Inspection Report

Date of Inspection: 19-20 September 2012
Purpose of inspection: Renewal of Treatment and Storage Licence
Licence: L/0077/17/C
Length of inspection: 14 hours over two days
Inspectors: Wil Lenton (HFEA, Lead Inspector)
Susan Jolliffe (HFEA, Clinical Inspector)
Lynne Nice (External, Scientific Inspector)
Douglas Gray (HFEA, Observer)
Chris Hall (HFEA Audit)
Neil McComb (HFEA Audit)

Inspection details:
The report covers the pre-inspection analysis, the visit and information received from the centre between 20 October 2011 and 6 December 2012

Date of Executive Licensing Panel: 14 December 2012

Purpose of the Inspection Report
The purpose of the inspection is to assess whether centres are complying with the Human Fertilisation and Embryology (HF&E) Act 1990 (as amended), the HF&E Act 2008 and the HFEA Code of Practice (CoP), to ensure that centres are providing a quality service for patients. The report summarises the findings of the licence renewal inspection highlighting areas of good practice, as well as areas where further improvement is required to improve patient services and meet regulatory requirements. It is primarily written for the Authority's Executive Licensing Panel which makes the decision about the centre's licence renewal application.

Centre details

Centre name	Regional Fertility Centre, Belfast.
Centre number	0077
Licence number	L/0077/17/C
Centre address	Grosvenor Road, Belfast, BT12 6BB, UK
Person Responsible	Dr Peter McFaul
Licence Holder	Mr Brian Barry
Date licence issued	01/03/2010
Licence expiry date	28/02/2013
Additional conditions applied to this licence	None

Contents

Report to Executive Licensing Panel

Brief description of the centre and its licensing history:

The centre has been licensed since 1992 and offers treatment to NHS and privately funded patients, including IVF, ICSI, egg sharing, and egg donation.

The centre is in a self-contained unit within the Royal Hospital (Belfast). The centre is open six days a week, including Sundays. The centre attempts to meet patient requests for treatment throughout the week if possible, following consultation. The centre is ISO 9001:2008 certified.

The Person Responsible (PR), Dr Peter McFaul, has been in post since February 2005, is registered with the General Medical Council (GMC), is on the specialist register for Obstetrics and Gynaecology and has completed his HFEA PR Entry programme (PREP number T/1045/7).

The last renewal inspection at the centre took place on 24 September 2009. The Executive Licensing Panel (ELP) considered the renewal application on 3 December 2009 and issued the current licence, which expires on 28 February 2013. More recently, ELP on 22 July 2011 agreed to a change of Licence Holder (LH) at the centre. An interim inspection took place on 20 October 2011, during which three major and four 'other' non-compliances were noted. The PR resolved six of the seven issues prior to the ELP on 27 January 2012 and gave a commitment to fully implement the remaining issue. The ELP decided to continue the centre's licence.

Activities of the Centre:

Type of treatment	Number of treatment cycles between 1 August 2011 and 31 July 2012*
In vitro fertilisation (IVF)	600
Intracytoplasmic sperm injection (ICSI)	550
Gamete intrafallopian transfer (GIFT)	0
Frozen embryo transfer (FET)	240
Donor insemination (DI)	1
Partner insemination	26**
Egg share provider (sharer)	0
Egg share recipient	0
Egg donation (non-egg share)	19

Other licensable activities	✓ or Not applicable (N/A)
Storage of eggs	✓
Storage of sperm	✓
Storage of embryos	✓
Research	N/A

*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.

**Partner insemination data for year 1 January to 31 December 2011 (stimulated cycles).

Outcomes*

For IVF/ICSI, HFEA held register data for the period 1 May 2011 to 30 April 2012 show the centre's success rates are in line with national averages with the following exceptions, which are all significantly lower than the national average:

i. IVF treatments for patients 16-37, using fresh embryos derived from their own eggs.

ii. ICSI treatments for patients 16-37, using fresh embryos derived from their own eggs.

iii. Frozen embryo transfers for patients 16-39, using frozen/thawed embryos created from their own eggs.

Both the PR and laboratory manager discussed ways of how the above disappointing success rates could be improved, which involved;

- a thorough review of all laboratory and clinical procedures
- closer monitoring of laboratory and clinical key performance indicators (KPI)
- introduction of blastocyst culture of embryos

The PR stated that they were presently discussing all of the above with regional commissioners and preparing a business case to develop the service to provide treatment services seven days a week.

For the year 2011 the centre reported 26 cycles of partner insemination with six pregnancies.

*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.

Summary for licensing decision

In considering overall compliance, the inspection team considers that they have sufficient information drawn from documentation submitted by the centre prior to inspection and from observations and interviews conducted during the inspection visit, to conclude that:

- the PR is suitable and has discharged his duty under section 17 of the HF&E Act 1990 (as amended)
- the premises are suitable
- the practices are suitable
- the centre has submitted appropriately completed documentation in accordance with 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 improvement, including seven major areas of non-compliance and four other areas of non-compliance or areas of poor practice.

Since the inspection visit the centre has confirmed or provided evidence that the following recommendations have been fully implemented:

Major areas of non compliance:

- Further quality indicators (QIs) need to be developed.

'Other' areas of practice that require improvement:

- The laboratory witnessing sheet needs to be reviewed and amended.
- The information provided to sperm donors needs to be reviewed and amended.

