Human Fertilisation and Embryology Authority

Minutes of the Executive Licensing Panel

Meeting held at HFEA, Finsbury Tower, 103-105 Bunhill Row, London, EC1Y 8HF on
5 June 2015

Minutes – item no. 2

Centre 0258 (The Whittington Hospital Fertility Unit) – Renewal Inspection Report

Members of the Panel:	**Juliet Tizzard** Director of Strategy & Corporate Affairs (Chair) **David Moysen** Head of IT **Hannah Verdin** Head of Regulatory Policy
Members of the Executive in attendance:	**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 the 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 the 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 the publication of Authority and committee papers

Consideration of application

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

2. The panel noted that this is a treatment (insemination using partner sperm) centre which provides basic fertility services. The clinic operates as a satellite IVF centre for CRM London. The centre provides partner intrauterine insemination treatment only.

3. The panel noted that the centre has was last inspected in February 2013 for a short notice interim inspection. The centre has been licensed by the HFEA since 2007 and is on a four-year licence due to expire on 30 June 2015.

4. The panel noted that in 2014, the centre reported 175 cycles of partner insemination resulting in 10 pregnancies. This corresponded to a clinical pregnancy rate of 5% which is likely to be consistent with the national average.

5. The panel noted that at the time of the inspection on 3 February 2015, the Inspectorate identified a number of areas of practice that require improvement including six major and two other areas of non-compliance.

6. The panel noted that since the inspection the Person Responsible (PR) has provided evidence that one recommendation has been implemented and committed to fully implement three major, and one other, recommendations. The PR has yet to provide sufficient evidence or commitment to implement the remaining three major recommendations. The panel noted that the Inspectorate was concerned, in the absence of a commitment and robust action plans to demonstrate how key requirements will be met, that the PR is at risk of failing to discharge his duty under Section 17 of the HFE Act 1990 (as amended). The Inspectorate concluded that renewal of the licence could not be confidently recommended at this point.

7. The panel noted that the Inspectorate had concerns about the PR's response to the draft report, and therefore a management review meeting was held on 20 May 2015. It concluded that, while it was considered that there is no immediate risk to patients or to the safety of their gametes, the PR had not demonstrated that he is fully engaged or able to engage with the HFEA in achieving compliance against the recommendations.

8. The PR was informed of these concerns, and that a licence renewal could not be recommended. The PR and LH had been invited to attend a meeting with HFEA representatives to discuss the concerns raised by the Inspectorate. The panel noted that, due to delays on the part of both the Inspectorate and the PR, there was insufficient time available to consider the outcome of the informal action agreed at the management review meeting, before the licence expires on 30 June 2015.

9. The Inspectorate recommends that the panel defer the decision regarding the granting of a licence and issues special directions for the continuation of the centre's current licensed activities for a period of three months, in order to give time for the Inspectorate to engage with the PR and conclude a recommendation regarding the centre's licence renewal.

Decision

10. 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.

11. The panel had serious concerns regarding the lack of progress made by the PR against the recommendations. In particular, it could not be reassured by the report that the non-compliances would be addressed in a timely fashion.

12. The panel agreed with the Inspectorate that there was not sufficient evidence to support the granting of a licence. The panel recognised that, despite its serious concern about the lack of progress and engagement from the PR, it would not be proportionate at this stage to refuse the grant of a licence. In particular, it acknowledged that the evidence in front of it suggested that there was no immediate risk to patients or their gametes.

13. The panel therefore agreed with the Inspectorate's recommendation to adjourn this decision pending further engagement and progress from the PR in respect of the outstanding recommendations. It urged the PR to fully engage with the Inspectorate, and adhere to the outstanding recommendations in the report. The panel also urged the Inspectorate to carefully consider whether the subsequent update and recommendations for renewal should be considered by the panel or the Authority's Licence Committee, in light of the serious concerns it had.

14. The panel noted that the centre's licence was due to expire on 30 June 2015. It therefore agreed to issue special directions to allow the continuation of licensed activity for a period of three months from the expiration of the licence, or until any new licence comes into force.

Signed: Date: 15 June 2015

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: 3 February 2015

Purpose of inspection: Renewal of a licence to carry out treatment (intrauterine insemination using donor sperm).

