets of records of patients who had had successful treatment with donor sperm (in November 2014, April 2015 and October 2015) in circumstances where consent to legal parenthood was required. In one case (treated in April 2015) the patient had put their year of birth in the date of consent form completion section. In the other two records there were alterations in the consent forms that the inspection team was concerned may impact the effectiveness of the consents (recommendation 1, Sections 37(1) and 44(1) of Part 2 of the HF&E Act 2008 and SLC T47).

Immediately on discovery of these anomalies, the PR assured the inspection team that she would seek legal advice on these issues and repeat her audit of all records of consent to legal parenthood, to determine if there are any further unidentified anomalies. The PR had not identified these errors in her audit of records of consent to legal parenthood (see 'Quality Management System' section above).

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 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 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 does not currently use embryos in training therefore this area of practice is not relevant to this inspection.
What the centre could do better Nothing identified at this inspection.

4. Information management

Record keeping
Obligations and reporting requirements

What the centre does well

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

Obligations and reporting requirements (Guidance note 32; General Direction 0005)
The centre's procedures for submitting information, about licensed activities to the Authority are broadly 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.

What the centre could do better

Record keeping and document control (Guidance note 31)
The centre does not maintain a record of how, and by whom, the patient/donor has been reliably identified. In one set of records the patient's photographic identity document and sample signature used her maiden name, whereas the consent forms and treatment records were signed with her married name, which is different (recommendation 11, SLC T46b).

In one set of records, some of the pages recording pre, peri and post-operative observations were not labeled with the patient identifier; unlabeled pages could go missing or get mixed up with other patients notes (recommendation 11, SLC T48, NHS Professionals CG2 Record Keeping Guidelines 2016 section 1.9, and Nursing and Midwifery Council (NMC) code of professional practice 2015 (sections10.1, 10.2, 10.3 and 10.4)).

Obligations and reporting requirements (Guidance note 32; General Direction 0005)
A sample of the centre's data submissions to the HFEA were reviewed. It was noted that 26% of 127 IVF treatments and 12% of the 8 donor insemination treatments had been reported to the HFEA outside the time period required (recommendation 12, General Direction 0005).

The centre's processes for data submission to the HFEA did not ensure the reporting of all types of treatment cycles, as unreported donor insemination cycles were found by centre staff when preparing notes for archiving (see 'Quality Management System' section above). These cycles were reported to the Authority as soon as they were identified.

Section 3: Monitoring of the centre's performance

Following the interim inspection in 2014, recommendations for improvement were made in relation to two areas of major non-compliance and two 'other' areas of non-compliance.

The PR provided information and evidence that all of the recommendations were fully implemented within the prescribed timescales. Three areas of non-compliance described in this inspection report have been noted at previous inspections of this centre. These areas of practice are: traceability, process validation and recording the time of witnessing checks.

On-going monitoring of centre success rates

In 2016, the centre was asked to review practices with regard to multiple pregnancy rates. The PR responded to the request and during discussions at the time of the inspection, provided a commitment to keep this area of practice under review.

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, General Direction 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
Consent to legal parenthood 1. The inspection team reviewed three sets of records of patients who had had successful treatment with donor sperm (in November 2014, April 2015 and October 2015) in circumstances where consent to legal parenthood was required. In one case the patient had put their year of birth in the date of consent form completion section and in the other two records there were alterations in the	The PR should ensure that effective consent to legal parenthood is obtained. The centre should seek legal advice regarding the legal parenthood consent anomalies identified by the inspection team. When responding to this report, the PR should provide the centre's inspector with a summary of the legal advice obtained and the actions planned in response to this advice, including how the centre intends to communicate	The centre's current practice does ensure that effective consent to legal parenthood is obtained. We note that the issues relating to legal parenthood that were identified during the inspection do not reflect the centre's current practice or the improvements which it made in January 2016. Since we have become aware of this issue following the Chief Executive's letter CE(14)01 and the recent case law relating to legal	The executive acknowledges the PR's response and her commitment to fully implementing this recommendation. The executive notes that the PR has confirmed that legal advice has been sought and that affected patients will be contacted in January 2017. Further progress with these actions is being followed up by the centre's inspector. The PR has provided a review

