Executive Licensing Panel - minutes

Centre 0293 (Andrology Solutions) Renewal Inspection Report

Friday, 6 May 2016

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Juliet Tizzard (Chair) Joanne Anton Howard Ryan	Director of Strategy & Corporate Affairs Head of Regulatory Policy Technical Report Developer
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 Andrology Solutions (centre 0293) is a treatment (insemination using partner/donor sperm) and storage centre. The panel noted that in relation to activity levels this is a small centre.

1.3. The centre shares its premises with The Doctors Laboratory (TDL) in a building located at 75-76 Wimpole Street, London. Although this is one building, it retains two entrances adjacent to each other and patients visiting both TDL and Andrology Solutions use the door to 76 Wimpole Street. The Person Responsible (PR) has requested that the centre's address is changed to 75 Wimpole Street as patients will now use the door to number 75 leading to a separate reception area. The rest of the premises however remain unchanged.

1.4. The panel noted that the centre has been licensed by the HFEA since 2007.

1.5. The panel noted that in the 12 months to 31 January 2016, the centre provided 6 cycles of intrauterine insemination using donor sperm.

1.6. The panel noted that in 2015, the centre reported 151 cycles of intrauterine insemination using partner sperm with 22 pregnancies. This equated to a 15% clinical pregnancy rate. The national average clinical pregnancy rate has not yet been calculated for 2015. The centre's clinical pregnancy rates during 2014 were however consistent with the national average.

1.7. The panel noted that at the time of the inspection on 23 February 2016 two major and four other areas of non-compliance were identified. The panel noted that since the inspection the Person Responsible (PR) has implemented most of the recommendations and has committed to implementing the outstanding recommendations.

1.8. 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 compliance with the recommendations made in this report being implemented within the prescribed timescales.

1.9. The panel noted that the inspectorate also recommends that the centres' address is changed to 75 Wimpole Street, London, W1G 9RT.

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 her 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.

2.5. The panel also endorsed the inspectorate's recommendation to change the centres' address to 75 Wimpole Street, London, W1G 9RT.

3. Chair's signature

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

Signature

Name

Juliet Tizzard

Date

19 May 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: 23 February 2016

Purpose of inspection: Renewal of a Treatment (inseminating using partner / donor sperm) and Storage licence.

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: Douglas Gray, Heidi Birch

Date of Executive Licensing Panel: 6 May 2016

Centre name	Andrology Solutions
Centre number	0293
Licence number	L/0293/3/b
Centre address	76 Wimpole Street, London, W1G 9RT.
Person Responsible	Sheryl Homa
Licence Holder	Sara Matthews
Date licence issued	01 August 2012
Licence expiry date	31 July 2016
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:

Andrology Solutions has held a Treatment (insemination using partner / donor sperm) and Storage licence with the HFEA since 2007. This current licence was varied in October 2014 to reflect a change of premises.

The centre provided 6 cycles of intrauterine insemination using donor sperm in the 12 months up to 31 January 2016, and 151 cycles using partner sperm during 2015. In relation to activity levels this is a small centre.

The centre shares its premises with The Doctors Laboratory (TDL) in a building located at 75-76 Wimpole Street London. Although now one building, it retains two entrances adjacent to each other and patients visiting both TDL and Andrology Solutions use the door to 76 Wimpole Street. The PR has requested that the centre's address is changed to 75 Wimpole Street as patients will now use the door to number 75 leading to a separate reception area. The rest of the premises however remain unchanged.

Pregnancy outcomes[1]

In 2015, the centre reported 151 cycles of partner insemination with 22 pregnancies. This equates to a 15% clinical pregnancy rate. The national average clinical pregnancy rate has not yet been calculated for 2015. The centre's clinical pregnancy rates during 2014 were however consistent with the national average.

Multiple births[2]

The single biggest risk of fertility treatment is a multiple pregnancy. During 2015 the centre reported one multiple pregnancy following IUI.

