Executive Licensing Panel - minutes

Centre 0336 (Simply Fertility) – Renewal Inspection Report

Friday 16 October 2015

HFEA, Finsbury Tower, 103-105 Bunhill Row, London, EC1Y 8HF

Panel members	Paula Robinson (Chair) Joanne Anton Ian Peacock	Head of Business Planning Policy Manager Analyst Programmer
Members of the Executive	Sam Hartley	Head of Governance and Licensing (Secretary)
External adviser	None	
Observers	Howard Ryan Jessica Watkin Polly Todd	

Declarations of interest

- Members of the panel declared that they had no conflicts of interest in relation to this item.

The panel had before it:

- 8th edition of the HFEA Code of Practice
- Standard licensing and approvals pack for committee members.

1. Consideration of application

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

1.2. The panel noted that this is a treatment (insemination using partner/donor sperm) and storage centre. The panel noted that in relation to activity levels this is a small centre.

1.3. The panel noted that the centre has been licensed by the HFEA since 2013.

1.4. The panel noted that in the 12 months to 31 May 2015, the centre provided four cycles of stimulated intra uterine insemination (IUI) and 11 donor inseminations (DI).

1.5. The panel noted that in 2014/15, the centre reported 11 cycles of partner insemination with no pregnancies, and four cycles of donor insemination with one pregnancy. The PR has reported one multiple pregnancy resulting from insemination treatment in 2014/15.

1.6. The panel noted that at the time of the inspection on 28 and 29 July 2015, six major and one other areas of non-compliance were identified. The panel noted that the Person Responsible (PR) is committed to fully implementing all of the inspectorate's recommendations within the prescribed timescales.

1.7. The panel noted that some improvement is required in order for the centre to demonstrate suitability of their practices. The centre has a QMS in place and the PR is encouraged to use the QMS to best effect to monitor and improve the service provided.

1.8. The panel noted that the inspectorate recommends the renewal of the centre's treatment 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.

2.2. The panel agreed it was in receipt of the appropriate documentation as required by the HFE Act 1990. 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.

2.3. 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 has discharged his duty under section 17 of the HFE Act 1990 (as amended).

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

2.5. The panel endorsed the inspectorate's recommendation and agreed to renew the centre's treatment (insemination using partner/donor sperm) and storage licence for a period of four years without additional conditions.

3. Chair's signature

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

Signature

Name

Paula Robinson

Date

16 October 2015

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: 28 and 29 July 2015

Purpose of inspection: Renewal of a licence to carry out Treatment (Insemination using partner / donor sperm) and Storage.

The centre has applied to add the following activities: none

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: Janet Kirkland MacHattie, Gill Walsh, Douglas Gray and Grace Lyndon

Date of Executive Licensing Panel: 16 October 2015

Centre name	Simply Fertility
Centre number	0336
Licence number	L/0336/1/a
Centre address	Baddow Hospital, Simply Fertility Ltd, West Hanningfield Road, Great Baddow, Essex, Chelmsford, CM2 8HN, UK
Person Responsible	Dr. Andy Glew
Licence Holder	Dr. Subrata Gangooly
Date licence issued	27 November 2013
Licence expiry date	26 November 2015
Additional conditions applied to this licence	No additional conditions applied

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:

Simply Fertility has held a Treatment (insemination using partner / donor sperm) and Storage licence with the HFEA since August 2013 when a two year licence was granted; this is the usual term for an initial licence. The centre is situated within, but separate from Baddow Hospital, Chelmsford, which is a small independent hospital providing day case surgery.

Treatments provided at the centre include: partner insemination, donor insemination and storage. Simply Fertility is also a satellite centre to Boston Place (centre 0327).

The centre provided four cycles of stimulated intra uterine insemination (IUI) and 11 donor inseminations (DI) in the 12 months to 31 May 2015. In relation to activity levels this is a small centre.

Other licensed activities of the centre include storage of sperm and recruitment of sperm donors.

Pregnancy outcomes[1]

In 2014/2015, the centre reported 11 cycles of partner insemination with no pregnancies and four cycles of donor insemination with 1 pregnancy.

