Executive Licensing Panel - minutes

Centre 0098 (Lanarkshire Acute Hospital NHS Trust) Renewal Inspection Report

Friday, 22 April 2016

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Paula Robinson (Chair) Anna Rajakumar Trisram Dawahoo	Head of Business Planning Scientific Policy Manager Digital Communications Manager
Members of the Executive	Dee Knoyle Ian Brown	Secretary Head of Corporate Governance
External adviser		
Observers		

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. Consideration of application

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

1.2. The panel noted that this is a treatment (insemination using partner/donor sperm) and storage centre. The centre provides storage of sperm for patients undergoing treatment which may affect their fertility. The panel noted that the centre has not used donated sperm in treatment since 2008.

1.3. The panel noted that the centre has been licensed by the HFEA since May 1992.

1.4. The panel noted that in 2014, the centre reported 218 cycles of treatment (partner intrauterine insemination (IUI)) with 18 pregnancies. This equated to an 8% clinical pregnancy rate which was consistent with the national average. In relation to activity levels this is a small centre.

1.5. The panel noted that at the time of the inspection on 2 February 2016, one critical, five major and three other areas of non-compliance were identified. The panel noted that since the inspection the Person Responsible (PR) has committed to fully implementing all of the outstanding recommendations.

1.6. The panel noted that the success rates were consistent with the national average. However, improvement is required in order for the centre to reflect suitability practices. The centre has a Quality Management System (QMS) in place and the PR was encouraged to continue to use it to best effect to monitor and improve the service provided.

1.7. The panel noted that the inspectorate recommended the renewal of the centre's treatment (insemination using partner/donor sperm) and storage licence for a period of four years without additional conditions subject to the recommendations made in the inspection report being implemented within the prescribed timescales.

2. Decision

2.1. 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.

2.2. The panel was satisfied that the qualifications and character of the PR are such as is required for the supervision of licensed activities and the PR will discharge her duty under section 17 of the HFE Act 1990 (as amended).

2.3. The panel noted that the premises to be licensed are suitable for the conduct of the licensed activities.

2.4. The panel noted the centre's non-compliances and urged the PR to continue to use the QMS to best effect to monitor and improve the service provided.

2.5. The panel noted that the inspectorate will continue to monitor the centre's performance and compliance with the recommendations. Therefore, the panel endorsed the inspectorate's recommendation to renew the centre's treatment (insemination using partner/donor sperm) 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. Chair's signature

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

Signature

Name

Paula Robinson

Date

29 April 2016

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 Licence Committee (LC) and Executive Licensing Panel (ELP) use 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: 2 February 2016.

Purpose of inspection: Renewal of a licence to carry out Treatment (insemination including partner/donor sperm) 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: Andrew Leonard, Polly Todd, Eileen Graham (external advisor).

Date of Executive Licensing Panel: 22 April 2016

Centre name	Lanarkshire Acute Hospital NHS Trust
Centre number	0098
Licence number	L/0098/15/c
Centre address	Infertility Department, Monklands Hospital, Monkscourt Avenue, Airdrie, Lanarkshire, ML6 0JS, UK
Person Responsible	Ms Seema Jain
Licence Holder	Dr Iain Wallace
Date licence issued	1 July 2012
Licence expiry date	30 June 2016
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:
The Lanarkshire Acute Hospital NHS Trust infertility department has held a Treatment (including partner/donor sperm) and Storage licence with the HFEA since May 1992 and provides basic fertility services. The centre has not used donated sperm in treatment since 2008.

The centre provided 218 cycles of treatment (partner intrauterine insemination (IUI)) in 2014. In relation to activity levels this is a small centre. Other licensed activities at the centre include the storage of sperm for patients undergoing treatment which may affect their fertility.

The current licence has been varied to reflect a change of Licence Holder on 2 August 2013 and a change of Person Responsible on 13 December 2013.

Pregnancy outcomes[1]
In 2014 the centre reported 218 cycles of partner insemination with 18 pregnancies. This equates to an 8% clinical pregnancy rate which is consistent with the national average.