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 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 their licence;
- the centre has submitted an application fee to the HFEA in accordance with requirements.

The ELP is asked to note that at the time of the inspection recommendations were made in relation to two major areas of non-compliance and four 'other' areas of practice that require improvement as follows:

Major areas of non compliance:

- Policies and procedures governing the holding and administration of medicines for use in emergency situations should be reviewed.
- The PR should ensure that agreements between TDL and the centre are formalised and accurately reflect the services to be provided and their respective responsibilities.

'Other' areas of practice that require improvement:

- The PR should review the required witnessing steps taking into account their local environment, and if all steps in their current SOP are considered necessary, ensure that a second person is available to witness those steps at the time they take place.
- Specimen pots used for the collection of sperm for use in treatment or storage should be CE marked for use this use.
- Validations for all critical processes should be documented.
- The competency of clinical staff providing treatment services at the centre should be reviewed at appropriate intervals.

The PR has fully implemented recommendations in relation to one major and three 'other' areas of practice, and provided a commitment to implement those that remain

Recommendation to the Executive Licensing Panel

The centre has no critical areas of non-compliance. The inspection team recommends the renewal of the centre's 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 executive also recommends that the centres' address is changed to 75 Wimpole Street, London, W1G 9RT.

Section 2: Inspection findings

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

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

1. Protection of the patient and children born following treatment

Witnessing and assuring patient and donor identification

What the centre does well

Witnessing (Guidance note 18)
Having procedures for double checking the identification of gametes and embryos and the patient or donor to whom they relate ensures that patients receive treatment using the correct gametes. The centre has procedures in place that are broadly compliant with HFEA requirements.

What the centre could do better
The centre's SOP requires a second person witnesses the transfer of sperm between tubes when it is being processed for use Staff reported that a second person is not always available to witness these steps at the time those steps take place (SLC T71; see recommendation 3). There has been no assessment of whether those witnessing points, adapted from HFEA's model protocol, are required based on their local systems and conditions that may mitigate the risk of a mismatch (CoP Guidance Note 18.2, 18.27 – 18.33). For example, the inspector is assured that when a second person is unavailable to witness the movement of gametes, only one person's sample is being processed in the laboratory therefore the risk of any mismatch is mitigated.

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's procedures for screening donors are compliant with HFEA requirements. It is important that donors are appropriately screened to minimise the risks of cross infection during treatment, processing and storage of gametes.

Payments for donors (Guidance note 13; General Direction 0001)
The centre's procedures are compliant with HFEA requirements for giving and receiving money or other benefits in respect to any supply of gametes. It is important that the principle of altruistic donation be upheld but at the same time donors receive appropriate compensation for their time and any inconvenience caused.

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

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

Laboratory accreditation (Guidance note 25)
The centre's third party laboratories which undertake the diagnosis and investigation of patients, patients' partners or donors, 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 appeared to be clean and there have been no reported instances of infection. Their systems and process for monitoring infection control are partially compliant with requirements.

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

Pre-operative assessment and the surgical pathway
The centre does not offer treatment services to which these standards apply.

Multiple births (Guidance note 7; General Direction 0003)
The single biggest risk of fertility treatment is a multiple pregnancy. The centre has policies and procedures in place to minimise the risk of a multiple pregnancy following intrauterine insemination.

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 (or embryos created with their gametes) in treatment, based on the patient's medical history and therapeutic indications;

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 has enough information to permit the gametes 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;
- identify the donor and recipient of particular gametes;
- identify any person who has carried out any activity in relation to particular gametes; and
- identify and locate all relevant data relating to products and materials coming into contact with particular gametes and which can affect their quality or safety.

Quality management system (QMS) (Guidance note 23)
The centre has a QMS in place that is 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 offer transport or satellite IVF services.

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 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)
Validating critical processes ensures that these processes are effective and do not render gametes clinically ineffective or harmful to the recipient. The centre's procedures are broadly compliant with HFEA requirements to validate critical processes.