Multiple births[2]

The single biggest risk of fertility treatment is a multiple pregnancy. The PR has reported one twin pregnancy resulting from insemination treatment in 2014/15.

[1]The data in the Register may be subject to change as errors are notified to us by clinics, or picked up through our quality management systems. Centre success rates are considered statistically different from the national averages, and multiple pregnancy rates are considered statistically different from the 10% multiple live birth rate target, when $p \leq 0.002$.

[2]The HFEA use a conversion factor of 1.27 to convert the 10% multiple live birth rate (MLBR) target to a multiple pregnancy rate (MPR) target of 13%.

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 ELP is asked to note that at the time of the inspection there were a number of areas of practice that required improvements, including six major areas of non compliance and one 'other' area of non-compliance.

Since the inspection visit the PR has confirmed and provided evidence that the following recommendations have been implemented:

Major areas of non compliance:

- the PR should ensure that egg donors are screened in accordance with relevant regulation and guidance;
- the PR should ensure that the validation of laboratory processes includes assessment of and reference to the centres own data;
- the PR should ensure that audits of activities include audit against compliance with regulatory requirements;
- the PR should ensure that a third party agreement is established with the hospital providing theatre facilities for surgical sperm retrieval (SSR);
- the PR should ensure that procedures for assessing the suitability of staff are reviewed and robust;
- the PR should ensure that records maintained by the centre are complete and legible.

'**Other' area of non-compliance:**

- the PR should ensure that witnessing steps are consistently and accurately documented.

Recommendation to the Executive Licensing Panel:

The centre has no critical areas of concern but does have six major of areas of concern. Some improvements are 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 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) 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 or embryos.

What the centre could do better
During a review of witnessing records on inspection it was noted that one witnessing step was missing in one donor's notes and there was a discrepancy in the dates recorded in two related witnessing forms in a second donor's notes. The centre provided assurance that witnessing had been carried out in accordance with requirements and that these anomalies represented errors in documentation only (SLC T46).

See recommendation 7.

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 partially 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 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

Screening of donors (Guidance note 11)
A review of records for egg donors recruited and undergoing ovarian stimulation at Simply Fertility prior to egg collection at centre 0327 Boston Place showed that screening had not been performed within the time frame specified by the Authority i.e. at the time of donation (SLC T53 b).

See recommendation 1.

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
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 centre's laboratories conducting tests that impact on the quality and safety of gametes and/or embryos (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 laboratories and/or third party laboratories which undertake the diagnosis and investigation of patients, patients' partners or donors, or their gametes, embryos 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
The centre has policies and procedures in place that are compliant with professional body guidelines for pre-operative assessment and management of the surgical pathway. This is important to ensure that all patients are safely assessed and cared for pre, peri and post operatively.

Procurement of gametes (Guidance note 15)
The centre's procedures are partially 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;
- 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's procedures for the transport, distribution and recall of sperm are compliant with HFEA requirements. This is important to ensure that sperm sent to other licensed centres within or outside the UK is:

- packaged and transported in a manner that minimises the risk of contamination and preserves the characteristics and biological functions of the sperm;
- shipped in a container that is designed for the transport of biological materials and that maintains the safety and quality of the sperm;
- appropriately labelled with the transport conditions, including temperature and time limit being specified;
- the container/package is secure and ensures that the sperm is maintained in the specified conditions. All containers and packages are validated as fit for purpose.

Receipt of sperm (Guidance note15)
The centre's procedures for the receipt of sperm are compliant with HFEA requirements. This is important to ensure that the centre only accepts sperm from other centres if it is appropriately labelled and has enough information to permit it to be stored or used in treatment in a way that does not compromise its quality and safety.

Imports and exports (Guidance note 16; General Direction 0006)
The centre has not performed any imports or exports.

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 sperm during any step from procurement to use for human application or disposal,
- identify the donor and recipient of particular gametes,
- to identify any person who has carried out any activity in relation to particular sperm, and
- to identify and locate all relevant data relating to products and materials coming into contact with particular sperm samples and which can affect their quality or safety.