Summary for licensing decision – post review of draft by PR

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

- the application has been submitted in the form required;
- the application has designated an individual to act as the Person Responsible (PR);
- the PR's qualifications and experience comply with section 16 (2) (c) of the HF&E Act 1990 (as amended);
- the PR has discharged her duty under section 17 of the HF&E Act 1990 (as amended);
- the premises (including those of relevant third parties) are suitable with the exception of observations noted later in this report;
- the centre's practices are suitable with the exception of observations noted later in this report;
- 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, five major and three 'other' areas of non-compliance.

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

Critical areas of non compliance:

- **The PR must ensure that patients considering consenting to gamete storage are offered an opportunity to receive 'proper' counselling before they provide consent.**

Major areas of non compliance:

- The PR must ensure that the fire extinguishers are inspected immediately and annually thereafter;
- The PR must ensure that medicines are administered under appropriately completed and signed Patient Group Directives.

'Other' areas that require improvement:

- The PR must ensure that procedures are established to identify when additional screening tests may be indicated (based on the patient's travel and exposure history) and develop procedures for carrying out additional testing;
- The PR must ensure that Standard Operating Procedures (SOPs) are updated to include the specifications for critical materials and reagents.

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

Major areas of non compliance:

- The PR must ensure that sperm processing and cryopreservation processes are validated;
- The PR must ensure that there is ongoing periodic assessment of the competence of staff to perform specific activities;

- The PR must ensure the development of an audit programme to review key laboratory and clinical processes undertaken at the centre.

'Other' areas that require improvement:

- The PR must ensure the establishment of quality indicators or objectives for key laboratory and clinical processes undertaken at the centre whilst performing licenced activities.

Recommendation to the Executive Licensing Panel – post-review by PR

The inspection team notes that the success rates are consistent with the national average, however, improvement is required in order for the centre to reflect suitable practices. The centre has a quality management system (QMS) in place. The PR is encouraged to continue to use the QMS to best effect to monitor and improve the service provided.

The inspector will continue to monitor the centre's performance and compliance with the recommendations.

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

Section 2: Inspection findings

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

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

1. Protection of the patient and children born following treatment

▶ **Witnessing and assuring patient and donor identification**
What the centre does well **Witnessing (Guidance note 18)** The centre's procedures for double checking the identification of gametes and the patient to whom they relate are compliant with HFEA requirements. This ensures that patients receive treatment using the correct gametes or embryos.
What the centre could do better Nothing identified at this inspection.

▶ **Donor selection criteria and laboratory tests** Screening of donors prior to procuring, processing gametes and embryos Payments for donors Donor assisted conception
What the centre does well **Screening of donors (Guidance note 11)** The centre does not recruit donors for the provision of treatment services therefore this area of practice does not apply. **Payments for donors (Guidance note 13; General Direction 0001)** The centre does not recruit donors for the provision of treatment services therefore this area of practice does not apply. **Donor assisted conception (Guidance note 20)** The centre has not used donated sperm in treatment since 2008 therefore this area of practice does not apply.
What the centre could do better Not applicable to this inspection.

Suitable premises and suitable practices

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

What the centre does well

Safety and suitability of premises and facilities (Guidance note 25)
The centre's premises are partially suitable. Suitable facilities are 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 partially 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 has no satellite or transport arrangements therefore the suitability of satellite and transport premises was not relevant at this inspection.

The centre is compliant with HFEA requirements to process gametes 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 their gametes, or any material removed from them, are compliant with HFEA requirements for accreditation by CPA (UK) Ltd or another body accrediting to an equivalent standard. This is important to assure the quality of the services provided.

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

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.

Pre-operative assessment and the surgical pathway
The centre does not perform treatments that fall within the scope of this inspection theme, therefore this area of practice does not apply.

Multiple births (Guidance note 7; General Direction 0003)
The centre provides insemination with partner sperm and storage only. The multiple birth requirements relate to the placement of multiple embryos into women. Considering this centre does not create embryos, compliance against these standards was not assessed.