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

Premises, practices and facilities (Guidance Note 25)
The centre is situated within premised owned by another organisation, The Doctor's Laboratory (TDL). The PR described that that TDL is responsible for the building, cleaning and maintenance of the facilities and for managing health and safety, infection control and policies on clinical and non clinical emergencies. However, there is no formally documented agreement between the centre and TDL setting out the services to be provided by TDL and their respective responsibilities (SLC T17; recommendation 2). The inspectors are concerned that without a documented agreement, there is a risk of a discrepancy between the PR and TDL regarding their expectations of the services to be provided and whose responsibility these are.

Medicines management
The centre holds a number of medicines that they report would be used only in an emergency. All of these medicines are prescribed to the Person Responsible. Medicines held included a glucose infusion although there is no intravenous giving set required to administer this medicine, and staff seemed unsure in what circumstances it would be used and how (recommendation 1).

Equipment and materials (Guidance note 26)
Wherever possible only CE marked medical devices must be used (SCL T30). All medical devised used in the laboratory are appropriately CE marked except specimen containers used to for the collection of sperm. Whilst they carry a CE mark for in vitro use only, this mark is not suitable when sperm is to be used for insemination or storage (recommendation 4).

Process validation (Guidance note 15)
Validating critical processes ensures that these processes are effective and do not render gametes clinically ineffective or harmful to the recipient (SLC T72). Whilst the centre has data and supporting evidence that could be used for validation purposes, there are no formally documented process validations (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 (PREP number T/1138/7).

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 centre acts as a base from which external clinical consultants can perform intrauterine insemination. Whilst the PR completes an initial assessment of the suitability and competency of these consultants to perform treatments under the auspices of the licence, the ongoing competence of the clinicians using the service is not re-evaluated at regular intervals (SLC T12; recommendation 6). The PR provided assurance that all clinicians providing treatment at the centre work to common protocols and SOPs authorised by the PR and accredited consultant, who is also the Licence Holder.

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

The centre is not licensed for these activities.

2. The experience of patients

Patient feedback

What the centre does well

During the inspection visit the inspectors spoke to two patients who provided feedback on their experiences. Feedback was positive. No patients provided feedback directly to the HFEA in the time since the last inspection.

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 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 and donors providing relevant consent and prior to consenting to legal parenthood.

Egg and sperm sharing arrangements (Guidance note 12; General Direction 0001)
This service is not offered.

Surrogacy (Guidance note 14)
The centre's procedures for treatment involving surrogacy are compliant with HFEA

requirements. This is important to protect the surrogate and any children born as a result of the treatment.

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 and / or donors are compliant with HFEA requirements. This ensures that the centre gives prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions.

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

Consent
Legal Parenthood
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)
When a couple are to be treated with donated gametes or embryos and they are 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 provided evidence that their audit was comprehensive and that their procedures for obtaining consent to parenthood are robust. The audit identified no errors.

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 to ensure on-going compliance with consent taking requirements are in place. The PR provided confirmation of this.

To provide further assurance of the effectiveness of the centre's procedures, the inspection team reviewed three sets of patient notes, in which treatment with donor sperm had recently been provided in circumstances where consent to legal parenthood is required. The centre's procedures are compliant with legal parenthood 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

This area is not relevant as the centre does not create, use or store embryos.

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. 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)

The centre are not licensed for this activity.

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 one area major non-compliance and one 'other' area of practice that required improvement.

The PR provided evidence that the recommendation in relation to the major non compliance was fully implemented within the prescribed timescale. Whilst actions were also taken to address the 'other' recommendation related to witnessing practices, observations at this inspection have led to a similar recommendation.

On-going monitoring of centre success rates

Success rates for treatments provided by this centre (IUI/DI) are not monitored through the HFEA's risk tool.

