Executive Licensing Panel - minutes

Centre 0096 (Sunderland Fertility Centre)

Renewal Inspection Report

Friday, 2 March 2018

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Caylin Joski-Jethi (Chair) Erin Barton Anna Coundley	Head of Intelligence Policy Manager Information Access & Policy Manager
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers	Niamh Marren	Regulatory Policy Manager (Observing)

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 centre has held a licence with the HFEA since 1992. The centre provides basic fertility services and long term sperm storage facilities. The centre holds a treatment (insemination using partner/donor sperm) and storage licence. The centre currently does not provide treatments with donor sperm; however, this licence type is the most suitable for the centre's range of activities.

1.3. The panel noted that in 2016, the centre reported 81 cycles of of partner insemination with 12 pregnancies. This represents a clinical pregnancy rate of 15%, which is in line with the national average.

1.4. The panel noted that in 2016, the centre reported no multiple births.

1.5. An inspection was carried out at the centre on 6 December 2017.

1.6. The panel noted that at the time of the inspection, there were four major areas of non-compliance, concerning storage, the Quality Management System (QMS), equipment and materials and screening of patients, alongside three 'other' areas regarding staffing, Third Party Agreements (TPAs) and record keeping. Since the inspection, the Person Responsible (PR) has provided evidence that actions have been taken to implement the recommendations regarding storage and staffing and has fully committed to implementing the outstanding recommendations surrounding the QMS, equipment and materials, screening of patients, TPAs and record keeping.

1.7. The panel noted that some improvement is required in order for the centre to demonstrate the suitability of their practices. The PR is encouraged to review the centre's QMS to ensure that it can be used to best effect to monitor and improve the services provided to patients.

1.8. The panel noted that the inspector will continue to monitor the centre's performance and the implementation of this report's recommendations within the required timescales.

1.9. The panel noted the inspectorate's recommendation to renew the centre's treatment (insemination using partner/donor sperm) licence for a period of four years without additional conditions, subject to the recommendations being implemented within the prescribed timescales.

1.10. The panel also noted that the postcode recorded for the centre on its current licence is incorrect. This is a historical administrative error only and does not relate to any variation to the centre's premises. The executive therefore recommends that the following correct address is reflected on the centre's renewed licence:

Sunderland Royal Hospital
Kayll Road
Sunderland
Tyne & Wear
SR4 7TP

2. Decision

2.1. The panel had regard to its decision trees. 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 noted that the premises to be licensed are suitable for the conduct of the licensed activities.

2.3. The panel congratulated the centre on its positive feedback from patients.

2.4. The panel endorsed the inspectorate's recommendation to renew the centre's treatment (insemination using partner/donor sperm) licence for a period of four years, without additional conditions, subject to the recommendations being implemented within the prescribed timescales.

2.5. The panel agreed that the address on the licence should be altered to:

Sunderland Royal Hospital
Kayll Road
Sunderland
Tyne & Wear
SR4 7TP

3. Chair's signature

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

Signature

Name

Caylin Joski-Jethi

Date

7 March 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: 6 December 2017.

Purpose of inspection: Renewal of a licence to carry out Treatment (insemination using 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: Lesley Brown (Lead), Shanaz Pasha.

Date of Executive Licensing Panel: 2 March 2018.

Centre name	Sunderland Fertility Centre
Centre number	0096
Licence number	L/0096/21/b
Centre address	Sunderland Royal Hospital, Kayll Road, Sunderland, Tyne & Wear, SR3 1AA, United Kingdom.
Person Responsible	Dr Madhavi Gudipati
Licence Holder	Mr Ken Bremner
Date licence issued	1 June 2014
Licence expiry date	30 May 2018
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:

The Sunderland Fertility Centre has held a licence with the HFEA since 1992. The centre provides basic fertility services and long term sperm storage facilities. The centre holds a treatment (insemination using partner/donor sperm) and storage licence. The centre currently does not provide treatments with donor sperm, however, this licence type is the most suitable for the centre's range of activities.