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

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

Transport and satellite agreements (Guidance note 24; General Direction 0010)
Centre 0336 is not a primary centre for transport or satellite treatment.

Equipment and materials (Guidance note 26)
The centre uses equipment and materials that are compliant with HFEA requirements. All of the equipment and materials used in licensed activity are designated for the purpose and are appropriately maintained in order to minimise any hazard to patients and/or staff.
The centre is compliant with HFEA requirements to validate critical equipment.
The centre has documented procedures for the operation of critical equipment and procedures to follow if equipment malfunctions.

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

Procurement of gametes and embryos (Guidance note 15)
A review of patient records showed that in a number of instances entries made by the clinician recording the patient's medical history or indication for treatment were not clear or fully legible (SLC T49 and T46 (c and d)).

See recommendation 6 (records management).

Process validation (Guidance note 15)
Validation documents reviewed on inspection did not include reference to an evaluation of the centres' own data This means that the centre is not able to demonstrate that they have achieved the expected outcome using their chosen process (SLC T72).

See recommendation 2.

Quality management system (QMS) (Guidance note 23)
The centre has audited their activities against their own protocols and quality indicators however they had not audited against compliance with the regulatory requirements (SLC T36). This was identified by the inspection team in relation to the following SOPs:

- legal parenthood
- screening of patients and donors for treatment including treatments involving intrauterine insemination
- retention of records

See recommendation 3.

Third party agreements (Guidance note 24)
Where required, surgical sperm retrieval (SSR) is conducted in the theatre at Baddow hospital by a surgical team that are not working under the auspices of the licence however a third party agreement is not in place (SLC T111).

See recommendation 4.

Staff engaged in licensed activity
Person Responsible (PR)
Staff

What the centre does well

Person Responsible (Guidance note 1)
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 (T/1191/8 PREP number).

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
In a check of the professional body registration of two members of staff, it was observed that the names by which the staff members are registered with their professional bodies differ from that recorded by the centre. The PR has provided assurance that he is satisfied that both members of staff are suitably registered with the relevant professional bodies however it was considered by the inspection team that as the PR had up until the time of the inspection been unaware of this anomaly that this may be indicative that the selection and recruitment of staff, including checks of registration with their professional bodies, was not robust (SLC T14 CoP guidance 2.2g and 2.7)

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 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 do not provide treatments involving preimplantation genetic screening, embryo testing or sex selection.

What the centre could do better
Not applicable.

2. The experience of patients

Patient feedback

What the centre does well

There were no patients attending the centre on the day of the inspection therefore the team were unable to speak to any patients directly regarding their experiences at the centre.

Three patients had provided feedback directly to the HFEA in the time since the last inspection. Feedback was positive, with two of the individuals providing written feedback to the HFEA commenting that they have compliments about the care that they received.

From 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 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 sharing arrangements (Guidance note 12; General Direction 0001)

The centre's procedures for egg sharing arrangements (offered as part of satellite services with Boston Place) are broadly compliant with HFEA requirements. This is

important to ensure that:

- care is taken when selecting egg providers donating for benefits in kind
- egg providers are fully assessed and medically suitable, and
- the benefit offered is the most suitable for the egg provider and recipient(s) (where relevant).

Surrogacy (Guidance note 14)
Not relevant 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 and donors.

What the centre could do better

Egg sharing arrangements
Simply Fertility patients wishing to egg share are provided with licensed treatment at the primary centre, 0327 Boston Place. Simply Fertility patient information and SOPs state that where it is considered the patient has an insufficient number of eggs to share, she may elect to donate all eggs in that cycle and return for a second cycle for her own treatment free of charge. This is not in accordance with General Direction 0001 which states that any benefit in kind should be provided within the cycle of donation, unless there is a medical indication why this should not happen. It is noted that this scenario has not occurred to date and the PR has agreed that information and SOPs will be amended to reflect the requirements of General Direction 0001; therefore no further recommendation has been made.

Information

What the centre does well

Information (Guidance note 4; CH(11)02)
The centre's procedures for providing information to patients and / or donors are partially 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
Patient information in relation to screening required prior to insemination treatment was incorrect in that it stated that the HFEA required that all patients rather than gamete providers undergo viral screening. This implies that individuals not providing gametes are required by HFEA to undergo viral screening (SLC T58(c)).