records that the inspection team was concerned may may impact the effectiveness of the patient's consent. Sections 37(1) and 44(1) of Part 2 of the HFE Act 2008 and SLC T47.	with and support all couples affected. The PR should review the findings of the inspection and the failings of the previous audits, to establish a more robust methodology for auditing consent to legal parenthood in all relevant cases. A copy of this review should be provided to the centre's inspector when responding to this report. The PR should conduct an audit of legal parenthood consent using the revised methodology, in treatments involving the use of donor sperm or embryos created with donor sperm provided between 6 April 2009 and 9 November 2016, to ensure that there are no anomalies in legal parenthood consent that have not been identified previously. A copy of the audit including the methodology used, should be provided to the centre's inspector by 9 February 2017. The PR should conduct a root	parenthood, the centre has reviewed its protocol to ensure compliance with the HFEA's practice directions and legal requirements. Actions include separating its treatment chats for patients having treatment with donor sperm. Patients now have a separate chat about the use of donor sperm and the legal implications of this, including legal parenthood consent. Patients attend for a separate treatment chat to discuss the implications of treatment. In this way consent to legal parenthood and the implications of using donor sperm are separated from discussions about treatment. All WP and PP forms are now checked by the PR (clinical) and the Director of Clinical Services or Executive Director (non-clinical) before the patient moves to treatment. The centre is confident that having taken these steps, patients are fully cognizant with the issues involved and that the consent forms are accurately and	of the centre's processes and a copy of the revised methodology for auditing consent to legal parenthood. The findings of the repeat audit and the root cause analysis due by 9 February 2017 are awaited. Further action is required.

	cause analysis into the circumstances which led to the failure of previous audits to identify the consent anomalies found by this inspection. A copy of the root cause analysis should be provided to the centre's inspector by 9 February 2017.	properly completed. In relation to the historic issues identified during the inspection, the centre accepts these mistakes in its processes, as was, but we confirm that the steps have been put in place, as described to ensure that those errors are not repeated. While we are unable to provide a summary of our legal advice for reasons of legal privilege and confidentiality, we confirm we have taken legal advice, and we will be contacting those affected patients soon and provide, where required, ongoing support and guidance, including appropriate support through any legal process that may be necessary. We will also invite affected patients to meet with the centre's management team and have an opportunity to ask questions or to raise particular concerns. That said, given the time of year, we consider contacting patients so close to Christmas would be inappropriate, and so we are	

		therefore proposing to defer any contact until the New Year. We do not consider anyone will be prejudiced by this natural delay and is intended to avoid unncessary distress. As for details of the revised methodology for the audit and the root cause analysis, these will be provided to the inspector within the required timeframe.	

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
Screening of donors 2. The centre does not screen egg donors for syphilis at the time of donation. Egg donors are screened for syphilis as part of the donor recruitment process but this test is not repeated at the time of donation The SOP for screening egg donors does not describe the requirement to screen egg donors at the time of donation, or the screening tests required. The SOP for sperm donor screening does not fully reflect professional guidance with regard to post quarantine screening	The PR should ensure that all gamete donors are screened in accordance with regulatory requirements and professional guidelines. The PR should provide the centre's inspector with confirmation of revised donor screening practices, evidence of relevant staff training and a summary of the changes made to the gamete donor screening SOPs when responding to this report. The PR should audit the treatments carried out with egg donors in the centre since the last renewal inspection in 2012 to assess the number of	The centre has amended its protocols to reflect professional guidelines for the screening of donors immediately prior to donation for syphilis. The centre has amended its protocol so that the screening immediately prior to donation is recorded in the SOP. The centre acknowledges that it was performing HIV, Hep B and Hep C screening immediately prior to egg donation but that this was not reflected within the SOP. This omission has been corrected. The changes to donor screening will be discussed at the unit meeting on the 20th	The executive acknowledges the PR's response and her commitment to fully implementing this recommendation. The PR has provided the revised gamete screening SOPs and has confirmed that these changes in practices were discussed with staff at a unit meeting. The executive has reminded the PR that the requirement is that donors are screened at the time of donation and will continue to liaise with the centre to ensure compliant practices. The findings of the audit and the expert opinion due by 9