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: Gill Walsh, Karen Conyers and Louise Winstone (observing)

Date of Executive Licensing Panel: 5 June 2015

Centre name	The Whittington Hospital Fertility Unit
Centre number	0258
Licence number	L/0258/3/b
Centre address	Clinic 4C, Whittington Hospital, Magdala Avenue, London, N19 5NF
Person Responsible	Mr Gidon Lieberman
Licence Holder	Mr Paul Atwell (The Body Corporate)
Date licence issued	1 July 2011
Licence expiry date	30 June 2015
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of *t*he centre and its licensing history

The Whittington Hospital Fertility Unit is located in London and has held a licence with the HFEA since 2007. The clinic operates as a satellite IVF centre for CRM London, HFEA centre 0199.

The centre provides partner intrauterine insemination treatment (IUI) only.

The centre was last inspected in February 2013 for a short notice interim inspection.

The inspection team is satisfied that the activities carried out at the centre are necessary or desirable in order to provide licensed treatment services.

Pregnancy outcomes

In 2013 the centre reported 173 cycles of partner insemination with 13 pregnancies. This equates to a 7.5% pregnancy rate which is consistent with the national average.

In 2014, the centre reported 175 cycles of partner insemination with 10 pregnancies. This equates to a clinical pregnancy rate of 5%. HFEA analysis of the sector's results for 2014 has not yet been performed; therefore a comparison of the centre's 2014 results against the national average is not yet available but it is likely to be in line with national average.

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 not fully 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 largely suitable but cannot be fully assessed at this time;
- 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 six major and two other areas of non-compliance.

Since the inspection visit, the following recommendation has been fully implemented:

Other areas that requires improvement:

- The PR should review how the positive identification of patients and their partners is verified and how any changes to patient and partner details are subsequently verified.

The PR has given some commitment to the implementation of the following recommendations:

Major areas of non-compliance:

- The PR should review the process by which welfare of the child assessments are evaluated prior to treatment being offered to ensure that where potential issues come to light, how this is assessed and follow up is demonstrated and documented.
- The PR should review current practice to ensure that the disposal of sperm is witnessed and documented and that the batch numbers for sperm pots are recorded for traceability.
- The PR should ensure that all critical equipment used during the processing of sperm is validated and that where applicable all temperature sensitive equipment is monitored and that actions are when 'out of range' values are recorded.

Other areas that requires improvement:

- The PR should ensure that there is an appropriate SOP in place for all activities performed by the centre.

The PR had not provided sufficient evidence or committment to conclude that the following recommendations will be implemented:

Major areas of non-compliance:

- The PR should ensure that there is a suitably qualified individual to oversee the activities of the andrology laboratory. The PR should review the process by which new staff are inducted, staff are updated and staff competence is re-evaluated following any significant absence.
- The PR should ensure that the process for sperm preparation is validated by an appropriately experienced andrologist.
- The PR should review the provision of the quality management system to ensure that audits are documented and that corrective actions required are fully implemented.

Recommendation to the Executive Licensing Panel

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

Significant improvement is required in order for the centre to reflect suitable practices.

At the time a draft of this report was provided to the PR for comment, the Executive recommended the renewal of the centre's Treatment (IUI partner sperm) licence for a period of four years on the understanding that the PR was engaged with the process and was committed and able to fully discharge his duty.

The Executive considers that the responses to this report provided by the PR on 20 May 2015 do not provide sufficient assurance that the PR will fully implement the recommendations made as required. On the basis of this, the Executive is concerned that in the absence of a commitment and robust action plans to demonstrate how key requirements will be met, the PR is at risk of failing to discharge is duty under Section 17 of the HF&E Act 1990 (as amended) and therefore licence renewal cannot confidently be recommended at this point.

In response to these concerns a management review meeting was held on 20 May 2015 in accordance with paragraph 4.6 of the HFEA's compliance and enforcement policy. During that meeting it was concluded that whilst it is considered that there is no immediate risk to service users or to the safety of their gametes, the PR has not demonstrated that he is fully engaged or able to engage with the HFEA in achieving compliance. In accordance with paragraph 4.2 of the HFEA's compliance and enforcement policy it was agreed that informal action was warranted in the first instance if formal regulatory action was to be avoided.

To this effect the PR has been informed of these concerns and that licence renewal cannot be recommended at this time and a copy of the report to be presented to ELP has been provided. The PR and Licence Holder (LH) have been invited to attend a meeting with HFEA representatives to discuss the concerns raised by the Executive regarding the PR's responses to this report and his ability to commit to the implementation of the recommendations in full.

Due to a delay in the Executive being able to provide this report to the PR within the usual timeframes and a subsequent delay to the PR being able to provide a response to

this report as he was on leave, there is now insufficient time available to consider the outcome of the informal action agreed at the management review meeting or any subsequent response provided by the PR before the centre's licence is due to expire at on 30 June 2015.