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 in treatment, based on the patient's medical history and therapeutic indications;
- if 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 are compliant with HFEA requirements. This is important to ensure that all gametes 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;
- shipped in a container that is designed for the transport of biological materials and that maintains the safety and quality of the gametes;
- appropriately labelled with the transport conditions, including temperature and time limit being specified;
- The container/package is secure and ensures that the gametes 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 does not receive gametes or embryos therefore this area of practice does not apply.

Imports and exports (Guidance note 16; General Direction 0006)
The centre does not import or export gametes or embryos, therefore this area of practice does not apply.

Traceability (Guidance note 19)
The centre's procedures are 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;
- to 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 and which can affect their quality or safety.

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

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

Transport and satellite agreements (Guidance note 24; General Direction 0010)
The centre does not have any transport or satellite agreements therefore this area of practice does not apply.

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 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, investigates them and takes corrective and preventative actions. 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

Safety and suitability of premises and facilities (Guidance note 25)
The fire extinguishers in the centre had not been subjected to annual inspection for two years (SLC T26; recommendation 2);

Medicines management
Nurses were administering medication under Patient Group Directives that were incomplete and had not been signed by the appropriate personnel (Nursing and Midwifery Council (NMC) 'Standards for medicines management' (2007), Standard 1(12); SLC T2; recommendation 3);

Process validation (Guidance note 15)
The sperm preparation for IUI and cryopreservation processes have not been validated (SLC T72; recommendation 4);

QMS (Guidance note 23)
The breadth of the audit programme was considered inadequate to satisfy the

requirements to audit practice against the regulatory requirements, approved protocols and quality indicators (SLC T36; recommendation 6);

The SOPs do not contain the specifications for critical materials and reagents. The SOP describing the cryopreservation process also refers to the use of a non-CE marked reagent (SLC T31; recommendation 8);

The quality indicator monitoring programme is based on the results of the annual retrospective audit of patent records. The frequency and breadth of quality indicator monitoring were considered inadequate to satisfy CoP requirements (SLC T35; recommendation 9).

Staff engaged in licensed activity
Person Responsible (PR)
Staff

What the centre does well

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

The PR has academic qualifications in the field of medicine and has more than two years of practical experience which is directly relevant to the activity to be authorised by the licence. The PR has successfully completed the HFEA PR Entry Programme (PREP number: T/1259/81).

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 and scientist, within the UK, to advise on and oversee medical and scientific activities respectively.

What the centre could do better

Staff (Guidance note 2)
There was no evidence of on-going periodic assessment of the competence of staff to perform specific activities, for example, of laboratory staff to process sperm for use in insemination and cryopreservation or of clinical staff to perform welfare of the child assessments, medicines management, nurse-led clinics, intrauterine insemination (IUI) and infection control (SLC T12 and T15a; recommendation 5).

Also see: ‘Section 2. The experience of patients: Treating patients fairly: Counselling’,

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 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);
The centre does not undertake preimplantation genetic screening therefore this area of practice does not apply.

Embryo testing and sex selection (Guidance note 10)
The centre does not undertake embryo testing and sex selection therefore this area of practice does not apply.

What the centre could do better
Not applicable to this inspection.

2. The experience of patients

Patient feedback

What the centre does well

There were no patients available on the day of inspection to speak to the inspectors about their experiences at the centre. However 35 patients have provided feedback directly to the HFEA in the time since the last inspection. Feedback was fairly 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;
- 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's counselling procedures are partially compliant with HFEA requirements. This is important to ensure that counselling support is offered to patients providing consent to the storage of their gametes.

Egg [and sperm] sharing arrangements (Guidance note 12; General Direction 0001)
The centre does not undertake any egg or sperm sharing arrangements so this area of practice does not apply.

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

apply.

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.

What the centre could do better

Counselling (Guidance note 3)
The counsellor provided evidence of compliant practice but said she has recently taken on a new role and stopped working at the centre in December 2015. A new counsellor has not yet been appointed so patients who request counselling are being placed on a 'holding list' until a counsellor is available. The inspection team conclude that the centre does not offer 'proper' counselling to men storing sperm before seeking their consent (HF&E Act 1990 (as amended), Schedule 3, paragraph 3(1) (a); recommendation 1).