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

Major areas of non compliance:

- The PR should monitor and periodically review the centre's multiple birth rate in order to meet the HFEA target and ensure that three embryo transfer data is accurately maintained.
- The quality of service to patients needs to be improved in relation to clinical pregnancy rates.
- The diagnostic Andrology laboratory should be CPA certified.
- WoC forms need to be completed prior to any licensed treatment.
- Data required to be submitted to the Authority should be reported both accurately and in a timely fashion.
- Consents for the disclosure of information to researchers should be reported accurately to the Authority.

'Other' areas of practice that require improvement:

- The audit proforma for the submission of data to the Authority needs to be reviewed and amended.
- A documented procedure for the dissemination of information concerning legal parenthood needs to be developed.

The inspection team considers that, overall there is sufficient information available to recommend the renewal of this centre's licence for a period of four years without additional conditions. In making this recommendation it is noted that the PR has responded to all recommendations made in this inspection report and further improvement is required in only a few areas of practice.

Details of inspection findings

1. Protection of patients and children born following treatment

Focus

The purpose of the inspection was to assess whether the centre:

- conducts all licensed activities with skill and care and in an appropriate environment, in line with good clinical practice, to ensure optimum outcomes and minimum risk for patients, donors and offspring
- takes into account the welfare of any child who may be born as a result of the licensed treatment provided by the centre, and of any other child who may be affected by that birth
- ensures that all premises, equipment, processes and procedures used in the conduct of licensed activities are safe, secure and suitable for the purpose
- reports all adverse incidents (including serious adverse events and reactions) to the HFEA, investigates all adverse incidents and shares lessons learned.

▶ **Witnessing and assuring patient and donor identification** (Guidance Note 18)
What the centre does well. The centre has a witnessing process in place, to ensure that all gametes and embryos, together with their associated patients/donors are contemporaneously identified and witnessed, at all critical points within the clinical and laboratory process. Apart from the issue discussed below, a full witnessing record is kept within each patient's record, as confirmed via an on-site audit of five sets of records and observation of laboratory practice. QIs for witnessing were seen to be in place (Standard Licence Conditions (SLC) T71, T36 & T35). A standard operating procedure (SOP) covering the witnessing process was seen together with documented records of the assessment of staff competence when performing these tasks (SLC T33b & T12). Observation of specific laboratory practices, including oocyte recovery, sperm preparation and the transfer of gametes and embryos between different tubes and dishes was undertaken during the inspection. All of the above practices were seen to be witnessed in accordance with current HFEA requirements.
What the centre could do better. The laboratory witnessing sheet does not currently record the witnessing check which occurs when thawed embryos are transferred from the thaw dish to the embryo culture dish. The practice is witnessed by two staff members but this check is not documented (SLC T71).

Patient selection criteria and laboratory tests

- Procuring, processing and transporting gametes and embryos (Guidance Note 15)
- Counselling (Guidance Note 3)

What the centre does well.

Procuring, processing and transporting gametes and embryos
SOPs are in place describing all critical processes including those for procurement involving the receipt/transfer of gametes/embryos between HFEA licensed centres and the import/export of licensed material (SLC T33b).

Critical procurement and processing procedures were seen to have been audited against approved protocols, regulatory requirements and the centre's own QIs within the last two years (SLC T35 and T36).

Prior to processing, all gametes and embryos intended for use in treatment or storage are screened in accordance with SLC T50, as confirmed from test results from an appropriately accredited laboratory (SLC T51) held in medical records and seen on inspection.

Evidence of the validation of all critical equipment and processes involved in the procurement, processing and transport of gametes and embryos was seen during the inspection (SLC T24 & T72).

Training folders observed in the course of the inspection demonstrated that staff competence to perform critical procurement processes was periodically assessed (SLC T15a).

Counselling
Through interviews with staff including one of the counsellors, it was established that counselling is offered to all patients (HF&E Act 1990 (as amended), Schedule 3, S.3 (1)a), which incorporates counselling about agreed fatherhood and agreed female parenthood if necessary (HF&E Act, Schedule 3Z part 2). A counselling SOP is in place, an audit of the counselling service between September 2011 and August 2012 was provided, and QIs for counselling have been developed (SLC T33b, T35 & T36).

What the centre could do better.
Nothing noted.

Donor recruitment, assessment and screening (Guidance Note 11)
Payments for Donors (Guidance Note 13)
Donor assisted conception (Guidance Note 20)

What the centre does well.

Donor recruitment, assessment and screening
From discussions with staff, a review of donor records and documentation seen on inspection, it was established that the centre recruits, assesses and screens gamete donors in line with current regulations (SLC T52). A SOP is in place which describes the recruitment process (SLC T33b), audits of practice have been undertaken and QIs

established (SLC T36 & T35).

Screening tests are in line with current professional guidelines and are performed in an appropriately accredited laboratory (SLC T53a). Donated sperm samples are quarantined in line with current regulations (SLC T53c). Upon request donors can be provided with information concerning the numbers, gender and birth year of all offspring born as a result of their donations (HF&E Act 1990 (as amended), Section 31ZD (3)).

Payments for Donors
Following the review of donor records, discussions with staff and from documentation seen during the inspection, it was established that payments to donors are compliant with current regulations (SLC T69).