See recommendation 3.

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.

Disclosure of information, held on the HFEA Register, for use in research (General Direction 0005)
Consent to disclosure decisions for Simply Fertility patients are provided to the HFEA by the primary centre 0327 therefore this was not inspected.

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 store embryos.

What the centre could do better
Not applicable

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 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
Nothing identified during this inspection

Use of embryos for training staff

What the centre does well

Use of embryos for training staff (Guidance note 22)
The centre does not create embryos or store embryos therefore this is not applicable.

What the centre could do better
Not applicable

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 partially 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 ; 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.

The HFEA register information team did not attend the inspection due to the small number of treatments that had been provided however the register audit team on reviewing the centres' submissions reported that they are compliant with data reporting requirements.

What the centre could do better

Record keeping and document control (Guidance note 31)
It was not documented in patient records by whom the patient/donor had been reliably identified (SLC T46 (b)).

See recommendation 6

Section 3: Monitoring of the centre's performance

Following the initial licencing inspection in 2013, recommendations for improvement were made in relation to one area of major non-compliance and two 'other' area(s) of 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

In 2015, the centre did not receive any performance alerts related to their treatment outcomes for donor insemination.

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, Directions or the Code of Practice, and the recommended improvement actions required are given, as well as the timescales in which these improvements should be carried out.

Critical area of non compliance

A critical area of non-compliance is an area of practice which poses a significant risk of causing harm to a patient, donor, embryo or to a child who may be born as a result of treatment services, or a significant shortcoming from the statutory requirements. A critical area of non-compliance requires immediate action to be taken by the Person Responsible.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
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. A review of donor records on inspection showed that screening had not been performed within the time scales authorised by the Authority (SLC T53b).	The PR should ensure that with immediate effect all donors of gametes are screened in accordance with the requirements of SLCT53 b. The PR should review the centres procedures for donor recruitment and screening. A summary report of the findings of the review including corrective actions and the timescale for their implementation should be provided by 18 September 2015. The PR should perform an audit three months after the implementation of corrective	Since the inspection the Protocol for screening donors has changed to require that donors are screened and counselled post consultation with the doctor and prior to any co-ordination appointments with the nurses. This will ensure that there are no issues that prevent the donor from donating in advance of being offered to a patient. Current practice is to re screen the donor at the point of donation, Simply Fertility interprets this as being at the point of cycle commencement. The HFEA does not have any defined 'time of donation' and therefore in the absence of this we feel this is acceptable and	The inspector is satisfied with the response however the screening SOP which was submitted to the HFEA does not reflect the PR's definition of 'time of donation' The PR should review the SOP and forward to the inspector. The PR should provide a summary report of the audit by 18 December 2015. Further action required.

	actions a summary report should be provided by 18 December 2015.	manageable. The Screening SOP has been amended as has the egg donor management SOP (both attached) We will audit these changes and report in the timescale provided.	
2. The documentation of the validation of critical processes performed in the laboratory did not include reference to an evaluation of the centres' own data (SLC T72).	The PR should provide a list of all procurement and processing procedures that are considered critical including the date of validation or the planned date by which validation is expected to be complete. The list should be provided to the HFEA by 18 September 2015. The PR should ensure that the validation of critical processes includes reference to an evaluation of the centres' own data. On completion of the validation programme the inspector will ask for a sample of validation documents to be submitted for review.	Simply Fertility has validated all processes except for surgical sperm retrieval. This will be undertaken with immediate effect. Validation requires verification using, where possible, the results of our own patients, we will complete the verification of all processes within 3 months as suggested at the inspection. The attached document states the current status of the processes that are being validated within Simply Fertility.	The inspector is satisfied with the response. The inspector looks forward to being informed of the completion of the validation programme. Further action required.