tests but this has not led to a non-compliance as the centre does not currently recruit sperm donors. SLC T52b, T53b and T33b.	recipients affected by the use of donors where screening has not been compliant. The PR should also determine if any sperm donors or sperm sharers have been recruited and used since the last renewal inspection in 2012 to consider if there are any recipients affected by the use of sperm donors where screening has not been compliant. A summary of the findings of the audit should be provided to the centre's inspector by 9 February 2017. The PR should seek the advice of an expert virologist to assess the risk to patients who have received treatment with sperm, eggs or embryos created with donated gametes, from donors where the screening has not been compliant. The PR should inform the centre's inspector of the timeline for obtaining this expert advice by 9 February 2017. In view of the small number of treatments provided with	december, 2016 The centre will respond to the audit requests within the required timeframe.	February 2017 are awaited. Further action is required.

	gamete donors, the PR should audit the effectiveness of changes introduced in this area of practice within six months. A copy of the audit should be provided to the centre's inspector by 9 August 2017.		
Medicines management 3. Controlled drugs needed for patients being treated that day are brought in from the controlled drugs cupboard (in the main hospital's recovery area) in the morning and are kept in a non-controlled drugs cupboard in the procedure room until used. There was a medicine stored in the controlled drugs cupboard (in the main hospital's recovery area) which was past its expiry date. Drugs from this cupboard are used for the centre's patients. SLC T2, The misuse of drugs (safe custody) regulations 1973 and NICE	The PR should ensure compliance with medicines management regulations and best practice guidance. The PR should review the centre's practices for the safe handling and storage of controlled drugs to ensure compliance with medicines management regulations and best practice guidance. A summary of the findings of the review should be provided to the centre's inspector when responding to this report. Within six months of the implementation of changes to the medicines management procedures, the centre should conduct an audit of practice in this area. A summary report of	Controlled drugs are never left unattended within The Fertility Centre procedure room. The ODP signs the drugs out from the controlled drugs cupboard in Theatres and brings the drugs to the department. Although the ODP leaves the procedure room to escort the patient to PACU, the drugs are never left unattended. They remain within the care of a suitably qualified theatre scrub nurse. When the drug is to be administered to the patient it is checked by both the ODP and the anaethetist and both sign the controlled drug register. We accept that a non-controlled drugs cupboard was used during the procedures to store the durgs whilst under	The executive acknowledges the PR's response and her commitment to fully implementing this recommendation. The PR has provided the requested review of practices in this area. Given the number of changes described, the executive will seek further clarification on the new medicines management practices and the new controlled drugs cupboard to ensure they are compliant with all relevant regulatory requirements. The audit due by 9 May 2017 is awaited. Further action is required.

guidance: Controlled drugs: safe use and management April 2016'.	the audit findings should be submitted to the centre's inspector by 9 May 2017.	the control of either the ODP or scrub nurse. To rectify this issue the centre has aleady had a controlled drugs cupboard fitted in the procedure room prep area, and a key safe within the medical records room. Controlled drugs will now be signed out by the ODP prior to the cases commencing. the controlled drugs will be stored within the controlled drugs cupboard. The ODP will be handed the key for the controlled drugs cubboard by a member of clinical staff at The Fertility Centre as they will be the only personelle able to access both the medical records room and the key safe therein. The controlled drugs will be locked in the controlled drugs cupboard until their use. The key will remaion with the ODP at all times until the completion of the cases. If drugs are unused nat the end of the case list the drugs are discarded by the ODP. Controlled drugs are never to be left within the controlled drugs cupboard within The	