Donor Assisted Conception
Evidence was provided that those who are to receive treatment with donated gametes or embryos are provided with information on the importance of informing any resulting child at an early age of their donor origins and how this may be best achieved (SLC T63).

Confirmation was given by the centre that where the provider of gametes, donated prior to April 2005, has not consented to being identifiable, the donated gametes and any embryos created with those gametes, are only used in treatment to achieve a sibling pregnancy (SLC T54).

What the centre could do better.
Nothing noted.

Good clinical practice

- Quality management system (Guidance Note 23)
- Traceability (Guidance Note 19)
- Validation (Guidance Note 15)
- Equipment and materials (Guidance Note 26)
- Premises – suitability of the premises and air quality (Guidance Note 25)
- Adverse incidents (Guidance Notes 27)
- Third party agreements (Guidance Note 24)
- Intracytoplasmic sperm injection (ICSI) (Guidance Note 21)

What the centre does well.

Quality management system
The centre has a quality manager in post who has maintained a quality management system (QMS), including a quality manual, training and reference materials, which underpins the centre's activities (SLC T33).

From discussions with staff, observation of practice and a review of documentation during inspection, it was found that SOPs are in place (SLC T33b) which direct all treatment service activities and, where relevant, specify any critical materials and reagents to be used (SLC T31). Except for the areas mentioned below, QIs are in place for the centre's critical activities (SLC T35) and audits of them have been conducted within the last two years (SLC T36). An independent audit of the QMS is undertaken annually and the last

annual management review of the services provided was undertaken on 8 February 2012. The centre is ISO 9001:2008 certified.

Traceability
From observation of laboratory practice, a review of patient / donor records and discussions with staff, it was seen that all gametes and embryos, and all equipment and materials which may come into contact with them and affect their quality and safety, are traceable from procurement to treatment or disposal. A SOP is in place specifying the processes by which traceability is assured (SLC T22, T33b and T99). Traceability procedures were last audited on 6 August 2012; two non-conformities were identified and corrective actions implemented (SLC T36). QIs for traceability have been developed and are evaluated during audit (SLC T35). Evidence of the periodic assessment of staff competence when performing traceability procedures was seen (SLC T15a).

Process validation
Critical procurement and processing procedures and all equipment used in these processes have been validated. Validation documents were available to view on inspection (SLC T24 and T72).

Equipment and materials
Staff are alerted via alarms if equipment parameters breach defined limits (SLC T24). Equipment and materials used in service delivery are designated for their specific purpose and are regularly serviced and maintained (SLC T23 & T26). SOPs are in place for the use of all critical equipment and include how to proceed in the event of malfunction (SLC T27). CE marked equipment and materials are used wherever possible (SLC T30).

Premises
A tour of the centre confirmed that the centre's premises are suitable for the licensed activities and that all licensed activities are conducted in the licensed premises (SLC T1). Evidence was provided that the processing of gametes and embryos takes place in an environment of appropriate air quality (SLC T20). Air quality is comprehensively assessed in critical areas and the laboratory background by monthly settle plate testing, quarterly airborne bacteria and fungal counting and annual particle counting. The most recent settle plate results were recorded on 10 August 2012 and included a test result from a laboratory workbench which breached a warning limit; the corrective actions taken were documented (SLC T20).

Adverse incidents
The centre has an adverse incident SOP, documenting the procedure to follow in the event of an incident, including HFEA reporting requirements. Via review of the incident log, it was determined that all required incidents had been reported to the Authority in accordance with current requirements (SLC T118).

Third party agreements
Following discussions with staff and document review it was established that the centre has written third party agreements (TPAs) in place with all third parties providing goods and services, which may influence the quality and safety of gametes and embryos; the centre has evaluated the ability of these third parties to meet required standards (SLC T111 & T112).

Intracytoplasmic sperm injection (ICSI)
The centre has a SOP in place for performing ICSI (SLC T33b). QIs have also been developed and are evaluated during the quarterly audit of ICSI practice (SLC T36 & T35). QI monitoring data is reviewed as part of the periodic assessment of staff competence to perform ICSI; these assessments are documented (SLC T15a).

What the centre could do better.
No QIs are presently in place (SLC T35) for;

- The provision of information for patients
- The taking of consent
- Welfare of the child (WoC) assessment.

Multiple Births (Guidance Note 7)

For the period 1 April 2010 to 30 March 2011, the centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 23%. This represents performance that is likely to meet the 20% live birth rate target.

For the period 1 April 2011 to 30 March 2012 the centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 24%. This represents performance that is likely to be statistically different from the 15% live birth rate target.

What the centre does well
The PR has provided sufficient evidence to demonstrate compliance with HFEA General Direction 0003 in that:

- Staff were able to describe their progress towards reducing their multiple pregnancy rate and subsequent multiple birth rate;
- Staff at the centre have audited their multiple birth minimisation strategy and protocols as part of the quality management audit programme;
- Staff have maintained a log which indicates the reasons for variation from the single embryo transfer policy and the outcomes; these are also recorded in the patient's records.

What the centre could better
On-going monitoring of the centre's multiple clinical pregnancy rate suggests that the centre is likely to exceed the 2011/12 maximum multiple birth rate target of 15% (SLC T123).

