Executive Licensing Panel - minutes

Centre 0080 (Androlgy Unit, Hammersmith Hospital)

Renewal Inspection Report

Monday, 22 January 2018

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Caylin Joski-Jethi (Chair) Jessica Watkin Helen Crutcher	Head of Intelligence Policy Manager Risk & Business Planning Manager
Members of the Executive	Bernice Ash Nana Gyamfi	Secretary Licensing Information Officer (Observing)
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 the Andrology Unit, Hammersmith Hospital has held a storage only licence with the HFEA since 1992. The centre is part of Imperial College NHS Trust and provides storage of sperm for patients who are undergoing treatment that may impair their fertility. The centre occasionally provides the same service to patients seeking short-term storage of sperm when undergoing fertility treatment.

1.3. The panel noted that an inspection was carried out at the centre on 31 October 2017.

1.4. The panel noted that at the time of the inspection on 31 October 2017, there was one critical area of non-compliance concerning consent. There were also five 'other' areas of non-compliance or poor practice regarding premises and facilities, record keeping, infection control, equipment and materials and staff competencies. Since the inspection, the Person Responsible (PR) had given a commitment to fully implementing all the recommendations within the timescale.

1.5. The panel noted that with regard to the critical non-compliance concerning consent, the issue concerning the three incomplete consent forms had been addressed.

1.6. The panel noted that the centre's inspector will continue to monitor the centre's performance and whether implementation of the report's recommendations are made within the prescribed timescales.

1.7. The panel noted that as the centre had one critical area of concern, at the time of inspection, the inspectorate had considered the 'Guidance on Licensing'. However, as the issue on consent forms had been addressed, the inspectorate recommended the renewal of the centre's storage licence for a period of four years without additional conditions, subject to the recommendations 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 forms and fee had been submitted and that the application contained the supporting information required by General Directions 0008.

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

2.3. The panel endorsed the inspectorate's recommendation to renew the centre's storage licence for a period of four years, without additional conditions, subject to the recommendations 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

Caylin Joski-Jethi

Date

23 January 2018

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. 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: 31 October 2017

Purpose of inspection: Renewal of a licence to carry out 'Storage only'

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: Susan Jolliffe and Louise Winstone

Date of Executive Licensing Panel: 19 January 2018

Centre name	Andrology Unit, Hammersmith Hospital
Centre number	0080
Licence number	L/0080/14/c
Centre address	South Corridor, Area C/FR30, Hammersmith Hospital, Du Cane Road, London, W12 0HS, United Kingdom
Person Responsible	Ms Pauline Macmillan
Licence Holder	Dr Johnathan Ramsay
Date licence issued	1 March 2014
Licence expiry date	28 February 2018
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:

The Andrology Unit, Hammersmith Hospital has held a storage only licence with the HFEA since 1992. The centre is part of Imperial College NHS Trust and provides storage of sperm for patients who are undergoing treatment that may impair their fertility. The centre occasionally provides the same service to patients seeking short-term storage of sperm when undergoing fertility treatment.

Since the last renewal inspection an application to vary the centre's licence to reflect a change of Licence Holder was agreed by Executive Licensing Panel (ELP) on 4 September 2015 to Dr Johnathan Ramsay, and a change of Person Responsible (PR) was agreed by ELP on 28 July 2017, the new PR is Pauline Macmillan.

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 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 the centre's 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, and five 'other' areas of non-compliance or poor practice.

The PR has given a commitment to fully implementing all of the recommendations within the timescale.

Critical area of concern:

- **The PR should ensure that for each patient, the centre must maintain a record that is complete, clear and legible.**

Major areas of non compliance: None

'Other' areas of non compliance or poor practice that require improvement:

- The PR should ensure that the processing of gametes takes place in a background environment of at least Grade D air quality.

- The PR should ensure that the patient's identification is recorded in the patients records.
- The PR should appoint a competent infection control lead, who will use their skills and knowledge to complete an infection control audit.
- The PR should ensure appropriately CE marked medical devices are used where available.
- The PR should ensure that staff competencies for witnessing and traceability are evaluated and documented.

