Executive Licensing Panel - minutes

Centre 0149 (Royal Derby Hospital) Renewal

Friday, 29 July 2016

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Paula Robinson (Chair) Joanne Anton Anjeli Kara	Head of Business Planning Head of Regulatory Policy Regulatory Policy 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 the Royal Derby Hospital, centre 0149 is located in Derbyshire. The centre provides treatment (insemination using partner/donor sperm) and storage services. The centre resumed donor insemination (DI) treatment in December 2013, having stopped in 2008 due to a shortage of donor sperm. The centre provides a satellite service and CARE Nottingham, centre 0101 is the primary centre for this service, providing all licensed activities including egg collection, embryo culture, storage and use in treatment services. In relation to activity levels this is a small centre.

1.3. The panel noted that the centre has held a licence with the HFEA since July 1995.

1.4. The panel noted that in the 12 months to 31 March 2016, the centre provided one cycle of donor insemination with no pregnancy.

1.5. The panel noted that in 2015, the centre reported 184 cycles of partner insemination with 26 pregnancies. This equates to a 14% clinical pregnancy rate.

1.6. The panel noted that in 2015, two of the 26 pregnancies following partner insemination were multiple pregnancies.

1.7. The panel noted that at the time of the renewal inspection on 17 May 2016, one major and two other areas of non-compliance were identified. The panel noted that the Person Responsible (PR) has committed to fully implementing all of the recommendations.

1.8. The panel noted that some improvement is required in order for the centre to demonstrate the suitability of their practices.

1.9. The panel noted that the centre has a Quality Management System in place and the PR is encouraged to use it to best effect to monitor and improve the service provided. The inspectorate will continue to monitor the centre's performance.

1.10. The panel noted that the inspectorate 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.

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

2.3. 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 their duty under section 17 of the HFE Act 1990 (as amended).

2.4. 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

2 August 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 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: 17 May 2016

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: Vicki Lamb and Grace Lyndon

Date of Executive Licensing Panel: 29 July 2016

Centre name	Royal Derby Hospital
Centre number	0149
Licence number	L/0149/10/a
Centre address	Fertility Unit, Women's and Children's Services, Derby City General Hospital, Uttoxeter Road, Derby, Derbyshire, DE22 3NE
Person Responsible	Dr Kannamannadiar Jayaprakasan
Licence Holder	Mr Saad Amer
Date licence issued	1 November 2012
Licence expiry date	31 October 2016
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:
The Royal Derby Hospital has held a treatment (insemination using partner / donor sperm) and storage licence with the HFEA since July 1995. The centre re-commenced donor insemination (DI) treatment in December 2013, having stopped in 2008 due to a shortage of donor sperm.

The centre provided one cycle of donor insemination treatment in the 12 months to 31 March 2016. In 2015 the centre provided 184 cycles of partner insemination treatment. In relation to activity levels this is a very small centre.

The centre provides a satellite service. CARE Nottingham is the primary centre for this service providing all licensed activities including egg collection, embryo culture, storage and use in treatment services.

Pregnancy outcomes

In the 12 months to 31 March 2016, the centre reported one donor insemination treatment with no pregnancy.

In 2015, the centre reported 184 cycles of partner insemination with 26 pregnancies. This equates to a 14% clinical pregnancy rate.

Multiple births[1]

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

In 2015, two of the 26 pregnancies following partner insemination treatment were multiple pregnancies.

Summary for licensing decision

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

- the application has been submitted in the form required;
- the application has designated an individual to act as the Person Responsible (PR);
- the PR's qualifications and experience comply with section 16 (2) (c) of the HF&E Act 1990 (as amended);
- the PR has discharged his duty under section 17 of the HF&E Act 1990 (as amended);
- the premises (including those of relevant third parties) are suitable;
- the centre's practices are suitable;
- the application contains the supporting information required by General Direction 0008, in application for renewal of their licence;
- the centre has submitted an application fee to the HFEA in accordance with requirements.

The satellite activities of this centre have been effectively audited by the primary centre and are compliant.

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 major and two 'other' areas of non-compliance which have resulted in the following recommendations. The PR has given a commitment to fully implement all the recommendations:

Major areas of non compliance:

- The PR should review the information provided to patients seeking treatment with donor sperm.

'Other' areas that requires improvement:

- The PR should take immediate action to ensure that documentation is available to evidence that witnessing is completed and recorded at the time the relevant procedure takes place.

- The PR should ensure the development of documented standard operating procedures (SOPs) for all relevant procedures.

Recommendation to the Executive Licensing Panel

The centre has no critical areas of concern but does have one major of area of concern. Some improvement is required in order for the centre to demonstrate suitability of their practices. The centre has a quality management system (QMS) in place and the PR is encouraged to use the QMS to best effect to monitor and improve the service provided.

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

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.

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) 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 or donor to whom they relate are broadly compliant with HFEA requirements. This ensures that patients receive treatment using the correct gametes.