The PR has not provided sufficient evidence to demonstrate compliance with HFEA General Direction 0003 in that staff have not maintained an accurate log of women receiving triple embryo transfers.

Staff engaged in licensed activity

- Person Responsible (Guidance Note 1)
- Staff (Guidance Note 2)

What the centre does well.
The PR has academic qualifications in the field of medicine as required by the HF&E Act 1990 (as amended) section 16(2)(c)(i) and (ii) and has many years of practical experience which is directly relevant to the activity to be authorised by the licence. He has successfully completed the HFEA PR Entry Programme (PREP number: T/1045/7).

From documentation reviewed, discussions with staff and observations made during the inspection, the inspection team conclude that the PR has carried out his duties appropriately (SLC T9) and has provided assurance that;

- staff are suitably qualified and are available in sufficient numbers to carry out all the services offered and workforce requirements have been reviewed within the last year (SLC T12);
- medical practitioners are registered with the GMC (SLC T14);
- nursing staff are registered with the Nursing and Midwifery Council (SLC T14);
- eligible scientific staff are registered with the Health Professionals Council (SLC T14);
- all staff can show evidence that they are trained to carry out their designated tasks (SLC T15);
- all staff can show evidence of their competence to carry out their designated tasks (SLC T12);
- staff have access to clinical professional development (CPD) (SLC T15);
- all medical activities are overseen by a medical practitioner (SLC T16);
- the centre's patients, their partners and donors have access to a suitably qualified counsellor (SLC T12).

What the centre could do better.
Nothing noted.

Welfare of the Child (Guidance Note 8)

What the centre does well.
Following discussions with staff it was established that before providing treatment services, the centre makes an assessment of the welfare of the child (WoC) who may be born as a result of licensed treatment and of any other child who may be affected by that birth.

The centre has a documented SOP in place for when staff undertake a WoC assessment and nursing staff competence when performing a WoC assessment is periodically appraised and documented. A similar system is being established by the PR to periodically assess and record medical staff competence when undertaking WoC assessments (SLC T33b & T15a).

Evidence was reviewed showing that 42 sets of records were audited for completion of WoC forms on 6 July 2012; no discrepancies were found (SLC T36).

What the centre could do better.
Five sets of patient notes were reviewed during inspection and it was found that WoC

assessments had been completed by both patient and partner in all but one of the records, prior to any treatment taking place (SLC T56).

2. Patient Experience

Focus

The purpose of the inspection visit was to assess whether the centre:

- treats prospective and current patients and donors fairly, and ensures that all licensed activities are conducted in a non-discriminatory way
- has respect for the privacy, confidentiality, dignity, comfort and well being of prospective and current patients and donors
- gives prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions
- ensures that patients and donors have provided all relevant consents before carrying out any licensed activity

Treating patients fairly

- Treating patients fairly (Guidance Note 29)
- Confidentiality and privacy (Guidance Note 30)
- Complaints (Guidance Note 28)
- Provision of costed treatment plans (Guidance Note 4)
- Egg sharing arrangements (Guidance Note 12)
- Surrogacy (Guidance Note 14)

What the centre does well.

Treating patients fairly
From discussions with staff and observations made on inspection, the centre ensures that all licensed activities are conducted in a non-discriminatory way and with proper respect for the privacy, confidentiality, dignity, comfort and well being of all prospective and current patients and donors. Patient feedback questionnaires are used to inform the centre about any patient issues which could be improved upon as part of the QMS.

Confidentiality and privacy
From observations made on inspection and following discussions with staff it appeared that centre staff understand the need to maintain patient confidentiality, have received training in this area, and keep all confidential information secure (SLC T43; T44 & T45).

Complaints
The centre actively seeks patient feedback and investigates and learns from patient complaints. A complaints policy is located both within the patient waiting area and on the centre's website. Staff stated that the centre utilises the Belfast Health and Social Care Trust complaints policy. They always attempt to resolve patient issues locally in the first instance by private discussion. If this is not possible the issue is escalated in line with the complaints procedure (SLC T33b). The complaints log was reviewed and found to be compliant with CoP Guidance 28.7.

Provision of costed treatment plans
A current (2012) treatment price-list is provided to all prospective patients via both the centre's information booklet and its website. The cost of any required drugs is also discussed with the patients prior to any treatment, storage or both being offered (CoP Guidance 4.3).

Egg sharing arrangements
The centre has not provided this type of treatment over the last twelve months but has documented procedures for its provision (SLC T33b). The egg providers in egg share arrangements are screened as donors, in accordance with SLCs T52 and T53 and current professional guidelines; they are also registered with the HFEA as donors. Egg-share patient records reviewed demonstrated that the required screening tests had been undertaken, counselling offered and relevant consents completed, prior to treatment.

Records reviewed and discussions with staff confirmed that treatment is only provided to the egg sharer in the course of the donation cycle unless there is a documented medical reason as to why treatment cannot be provided at that time (General Direction 0001).

Surrogacy
The centre provides surrogacy treatment as and when required and has documented procedures in place (SLC T33b). The centre screens all gamete providers in surrogacy arrangements as registered donors and in line with current professional body guidelines (SLCs T52 and T53 and General Direction 0001).

What the centre could do better.
Nothing noted.

