Inspection Report

Date of Inspection: 22 and 23 February 2012
Purpose of inspection: Renewal of Treatment (insemination using partner / donor sperm) and Storage Licence
Length of inspection: 12 hours
Inspectors: Mrs Gill Walsh, Dr Vicki Lamb

Inspection details:
The report covers the pre-inspection analysis, the visit and information received from the centre between 2 December 2009 and 15 May 2012

Date of Executive Licensing Panel: 15 June 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 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 (ELP) which makes the decision about the centre's licence renewal application.

Centre details

Centre name	Queen's Medical Centre Fertility Unit
Centre number	0162
Licence number	L0162/13/c
Centre address	Fertility Clinic B Floor, East Block, Queen's Medical Centre, Derby Road, Nottingham, NG7 2UH
Person Responsible	Mr James Hopkisson
Licence Holder	Ms Marion Macpherson
Date licence issued	1 October 2009
Licence expiry date	30 June 2012
Additional conditions applied to this licence	None

Contents

Report to Executive Licensing Panel

Brief description of the centre and its licensing history:

Queen's Medical Centre Fertility Unit has been licensed by the HFEA for treatment and storage of gametes since 1992. The centre is a NHS clinic which is located within the Queen's Medical Campus which is part of Nottingham University Hospitals NHS Trust.

The centre provides a service for the diagnosis and treatment of sub-fertility and insemination with partner or donor sperm. The centre also incorporates an andrology department which provides a service for those wishing to donate sperm and for those wishing to store their sperm for the preservation of fertility. The andrology laboratory currently has conditional approval status with Clinical Pathology Accreditation UK Ltd (CPA) and is awaiting further inspection following which full approval is anticipated.

The centre's website makes no reference to success rates therefore the requirements of Chairs letter CH(11)02 *Responsible use of websites: the duty of centres* does not apply.

There has been no substantial change to the centre since the last inspection on 2 December 2010, but the sperm production room was undergoing refurbishment at the time of inspection. The Person Responsible (PR) stated that he has been given notice that the Trust intends to reconfigure the footprint of the neonatal unit which sits alongside the centre and therefore the centre will need to move premises within the next year to a site to be decided.

Activities of the Centre:

Type of treatment	Treatment cycles, 01 Feb 2011 - 31 Jan 2012
Donor insemination (DI)	48
Partner insemination (IUI) (2010)	252

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

Outcomes*
For the year 1 July 2010 to 31 June 2011 the centre reported 252 cycles of partner insemination resulting in 39 pregnancies, three of which were twin and one triplet pregnancy. This equates to a 15% pregnancy rate which is consistent with the national average across all age ranges treated. Pregnancy rates for donor insemination treatment are also consistent with the national average.

*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 Executive Licensing Panel is asked to note that at the time of the inspection there were a number of areas of practice that required improvement, including four major areas of non-compliance and three other areas of non-compliance or areas of poor practice.

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

Major areas of non compliance:

- **Staffing levels** -The PR should monitor the centre's activity to ensure appropriate staff are in place to accommodate the current and anticipated workload. If the anticipated restoration of acceptable staff levels with the return of key staff does not happen, activity levels must be managed to ensure that there is sufficient staff available to treatment patients safely and compliantly and that staff are able to take allocated rest days and scheduled leave.
- **Traceability** - The PR should ensure that all relevant data about anything coming into contact with gametes is documented to ensure traceability.
- **Transport conditions for gametes** – The gamete distribution SOP (SOP 019) should be reviewed to ensure that the transport conditions and time limits for the safe transport of gametes are specified.

Other areas of practice that require improvement:

- **Quality management system** – the PR should ensure that:
  - Quality indicators are established relevant to the four areas of practice identified in this report.
  - A SOP for the provision of information to those giving consent to treatment should be documented.
- **Recall of gametes** - The PR should ensure that a mechanism is established to manage the recall of gametes and subsequent actions in the event that this is required. Once agreed, this procedure must be documented and communicated to all staff involved in the distribution of gametes.
- **Confidentiality -** The PR should review the patient information regarding how to make a complaint and the mechanism by which complaints should be made directly to the centre or via the Trust Patient Liaison Service, to ensure there is no potential for the accidental disclosure of treatment or donor information to persons not covered by the centre's HFEA licence.

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

- **The alarm and monitoring of key equipment** - The PR must ensure that the cryostorage dewars in which gametes are kept are subject to appropriate monitoring and alarms to ensure the safety of the gametes.

- **Quality management system**
    - An audit of practice against approved protocols, quality indicators and regulatory requirements is conducted for the five areas of practice identified in this report.