The centre's licence was varied in September 2016 to reflect a change of Person Responsible (PR).

Pregnancy outcomes

In 2016, the centre reported 81 cycles of partner insemination with 12 pregnancies. This represents a clinical pregnancy rate of 15%, which is in line with the national average.

Multiple births

The single biggest risk of fertility treatment is a multiple pregnancy. In 2016, the centre reported no multiple births.

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, four major and three 'other' areas of non compliance.

Since the inspection visit, the PR has provided evidence that actions have been taken to implement the following recommendations:

Major areas of non compliance:

- The PR should take appropriate actions to ensure that all gametes are stored lawfully.

'Other' areas of non compliance:

- The PR should complete a workforce assessment.

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

Major areas of non compliance:

- The PR should ensure that the centre's quality management system (QMS), auditing processes and documented procedures are suitable and effective.
- The PR should ensure that all critical equipment is validated and medical devices are appropriately CE marked.
- The PR should assess the risks of infection with Ebola and Zika virus based on a patient's travel history.

'Other' areas of non compliance:

- The PR should ensure all third party agreements are fully compliant with regulatory requirements.
- The PR should ensure there is a record of how, and by whom a patient has been reliably identified.

Recommendation to the Executive Licensing Panel

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

The inspection team notes that the success rates are consistent with the national average.

Some improvement is required in order for the centre to demonstrate the suitability of their practices. The PR is encouraged to review the centre's QMS to ensure that it can be used to best effect to monitor and improve the services provided to patients.

The inspector will continue to monitor the centre's performance and the implementation of this reports recommendations within the required timescales

The inspection team recommends 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 this report being implemented within the prescribed timescales.

The ELP is also asked to note that the postcode recorded for the centre on its current licence is incorrect. This is a historical administrative error only and does not relate to any variation to the centre's premises. The executive therefore recommends that the following correct address is reflected on the centre's renewed licence:

Sunderland Royal Hospital
Kayll Road
Sunderland
Tyne & Wear
SR4 7TP.

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 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.
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 provide treatment with donor gametes, therefore this area of practice is not applicable to this inspection. **Payments for donors (Guidance note 13; General Direction 0001)** The centre does not recruit donors or provide treatment with donor gametes, therefore this area of practice is not applicable to this inspection. **Donor assisted conception (Guidance note 20)** 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 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 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 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 compliant with guidance.

Medicines management (Guidance Note 25)
The centre does not keep or dispense medicines.

Prescription of intralipid 'off label'
Intralipid is an intravenous nutritional supplement sometimes prescribed to facilitate IVF treatment in a particular subset of women. This centre does not prescribe intralipid therapy therefore requirements related to its use were not relevant at this inspection.

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

Multiple births (Guidance note 7; General Direction 0003)
The centre is providing only insemination treatments, but such treatments still expose patients to the risks of multiple pregnancies and births if incorrectly applied. The single biggest risk of fertility treatment is a multiple pregnancy and birth. Thus it is important for centres providing insemination treatments to have a multiple births minimisation strategy. The centre's procedures are compliant with HFEA requirements to have a multiple births minimisation strategy and to conduct regular audits and evaluations of the progress and effectiveness of the strategy.

Procurement of gametes (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;
- where the sperm is procured at home, the centre keeps a record of this in the gamete provider's records.

Transport and distribution of gametes (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 note15)
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 not 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 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 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 (TPAs) are partially compliant with HFEA requirements.

Transport and satellite agreements (Guidance note 24; General Direction 0010)
The centre does not have transport and satellite 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 broadly compliant with HFEA requirements. Most 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 partially 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

Imports and exports (Guidance note 16; General Direction 0006)
When discussing transport procedures during the inspection, the centre reported that they have not received any requests from patients with stored gametes, for those gametes to be exported for treatment abroad. They had not considered the need to include steps to direct such a request within their transport standard operating procedure (SOP) (GD 0006, SLC T33). The recommendation associated with this observation is discussed together with the QMS recommendation. See recommendation 2.