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 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, except in regards to the counselling non compliance referred to above. This ensures that patients have provided all relevant consents before carrying out any licensed activity.

Disclosure of information, held on the HFEA Register, for use in research (General Direction 0005)
Clinics are required by law to provide information to the HFEA about all licensed fertility treatments they carry out.

'Consent to disclosure to researchers' requirements are not relevant to basic partner IUI services and storage, and, given the centre has not used donated sperm in treatment since 2008 and has no plans to do so, this area of practice was not reviewed 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 does not apply.

What the centre could do better
Not applicable to this inspection.

Screening of patients
Storage of gametes and embryos

What the centre does well

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

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

What the centre could do better

Screening of patients (Guidance note 17)
The centre does not consider the need for additional screening tests which may be required because of a patient's travel and exposure history (SLC T50d; recommendation 7).

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 use embryos for training staff, therefore this area of practice does not apply.

What the centre could do better
Not applicable to 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 ; General Direction 0005)
The centre's procedures for submitting information about licensed activities to the Authority are compliant with HFEA requirements.

The centre provided an annual return for treatments undertaken in 2014 within the required timeframe.

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

Section 3: Monitoring of the centre's performance

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

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 only provides partner IUI treatment, their success rates are not subject to ongoing monitoring via the HFEA risk tool and therefore the centre has not been issued with any performance alerts since the last inspection.

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
1. The centre does not offer proper counselling to those providing consent to storage HF&E Act (1990), as amended, Schedule 3, paragraph 3(1) (a).	The PR must ensure that patients considering consenting to gamete storage are offered an opportunity to receive 'proper' counselling before they provide consent. This counselling should be provided by a counsellor who is BICA accredited or working towards BICA accreditation or equivalent. The PR must advise the centre's inspector of the actions taken when responding to this report.	The Board is advertising the post for a new Counsellor and in the interim having discussions with adjoining health-board(Glasgow Royal) to make an arrangement whereby our patients can access their Counsellor	Since responding to this report the PR has provided written confirmation that NHS Greater Glasgow and Clyde have agreed to provide counselling services to patients referred to them from the Lanarkshire Acute Hospital NHS Trust infertility department and that these services will be provided by a BICA accredited counsellor. No further action required.

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
2. The fire extinguishers in the centre had not been subjected to annual inspection for two years. SLC T26.	The PR must take action to ensure that the fire extinguishers are inspected immediately and annually thereafter. Evidence of the inspection of the fire extinguishers must be provided by the PR to the centre's inspector when responding to this report.	The fire-extinguishers were checked on 5/02/2016 and will undergo annual maintainence checks by the Fire department	The inspection team acknowledge the PR's response and action taken to implement this recommendation. No further action required.
3. Nurses were administering medication under Patient Group Directives that were incomplete and had not been signed by the appropriate personnel. NMC 'Standards for medicines management'	The PR must ensure that medicines are administered under appropriately completed and signed Patient Group Directives. 12 February 2016: The inspection team were advised that appropriately completed	This has been done and already e-mailed to you	The inspection team has received and reviewed the Patient Group Directives which demonstrate the implementation of this recommendation. No further action required.

(2007), Standard 1 (12); SLC T2.	Patient Group Directives were in place. Copies of a sample of these directives have been received by the centre's inspector. No further action required.		
4. The sperm preparation for IUI and cryopreservation processes have not been validated. SLC T72.	The PR must ensure that sperm processing and cryopreservation processes are validated. The PR must provide evidence of the validation of these processes to the centre's inspector by 2 May 2016.	Validation form which will be used henceforth are attached	The inspection team note the PR's commitment to implement the recommendation and that the processes have been initially validated on the basis that they are established methods cited in reference manuals. The PR has provided a SOP for the method by which the validations will be completed, which includes a review of process outcomes. The inspection team therefore await receipt of the final validation documents, which can only be completed when the requisite number of cases have been performed. Further action is required.
5. There was no evidence of on-going periodic	The PR must ensure that there is ongoing periodic	Nursing Competencies regarding Scanning has	The inspection team acknowledge the PR's response