Recommendation to the Executive Licensing Panel

The centre has one critical area of concern. The issue with the three incomplete consent forms has been addressed however, in consideration of the 'Guidance on Licensing' the inspection team recommends the renewal of the centre's 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 PR has given a commitment to implement all the required recommendations within the agreed timescale, and there are no serious concerns about the quality of service based on observations at the inspection.

The inspector will continue to monitor the centre's performance and the implementation of this report's recommendations within the required 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 at this centre
2. The experience of patients at this centre
3. The protection of gametes at this centre
4. How this centre looks after important information

1. Protection of the patient

▶ **Witnessing and assuring patient 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.
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 therefore this does not apply. **Payments for donors (Guidance note 13; General Direction 0001)** The centre does not recruit donors therefore this does not apply. **Donor assisted conception (Guidance note 20)** The centre does not provide treatment and therefore this does not apply.
What the centre could do better Nothing identified at this inspection.

Suitable premises and suitable practices

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

What the centre does well

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

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

The premises of the centre's laboratories conducting tests that impact on the quality and safety of gametes (relevant third parties) are suitable.

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

Laboratory accreditation (Guidance note 25)
The centre's laboratories which undertake the diagnosis and investigation of patients or their gametes or any material removed from them, are compliant with HFEA requirements to be accredited 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 (Guidance Note 25)
The centre has systems in place to manage and monitor the prevention and control of infection that are broadly compliant with guidance.

Medicines management (Guidance Note 25)
The centre does not stock or dispense any intralipids or medicines.

Pre-operative assessment and the surgical pathway (Guidance Note 25)
This area of practice is not relevant to this inspection.

Multiple births (Guidance note 7; General Direction 0003)

This area of practice is not relevant to this inspection.

Procurement of gametes (Guidance note 15)
The centre's procedures are compliant with HFEA requirements to:

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

Transport and distribution of gametes (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 (Guidance note 15)
The centre's procedures for the receipt of gametes are compliant with HFEA requirements. This is important to ensure that the centre only accepts gametes from other centres if they 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 import and export of gametes are compliant with HFEA requirements.

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 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 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; General Direction 0010)
The centre does not have any transport or satellite arrangements.

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

The centre is compliant with HFEA requirements to validate critical equipment. The centre has documented procedures for the operation of critical equipment and procedures to follow if equipment malfunctions.

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

Safety and suitability of premises and facilities (Guidance note 25)
The centre could not provide documented evidence that the processing of gametes takes place in a background environment of at least Grade D air quality. This has been down graded to an 'other' non compliance in consideration that the air quality in the critical working area does meet the required grade' (SLC T20; see recommendation 2).

Infection control (Guidance Note 25)
The centre does not have an infection control lead, and the centre has not completed an infection control audit in the last two years. Cleaning records are kept, however the room where patients sit to give consent was cluttered and difficult to clean thoroughly and would benefit from the advice of an infection control lead. (SLC T2; Code of Practice 25.19 and 25.20; see recommendation 4).

Quality management system (QMS) (Guidance note 23)
The inspection team record audit found one set of patient records with no evidence of how, and by whom, the patient had been reliably identified, other records had photo identification in the file. Also see record keeping and document control section.

The centre has not completed a record keeping audit in the last two years (SLC T46b; see recommendation 3).

Equipment and materials (Guidance note 26)

During a review of laboratory media and consumables the sperm collection pots were found to not be appropriately CE marked (SLC T30; See recommendation 5).

Staff engaged in licensed activity

Person Responsible (PR)
Staff

What the centre does well

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

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 broadly 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 competencies
There were no documented staff competencies for witnessing and traceability, other competencies were recorded comprehensively (SLC T12; see recommendation 6).

Welfare of the child and safeguarding

What the centre does well

Welfare of the child (Guidance note 8)
The centre does not provide treatment services therefore this guidance note does not apply.

Safeguarding (Guidance Note 25)
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)
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 inspectors did not speak to any patients. However, the centre feedback in April 2016 (due to be repeated shortly) from 48 patients was positive, with 20 of the individuals stating care was excellent, staff had acted on any recommendations for improvement and welcomed feedback.

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's counselling procedures are compliant with HFEA requirements. This is important to ensure that counselling support is offered to patients providing relevant consent.