		Fertility centre as the end of a list. We believe this ensures the centre is compliant with the Medicines Management Policy. The incident with out of date drugs took place within the Theatre department of the hospiatl. It has been discussed by the PR with the Director of Clinical Services, Hospital Risk Manager, Pharmacy Manager and Theatre Manager. The incident was investigated by the Theatre Manager and Risk Manager. 1. There is a Theatre Drugs Administration Policy which is used for the checking of Controlled Drugs in the Recovery area. Two qualified Practitioners check stock numbers against a controlled drugs register. During this process the strength, dilution, dosage and expiry dates are checked and signed for in the appropriate register. The failure to check expiry dates on the oral Tramadol was human error. The drug is infrequently	

		used could it therefore be removed from stock. 2. On investigation the Tramadol was sent to Theatres with a short expiry date and the box had the dates embossed in white and was difficult to read. Pharmacy taking the lead with actions to highlight short date drugs in Theatres. Record on the specific drug page that the medication is due to expire and record the date in red ink. 3. The incident was reported to the Clinical Services Manager for Theatres and the event was investigated by the Senior Nurse for the Recovery area. 4. There were one to one discussions with the staff members involved with the drugs checking on the day and a Team Briefing for Recovery staff to discuss the incident and actions to prevent a future problem with expiry dates. Staff attended a debriefing session. 5. Actions taken : Pharmacy and Recovery staff to highlight short expiry date	

		drugs 6. Pharmacy carry out 3 monthly drug Audits 7. Monthly Theatre Drug Audits (Random) by MH Theatre Audit Lead 8. To be discussed at the Clinical Governance meeting with a view to writing a specific SOP for the checking of Controlled Drugs in the Theatre Department.	
Traceability 4. One of six items currently in use in the laboratory was not correctly documented in the centre's traceability records. It is noted that this area of practice was also identified as a non-compliance at the renewal inspection in 2012. SLC T99.	The PR should ensure that all relevant data about anything coming into contact with gametes or embryos is traceable. The PR should review the centre's processes for recording all items for traceability purposes including any staff training needs, as previous actions have not been effective in ensuring compliance in this area. A summary of the findings of the review should be provided to the centre's inspector by 9 February 2017. Within three months of the	The centre accepts that one item in clinical use was not fully traceable. The centre is grateful to the inspection team for highlighting this difficulty. The traceability sheet was immediately updated and this issue remains under two monthly audit as it did before the inspection. You have also referred to a point of non-compliance that was identified at the renewal inspection in 2012. This related to the marking of tubes used during egg collection – the issue being whether the labelling of tubes used during egg collection was traceable or	The executive acknowledges the PR's response and her commitment to fully implementing this recommendation. The non-compliance in this area of practice noted during the renewal inspection in 2012 that is referred to here is: **'11: Traceability audit** An audit of traceability completed by the inspection team showed that not all equipment had been recorded in one set of patient records.' The findings of the review due by 9 February 2017 and the audit due by 9 May 2017 are

	implementation of changes to the traceability procedures, the centre should conduct an audit of practice and a summary report of the findings of the audit should be submitted to the centre's inspector by 9 May 2017.	not. At the time, the inspector required that "the PR should ensure that the tubes used during egg collection are labelled using unique patient identifiers or the current practice is fully risk assessed and the outcome of that risk assessment." The centre immediately put in steps to comply with this request and the matter was closed. We do not believe that the issue raised in 2012 and this current one should be linked and we consider it is inappropriate that the inspector may seek to use it as supporting evidence within this inspection report. The centre requests that this reference to the 2012 inspection is removed.	awaited. Further action is required.
Quality management system 5. The centre has not effectively audited their processes against regulatory requirements as: • the SOP for egg donor screening does not describe the requirement to screen	The PR should ensure that the centre's QMS and auditing processes are effective, that they include an audit against regulatory requirements and professional guidance, and that audits, including proposed corrective actions, are	The contents of SOPs are reviewed annually by suitably qualified staff. The centre accepts the inspection team's findings and had amended the required protocols. All have been sent to the inspector. The audit timetable and audits will	The executive acknowledges the PR's response and her commitment to fully implementing this recommendation. The PR has provided the updated SOPs as requested.