assessment of the competence of staff to perform specific activities, for example, of laboratory staff to process sperm for use in insemination and for cryopreservation, or of clinical staff to perform welfare of the child assessments; medicines management; nurse-led clinics; inter-uterine insemination (IUI) and infection control. SLC T12 and T15a.	assessment of staff competence to carry out specific activities. The PR must provide a report documenting the names of all centre staff; the training and competence assessments relevant to each staff member, and the anticipated date for completion of the relevant training and assessments to the centre's inspector by 2 May 2016. The PR must provide quarterly updates from 2 May 2016, to the centre's inspector documenting progress in the provision of all outstanding training and competence assessments until all have been provided. It is recommended that the provision of training be prioritised on the basis of risk.	been arranged by External sonographer for June 2016 Competencies for Insemination procedure, Drugs management, Nurse Led Clinics are in progress. Specific Welfare of child assessment questions being added to our history sheet and will be audited Audits to be done on Uniform policy, Hand-washing and Trans-vaginal probe cleaning, Personal Protective Equipment to encompass Infection Control	and action taken to implement this recommendation. The inspection team have received a competency assessment plan which indicates the assessment programme for each member of the laboratory team; clinical staff members have not been included on this plan. Further action is required to fully implement this recommendation.
6. The breadth of the audit programme was considered inadequate to satisfy regulatory	The PR must ensure the development of an audit programme to review key laboratory and clinical	Audits indicated as above, Audits on Pregnancy Outcomes, Abandoned IUI	The inspection team acknowledge the PR's response and commitment to implement this recommendation.

requirements, approved protocols or quality indicators SLC T36	processes undertaken at the centre within the next year. Documentation demonstrating the establishment of this programme must be provided to the centre's inspector when responding to this report. The PR must provide reports of audits performed to the centre's inspector, as they are completed, within the next year.	cycles, Patient Complaints and Patient feedback, various lab audits already taking place	The inspection team await documentation of the established programme of audits, as required by the recommendation. Further action required.

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. The centre does not consider the need for additional screening tests which may be required because of a patient's travel and/or exposure history. SLC T50d.	The PR must ensure that procedures are established to identify when additional screening tests may be indicated (based on the patient's travel and/or exposure history) and develop procedures for carrying out additional testing. The centre's inspector must be advised of the measures taken to ensure that this happens by 2 May 2016. The PR must conduct an audit of screening and a summary report of the findings of the audit must be provided to the centre's inspector by 2 August 2016.	Recent Relevant Foreign Travel (last 12 months) is being added to the History Sheet and where required discussions will take place with Microbiology/Infectious disease and relevant investigations organised . The laboratory Scientists will also specifically inquire regarding travel before accepting a semen sample for analysis.	The inspection team acknowledge the PR's response and commitment to this recommendation. No further action is required beyond submission of the screening audit by 2 August 2016.
8. The SOPs do not contain the specifications for critical materials and reagents. The SOP describing the	The PR must ensure that SOPs are updated to include the specifications for critical materials and reagents.	The Non-CE marked reagent	The inspection team acknowledge the PR's response and notes that critical materials and reagents

cryopreservation process also refers to the use of a non-CE marked reagent. SLC T31.	The PR must ensure that only CE marked reagents are used wherever possible and ensure that all SOPs reflect appropriate practice and regulatory requirements. The PR must provide updated SOPs to the centre's inspector by 2 May 2016.	has since been removed	are now specified in the andrology manual. No further action required.
9. The quality indicator monitoring programme is based on the results of the annual retrospective audit of patent records. The frequency and breadth of quality indictor monitoring were considered inadequate to satisfy standard licence condition requirements. SLC T35	The PR must ensure the establishment of quality indicators or objectives for key laboratory and clinical processes undertaken at the centre whilst performing licenced activities. The PR must provide documentation demonstrating the establishment of the quality indicators and objectives to the centre's inspector by 2 May 2016.	Quality Management System Review due to take place in April.	The inspection team acknowledge the PR's response. Further action required.

Reponses from the Person Responsible to this inspection report