Gamete sharing arrangements (Guidance note 12; General Direction 0001)
The centre stores sperm only and does not offer treatment services, therefore this guidance note does not apply.

Surrogacy (Guidance note 14)
The centre stores sperm only and does not offer treatment services, therefore this guidance note 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
Nothing identified at this inspection.

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 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 partially compliant with HFEA requirements. This ensures that patients have provided all relevant consents before carrying out any licensed activity.

Legal parenthood (Guidance note 6)
The centre stores sperm only and does not offer treatment services, therefore this guidance note does not apply.

Disclosure of information, held on the HFEA Register, for use in research (General Direction 0005)
The centre provides gamete storage services only and does not ask patients to consider consent to disclosure to researchers; therefore this area of practice is not relevant to this inspection.

What the centre could do better

Consent (Guidance note 5; 6)
The centre completed an audit of consent forms in June 2017, and found that three out of 14 records had no date and patient signature on the consent declaration page of the GS form, in cases where samples were in storage at the centre. The three patients have been contacted to complete the form.

In an audit by the inspection team, five out of seven consent forms were found to have amendments on the GS form, making the length of storage consented to difficult to interpret in some cases (SLC T46 and 47; See recommendation 1).

3. The protection of gametes and embryos

Respect for the special status of the embryo

What the centre does well
This is not applicable to this centre, as the centre does not create or store embryos.

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

Screening of patients and Storage of gametes

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.

Storage of gametes (Guidance note 17)
The centre stores sperm only.

The storage of gametes is an important service offered by fertility clinics, as it can enable patients to preserve their fertility prior to undergoing medical treatment such as chemotherapy and radiotherapy.

The centre's procedures for storing gametes are compliant with HFEA requirements. These measures ensure that the gametes are stored appropriately to maintain their quality and safety.

The centre operates a bring forward system to ensure sufficient advance notice is given to patients that the end of the consented storage period is approaching; this system, as it applies to recently stored material, was discussed on inspection and was considered by the inspectors to be robust.

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 relevant to this inspection.

What the centre could do better

Nothing identified at this inspection.

4. Information management

Record keeping and 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 broadly 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 stores sperm only and does not offer treatment services, therefore this guidance note does not apply.

What the centre could do better

Record keeping and document control (Guidance note 31)
The inspection team record audit found one set of patient records with no evidence of how, and by whom, the patient had been reliably identified, other records had photo identification in the file.

The centre has not completed a record keeping audit in the last two years (SLC T46b; see recommendation 3). Also see Quality Management section.

Section 3: Monitoring of the centre's performance

Following the interim inspection in 2015, recommendations for improvement were made in relation to one area of critical non compliance and one area of major non compliance.

The PR provided information and evidence that all of the recommendations were fully implemented within the prescribed timescales, however, the completion of the consent forms was a 'major' noncompliance at the last inspection, and has therefore been escalated to a critical non-compliance.

Areas of practice requiring action

This 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 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
1. Consent The centre completed an audit of consent forms in June 2017; three out of 14 records had no date and patient signature on the GS form. The three patients have been contacted to complete the form. In an audit by the inspection team, five out of seven consent forms were found to have amendments on the GS form; all records must be clear and readable.	The PR must ensure that for each patient the centre holds a record of consent that is complete, clear and legible. As this was a non-compliance at the last inspection, the PR must review why changes implemented were not effective. The PR should review the procedure for taking consent and checking the forms with the patient, as well as the audit procedures used to check patient consent forms,	Review of the response of the PR at the time of the previous inspection to this finding was to ensure any changes to the form must be initialled by the patient and this had been the practice in place since that time. As identified at the current inspection such crossings out and initialling by the patient is deemed to have uncertain legality thus the following changes will be implemented.	The Executive acknowledges the PR's response and commitment to meet the requirement by the agreed timescale. The three incomplete consent forms identified by the centre's own audit have been completed correctly. Further action is required