at the time of donation, or the tests required; • the SOP for sperm donor screening does not fully reflect professional guidance with regard to post quarantine screening tests, • the SOP describing the allowed payments to sperm donors does not include the requirements of General Direction 0001 and refers to a previous version of General Direction 0001; • the consent SOP refers to consent for research using WT and MT forms which is no longer possible in the forms current versions. The centre's QMS is not effective because: • audits failed to identify issues which were identified by the inspection team (anomalies in consent to legal parenthood,	consistently documented. The PR should update the SOPs identified to ensure they are compliant with regulatory requirements and professional guidelines, and provide the centre's inspector with a summary of the changes made to each SOP, when responding to this report. The PR should develop an action plan to ensure that all the centre's processes are reviewed against regulatory requirements and provide a copy of the plan to the centre's inspector by 9 February 2017. It is expected that this review of processes will be completed by 9 May 2017. The PR should review the centre's auditing processes to determine why non-compliances noted during the inspection were not identified by the centre, why previous audits were not effective in ensuring compliance with regulatory requirements, and why non-compliances and	be sent to the inspector within the required timeframe.	The action plan due by 9 February 2017 and the findings of the reviews due by 9 May 2017 are awaited. Further action is required.

version control), • audits have not been effective in ensuring compliance with regulatory requirements (donor screening, witnessing, traceability, HFEA data submission), and • non-compliances or corrective actions following audits have not been fully documented (hand hygiene, frozen samples), as discussed in detail in the body of the report. SLC T33b, T34 and T36.	corrective actions are not consistently documented in audit reports. The PR should provide the centre's inspector with a summary of the findings of the review including corrective actions and timescales for implementation by 9 May 2017.		
Process validation 6. The process validation for the use of 'EmbryoGlue®' was not specific to the product and did not include evidence from studies performed by the centre, reference to data from published studies or retrospective evaluation of the centre's own results.	The PR should ensure that all critical processes are validated. The PR should provide a copy of the centre's process validation for the area of practice identified to the centre's inspector by 9 February 2017.	The centre acknowledges the need for the validation of all critical processes. The centre did discuss the use of Embryo Glue within its validation of the culture system and performs six monthly audits of its efficacy. The centre will produce a full validation report within the specified time scale.	The executive acknowledges the PR's response and her commitment to fully implementing this recommendation. The PR is reminded of the requirement that all critical processes involving gametes and embryos must be validated.

SLC T72. It is noted that this area of practice was also identified as a non-compliance at the renewal inspection in 2012.	The PR should conduct a review of all the centre's validations of their critical procurement and processing procedures to ensure that all activities have been appropriately validated. The review should also include the process by which validations are completed and/or approved prior to the introduction of new activities. A summary of the findings of the review should be provided to the centre's inspector by 9 May 2017.	The centre would like it acknowledged that the inspection report in 2012 relates to a critical process which it had not been thought necessary to validate. The centre complied with the request to validate this process. In the case of Embryo Glue the introduction into clinical service was researched and trialled, and continues to be regularly audited and was discussed as part of the process validation of the embryo culture system.	The non-compliance in this area of practice noted during the renewal inspection in 2012 that is referred to here is: **'2: Validation of critical processes** The centre has not validated the procedure for assisted hatching.' The process validation due by 9 February 2017 and the findings of the review due by 9 May 2017 are awaited. Further action is required.
Consent 7. Three consent forms had omissions, alterations or amendments that were not initialled; the inspection team considered these could raise doubt over the patient's consent intentions. These were in addition to the issues identified in the consent to legal parenthood forms. Two pairs of WT and MT consent forms had discrepancies in the	The PR should ensure that all consents are clear and readable, and protected from unauthorised amendment. The PR should undertake a review of the centre's processes for obtaining consent, for making amendments in consent forms, and for checking consent forms. The review should include the centre's assessment of staff competencies in this area of	The issue of providing accurate, clear and valid consent was discussed on 7th December 2016 by the BMI Fertility Special Advisory Group at which the Quality Manager was present. A training presentation was given by our legal team on this area of concern. A departmental meeting with all staff and consultants is planned for 20 December 2016. This issue will be discussed by the PR and all staff reminded of the	The executive acknowledges the PR's response and her commitment to fully implementing this recommendation. The findings of the review due by 9 February 2017 and the audit due by 9 May 2017 are awaited. Further action is required.