What the centre could do better
In two of the five patient records reviewed, there was no time recorded for witnessing the containers at insemination to evidence that this witnessing step had been completed at the time of insemination (SLC T71) (recommendation 2).

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)
Donors are not recruited at this centre, therefore this guidance note is not relevant.

Payments for donors (Guidance note 13; General Direction 0001)
Donors are not recruited at this centre, therefore this guidance note is not relevant.

Donor assisted conception (Guidance note 20)
A donor-conceived person is entitled to know details of their donor and any donor-conceived genetic siblings they may have. Parents of a donor-conceived child are able to access information on their child's donor (and about any donor-conceived genetic

siblings) from the HFEA or the clinic where they received treatment.

Therefore it is important that centres use donated gametes or embryos from identifiable donors. The centre's procedures are compliant with HFEA requirements to ensure the donor conceived will be able to receive this information.

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 to ensure patients and staff are in safe surroundings that prevent harm.

The premises of laboratories conducting tests that impact on the quality and safety of gametes are suitable.

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 or 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 compliant with guidance.

Pre-operative assessment and the surgical pathway
No surgical procedures are performed at this centre and therefore this is not relevant.

Multiple births (Guidance note 7; General Direction 0003)
The centre provided insemination treatments only, but such treatments still expose patients to the risks of multiple pregnancies. The single biggest risk of fertility treatment is a multiple pregnancy. 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 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;
- where the sperm is procured at home, the centre keeps a record of this in the gamete provider's records.

Transport and distribution of gametes and embryos (Guidance note 15; General Direction 0009)
The centre does not distribute gametes, and therefore this guidance note is not relevant.

Receipt of gametes and embryos (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 the gametes are appropriately labelled and has enough information to permit the gametes 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 has not received any imports or exported any samples and has no plans to do this in the immediate future. This guidance note was not inspected.

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 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 centres, therefore this guidance note is not relevant.

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 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

Quality management system
Not all procedures were covered by up to date SOPs. This included, but was not necessarily limited to, superovulation procedures and the insemination procedure (SLC T33b) (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 (PREP number T/1211/8).

Staff (Guidance note 2)
The centre is compliant with HFEA requirements to have suitably qualified and competent staff, in sufficient number, to carry out the licensed activities and associated services. The centre has an organisational chart which clearly defines accountability and reporting relationships.

The centre has access to a nominated registered medical practitioner and scientist, within the UK, to advise on and oversee medical and scientific activities respectively.

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

Welfare of the child and safeguarding

What the centre does well

Welfare of the child (Guidance note 8)
The centre's procedures to ensure that the centre takes into account 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); Embryo testing and sex selection (Guidance note 10)
The centre does not perform embryo testing, therefore these guidance notes are not relevant.

What the centre could do better

2. The experience of patients

Patient feedback

What the centre does well

During the inspection visit the inspectors spoke to one patient couple who provided feedback on their experiences. Another patient also provided feedback directly to the HFEA in the time since the last inspection. Feedback was positive.

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; and
- 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 and donors are treated fairly and that all licensed activities are conducted in a non-discriminatory way.

Counselling (Guidance note 3)
The centre's counselling procedures are compliant with HFEA requirements. This is important to ensure that counselling support is offered to patients providing relevant consent and prior to consenting to legal parenthood.

Egg and sperm sharing arrangements (Guidance note 12; General Direction 0001)
The centre does not offer egg or sperm sharing, therefore this guidance note is not relevant.

Surrogacy (Guidance note 14)
The centre does not offer treatments involving surrogacy arrangements, therefore this guidance note is not relevant.

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

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

What the centre could do better
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 partially compliant with HFEA requirements. This is important to ensure 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
Centre staff were not able to demonstrate that all appropriate information, for example, what information may be disclosed to people born as a result of donation, is provided to patients seeking treatment with donor sperm (SLC T60 and T63) (recommendation 1).

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

What the centre does well

Consent (Guidance note 5;6)
The centre's procedures for obtaining consent are compliant with HFEA requirements. This ensures that patients and donors have provided all relevant consents before carrying out any licensed activity.

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

In February 2014, the HFEA asked all centres to audit their practices in this area to ensure they are suitable, to report the findings of the audit to the HFEA and to respond to those findings. The centre sent the report of the audit to the HFEA within the required timeframe. The audit showed that no couples were affected by legal parenthood consent anomalies.

On this inspection, we reviewed the centre's audit and found that it had been performed according to the method specified by the HFEA.

As part of the HFEA's ongoing activities relating to 'legal parenthood', in October 2015 all PRs were asked to confirm that specific actions had been undertaken; that there are effective methods for assessing the on-going competence of staff to take this consent; and that effective audit procedures are in place to ensure on-going compliance with consent taking requirements. The PR confirmed this had been done.