Information

- Information to be provided prior to consent (Guidance Note 4)
- Information about storage of embryos (including cooling off periods)
- Information about Intracytoplasmic sperm injection (Guidance Note 21)
- Information about legal parenthood (Guidance Note 6)

What the centre does well.
From discussions with staff, documents reviewed and information provided prior to inspection, it was established that prior to the signing of consents and before treatment services are provided, prospective patients and their partners, and donors, are supplied with information (SLC T58) relating to;

- the nature of any treatment provided,
- any consequences/risks of treatment,
- any analytical tests required,
- confidentiality,
- the giving of consent, and
- the availability of counselling.

There is a SOP in place for this process (SLC T33b). Staff complete a checklist of information provided to patients, which was observed during the inspection (HF&E Act Schedule 3; 3(1b)). An audit of 42 sets of medical records undertaken on 6 July 2012 confirmed that appropriate, accurate and up-to-date information is provided to patients,

prior to the signing of consent forms (SLC T36). Documented evidence of the periodic assessment of staff competence when providing information to patients was reviewed and found to be appropriate (SLC T15a).

An audit of patient information provided on the centre's website was undertaken which showed the information content to be compliant with Chair's Letter CH(11)02.

What the centre could do better.

Legal Parenthood
Staff stated that information concerning legal parenthood was discussed with patients as part of the implications counselling process, but that no formal documented procedure was in place to guide this process.

The centre also does not have a documented procedure describing the process to follow if a woman being treated, withdraws her consent to a nominated second parent being the legal parent to any child born, or stating the need to inform the nominated second parent of the consent withdrawal (SLC T33b).

Donor compensation
The centre has not reviewed or amended its information for donors in consideration of the changes made to General Direction 0001 introduced as of 1 April 2012 (SLC T33b).

Consent

- Consent to treatment, storage, donation, training and disclosure of information (Guidance Note 5)
- Consent to legal parenthood (Guidance Note 6)

What the centre does well.
From discussions with staff, documents reviewed and information provided prior to inspection, it was established that effective written consent is obtained from patients prior to any treatment being offered and that the centre has a documented SOP in place for this process (SLC T33b). Annual notes audits are undertaken to determine that effective written consent has been taken (SLC T36). Documented evidence of the periodic assessment of nursing staff competence to obtain written consent from patients was reviewed and found to be appropriate. The PR assured the inspection team that there was a process in place which incorporated, professional body registration, annual appraisal and on-going professional development, to ensure that all medical staff are competent in the activities that they perform (SLC T15a). Patients are never asked to sign consent forms on the day of treatment (HF&E Act Schedule 3; 3; 1a). The identity of the person giving consent is verified at the time of signing by photographic evidence (Guidance 5.10 and 5.11).

What the centre could do better.
Nothing noted.

3. Protection of gametes and embryos

Focus
The purpose of the inspection was to assess whether the centre has respect for the special status of the embryo when conducting licensed activities

Legal Requirements [Human Fertilisation and Embryology Act 1990 (as amended)]

- Licensed activities only take place on licensed premises
- Only permitted embryos are used in the provision of treatment services
- Embryos are not selected for use in treatment for social reasons
- Embryos are not created by embryo splitting
- Embryos are only created where there is a specific reason to do so which is in connection with the provision of treatment services for a particular woman
- Embryos are only stored if those embryos were created for a woman receiving treatment services or from whom a third party agreement applies
- Embryos which are or have been stored are not given to a person, other than in the course of providing treatment services, unless that person is a person to whom a licence applies
- No money or other benefit is given or received in respect of the supply of gametes or embryos unless authorised by the Authority

What the centre does well.
Discussions with the PR and a tour of the centre demonstrated that the activities authorised by the centre's licence are carried out at the premises specified in the licence or at third party premises (SLC T1).

Observations and discussions with staff on inspection indicated that all staff at the centre have respect for the special status of the embryo when carrying out assisted conception treatment services. Only permitted embryos are created and used in the provision of treatment services and the medical reasons for treatment were seen to be recorded in all patient records reviewed on inspection.

Donor compensation
The centre keeps a record of all reimbursements made to donors via an in-house form. Evidence was provided that all money and other benefits given or received for the supply of gametes or embryos are compliant with General Direction 0001.

What the centre could do better.
Nothing noted.

Storage of gametes and embryos

- Storage of gametes and embryos (Guidance Note 17)

What the centre does well.
From discussions with staff, review of documentation and observation of practice it was established that the centre has a documented SOP in place for cryopreservation of gametes and embryos (SLC T33b). Staff competence to perform cryopreservation has been assessed and documented (SLC T15a). Before any material is stored the gamete providers are screened in accordance with regulatory requirements (SLC T50). All screening tests are performed in an appropriately accredited laboratory (SLC T51). Storage procedures have been validated (SLC T72) and are subject to QI monitoring (SLC T35).

All currently stored licensed material is within its consented storage period (HF& E Act 1990 (as amended) Section 14(1)c). The centre operates a bring-forward system in order to monitor licensed material which is approaching the end of its consented storage period (CoP Guidance 17.18). The centre operates an on-going, rolling audit of its cryostored material. The last audit took place on 6 August 2012; no corrective actions were required (SLC T36).

What the centre could do better.
Nothing noted.

Distribution and / or receipt of gametes and embryos

- Distribution of gametes and embryos (Guidance Note 15)
- Export of gametes and embryos (Guidance Note 16)
- Receipt of gametes and embryos (Guidance Note 15)
- Import of gametes and embryos (Guidance Note 16)

What the centre does well.