number of years of embryo storage consented to by each partner. In three records, a member of the centre staff had signed the representative's section in the consent form as a way of documenting their checking of the form. Schedule 3 of the HF&E Act 1990 (as amended), SLC T47 and SLC T57.	practice. A summary of the findings of the review including corrective actions and the timescales for implementation should be provided to the centre's inspector by 9 February 2017. Within three months, the centre should carry out an audit of consent forms to ensure that the proposed corrective actions have been effective in ensuring compliance. A summary report of the findings of the audit should be provided to the centre's inspector by 9 May 2017.	requirements for clear consent to be provided by patients. A tutorial will be given to highlight the common areas where patients make errors when completing consent forms. A form will be generated by the Quality Manager which will be completed by a member of staff when they collect consent forms completed by a patient. This form will detail who collected consent and what variables within that particular form have been verified. This form will be sent to the inspector in due course. This form will require the length of embryo storage to be documented and any discrepancies and the discussion with the consultant around this to be documented. The consultant, who was signing under the patients' representative's section as their way of documenting their checking of the form, was present at the end of inspection feedback. They	

		immediately discontinued this practice, which they used not only at this centre but another recently inspected centre where this issue was not highlighted.	

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
Witnessing 8. The centre does not record the time at which any of the witnessing steps are undertaken during the sperm preparation and insemination procedures used during intrauterine insemination treatment It is noted that a similar non-compliance was identified at the interim inspection in 2014. SLC T71 and CoP 18.8.	The PR should ensure that the time at which all witnessing checks take place is recorded. The PR should ensure that the time of witnessing checks are recorded and confirm the immediate actions taken to ensure this happens, including copies of any amended documentation, when responding to this report. The PR should review the centre's witnessing procedures to ensure they are compliant with regulatory requirements and review the competence assessments of staff undertaking witnessing procedures, to ensure that they include all regulatory requirements (for example the need to record the time at which a witnessing step is	We are grateful for the inspection team identifying the shortcoming in the centre's laboratory sheet for the preparation of sperm for IUI. This has now been amended and submitted it to the inspector. The centre now believes that it is fully compliant in this area. The IUI laboratory sheet was last updated on 29 October 2013 prior to the centre being inspected in November 2014 where this oversight was not identified. There is a factual inaccuracy as the area of non-compliance was not identified by the inspection team in 2014. (The November 2014 inspection report states: "In one of five records reviewed the time of the witnessing check was not recorded. SLC	The executive acknowledges the PR's response. The executive notes the PR's comments regarding the findings at the time of the interim inspection in 2014 and of this inspection. The executive considers that further to the non-compliance identified in 2014, it would be expected that the PR would have reviewed witnessing practices across all activities not just those identified by the inspection team, to ensure that the time of witnessing is being recorded. The executive reminds the PR that interim inspections are intentionally observational and are not intended to review all areas of practice in detail. The executive noted that staff