In consideration of this and wishing to take a proportionate approach, the Executive recommends that the ELP defers the decision regarding the renewal of the centre's licence and issues Special Directions for the continuation of the centre's licensed activities (Treatment - IUI using partner sperm) for a period of three months to run concurrently from the end of the centre's licenced period (30 June 2015), during which time the centre's inspector will engage with the PR and conclude a recommendation to ELP regarding the centre's licence renewal. The Executive considers there is no immediate risk to service users or to their gametes by allowing the centre to continue to provide licensed treatment (IUI with partner sperm) under Special Directions.

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) 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 the patient to whom they relate are partially compliant with HFEA requirements. This ensures that patients receive treatment using the correct gametes or embryos.
What the centre could do better The centre does not witness and document the discard of sperm not required in treatment (SLC T71 and T99 CoP guidance 18.4 see recommendation 4) A sample audit of five patient records showed that in one instance the verified photo ID and signature for the woman being treated was in what appeared to be her maiden name. However her treatment consent and welfare of the child (WOC) documents were completed and signed in her married name. There was no evidence in the records to confirm that it was the same person or that the change had been verified by centre staff (CoP guidance 18:18 see recommendation 7).

► **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 The centre does not provide treatment with donor gametes therefore this area of practice is not applicable to this inspection.
What the centre could do better

What the centre does well

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

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

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

Laboratory accreditation(Guidance note 25)
The centre's third party laboratories which undertake the diagnosis and investigation of patients' and partner's gametes 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.

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

Pre-operative assessment and the surgical pathway
The centre does not perform surgical procedures as part of its licensed activities therefore this area of practice is not applicable to this inspection.

Multiple births (Guidance note 7; Directions 0003)
The requirements of General Direction 0003 are not applicable to centres providing IUI

treatment.

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 partner's gametes in treatment, based on the patient's medical history and therapeutic indications and;
- where sperm for use in treatment is procured at home, the centre keeps a record of this in the gamete provider's records.

Transport and distribution of gametes and embryos (Guidance note 15, Directions 0009)
The centre does not distribute gametes or embryos therefore this area of practice is not applicable to this inspection.
Receipt of gametes and embryos (Guidance note 15)
The centre does not receive distributed gametes therefore this area of practice is not applicable to this inspection.

Imports and exports (Guidance note 16, Directions 0006)
The centre does not import or export gametes therefore this area of practice is not applicable to this inspection.

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

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

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

Transport and satellite agreements (Guidance note 24, Directions 0010)
The centre does not have transport and satellite treatment links therefore this area of practice is not applicable to this inspection.

Equipment and materials (Guidance note 26)
The centre uses equipment and materials that are compliant with HFEA requirements. 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 partially compliant with HFEA requirements to validate and monitor 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 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 (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

Traceability (Guidance note 19)
The centre does not witness or record the disposal of sperm (SLC T71 and T99, see recommendation 4).

Batch numbers for the pots used for the collection of sperm for use in treatment are not recorded and therefore are not traceable (SLC T99 see recommendation 4).

Quality management system (QMS) (Guidance note 23)
When a 'dip' in success rates was noted in 2014, the PR commissioned an independent audit of their laboratory procedures and processes by a suitably experienced HCPC registered andrologist. The report of this audit was available on inspection. The findings of this audit somewhat echo the findings at this inspection. It is noted the actions recommended as a result from this audit have not been implemented. The PR advised that the recommendations for improvement could not be implemented as they currently do not have access to an appropriately experienced registered scientist to advise on or oversee these activities.

Rolling audits of patient consent, the provision of information and welfare of the child assessment was seen on inspection. Corrective actions have not been documented or evidence provided of implementation of actions required by the independent audit commissioned by the centre in August 2014 (SLC T36 see recommendations 5)

The PR reports that the Quality Manager role formerly fulfilled by the andrologist is still vacant and this has impacted on the centre's ability to document audits and maintain the quality management system (CoP guidance 23.4 see recommendation 5).

The centre elects to screen patients and their partners; however there is no SOP in place to ensure that where screening is conducted, this is done consistently. The SOP in place for sperm preparation for IUI does not fully describe current practices (SLC T33b, see recommendation 8).

Equipment and materials (Guidance note 26)
The fridge in which sperm preparation media is stored, has not been validated. The

thermometer used to monitor the fridge temperature has not been calibrated against a known standard, (SLC T24, see recommendation 6).