Distribution of gametes and embryos
From discussions with staff, review of documentation and observation of practice it was established that the centre has procedures in place to ensure gametes and embryos are distributed under conditions that protect their safety and quality (SLCs T33b; T105; T106; T107 & T108). During the transport of licensed material between licensed centres, appropriate documentation is transferred with the gametes and embryos (SLCs T109 & T110). Before any material is stored the gamete providers are screened in accordance with current regulatory requirements (SLC T50). The centre has a procedure in place for the recall of transported material. A TPA is in place with the courier used to transport cryostored material, which specifies transport conditions to be maintained during transit (SLC T107; CoP mandatory requirements 15B).

Import and export of gametes and embryos
Through discussions with staff and documentation review it was found that the centre had imported 18 ampoules of sperm in accordance with General Direction 0006 Schedule 3, since the last inspection. During the same time frame the centre had also exported six straws of cryopreserved semen in accordance with General Direction 0006, Schedule 2.

What the centre could do better.
Nothing noted.

Use of embryos for training staff (Guidance Note 22)

What the centre does well.
Through discussions with staff, documentation review and observation of practice it was established that embryos are only used for authorised training activities after consent has been obtained from the gamete providers; embryos used in training are not subsequently used for patient treatment (SLCs T92; T93 & T94). Prior to providing consent for use of embryos in training, gamete providers are provided with all required information by an appropriately trained member of staff (SLCs T97 & T98). Centre staff ensure that clinical and training roles are separated (SLC T95). Audits of practice were seen to be in place for this process (SLC T36).

What the centre could do better.
Nothing noted.

4. Good governance and record keeping

Focus

The purpose of the inspection was to assess whether the centre:

- maintains accurate records and information about all licensed activities
- conducts all licensed activities with regard for the regulatory framework governing treatment involving gametes and embryos within the UK, including
    - maintaining up-to-date awareness and understanding of legal obligations
    - responding promptly to requests for information and documents from the HFEA
    - co-operates fully with inspections and investigations by the HFEA or other agencies responsible for law enforcement or regulation of healthcare

Record keeping

- Record keeping and document control (Guidance Note 31)

What the centre does well.

Patient records reviewed during the inspection were seen to be well organised, clear, legible, and appeared to include all relevant patient information (SLCs T39 & T46).

To confirm that data submitted by the centre for inclusion on the HFEA register accurately reflects that found in source records on-site, a sample of 39 assorted form type data submissions were reviewed against source documentation in patient and donor files. No critical errors or omissions were found in the data (i.e. errors that would prevent the HFEA fulfilling its statutory obligations). Additionally, no systematic errors were identified within the sample. A small number of minor errors in submitted information were identified on inspection.

Documents reviewed during the inspection were version controlled. The quality manager confirmed that documents were generally reviewed annually or when revisions were required due to changing practice (SLC T34).

An audit of treatment data submitted to the Authority was undertaken in October 2011 (SLC T36). QIs for this process were seen to be in place (SLC T35).

What the centre could do better.

To determine whether all licensed treatment activity is reported to the HFEA within required timescales, a sample of treatments recorded within the centre's treatment information database and laboratory records was compared to treatment data submitted by the centre for inclusion on the HFEA register.

Some licensed treatment data that the Authority is required to hold on its register had not been reported by the centre to the HFEA register at the time of inspection (i.e. six of 127 or five percent of IVF treatments in the audit sample).

A significant proportion (38%) of the licensed treatments in the audit sample had been submitted to the HFEA outside the timeframe required by General Direction 0005 (SLC T9e).

The centre's audit pro forma for data submission is narrowly focused and does not address key regulatory requirements (e.g. whether all data required is submitted and whether submission error is corrected within two calendar months of identification).

Legal requirements [Human Fertilisation and Embryology Authority 1990 (as amended)]

- Obligations and reporting requirements of centres (Guidance Note 32)

What the centre does well.

The PR provided all information as required by the licence renewal application process prior to inspection. All members of staff cooperated fully with the inspection team and all further information requested at the time of and post inspection was provided in a timely manner.

On the licence renewal application form, the PR indicated that the centre plans to introduce two new laboratory techniques as part of their licensed treatment activities. On further discussion with the PR and laboratory manager it was established that 'assisted hatching' was only at the literature search stage, and would not be introduced in the near future.

The cryopreservation technique of 'vitrification' is due to be introduced shortly by the NHS Trust, to enable female cancer patients to have their eggs frozen prior to chemo and/or radiotherapy, which could potentially affect their future fertility. This was discussed during the inspection. Post-inspection the laboratory manager supplied information stating that all equipment and processes associated with the new technique had now been fully validated and that laboratory staff had been trained and their competence to perform the technique assessed and documented. The PR stated that he would notify the Authority via the clinic portal when this process is finally introduced (General Direction 0008 (18)).

What the centre could do better.

The PR has cooperated fully with the Executive in implementing recommendations from the previous inspection. There is one outstanding issue which requires full implementation but following discussions with the PR and centre staff, the Executive was reassured that;

- CPA accreditation of the Andrology laboratory will be completed as soon as a date for the accreditation inspection is organised by the CPA.