3. The centre has audited their processes and activities/procedures against their own protocols and quality indicators however; they had not audited against compliance with the regulatory requirement. This has resulted in patient information being inaccurate in some instances in particular information regarding screening for insemination treatment (SLC T36).	The PR should review the centre's processes for audit to ensure that the compliance with regulatory requirements is incorporated into the process. A summary report of the findings of the review including corrective actions and the timescale for their implementation should be provided by 18 September 2015. The PR should review patient information to ensure that any reference to regulatory requirements is accurate. The PR should inform the inspector when this has been completed.	Simply Fertility understands that the Audit SOP should reflect the need to audit each process against regulatory requirements. The SOP has been adapted to reflect this and all audits will ensure regulatory requirements have been checked for the processes being audited. All patient information has been audited and checked against regulatory requirements and it appears that the IUI process is the only document that needs review as it suggests that the HFEA requires Screening of the partner, in fact it is the policy of the centre. We will address this in the next version of this document.	The inspector is satisfied with the response. The PR should inform the centre's inspector when this action is complete. Further action is required.
4. Surgical Sperm Retrieval (SSR) is carried out in Baddow hospital theatre, however a third party agreement is not in place (SLC T111).	The PR should ensure that a third party agreement is established with Baddow Hospital. The PR should inform the inspector when this is in place.	The third party agreement with Baddow Hospital has been modified to include the operating theatres in order to ensure compliance with the regulatory requirements. The Baddow hospital TPA is attached	The inspector has received a copy of the third party agreement. No further action.

5. The selection and recruitment of staff including the check of their registration with their professional bodies, was not considered suitably robust (SLC T14; CoP guidance 2.2(g) and 2.7).	The PR should undertake a review of the centres recruitment procedures. A summary report of the findings of the review including corrective actions and the timescale for their implementation should be provided by 18 September 2015.	A new "Checking Professional Registration of Staff SOP" has been created to ensure a more vigilant approach to the checking of professional registrations. As PR I fully understand that where there are differences in the registered names with those used professionally a verification process is required. The new SOP is attached	The inspector is satisfied with the response. No further action.
6. Non-compliance noted in patient records included: • the name of the team member who performed the initial identification of patients at consultation was not documented • written entries in some patient records were illegible and it was therefore difficult to read patients history and the services provided to them (SLC T46).	The PR should ensure that all documentation is clearly and accurately completed. The PR should ensure that all entries in patient files are legible. The PR should perform an audit of patient records over a three month period and provide a summary of the audit results and corrective actions where applicable to the centre's inspector by 18 December 2015.	The Front of notes form has been adapted to ensure that the person who checks the ID of the patients confirms this process with a signature which is dated and timed. All patients have always been required to present their passports for ID and a copy is in every set of medical records. The Consultant has been told to review his written entries to ensure legibility. All medical records have a consultation summary which is clear giving facts such as diagnosis and	The inspector is satisfied with the response. The PR should submit a summary of the patient records audit by 18 December 2015. Further action is required.

		treatment pathway, this is is always repeated after each follow up appointment. The nursing records are exemplary according to the inspection team on the day. The new front of notes form is attached.	

Other areas of practice that requires improvement

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
7. A witnessing step was not recorded in one donor's notes and there was a discrepancy in the dates recorded in two related witnessing forms in a second donor's notes. The inspector was satisfied that witnessing had been carried out in accordance with requirements and that these anomalies represented errors in documentation only and therefore it was agreed by the team that this should be classified as an 'other' non-compliance SLC T46.	The PR should ensure that witnessing steps are consistently and accurately documented. The PR should perform an audit of witnessing records over a three month period and provide a summary of the audit results and corrective actions where applicable to the centre's inspector by 18 December 2015.	Simply Fertility accepts that there were some discrepancies in dates documented on witnessing steps on two forms and a witnessing step was missing on another. The inspector, as reported was satisfied with the witnessing procedures and the discrepancies were explained. Simply Fertility takes witnessing very seriously and accepts the request to perform an audit of witnessing steps which will be included in the scheduled witnessing audit programme.	The inspector looks forward to receiving the audit summary by 18 December 2015.

Reponses from the Person Responsible to this inspection report
I am happy with the report and felt the inspection was a fare review of our commitment to quality and regulation. I am happy that the inspection team were also able to see the diversity and volume of our satellite program.