A record of the temperature of this fridge is maintained, however it was noted that when a significant 'out of range' temperature value was recorded there was no record of corrective actions. It was also noted that the temperature of the sperm preparation 'hot block' is not monitored (SLC T24, see recommendation 6).

Process validation (Guidance note 15)
Validation documentation for the process for sperm preparation for use in IUI treatment no longer reflect current practice (SLC T73 see recommendation 3)

► Staff engaged in licensed activity
Person Responsible (PR)
Staff

What the centre does well

Person Responsible (Guidance note 1)
The PR has partially complied with HFEA requirements to fulfil his duty under 17 (1) (a and e) of the Act.

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/1111/7).

Staff (Guidance note 2)
The centre is partially 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, within the UK, to advise on and oversee medical duties.

What the centre could do better

Staff (Guidance note 2)
The service is clinically led nurses do the sperm preparation and conduct IUI.
The centre does not have access to a nominated registered scientist to advise on and oversee scientific activities since the unit's andrologist left the post in spring 2013.

HFEA guidance recommends that an IUI centre has access to a suitably experienced and qualified scientist to oversee laboratory activities. The inspection team consider this to be to be a major non-compliance given the findings of this inspection and the centre's own independent audit of sperm preparation and laboratory activities. The inspection team consider that this could impact on the quality of service and the centre's success rates (CoP guidance 2.14 see recommendation 1)

The centre has recently recruited a new registered nurse and a more experienced nurse has returned from maternity leave. There is no formal process in place for the local induction of new staff or the re-evaluation of competence of staff returning to work following a significant absence. Nursing staff in post were not able to demonstrate any recent relevant professional development (SLC T14 and T15 see recommendation 1).

► 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 two of five sets of patient and partner records audited on inspection, the welfare of the child forms completed by the patient and or her partner, contained information which might indicate a welfare of the child concern. There was no evidence of any evaluation or assessment of this information by centre staff prior to treatment being provided (SLC T56 see recommendation 2).

► Embryo testing

Preimplantation genetic screening
Embryo testing and sex selection

What the centre does well

The centre does not perform embryo testing therefore this area of practice is not applicable 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 an inspector spoke to one patient who provided feedback on her experience. A further 18 patients also provided feedback directly to the HFEA in the time since the last inspection. Feedback was positive, with 10 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 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 are treated fairly and that all licensed activities are conducted in a non-discriminatory way.

Counselling (Guidance note 3)

The centre provides basic partner treatment services only and therefore is not subject to the counselling requirements of schedule 3: therefore this area of practice is not applicable to this inspection. It is noted however that the centre works closely with the Trust Women's Health psychology and counselling department and that counselling is available to all patients and their partners.

Egg [and sperm] sharing arrangements (Guidance note 12; Direction 0001)

The centre does not provide egg or sperm sharing arrangements therefore this area of practice is not applicable to this inspection.

Surrogacy (Guidance note 14)
The centre does not provide surrogacy treatments 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 for maintaining confidentiality and privacy are compliant with HFEA requirements to ensure it has respect for the privacy, confidentiality, dignity, comfort and wellbeing of prospective and current patients and their partners.

What the centre could do better

Confidentiality and privacy (Guidance note 30)
It was noted by the inspectors that one computer in use at the centre did not appear to automatically 'log off' if left unattended for more than five minutes. The PR and staff assured the inspectors that the risk of this causing confidentiality breaches is minimal as access to the office where this computer is in use is restricted and confidential information held on Trust computers is password-protected. The inspectors are satisfied therefore that no formal recommendation is required, but urge the PR to consider consulting the Trust IT department to ensure that the 'lock out' time on the unit's computers meets Trust IT security requirements.

► Information

What the centre does well

Information (Guidance note 4; CH(11)02)
The centre's procedures for providing information to patients 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 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 (Directions 0005)
The HFEA does not hold any information about patient's IUI treatments therefore this area of practice is not applicable to this inspection.

What the centre could do better

Nothing identified at this inspection.

3. The protection of gametes and embryos

► Respect for the special status of the embryo
What the centre does well The centre does not create embryos therefore this area of practice is not applicable to this inspection.
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 of gametes. It was however noted that there is no SOP for the screening of patients (see recommendation 8) **Storage of gametes and embryos (Guidance note 17)** The centre does not store gametes or embryos therefore this area of practice is not applicable to this inspection.
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 create or store embryos therefore this area of practice is not applicable 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)** The centre's procedures for keeping records are compliant with HFEA requirements to ensure that accurate medical records are maintained. Good medical records are essential for the continuity of the patient's care. **Obligations and reporting requirements (Guidance note 32,; Direction 0005)** The centre provided an annual return for IUI treatments undertaken in 2014 within the required timeframe (General Direction 0005).
What the centre could do better Nothing identified at this inspection.