Quality management system (QMS) (Guidance note 23)

A number of audits undertaken by the centre were reviewed, at least two audits identified issues, however these were not cited as non conformances in the audit reports.

The centre has not undertaken the following audits in the last two years:

- confidentiality and privacy audit;
- Infection prevention and control audit.

The centre has not performed a full quality management review in the past year. Although a full quality management system review has not be performed, it should be noted that a quality review of the andrology service had been performed, to a high standard (CoP 23.12, CoP 23.13).

The centre does not systematically document root cause analysis of non-compliances, corrective and preventative actions and their time scales of implementation and dates of implementation (SLC T36).

The centre is included in an overarching business continuity plan with City Hospitals Sunderland NHS Trust, however this does not describe arrangements for the continuation of clinical services or safe transfer and storage of gametes to another licensed centre in the event of a disaster (SLC T2). See recommendation 2.

Third party agreements (Guidance note 24)
Three TPAs were reviewed as part of the inspection process. All of those reviewed had aspects which were non compliant with the relevant SLCs. The centre could not provide evidence that the TPAs had been fully reviewed since 2012 (SLC T112, SLC T113, SLC T114, SLC T116). See recommendation 6.

Equipment and materials (Guidance note 26)
The inspection team was able to review evidence of regular servicing of critical equipment, however, equipment validation has not been formally documented (SLC T24 and SLC T25).

The sperm pots in use at the centre are not appropriately CE marked (SLC T30, Clinic Focus September 2016). 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 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.

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 (Guidance note 2)
The PR has not completed a recent workforce assessment, but the inspection team notes that no concerns relating to staffing numbers were seen on inspection (CoP 25.13). See recommendation 5.

Welfare of the child and safeguarding

What the centre does well

Welfare of the child (Guidance note 8)
The centre's procedures to ensure that the centre takes into account before licensed treatment is provided, the welfare of any child who may be born as a result of that treatment and of any other child who may be affected by that birth, are compliant with HFEA requirements.

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)
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 the inspector spoke to three patient couples and one patient who provided feedback on their experiences. The centre's most recent patient survey responses were also reviewed. Feedback was positive, with 30 of the individuals providing written feedback giving compliments about the care 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's counselling procedures are compliant with HFEA requirements. This is important to ensure that counselling support is offered to patients providing relevant consent.

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

The centre does not provide treatment with donated gametes therefore this area of practice is not applicable to this inspection.

Surrogacy (Guidance note 14)
The centre does not provide treatment involving surrogacy therefore this area of practice is not applicable to this inspection.

Complaints (Guidance note 28)
The centre's procedures are compliant with HFEA requirements to seek patient feedback and to be responsive to patient complaints. This is important to ensure that the centre uses patient feedback and any complaints as an opportunity to learn and improve their services.

Confidentiality and privacy (Guidance note 30)
The centre's procedures are compliant with HFEA requirements to ensure it has respect for the privacy, confidentiality, dignity, comfort and wellbeing of prospective and current patients.

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 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 does not provide treatment with donated gametes therefore this area of practice is not applicable to this inspection.

Disclosure of information, held on the HFEA Register, for use in research (General Direction 0005)
This area of practice is not applicable to the activities of this centre.

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 provide treatment with 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 and Storage of gametes and embryos

What the centre does well

Screening of patients (Guidance note 17)
The centre's procedures for screening patients are partially 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 gametes are partially compliant with HFEA requirements. These measures ensure that the gametes are stored appropriately to maintain their quality and safety. Furthermore, the centre only stores gametes in accordance with the consent of the gamete providers. The storage of gametes 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 risks of Ebola and Zika virus infection patients prior to treatment or storage (SLC T50d). See recommendation 4.

Storage of gametes and embryos (Guidance note 17)
One set of gametes is being stored beyond the statutory storage period, without a valid medical practitioner certificate (The Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009, SLC T79). See recommendation 1.