The inspection team recommends the renewal of the centre's licence for a period of four years without additional conditions subject to the outstanding recommendations made in this report being implemented within the prescribed timescales.

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. All samples and the patients to whom they relate are identified and witnessed contemporaneously by two members of staff at all critical points of the clinical and laboratory process and a record of the witnessing checks is kept in the patient / donor's medical record, as confirmed by witnessing procedures observed and by a review of documentation seen on inspection (Standard Licence Condition (SLC) T71) The centre's standard operating procedures (SOPs) for activities and processes that require witnessing have witnessing requirements embedded in them (SLC T33(b)). An audit of four sets of patient records demonstrated that two members of staff witness the procedure contemporaneously and that a record of the witnessing steps is retained in the patient record. The date and time each witnessing step was performed plus the name, status and signature of both the practitioner and the witness are recorded. The centre has audited their witness checks and their documentation against the established quality indicators for witnessing (SLC T35), approved protocols and regulatory requirements within the last two years. Any non-conformities, corrective actions required and implementation of these corrective actions were seen to be recorded (SLC T36). Records of training and competence assessments for staff who conduct witnessing checks were seen on inspection (SLC T15(a)).
What the centre could do better. Nothing noted.

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.
An audit of four patient records on inspection demonstrated that records are kept which include the patient's medical history, the indication for treatment, the services provided, welfare of the child assessment, consent to treatment (and storage where applicable), clinical and laboratory data and the results of tests carried out. (SLC T49 and T46)

There are SOPs in place to direct all critical procurement and processing procedures (SLC T33(b))

Critical procurement and processing procedures were seen to have been audited against approved protocols, regulatory requirements and the centre's own quality indicator of 100% compliance with all measured points, within the last two years (SLC T35 and T36). Where required, corrective actions and the implementation of those actions was seen to have been documented in audit reports (SLC T36).

The consultant scientist in andrology stated that he is confident that his staff are competent to conduct their assigned tasks and described that a comprehensive competence appraisal scheme approved by the Association of British Andrologists is being implemented at the centre. Evidence of induction, training, continuing professional development and competence assessment was available for all laboratory staff members (SLCs T12, and T15(a)).

Patients generally produce their sperm sample on site but may, on occasion, produce their sample at home or elsewhere within the hospital if they are oncology patients. Evidence was seen in one set of patient records reviewed which confirmed that if a sample is produced away from the centre, this is recorded in the gamete provider's medical record (SLC T68).

Following comprehensive risk assessment of their practice and individual cases, the centre does not routinely screen patients providing fresh semen samples for use immediately in partner treatment, for HIV1 and HIV2, hepatitis B or hepatitis C, which is consistent with the European Union Tissue Directive (EUTD) 2006/17/EC Annex III 2.2. The centre uses standard precautionary risk control measures and good laboratory practice for the preparation of these samples. There are robust mechanisms in place to identify when screening or further testing may be required (SLC T50(d)).

All patients who are storing semen samples are screened in accordance with SLC T50 and the sperm is processed in a separate andrology laboratory. Blood testing for screening purposes was seen to be conducted by a CPA accredited laboratory.

Counselling
Independent counselling is offered to all patients and their partners before they provide consent for treatment (SLC T60) and is also available throughout their treatment process and following its conclusion, if required. Counselling is also offered to those providing

consent to donation, agreed legal fatherhood and legal parenthood where donor gametes are used.

The counsellor was able to demonstrate competence to perform her role, having practised in the field for many years and gained accreditation with the British Infertility Counselling Association (SLCs T14 and 15(a)). The counsellor described that she has been supported in her clinical professional development by the centre and participates in monthly independent clinical supervision sessions (SLC T15).

Quality indicators have been established which are monitored to assess performance and user satisfaction with the counselling service, and a counselling specific evaluation survey is sent out to previous service users biennially. The results of this survey are then evaluated and feed into the overall centre quality appraisal (SLC (T35). A comprehensive counselling service audit was completed in November 2010, the results of which were documented and tabled for discussion and action at the next multi-disciplinary team meeting. (SLC T36). The counsellor is able to refer individuals or couples for more specialist counselling, if required, including that for oncology or therapeutic counselling.

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
The centre recruits sperm donors and offers treatment with donor sperm usually sourced from their own donor bank but in some cases transferred in from other HFEA licensed centres.