Areas of practice requiring action

The section sets out matters which the Inspection Team considers may constitute areas of non compliance. These have been classified into critical, major and others. Each area of non-compliance is referenced to the relevant sections of the Acts, Regulations, Standard Licence Conditions, 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. Medicine management The centre holds medicines which were described as being available for use in an emergency but have been prescribed to the PR specifically. Essential components for the administration of intravenous fluids held were also missing. (CoP Guidance Note 25.22)	The PR should confirm when responding to this report that medicines prescribed to her are not held for use in the treatment of patients. In liaison with the accredited consultant and TDL, the PR should review the centres policies and procedures governing the holding and administration of medicines for use in emergency situations. A summary of the actions taken and a copy of any revised policies should be sent to the centre's inspector by 23 May 2016.	The clinic holds a resuscitation kit and medicines for its use. It is only to be used by a medical doctor in a medical emergency if it occurs at the time when a patient is undergoing an intrauterine insemination procedure by the doctor. At all other times, staff have been instructed to call 999. Medicines for the kit have been issued to the Person responsible on behalf of the clinic, not to me personally. The medicines in question referred to a resuscitation kit and not to any form of fertility treatment of patients. Furthermore, they would only ever have been used by a fully qualified doctor. We feel that it is unfair to	The executive acknowledges the action taken to review procedures for the provision of emergency care. No further action required.

		label this as a major non-compliance and would ask the committee to review the ranking of this non-conformity for the record As it is not a requirement in the HFEA Code of Practice to hold a resuscitation kit, the PR has decided to abandon the use of the kit and associated medicines and remove them from our premisis with immediate effect. From now on all emergencies will be dealt with by calling 999	
2. Premises, practices and facilities There is no formally documented agreement between the centre and The Doctor's Laboratory (the landlords) setting out the services to be provided by them, and their respective responsibilities. (SLC T17)	The PR should ensure that agreements between TDL and the centre are formalised and accurately reflect the services to be provided and their respective responsibilities. A copy of the agreement should be forwarded to their inspector by 23 August 2016.	Andrology Solutions has had a Third Party Agreement in place with TDL since 2007 for the provision of a CPA/UKAS accredited diagnostic testing service. The CEO of TDL has also provided Andrology Solutions with a Licence to Occupy for the premisis which includes a schedule of services to be provided and their respective responsibilities as Landlords. The Third Party Agreement will be updated to include schedule 2 of the Licence to Occupy stating the additional services to be provided by TDL and their respective responsibilities as Landlords. The signed amended agreement will be	The PR has taken appropriate action and we await a copy of the signed agreement.

		sent to the inspector by 23 August 2016.	

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
3. Witnessing A second person is not always available to witness points involved in the preparation of sperm at the time that step takes place. (SLC T71; CoP Guidance Note 18.2, 18.27 – 18.33)	Considering the assurances of staff that a second person may not be available to witness only when one person's sperm is being processed in the laboratory, the PR should consider how HFEA's witnessing guidance applies to their local environment in accordance with CoP Guidance Note 18.2, and 18-27-33, and the risks of departing from this protocol to better suit their local practices and environment. A summary of any changes made, including any documentation ammended as a result should be forwarded by 23 August 2016.	HFEA Licence condition T71 states: Centres must have in place robust and effective processes to ensure that no mismatches of gametes or embryos or identification errors occur. Centres must double check the identification of samples and the patients or donors to whom they relate at all critical points of the clinical and laboratory process. These checks must be completed and recorded at the time the relevant clinical or laboratory process/ procedure takes place. A record must be kept in each patient's/donor's medical record. The HFEA Code of practice 18.2 also states: Centres are responsible for ensuring that witnessing protocols are relevant to their local systems and conditions, based on HFEA model protocols. Where appropriate, clinics may adapt HFEA model protocols to take into account their local systems.	The PR has taken appropriate action to consider how HFEA's model witnessing protocol best fits their environment. No further action required.