Use of embryos for training staff

What the centre does well

Use of embryos for training staff (Guidance note 22)
The centre's does not use embryos for training staff, 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 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's procedures for submitting information about licensed activities to the Authority are compliant with HFEA requirements.
What the centre could do better **Record keeping and document control (Guidance note 31)** The centre does not systematically maintain a record containing how, and by whom, the patient has been reliably identified (SLC T46b. See recommendation 7.

Section 3: Monitoring of the centre's performance

Following the interim inspection in 2015, recommendations for improvement were made in relation to three 'other' areas of non compliance.

The PR provided information and evidence that all of the recommendations were fully implemented within the prescribed timescales.

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 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.

A critical area of non compliance is identified in the report by a statement that an area of practice is not compliant with requirements.

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.

A major area of non compliance is identified in the report by a statement that an area of practice is partly compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
1. **Storage** One set of gametes are being stored beyond the statutory storage period, without a valid medical practitioner certificate. The inspection team acknowledges that this was an isolated case and does not reflect poor practice or staff understanding relating to consent to storage at this centre. The Human Fertilisation and Embryology (Statutory Storage Period for Embryos and	The PR should ensure storage is only extended beyond the statutory storage period when there is compliance with the 2009 storage regulations, both in relation to patient consent and evidence of either premature infertility or of likely premature infertility in the future. The PR should take steps to resolve the one set of gametes being stored beyond the statutory storage period, with confirmation of resolution being provided when responding to this report.	Agreed. I appreciate the inspection team has made it clear that it was an isolated case in the report and understand the complexities of the case. Thank you for helping resolve the query and I take on board that in future I could contact you for advice in such situations rather than wait for an impending inspection. I can confirm following the expert advice and support received, the set of gametes were allowed to perish on 2/1/18.	The Executive acknowledges the PR's response and assurance of compliance. No further action required.

Gametes) Regulations 2009, SLC T79.			
2. **QMS** At least two audits identified issues, however, these were not cited as non-conformances in these audits. The centre has not undertaken The following audits in the last two years: • confidentiality and privacy audit • infection prevention and control audit The centre has not performed a full quality management review in the past year. The centre does not systematically document root cause analysis of non-compliances, corrective and preventative actions and their time scales of implementation and dates of implementation. The transport SOP does not describe the process for exporting gametes for treatment abroad.	The PR should ensure that the centre's quality management system, auditing processes and SOPs are suitable and effective. The PR should review the centre's audit process to ensure that where anomalies are found, these are identified as non-conformances and that corrective and preventative actions are implemented. The PR should consider if staff members tasked with auditing would benefit from formal audit training. The PR should review the transport SOP, to ensure it is suitable to guide staff in the event of patients with stored gametes wishing to export	Agreed. Can assure you work is in progress and will be completed by the required timeline.	The Executive acknowledges the PR's response and her commitment to fully implementing the recommendation within the given timescale. The PR has committed to provide the requested audits, SOPs and business continuity plan. Further action required.

The centre has a business continuity plan but this plan does not include a documented plan for the transfer of gametes and clinical service provision to a licensed clinic in the event of a disaster. SLC T2, SLC T33, SLC T36.	their own gametes for treatment abroad. The PR should ensure that the business continuity plan provides clear directions for the transfer of gametes and clinical services to another licensed clinic in the event of a disaster. Summaries of the quality management system audit, confidentiality and privacy audit, infection prevention and control, updated SOP and business continuity plan should be sent to the centres inspector by 6 March 2018.		
3. **Equipment and Materials** Equipment validation has not been formally documented.	The PR should ensure that all critical equipment and technical devices are identified and validated, by 6 March 2018. At this time a selection of equipment validation documents will be requested for review by the centre's inspector. The PR should ensure that appropriately CE marked	Agreed. Can assure you work is in progress and will be completed by the required timeline	The Executive acknowledges the PR's response and her commitment to fully implementing the recommendation. Further action required.