There is a SOP in place to direct the processes for the selection and recruitment of sperm donors (SLC T33(b)). The centre has set a quality indicator for donor recruitment and election (SLC T35) and last concluded an audit of donor selection, screening, consent and documentation processes in September 2011. The audit results, corrective actions required and their implementation were seen to have been documented (SLC T36). Since September 2010 the centre has employed a system whereby all donor records, screening and consents are checked and 'signed off' by the Consultant Andrologist prior to release of the samples for use in treatment.

From discussions with staff, a review of documentation and audit of three donor records conducted on inspection, it was demonstrated that donors are selected on the basis of their age, health and medical history and a personal interview performed by an appropriately trained healthcare professional (SLC T52). All donors are screened in accordance with SLC T52 and current professional body guidelines by a CPA accredited laboratory and donated sperm is quarantined in accordance with SLC T53(c). Measures are in place to identify when additional screening may be required (SLC T52(g) and (h)).

Staff provided documented evidence of training and the assessment of their competence to conduct donor selection, assessment and screening (SLCs T12 and T15 (a)).

Staff were able to confirm that all donor treatment is provided with gametes from donors who are identifiable (SLC T54) . Staff reported that all reserves of previously anonymous donor sperm held solely for sibling use have either been used in treatment or that the donors have agreed to re-register with the HFEA as identifiable.

Staff were able to demonstrate from donor records that if requested, they are able to provide donors with information about the number of infants born as a result of their donation, the sex of any child born and the year in which they were born. (HF&E Act 1990 (as amended), Section 31ZD(3)).

Payment of donors.
Records seen on inspection demonstrated that financial reimbursements made to donors for expenses incurred in the UK and any loss of earnings claimed, are within the limits prescribed in General Direction 0001. The centre has mechanisms in place to manage donor reimbursement under the revised terms effective from 1 April 2012.

Donor assisted conception.
Patients treated with donated gametes are informed of the importance of telling any resulting child of their donor origins at an early age and are advised on how best to do this (SLC T63(b)).

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)

What the centre does well.

Quality management system
The centre has a quality management system in place (SLC T32) for which there is a manual: training and reference manuals were also seen to be available (SLC T33).

There are documented SOPs in place for all activities conducted in the centre (SLC T33(b)). Where relevant, SOPs seen included specification for critical materials and reagents used in those procedures (SLC T31).
Quality objectives and indicators have been established relating to a number of licensed and other activities conducted in the course of providing treatment (SLC T35). The centre has within the last two years, audited their licenced activities and a number of other

activities conducted in the course of providing treatment (SLC T36). The centre has recently secured Trust approval to appoint a part time quality manager who is progressively updating the centre's schedule of audit and the establishment of quality indicators relative to activities that require audit. The quality manager has now begun to address the shortfall in the number of required audits to be conducted and has, amongst other initiatives, established a non – conformities log. This is reviewed monthly and is discussed at the team meeting with the actions and outcomes recorded, as seen in the meeting notes reviewed on inspection.

A full review of the quality management system and resources was last conducted in September 2011 demonstrating that systems are in place to ensure continuous and systemic improvement (CoP Guidance 23.13).

Traceability
Centre staff were able to demonstrate that all gametes are traceable from procurement to patient treatment or disposal and vice versa and that there are procedures in place to ensure that media used in the preparation of sperm for treatment and/or storage is traceable (SLC T99). There is an SOP in place to direct procedures for traceability (SLC T33(b)). Practice observed on inspection demonstrated that all containers (pots, dishes, vials etc) used in the procurement, processing, use and storage of gametes were seen to be identifiable being labelled with the patient/partner name and a unique code (SLC T101),

There are procedures and processes in place to ensure that the data collected to enable traceability, some of which is securely held off site, is stored for 30 years (SLC T103).

Validation
Critical procurement and processing procedures and all equipment used in these processes have been validated; these validation documents were seen on inspection (SLC T24 and T72). Staff stated that no repairs to critical equipment have been required since last inspection and therefore revalidation has not been necessary (SLC T25).

Equipment and materials
Instruction manuals and documented procedures for the operation of critical equipment which include actions to be taken in the event of failure are available to staff (SLC T27). Each key piece of equipment used in the processing of gametes intended for human application is traceable (SLCT22).

Equipment or materials which affect critical processing or storage parameters were seen to be appropriately alarmed and monitored, with the exception of the example described below (SLC T24). All are calibrated against traceable standards (SLC T24).

Records of regular cleaning and the decontamination of equipment were seen to be recorded in a laboratory database detailing quality management audits of housekeeping, temperature logs, and dry shipper checks (SLC T26). The centre uses CE marked medical devices (SLC T30) and only commercially produced disposable sterile instruments and devices are used for procurement and processing of gametes (SLC T28).