Disclosure of information

- Confidentiality and privacy (Guidance Note 30)
- Disclosure of information, held on the HFEA Register, for use in research

What the centre does well.

Confidentiality and privacy

Through discussions with staff, review of documentation and a tour of the premises and facilities, it was established that the centre ensures that all information about people having treatment, donors and children born as a result of assisted conception services, is kept confidential and is only disclosed in circumstances permitted by law (SLC T43).

Centre staff undertake initial NHS Trust training concerning privacy and confidentiality (SLC T15(a)(d)).

Processes are in place to ensure that access to the centre's health data and records are kept secure at all times and only made available to either people named on the centre's licence or as authorised by the PR (SLC T44).

What the centre could do better.

Consent to treatment, storage, donation and disclosure of information
To determine whether the register properly reflects the consent given by patients and their partners for the use of register information for research purposes, a sample of ten completed patient and partner consent to disclosure forms was reviewed against disclosure consent data supplied by the centre to the register.

A discrepancy was found in three of the ten patient and partner completed consent to disclosure forms in patient files compared to disclosure consent data held on the register.

In one instance the most recently completed disclosure consent form in the patient records indicates that consent has been withheld but the consent data submitted to the HFEA register records that disclosure consent has been given. In the other two instances, the discrepancies could mean that the consent expressly given by the patient and/or partner is frustrated and the pool of data available to researchers is reduced (General Direction 0007; Chair's Letter CH(10)05).

5. Changes / improvements since the previous inspection on 20 October 2011

Area for improvement	Action required	Action taken as evidenced during this inspection
The laboratory performing diagnostic semen analysis should be accredited by CPA (UK) Ltd or another body accrediting to an equivalent standard.	The PR should forward an updated action-plan and time-line for the attainment of CPA accreditation for the diagnostic semen analysis laboratory to the inspector by 20 December 2011.	The PR has kept the Executive informed of actions taken since the last inspection towards CPA accreditation. A mock CPA accreditation audit was undertaken on 15 May 2012 by an experienced CPA inspector. The audit report was provided to the Executive. The centre is awaiting an inspection date from the CPA. **Further action is required**.
The centre has no record of individual donor travel expenses or loss of earnings. (General Direction 0001)	The PR should ensure that receipts and invoices concerning payments to sperm donors are documented and retained. Evidence that the centre's procedure has been amended should be forwarded to the inspector by 20 December 2011.	SOPs and protocols have been amended to correct this. No further action required.
The centre has not audited its procedure for the selection and recruitment of sperm donors within the last two years and QIs have not been developed. (SLC T36; T35)	The process for the selection and recruitment of sperm donors should be audited and quality indicators (QI) developed. Evidence that the process has been audited and QIs developed should be forwarded to the inspector by 20 December 2011.	Audits of practice have been forwarded and QI developed. No further action required.

Areas of practice that require the attention of the Person Responsible

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. 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
Nothing noted.			

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.
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Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
The laboratory performing diagnostic semen analysis is not presently accredited by CPA (UK) Ltd or another body accrediting to an equivalent standard. SLC T21.	The PR should ensure that the laboratory performing diagnostic semen analysis is accredited by CPA (UK) Ltd or another body accrediting to an equivalent standard. The PR should ensure that the final CPA inspection is undertaken as soon as possible and should inform the inspector when this has been performed and accreditation achieved.	The RFC application for CPA accreditation was submitted to the CPA in May 2012. The date of the accreditation inspection is determined by the CPA and is out of our control. In submitting the application, however, we have signed up to working to the CPA standards and we feel ready for inspection at any time.	The Executive acknowledge that the PR has progressed this issue and is now just awaiting a final CPA inspection. The PR should inform the Executive as soon as the inspection has been completed. **Further action required**

IVF and ICSI outcomes for patients aged <38 years are below the national average. FET outcomes for patients aged <40 years are below the national average. HF&E Act 1990, Section 17(1)(d).	The PR should ensure that the laboratory and clinical practices are suitable to provide a good quality service to patients. The PR should provide reassurance to the Executive that the centre's practices are being rigorously reviewed in order to provide better outcomes for patients. An action-plan and timeline giving details of any measures to be implemented should be forwarded to the Executive by 19 December 2012. This issue will also be monitored by the inspector via the risk tool system.	The IVF and ICSI processes are being analysed in detail. The IVF insemination process has been altered in order to achieve better pH and temperature control. Processes are being established to monitor success rates on a monthly basis. Success rates will be presented and discussed monthly at the RFC Management and Clinical Meetings. Individual practitioner data will also be reviewed. Any necessary corrective actions will be taken in a timely manner. A benchmarking exercise of laboratory practices is ongoing.	The PR is addressing this issue. The Executive will continue to monitor HFEA Risk Tool outcomes in order to see improvements in outcome data. **Further action required**
Data required to be submitted to the HFEA and held on its register of information is, in some cases, either not being reported or is being submitted late. SLC T9e; General Direction 0005.	The PR should ensure that any data which the HFEA is required to hold on its register is provided within the timeframe specified in General Direction 0005. The process for submitting licensed treatment data to the HFEA should be reviewed and, where applicable, improved to ensure that licensed	All outstanding issues related to data submissions are actively being addressed. The protocol for data submission is being reviewed to clarify which discipline is responsible for the submission of each data set / form. Timeframes for submission of each form will also be clarified within the protocol. The 'task list' in the IDEAS database is being developed to highlight any data	The PR is addressing this issue. The Executive will continue to monitor HFEA Risk Tool and liaise with the Register team in order to confirm that data from the centre