(SLC T46 and T47). **This was a non-compliance at the last inspection, and has now been escalated to a critical.**	to identify and address the reasons for the incomplete and amended forms. A copy of the updated Consent SOP and a summary report of this review including corrective actions and the timescale for their implementation should be provided to the centre's inspector by 31 January 2018, including an update on the three forms with no date and signature identified by the centre. Six months after implementing any corrective actions the PR should audit consent forms to confirm that the actions have been effective. A summary report of the audit should be provided the centre's inspector by 31 July 2018.	To be submitted for deadline of 31/01/2018 1) New version of Consent SOP with instruction that crossing out and intialing is not acceptable. and a new page must be printed to be completed without change or correction. 2) A copy of the GS form with clear instruction as to which parts of the form need to be completed provided to patients. 3) Update on the GS forms for the 3 patients identified by the Lab will be provided. 4) Checklist for Consent / Patient record audit (combined with evidence for finding 3) to be completed in April 2018 To be submitted for deadline of 31/07/2018 4) Summary of Consent/Patient record audit completed in April.	

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
None			

Other areas of practice that requires improvement

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
2. Premises and Facilities. The centre could not provide documented evidence that the processing of gametes takes place in a background environment of at least Grade D air quality. (SLC T20).	The PR must ensure that the background air quality of the lab used to process gametes is regularly tested and meets at least Grade D. The PR should submit the results of the background air quality testing to the centre's inspector by 31 January 2018.	To be submitted for deadline of 31/08/2018 1) Results of background air quality check of gamete processing lab, performed by the ICHNT Pharmacy	The Executive acknowledges the PR's response and commitment to meet the requirement by 31 January 2018. Further action is required
3.Record keeping The inspection team record audit found one set of patient records with no evidence of how, and by whom, the patient had been reliably identified. The centre has not completed a record keeping audit in the last two years. (SLC T46b).	The PR should ensure that complete records are maintained for patients at the centre. The PR should review the process for patient identification and update their SOP. Three months after the review the PR should complete an audit of records to ensure patient identification is consistently fully documented. A copy of the audit and the	To be submitted for the deadline of 31/04/2018 1) Consent SOP updated with instructions for confirming the identity of patients without formal identification (combined with evidence for finding 1). To be submitted for deadline of 31/04/2018 1) Report of Consent/Patient record audit with findings, actions and implementation plan.	The Executive acknowledges the PR's progress in updating the consent SOP, and commitment to submit the audit in the agreed time. Further action is required

	summary report, with the centres findings, action and implementation plan should be sent to the centre's inspector by 31 April 2018.		
4.Infection control The centre does not have an infection control lead. The centre has not completed an infection control audit. (SLC T2; Code of Practice 25.19 and 25.20).	The PR should appoint a competent infection control lead to provide advice and updates to centre staff. The infection control lead should complete an audit of the centre, providing a summary report to the centre's inspector by 31 January 2018.	To be submitted for deadline of 31/01/2018 1) Confirmation of appointment of Infection Control Lead. 2) Summary of audit completed by Infection Control Lead	The Executive acknowledges the PR's response and commitment to meet the requirement in the agreed time. Further action is required
5. Equipment and materials During a review of laboratory media and consumables the sperm collection pots were found to not be appropriately CE marked. (SLC T30).	The PR should ensure appropriately CE marked medical devices are used where available. We would not recommend the implementation of precipitous changes that might impact on the quality of service that is provided to patients. In consideration of this the PR should identify a suitable CE marked alternative by 31 January 2018 and provide confirmation, along with a	To be submitted for deadline of 31/01/2018 1) Report on review and selection of suitable CE marked sample containers with a plan to be compliant by 30/04/2018.	The Executive acknowledges the PR's response and commitment to meet the requirement in the agreed time. Further action is required

	timeline of introduction to the centre's inspector. The PR should aim to be fully compliant with this requirement no later than 30 April 2018.		
6.Staff competencies There were no documented staff competencies for witnessing and traceability. (SLC T12).	The PR should ensure staff competency is evaluated and documented at appropriate intervals. A copy of the staff competencies for witnessing and traceability should be forwarded to the centre's inspector by 31 January 2018.	To be submitted for the deadline of 31/01/2018 1) Copies of staff training and competence records for Witnessing and Traceability procedures.	The Executive acknowledges the PR's response and confirmation that the staff competencies will be submitted by 31 January 2018 Further action is required

Responses from the Person Responsible to this inspection report
The findings presented in this report are accepted and the required actions will be conformed to by the deadlines specified.