Premises – suitability of the premises and air quality
A tour of the centre confirmed that the centre's premises are suitable for the licensed activities and that all activities to which the centre's licence applies are conducted in the

licensed premises (SLC T1). Evidence was provided that the processing of gametes takes place in an environment of appropriate air quality (SLC T20) and that air quality is regularly monitored. The regular cleaning and disinfection of the premises is the responsibility of the hospital housekeeping team; records of this are kept (SLC T26).

Adverse incidents
There is a SOP in place to direct the reporting of adverse incidents or near miss events to the HFEA. Staff were able to describe the process to be followed for reporting and the investigation of an incident or untoward event. They demonstrated a good understanding of the nature of events or incidents that should be reported to the HFEA (SLC T118). An audit of incidents reported to the HFEA since the last inspection against the centre's own incident reporting records demonstrated no non-compliances. All incidents were seen to have been appropriately investigated and follow up actions documented and implemented.

Third party agreements
The centre has written agreements with all third parties who provide goods or services that influence the quality and safety of gametes (SLC T111). Evidence was seen that confirmed that the centre has evaluated the ability of third parties to meet the required standards (SLC T112) and that the content of the agreements is compliant with SLC T113 and T114 where applicable. A list of all third party agreements is maintained by the centre (SLC T115). Five third party agreements were audited on inspection and all were considered to be compliant with CoP requirements. No non-conformities were noted. A third party agreement is in place with a neighbouring hospital for the surgical procurement of gametes; this was reviewed on inspection and seen to be compliant with SLC T117 and T116.

What the centre could do better.

Traceability
The process in place for ensuring the traceability of media and consumables used in sperm preparation, treatment and storage records when a new batch of media or consumables are received but not the date on which the batch was first used (SLC T99 and T100f)

Quality indicators for traceability procedures have not been established (SLC T35).

The traceability of consumables used in the sperm preparation process has not been audited within the last two years (SLC T36).

Equipment
Not all equipment that affects the critical processing or storage parameters of patient and donor gametes is subject to the monitoring, alerts and alarms required by SLC T24. Four cryostorage dewars are not linked to the cryostore continual monitoring and alarm system. The Consultant Andrologist responsible for the cryostore stated that the Trust's medical physics department could no longer support the maintenance or replacement of parts for the existing monitoring system, as it was now considered obsolete and would need significant renovation to meet current medical devices regulations. He also stated that a comprehensive risk assessment for the failure of an unalarmed storage dewar has been prepared and provided to the Trust Risk Management Board. In an attempt to reduce the risk, oncology patient's gametes are not stored in unalarmed dewars and they are used

only for the storage of donated gametes. The Consultant Andrologist also stated that the cryostore was approaching capacity and without a fully workable monitoring system being in place, he could not guarantee that this risk control measure could be maintained; it was possible therefore that gametes stored for a patient couple's own use, would have to be stored in unalarmed dewars in the near future. A proposal for capital funding to purchase a monitoring and alarm system, which is compliant with medical devices regulations and has the capacity to meet the needs of the centre, was submitted to the Trust some time ago and is currently awaiting consideration. The Consultant Andrologist expressed that he was concerned that consideration of this application was being delayed as the centre has been given notice by the Trust that it will have to vacate its current site within the next year, due to the redevelopment of an adjoining department. The Trust has yet to confirm the location of the new premises.

Multiple Births (Guidance Note 7)

The centre does not create embryos and therefore does not require a multiple birth minimisation strategy.

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 more than two years of practical experience which is directly relevant to the activity to be authorised by the licence.

Mr Hopkisson is registered by the General Medical Council (GMC) and has been on the GMC specialist register for obstetrics and gynaecology and reproductive medicine since 2002. From the discussion and documented evidence provided it is concluded that the PR has carried out his duties by ensuring compliance with SLC T9.

The PR successfully completed the HFEA Person Responsible Entry Programme in 2007.

The PR is satisfied that staff employed at the centre are suitably trained and experienced to fulfil their assigned tasks. Nursing staff are registered with the Nursing and Midwifery Council (NMC) and the Consultant Andrologist is registered with the Health Professionals Council (HPC). Induction, training and competence assessment files were seen for the newest member of the nursing team and for members of the laboratory team (SLC T15).

A workforce review was last conducted in September 2011 and was available to see on inspection.

What the centre could do better.