The sperm pots in use at the centre are not appropriately CE marked. SLC T24, SLC T25, SLC T30, Clinic Focus September 2016.	medical devices are used where available. We would not recommend the implementation of precipitous changes that might impact on the quality of treatment that you are providing to your patients. In consideration of this, the PR should identify a suitable CE marked alternative product by 6 March 2018, along with a timeline for introduction and provide this to the centre's inspector. The centre should be fully compliant no later than 6 June 2018.		
4. **Screening of patients** The centre does not consider the risks of Ebola and Zika virus infection in patients prior to treatment or storage. SLC T50d.	The PR should ensure that the risks of Ebola and Zika infection are considered prior to any patient being treated. The PR should review the centre's processes for considering and assessing the risks of infection with Ebola and Zika virus based on a patient's travel history. A summary of the findings of the review including corrective actions and the timescales for	Agreed. Can assure you work is in progress and will be completed by the required timeline. Until the time of inspection, we have not had a process in place to check the risks of Ebola and Zika virus infection in patients prior to treatment or storage. Now we have amended out structured history sheet / IUI check list and / history template prior to storage to	The Executive acknowledges the PR's response and her summary of corrective actions. The PR has committed to provide the requested audit. Further action required.

	implementation should be provided to the centre's inspector with the PR's response to this report. The PR should audit the effectiveness of changes introduced in this area of practice within three months. A summary report of the findings of the audit should be provided to the centre's inspector by 6 March 2018	include "Travel History". We have hard copy of advice for patients who intend to or travelled to these virus prone areas in our 'clinical Focus file' which stays on the shelves of our fertility specialist nurse Judith Edmondson's office for reference. All the amended forms are ready for use and will be used in the clinics now onwards. Audit will be carried out in early march to check the compliance on this requirement.	

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.

An 'other' area of non compliance is identified in the report by a statement that an area of practice is 'broadly' compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
5. **Staffing** The PR has not assessed the workforce requirements of the centre in the last year. CoP 25.13.	The PR should assess how many cycles of treatment can be safely accommodated taking into account staffing levels, the skills mix and competence of staff, equipment and premises. A copy of the assessment should be submitted to the centre's inspector by 6 March 2018. The PR should ensure that workload is maintained within the safe limits determined in this assessment.	Agreed.	The Executive acknowledges the workforce assessment submitted via email. The PR provides assurance that the workload is being maintained within safe limits. No further action required.
6. **TPAs** Three TPAs were reviewed as part of the inspection process. All of those reviewed had areas of non compliance. The centre	The PR should review all third parties and TPAs against the relevant licence conditions.	Agreed. Can assure you work is in progress and will be completed by the required timeline	The Executive acknowledges the PR's response and her commitment to fully implementing the recommendation.

could not provide evidence that the TPAs had been fully reviewed since 2012. SLC T112, SLC T113, SLC T114, SLC T116.	A copy of this review should be submitted to the centre's inspector by 6 March 2018. The PR should ensure that all third party agreements are fully compliant by 6 June 2018, at which time the centre's inspector will request a selection to review.		The PR has committed to provide the requested review. Further action required.
7. **Record keeping** The centre does not consistently maintain a record containing of how, and by whom, the patient has been reliably identified. SLC T46b T47	The PR should ensure that the identity of a patient is reliably confirmed and documented. The PR should undertake a review of the centre's processes for establishing the identity of patients. A summary of the findings of the review including corrective actions and the timescales for implementation should be provided to the centre's inspector by 6 March 2018 Within three months, the PR should carry out an audit of records to ensure that the proposed corrective actions have been effective in ensuring compliance. A summary report of the findings of the audit should be	Agreed. Can assure you work is in progress and will be completed by the required timeline	The Executive acknowledges the PR's response and her commitment to fully implementing the recommendation within the given timescale. The PR has committed to provide the requested review summary and associated audit. Further action required.

	provided to the centre's inspector by 6 June 2018		

Reponses from the Person Responsible to this inspection report
Agree with the recommendations and will aim to comply by the timelines allowed.