Section 3: Monitoring of the centre's performance

Following the interim inspection in 2013, recommendations for improvement were made in relation to two 'major' and three 'other' areas of non-compliance. The PR provided information and evidence that all of the recommendations were fully implemented within the prescribed timescales.

On-going monitoring of centre success rates

As this centre provides partner IUI treatment only, their centre's success rates are not subject to on-going monitoring through the HFEA risk tool..

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			

► 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 [1]	Executive Review
1. Staff The centre does not have access to a nominated registered scientist to advise on and oversee scientific activities. The inspection team considers that this may have a detrimental effect of the centre's success rates and has been escalated to a major non-compliance as a result. SLC T15 and COP 2.18 There is no formal process	The PR should ensure that there is a suitably qualified individual to oversee the activities of the andrology laboratory and provide the centre's inspector with an action plan as to how this is to be achieved when responding to this report. The PR should review the process by which new staff are inducted into unit and how staff competence is re-evaluated following any significant absence. The PR should also review the provision of relevant	I acknowledge the importance of appointing a suitable scientist to oversee the laboratory activity. I have already highlighted the need for this post to our Trust. We are updating an SOP on staff competence following absence.	The Executive does not consider that there is sufficient information on which to conclude that the PR will discharge his duty under section 17 (1) (a) of the Act. The PR has not provided assurance that there is (or will be) oversight of laboratory activities by a suitably qualified scientist. The Executive considers that whilst this does not pose an immediate risk to the safety of patients or their gametes, it

[1] The PR's responses were provided in a separate document to this report. The responses have been copied in to the section 'PR Response'.

in place for the local induction of new staff or the re-evaluation of competence of staff returning to work following a significant absence. Given that the scientific activities conducted are not overseen by a suitable scientist, this non-compliance has been escalated to major. SLC T14 and T15	professional development and update training for staff in post. The PR should provide a copy of this review and detail of actions to be taken and times scales for implementation to the centre's inspector by 3 May 2015.		is still of the opinion that not having access to suitable scientific oversight of practice may have a detrimental effect on the quality of the service and success rates. The PR has not provided a copy of the review of staff induction, re-evaluation of competence following any significant absence or the provision of relevant professional development. Further action is required in these areas.
2. Welfare of the child In two of five sets of patient and partner records audited on inspection, the welfare of the child (WoC) forms completed by the patient and or her partner, contained information which might indicate a welfare of the child concern. There was no evidence of any evaluation or assessment of this information by centre staff prior to treatment being	The PR should review the process by which welfare of the child assessments are evaluated prior to treatment being offered ensure that where potential issues come to light, how this is assessed or followed up is demonstrated and documented. The PR is to provide a summary of this review and detail of any actions and timescales for implementation to the centre's inspector when	I acknowledge the importance of Welfare of the Child. We have changed our SOP (C24) for WOC All couples starting treatment will be discussed in our weekly MDT and WOC decisions logged.	The PR has not provided a summary report of the review, however the changes to procedure reported by the PR provide reassurance that there is now a mechanism in place for evaluating the WoC assessments. Further action is required in relation to the centre's audit of WoC practice.

provided. SLC T56	responding to this report. Three months after the implementation of any corrective actions, the PR is to conduct an audit the of WoC assessment process and documentation to ensure any actions taken have been effective. The PR is to provide a copy of the full audit to the centre's inspector by 2 September 2015.		
3. Process validation Validation documentation for the process for sperm preparation for use in IUI treatment no longer reflects current practice. SLC T73	The PR should ensure that the process for sperm preparation is validated by an appropriately experienced andrologist. A copy of this should be provided to the centre's inspector by 2 May 2015.	Please see point one as above.	It is the understanding of the Executive that the PR's comment relates to the centre's inability to access a suitably qualified scientist. The PR's response provides no reassurance that the recommendation will be implemented. In consideration that the centre's success rates are likely to be in line with the national average, the Executive does not consider that the absence of process validation poses an