To provide further assurance of the effectiveness of the centre's procedures, the inspection team reviewed the only set of records where treatment with donor sperm had been provided since the last inspection. Effective consent to legal parenthood and the offer of counselling was in place prior to consent and treatment.

In summary, the inspection team was able to evidence that appropriate information is provided about legal parenthood and considers the processes used to collect legal parenthood consent at this centre are compliant with HFEA requirements.

Disclosure of information, held on the HFEA Register, for use in research (General Direction 0005)
The centre's procedures for taking consent to disclosure to researchers are compliant with HFEA requirements.

This is important to ensure that the HFEA holds an accurate record of patients' consent, so that it only releases the patients identifying information, to researchers, with their consent. Information can be used by researchers to improve the knowledge about the health of patients undergoing ART and those born following ART treatment.

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 process or store embryos, therefore this section is not relevant.

What the centre could do better

Screening of patients
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'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. Furthermore, the centre only stores gametes in accordance with the consent of the gamete provider. 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
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 use embryos for training staff, therefore this section is not relevant.

What the centre could do better

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. This is important to ensure the HFEA can supply accurate information to a donor-conceived person and their parents or donors.

What the centre could do better
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 three areas of major non-compliance.

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

On-going monitoring of centre success rates

The centre has not been asked to review procedures for the provision of treatment 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
None			

Major area of non compliance

A major area of non compliance is a non critical area of non compliance:

- which poses an indirect risk to the safety of a patient, donor, embryo or to a child who may be born as a result of treatment services
- which indicates a major shortcoming from the statutory requirements;
- which indicates a failure of the Person Responsible to carry out his/her legal duties
- a combination of several 'other' areas of non-compliance, none of which on their own may be major but which together may represent a major area of non-compliance.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
1. Centre staff were not able to demonstrate that all appropriate information is provided to patients seeking treatment with donor sperm (SLC T60 and T63).	The PR should take immediate action to ensure that appropriate information is provided to patients seeking treatment with donor sperm. The PR should review the information provided to patients seeking treatment with donor sperm and provide the HFEA with a summary report, including corrective actions when responding to this report. Three months after the implementation of corrective actions the PR should audit the provision of information to these patients and provide a summary of this audit, which	Our DI activity is very low due to difficulty in sourcing donor sperm. Our last out-patient consultation for DI was 24 months ago with no activity for over a year now. From our discussion at the team meeting, I note that we are providing appropriate information for the patients seeking DI treatment. However, we have received appropriate information (audit) from the HFEA (Dr Lamb) following the inspection, so we shall use this in practice to audit it in the future. However, auditing in three months may not be applicable as we may not have any patients, but if we	Further information was sought from the PR to clarify the comments made here. The PR confirmed that appropriate information will now be provided to patients. The inspector acknowledges that, due to the very low activity, audit in three months' time may not be appropriate. This issue will be reviewed through ongoing monitoring and the inspector will liaise with the PR to agree a suitable time for audit based on the level of treatments with donor sperm. The inspector acknowledges

	includes what information has been provided to the patients, to the HFEA by 17 October 2016.	do we shall certainly feed back to HFEA. While we acknowledge the deficiency here, we wonder whether this is a minor non-compliance than a major one.	the PR's query as to whether this is a minor non-compliance rather than a major non-compliance. In recognition that providing proper information to patients is key to obtaining valid consent, this non-compliance is graded as major. 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
2. In two of the five patient records reviewed, there was no time recorded for witnessing the containers at insemination to evidence that this witnessing step had been completed at the time of insemination (SLC T71).	The PR should take immediate action to ensure that documentation is available to evidence that witnessing is completed and recorded at the time the relevant procedure takes place. The PR should advise of the measures taken to ensure that this happens when responding to this report. Three months after the implementation of corrective actions the PR should audit the records of witnessing and provide a summary of this audit to the HFEA by 17 October 2016.	All the staff have been informed of this requirement at our monthly quality management meeting and will be audited as advised	The PR has taken the immediate action required. The inspector will follow up on the audit. Further action required.
3. Not all procedures were covered by up to date SOPs. This included, but was not necessarily limited to, superovulation procedures and	The PR should ensure the development of documented SOPs for all relevant procedures. Copies of the SOPs should be provided to the HFEA by 17 August 2016.	We have initiated the process of developing SOPs for IUI procedure and medicines management as advised. We shall provide the copies before the scheduled date	The PR has agreed to submit the SOPs by 17 August 2016. Further action required.

insemination (SLC T33b).			

Reponses from the Person Responsible to this inspection report
Thank you very much for providing the report and making the HFEA inspection so smooth for us. We appreciate all the feedback and we are happy to note that it was generally a satisfactory report. We shall make corrective actions as advised by the inspectors as soon as possible. As mentioned above we feel that the non-compliance mentioned in the report on the DI issues is probably a minor one rather than a major one although we accept the HFEA inspectors' views.