		Andrology Solutions keeps a full complement of Andrology Staff to ensure that at least 2 staff members are present to carry out witnessing checks during normal working hours. However, some of the processes and treatments need to be conducted outside of working hours, due to over running of clinics or difficulties scheduling timeslots for surgical sperm retrievals, or when emergency cancer patients require sperm cryopreservation. Under these circumstances, it is not always possible to have two staff members in attendance to carry out witnessing procedures. It has been determined that it is not possible to have any sample mix-ups if there is only one sample being handled in the laboratory, irrespective of whether it is outside of working hours. However, there is still a risk of writing incorrect or incomplete identifying data on patient records and a risk of error when copying details from sample containers and the patient records to other records. To minimise these	

		risks, the following steps are taken: 1. Patients are always asked to label their own samples with their name, date of birth and date of procedure, which is witnessed by the member of staff prior to processing the sample. 2. The labelling of final IUI preparations are witnessed in every case by the female patient and the inseminating doctor prior to insemination. 3. If a frozen sample is removed from storage, the inseminating doctor is asked to witness the labelling of the removed sample prior to insemination. 4. If a sample has been processed without a witness present at the time, all cryovials, straws, tubes and record sheets are checked for transcription errors or omissions in patient identifiers, such as the misspelling of names and the absence of unique identifiers on a record sheet, particularly in laboratory records by another member of staff the following day	

		Consequently, in order to accommodate the local procedures and protocols at Andrology Solutions, and to safeguard the patients, witnessing at every step will always be carried out when there is more than one sample being processed in the laboratory. However, witnessing is considered superfluous at every step when there is only one sample being processed in the laboratory. In these cases, samples are witnessed at the beginning and end of the procedure as detailed above, and additional checks for transcription errors are witnessed the next day. The SOP for Witnessing procedures will be updated accordingly	
4. Equipment and materials Specimen pots used for the collection of sperm are not appropriately CE marked for their use. (SLC T30)	The PR should ensure that specimen pots used during the collection of sperm for use in treatment or storage are CE marked for this use. The PR should identify a suitable CE marked alternative product and by 23 May 2016 provide the centre's inspector with a timeframe for the introduction of a suitable alternative.	Andrology Solutons has used Sterilin sample containers CE marked for in vitro use since its inception in August 2007. We carry batch testing records for these containers together with recovery rates for fozen thawed samples processed in these containers, and IUI pregnancy rates from samples collected in these containers. Our batch testing records show no anomalies in 9 years and our recovery rates and IUI pregnancy rates meet or supercede all expectations.	We await the PR's response in May 2016.

		We are currently looking into availability of appropriately CE marked specimen containers and will identify a product together with a timeframe for its introduction by 23 May 2016.	
5. Process validation There are no documented validations for critical processes. The inspector is however satisfied that processes are monitored to ensure they are safe, effective and meet the centre's expectations. (SLC T72)	Since the inspection the PR has provided documented validations for all necessary critical processes. No further action required.		
6. Staff The competency of clinicians providing licensed treatments at the centre is not assessed at regular intervals. (SLC T12)	With the accredited consultant, the PR should review the centre's procedures for ensuring that the ongoing competence of clinicians providing treatment at the centre is periodically review. The PR should provide a summary of the review and details of any actions to be taken in response to the review to the centre's inspector by 23 August 2016.	Doctors are asked to read and sign a duty list in order to be accepted as a staff member of Andrology Solutions (see attached). All doctors are asked to provide the following information: a) A recent CV b) GMC number c) A copy of occupational health status i.e hepatitis B immunity d) A copy of DBS check e) A copy of their certificate of	The PR has reviewed their procedures and their provided a suitable summary in their response. No further action required.

		appraisal f) A copy of their most recent revalidation certificate g) A copy of their medical indemnity insurance Doctors are legally required to be appraised professionally on an annual basis in order to continue to practice. They must also undergo revalidation every 5 years. Therefore, Andrology Solutions will require a copy of their certificate of appraisal every year and a copy of their revalidation certificate every 5 years in order to establish ongoing competency.Any doctor who fails to produce these certifcates will be removerd from the centre's licence	

Reponses from the Person Responsible to this inspection report
See respone to each individual point