	undertaken). A summary of the findings of the review including corrective actions and the timescales for implementation should be provided to the centre's inspector by 9 February 2017. Within three months of the implementation of changes to witnessing procedures, the centre should conduct an audit of witnessing and a summary report of the findings of the audit should be submitted to the centre's inspector by 9 May 2017.	T71." It is not accurate to compare the two issues, in 2014 there was an issue with staff failing to record the time a procedure occurred. However, at the time of the inspection the time of a procedure could not be recorded not due to the failings of staff but due to an oversight on the form used. Staff were unable to document the time of a procedure. The centre acknowledges its oversight in this area where the PR and Quality Manager use this form as part of their clinical practice. The omission has now been corrected and the centre believes it is now fully compliant. We request that the factual inaccuracy comparing this oversight with previous issues with witnessind in the interim inspection in November 2014 is corrected. We also note that the issue at the time of the last inspection related to the lack of times being recorded on the centre's	trained in witnessing procedures have implemented the requirement to record the time of any witnessing step for IVF/ICSI activities and that no non-compliances were identified in these areas of practice. However, the same staff have omitted recording the times of any of the witnessing steps during the sperm preparation and insemination procedures used during intrauterine insemination treatment merely because the form did not have a prompt to do so. Hence the executive's recommendation that the PR review staff competencies in this area of practice to ensure that witnessing practices are implemented consistently across all activities. The updated laboratory sheet has been provided. The requested review (to include consideration of staff competencies) due by 9 February 2017 and the audit due by 9 May 2017 are awaited.

		witnessing sheet used for all treatment cycles except IUI. The inspection of November 2016 did not highlight any issues in this area. What was highlighted was that witnessing times for IUI sperm preps ONLY were not recorded. This was because they could not be recorded due to the failure to recognise that the form did not have this section to complete. We do not believe it is appropriate for the centre to need to assess staff competence, given the competence of staff has NOT been drawn into question as they did not fail to record a time where they were required to do so. They were unable to do so and therefore did not fail on this task. The centre agrees however that it should re-audit its IUI process to ensure that staff are complying with the requirement to complete the new timing box.	Further action is awaited.
Infection control 9. The sink in the treatment room does not have 'hands-free' taps and not all	The PR should ensure infection control and prevention practices comply	Hands free taps were ordered the day after the inspection, the request has been	The executive acknowledges the PR's response and her commitment to fully

the chairs in the scan room have an impermeable cover and are 'wipe clean'. SLC T17 and Health Building Note 00-09: Infection control in the built environment, 2013.	with statutory requirements and best practice guidance. The PR should address the issues identified and confirm to the centre's inspector that they have been addressed by 9 February 2017. The PR should review the centre's infection control and prevention practices to include consideration of auditing compliance in this area of practice, and how any non-compliances with policies are recognised, documented and addressed. A summary of the findings of the review should be provided to the centre's inspector by 9 May 2017.	approved and the work is expected to be carried out within the next few weeks during the closure of the centre for Christmas. There was one non-compliant chair within the scanning room at the time of the inspection. The chair was removed the day after the inspection and has been replaced with another chair identical to those present on the day of the inspection. The centre therefore believes it is now fully compliant in this respect.	implementing this recommendation. Confirmation of the installation of the taps due by 9 February 2017 and the findings of the review due by 9 May 2017 are awaited. Further action is required.
Surgical pathway 10. In the record of a patient who had undergone egg collection, the section documenting allergies in the surgical safety checklist was left blank. WHO Patient Safety Implementation Manual WHO surgical safety	The PR should ensure that all patients are safely assessed and cared for pre, peri and post operatively The PR should review the centre's procedures for assessing and monitoring patient at all stages of the surgical pathway against	The centre has amended its processes to reflect the inspectors comments. All patients are now asked at treatment chat whether they have any known allergies. These are documented on the treatment chat paperwork and also on the inside of the fertility medical record for the patient.	The executive acknowledges the PR's response and her commitment to fully implementing this recommendation. The PR has provided the requested review of the centre's procedures and the actions taken in response to