			immediate risk to the safety of gametes but may have an influence on success rates. However in the absence of a commitment and action plan to demonstrate how this requirement will be met, the PR is at risk of failing to discharge is duty under Section 17 (1) (e) of the Act. Further action is required.
4. Traceability / witnessing The centre does not witness or record the discard of sperm not used in treatment. The centre does not ensure that relevant data about the sperm pots used for the collection of sperm is traceable. SLC T99 and T71	The PR should review current practice to ensure that the disposal of sperm is witnessed and documented and that the batch numbers for sperm pots are recorded for traceability. Detail of the review and any changes to the relevant SOPs should be provided to the centre's inspector by 2 May 2015. Three months after the implementation of any changes the PR should conduct an audit of traceability for disposal of sperm and sperm pots to ensure any	The Witness form (Q55) has now been updated to include witnessing of remainder of tubes/ sample. New specimen pots with batch numbers are being sourced.	The Executive acknowledges the PR's response and action regarding this recommendation. The PR has not provided copy of the amended form / SOP for review. Further action is required to submit this and the audit.

	actions taken have been effective. A summary of this audit is to be provided to the centre's inspector by 2 September 2015.		
5. Quality management system Audits of consent, provision of information and welfare of the child have not been formally documented or actions required implemented. Actions required as a result of independent audit of practice conducted in August 2014 have not been implemented. SLC T36 and COP guidance 23.4	The PR should review the provision of the quality management system to ensure that audits are documented and that corrective actions required are fully implemented. Detail of this review and an action plan with time scales for the implementation of any actions should be provided to the centre's inspector by 2 May 2015.	I acknowledge the importance of appointing a suitable Quality Manager to oversee the audit process. I have already highlighted the need for this post to our Trust.	It is the understanding of the Executive that the PR's comment relates to the centre's inability to secure a designated person to the Quality Manager role. The PR's response provides no reassurance that the recommendation will be implemented. In consideration that the centre's success rates are likely to be in line with the national average, the Executive does not consider that the failure to implement an effective quality management system presents any immediate risk however failure to implement the recommendations of the centre's own independent audit of practice may have an impact on the centre's

			success rates and the quality of service provided. In the absence of a commitment and action plan to demonstrate how this requirement will be met, the PR is at risk of failing to discharge is duty under Section 17 (1) (e) of the Act. Further action is required. .
6. Equipment validation The fridge in which sperm preparation media is stored, has not been validated. A record of the temperature of this fridge is maintained, however it was noted that when a significant 'out of range' temperature value was recorded there was no record of corrective actions. It was also noted that the temperature of the sperm preparation 'hot block' is not monitored	The PR should ensure that all critical equipment used during the processing of sperm is validated and that where applicable all temperature sensitive equipment is monitored and that action is taken when 'out of range' values are recorded. The PR should provide a copy of the validation documents and detail of the actions taken regarding temperature monitoring and actions when 'out of range' values are noted to the centre's inspector by 2 May 2015.	Fridge monitoring form updated to include the above (Z-14) Hot block monitoring form updated to include the above (Z-20)	The PR has provided assurance that the equipment will be monitored; it is acknowledged that this will go some way to providing evidence to support validation of this equipment. Further action is required to provide a copy of the equipment validation documents; a copy of the fridge and hot block monitoring forms and information on the actions taken to ensure that 'out of range' monitoring is acted on by the revised date of 2 July 2015.

SLC T24			

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
7. Positive identification of patients and their partners A sample audit of five patient records showed that in one instance the verified photo ID and signature for the woman being treated was in what appeared to be her maiden name. However her treatment consent and welfare of the child (WOC) documents were completed and signed in her married name. There was no evidence in the records to confirm that it was the same person or that the	The PR should review how the positive identification of patients and their partners is verified and how any changes to patient and partner details are subsequently verified. The PR should provide the centre's inspector with details of this review and any actions taken as a result by 2 May 2015.	SOP updated (Q 53) to include comment on checking of single / married name and status.	The PR has not provided detail of the review however the Executive acknowledges the PR's response and action with regard to this recommendation and is satisfied that there is a mechanism in place to assure the patient's identify. No further action is required.

change had been verified by centre staff. SLC T71 CoP guidance 18.18			
8. Quality management There is no documented SOP for patient and partner screening. The centre's SOP for the preparation of sperm for use in treatment does not accurately reflect current practice. SLC T33(b)	The PR should ensure that there is an appropriate SOP in place for all activities performed by the centre. The PR is to provide copies of the relevant SOPs by 2 May 2015.	SOP updated (C-04) patient and partner screening SOP updated (C-05) sperm preparation	The PR has not provided a copy of the amended SOPs. Further action is required to submit the SOPs by the revised date of 2 July 2015.

Reponses from the Person Responsible to this inspection report