	treatment activity is reported to the Authority within the given timeframes. This should be implemented immediately and the actions taken reported to the Executive by 19 December 2012. This issue will also be monitored by the inspector via the risk tool system.	that is due to be submitted. This should assist the timely submission of data.	is being reported as required by General Directions **Further action required**
The consent to disclosure of information to researchers is not being reported accurately in some cases. General Direction 0007; Chair's Letter CH(10)05).	The PR should ensure that any information concerning the disclosure of information to researchers is reported accurately to the Authority. The PR should undertake an audit of the last three month's submissions of such information to the Authority, against the original patient consents, in order to ensure that this information is being reported accurately. A summary of the audit should be forwarded to the Executive by 19 December 2012.	The quality team are undertaking an audit as instructed and a summary of the results will be forwarded to the Executive before 19 December. Any necessary corrective and preventative action will be taken in a timely manner.	The PR is addressing this issue and an audit report will be forwarded to the Executive by 19 December 2012. The inspector will continue to monitor centre progress on this issue. **Further action required**

The centre's current multiple pregnancy rate is such that it is significantly likely that the centre will not meet the HFEA year three target rate for multiple births of 15%. The centre is not maintaining an accurate log of women who have three embryos transferred. SLC T123; General Direction 0003.	The PR should immediately ensure that staff continually monitor treatment outcomes in line with their current MBMS policy, in order to determine whether any further adjustments are required. He should also immediately ensure that an accurate log is maintained of women who have three embryos transferred. This issue will be monitored by the inspector via the risk tool system.	Processes are being established to monitor treatment outcomes on a monthly basis in order to ensure compliance with the MBMS policy. Any further necessary adjustments to the RFC eSET policy will be made in a timely manner. An accurate log of women who have three embryos transferred is currently being maintained.	The PR is addressing this issue. The Executive will continue to monitor this issue via the HFEA Risk Tool **Further action required**
During the medical records audit it was discovered that one set of WoC assessments had not been completed by both patient and partner prior to treatment taking place SLC T56.	The PR should ensure that WoC assessments are completed by all patients/partners prior to treatment services being provided. The PR should review the process by which WoC assessments are undertaken, and discuss the importance of this procedure at the next team meeting. A spot audit of thirty sets of medical records should be undertaken to ensure that this area of practice is being addressed.	Agreed by the PR	**Further action required**

	Confirmation that this has been undertaken should be forwarded to the Executive by 19 January 2013.		
QIs are not in place for the following activities; • provision of information to patients • taking patient consent • WoC assessment SLC T35.	The PR should ensure that QIs are developed for all critical activities. The PR should ensure that the required actions are implemented by 19 December 2012 and forward the details of any actions taken to the Executive.	The RFC already undertake an annual audit of: • provision of information to patients • taking patient consent • WoC assessment QIs of 100% have now been set for each activity. The audit standard had been set at 95% and was being met. We have reset the standard to 100%.	The PR has addressed this issue **No 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
There is no SOP in place for the dissemination of information to patients concerning legal parenthood. SLC T33b.	The PR should ensure that a documented procedure is in place for the dissemination of information to patients concerning legal parenthood, which includes actions to be taken in the event of consent to a nominated second parent being the legal parent being withdrawn. The PR should ensure that the required actions are implemented by 19 December 2012 and forward the details of any actions taken to the Executive.	A SOP for the dissemination of information to patients concerning legal parenthood is being written.	The PR is addressing this issue. The inspector will continue to monitor centre progress on this issue **Further action required**
The laboratory witnessing sheet does not currently record the transfer of embryos between the thaw dish and the culture dish. SLC T71.	The PR should ensure that the witnessing of all critical points where embryos are transferred between different vessels within the laboratory are recorded on the laboratory worksheet. The PR should ensure that the required actions are implemented by 19 December 2012 and forward the	This issue has been addressed and the amended witnessing sheet and protocol for witnessing was submitted on 25/10/12.	The PR has addressed this issue **No further action required**

	details of any actions taken to the Executive.		
The information for sperm donors does not include up-to-date information regarding donor reimbursement. General Direction 0001.	The PR should ensure that the information for sperm donors is updated to include current requirements as stipulated in General Direction 0001. The PR should ensure that the required actions are implemented by 19 December 2012 and forward the details of any actions taken to the Executive.	This issue was addressed on the day of inspection. The amended patient information has been forwarded.	The PR has addressed this issue. **No further action required**
The audit proforma for the submission of data to the Authority does not ensure that all key regulatory requirements are met. General Direction 0005.	The PR should ensure that the proforma used for the submission of data to the Authority captures all current regulatory requirements specified in General Direction 0005. This should be implemented immediately and any actions taken reported to the Executive as soon as possible.	The audit proforma for the submission of data to the Authority is being amended by the quality team to ensure that all key regulatory requirements are met as detailed in General Direction 0005.	The PR is addressing this issue. The Executive will continue to monitor the HFEA Risk Tool and liaise with the Register team in order to confirm that data from the centre is being reported as required by General Directions. **Further action required**

Additional information from the Person Responsible