checklist.	relevant regulatory requirements and professional guidance. A summary of the findings of the review should be provided to the centre's inspector by 9 February 2017.	BMI had at the time of the inspection changed to format of its medical records folders. these now document allergies on the front of the record. The issue has been raised with the Director of Clinical Services and the the Clinical Services Manager - Wards. This will be discussed at the next nursing departmental meeting. The audit findings will be submitted within the required timeframe.	this review. No further action is required.
Record keeping 11. The centre does not maintain a record containing how, and by whom, a patient/donor has been reliably identified. In one set of records the patient's photographic identity document and sample signature used her maiden name, whereas the consent forms and treatment records were	The PR should ensure that the identity of a patient is reliably confirmed and documented, and that all patient records are accurately completed. The PR should undertake a review of the centre's processes for establishing the identity of patients. The review should include consideration of the centre's assessment of staff competencies in this area.	The centre is grateful to the inspection team for bringing this matter to its attention. This issue will be discussed at the unit meeting on 20 December 2016. All staff will be reminded of the need to verify identity and follow the prescribed protocol. The difficulties in verifying identity for patients using their married names who have a passport in their maiden / previous name will be	The executive acknowledges the PR's response and her commitment to fully implementing this recommendation. The findings of the review due by 9 February 2017 and the audit due by 9 May 2017 are awaited. Further action is required.

signed with her married name, which is different. In one of the records, the notes of pre, peri and post-operative observations were not labeled with the patient identifier. SLC T46b, T48, NHS Professionals CG2 Record Keeping Guidelines (2016) and NMC code of professional practice (2015).	A summary of the findings of the review including corrective actions and the timescales for implementation should be provided to the centre's inspector by 9 February 2017. Within three months, the centre should carry out an audit of records to ensure that the proposed corrective actions have been effective in ensuring compliance. A summary report of the findings of the audit should be provided to the centre's inspector by 9 May 2017.	discussed at the next unit meeting on 20th December, 2016. The issue of day case notes from the suite not being correctly stickered has been raised with the Director of Clinical Services and the the Clinical Services Manager - Wards. This will be discussed at the next nursing departmental meeting. Audit findings will be submitted within the required timeframe.	
Reporting requirements 12. A sample of the centre's data submissions to the HFEA were reviewed. It was noted that 26% of 127 IVF treatments and 12% of the 8 donor insemination treatments had been reported to the HFEA outside the time period required. The centre's processes for data submission to the HFEA do not ensure the	The PR should ensure that all licensed treatment activity is reported to the Authority within the timeframe required by General Direction 0005. The PR should review the systems and processes used for licensed treatment data submission to identify the reasons for this non-compliance. A summary of the findings of the review including corrective actions and the	The centre has reviewed its current practice and acknowledges that it has experienced some local difficulties with conforming to regulatory requirements in this area. The review has highlighted that there has at times been delays in completing laboratory sheets by embryology staff due to a reduction in staff numbers. This had already been addressed at the time of the	The executive acknowledges the PR's response and her commitment to fully implementing this recommendation. The PR has provided a review of processes and actions taken to address this non-compliance. The audit due by 9 August 2017 is awaited.

reporting of all types of treatment cycles, as unreported donor insemination cycles were found by centre staff when preparing notes for archiving. These cycles were reported to the Authority as soon as they were identified. General Direction 0005	timescales for implementation should be provided to the centre's inspector by 9 February 2017. The PR should conduct an audit six months after implementing any changes to confirm that any changes made to systems and processes are having the desired effect. A summary report of the findings of the audit should be provided to the centre's inspector by 9 August 2017.	inspection with a new member of embryology staff starting on 12 December 2016. Whilst it will take a period of time for this individual to be fully conversant in the protocols of the centre, we are confident that this will in time ensure the more timely release of records from the laboratory. At the time of the inspection, laboratory records were then passed to the administration team for billing purposes prior to being passed to the EDI data entry clerk for submission to the HFEA. In light of the inspection findings it has been decided to amend this protocol. Laboratory sheets will be passed to the EDI data entry clerk before they are used for billing purposes. A copy of the amended SOP has been submitted to the Inspector. The centre does not want to alter the data entry process itself as it wishes to maintain the high levels of accuracy demonstrated by the EDI data entry clerk.	Further action is required.

Reponses from the Person Responsible to this inspection report