The centre is currently running with less than full staff complement in the nursing team. (SLC T12)

From discussions with the PR and staff on inspection, there have been significant delays to the appointment of staff into a number of key roles (e.g. to cover maternity leave for a senior nurse and other staff changes including the quality manager and the counsellor) due to constraints imposed by the Trust. This was also an issue at the last inspection and was then addressed by the appointment of additional staff. Subsequent staff changes, maternity leave and Trust constraints on recruitment have however again resulted in the centre operating with less than its full staff complement. As a result, the PR has at times suspended treatment or restricted the number of treatment cycles performed to allow staff to take leave, however the senior nurse is still owed a considerable amount of time off. The Trust has agreed the appointment of a more junior nurse who is currently training in all aspects of the centre's treatment activities. The return to part time work of a second experienced fertility nurse is also anticipated within the next three months.

Counsellor
At the time of inspection, the Trust had not yet approved or agreed the time scale for the recruitment of a counsellor following the retirement of the present post holder or provided an alternative model for maintaining the counselling service.

Welfare of the Child (Guidance Note 8)

What the centre does well.

Documented evidence was available to show that patients are not provided with treatment until account has been taken of the welfare of any child who may be born as a result and of any other child who may be affected by the birth (SLC T56).

An audit of five patient records showed that both patient and partner had completed welfare of the child assessment questionnaires and that the forms had been reviewed by a member of the nursing team prior to treatment. Staff described that any indication of further information being required to inform the assessment would be documented and concerns discussed within the multidisciplinary team. There is an SOP in place to guide the assessment process (SLC T33(b)).

What the centre could do better.
Quality indicators relevant to welfare of the child assessments have not been established, nor have welfare of the child assessment practices been audited against approved protocols, regulatory requirements and quality indicators within the last two years (SLC T35 and T36).

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) – *n/a*

What the centre does well.

Treating patients fairly
From the information provided, observations made and discussion with staff, the inspection team were assured that all licensed activities are conducted in a non-discriminatory manner with proper respect for the privacy, confidentiality, dignity, comfort and well-being of all prospective and current patients and their partners and that information is kept confidential and only disclosed in circumstances permitted by law (SLC T43).

Confidentiality and privacy
Access to confidential records and the areas where confidential information may be seen, obtained or stored was demonstrated to be restricted to licensed centre personnel authorised by the PR (SLC T45).

SOPs direct how the confidentiality of patients, partners and donors is maintained and incorporate measures to ensure no unauthorised disclosure of information is possible (SLC T44(c)). There is also an SOP governing access to patient / donor records which includes measures for considering and responding to requests for access to confidential records (SLC T44 (b,c,d,e)).

Complaints
The centre's complaints log was reviewed on inspection, the last complaint having been received in 2009.

Staff at the centre actively seek patient feedback through monitoring of patient satisfaction questionnaires. All patients are offered a questionnaire and the results are collated and discussed for action at team meetings. The HFEA patient questionnaire showed high levels of satisfaction with the service.

Provision of costed treatment plans
The centre provides treatment to NHS patients only and consequently there is no cost to the patients

What the centre could do better.

Complaints
It was noted on inspection that information for patients and donors on how to make a complaint referred the individual to the Trust Patient Liaison Service directly and not to a nominated member of the centre team. Dependant on the patient's treatment type or if a donor, this could represent a potential breach of the individual's confidentiality in that persons not authorised under the centre's licence may have access to identifying personal or treatment information.

Information

- Information to be provided prior to consent (Guidance Note 4)
- Information about legal parenthood (Guidance Note 6)

What the centre does well.

From discussions with staff and patients, and from patient information literature reviewed, the inspectors consider that proper information is provided to patients giving consent to treatment and /or storage of their gametes, as required by the HFE Act 1990 (as amended), Section 13 (6).

Patient information literature was submitted prior to inspection and was found to provide information about the nature of the treatment, consequences and risks, and the requirements for consent (SLC T58).

There is an SOP in place to be followed when providing information to potential donors prior to taking consent to donation (SLC T33(b)). A review of three donor records showed that a list describing the information given is signed by the donor to confirm they have been given and understood this information. This list is retained in the donor notes. Only the Consultant Andrologist conducts donor interviews and provides information to prospective donors prior to consent being sought.

The centre has a quality indicator that 100% of patients and donors receive appropriate information as determined in audited practice and records reviewed (SLC T35).

The centre provides treatment with donor gametes to women and couples who may or may not be married or in a civil partnership. Those affected by legal parenthood legislation are informed of how the nomination of a second legal parent affects them and of the consent process prior to treatment being offered (SLC T60).

What the centre could do better.

There is currently no documented procedure to be followed when providing information to patients prior to them being asked to consent to treatment (SLC T33(b)).

The centre has not audited how far the provision of information to patients or donors complies with approved protocols or regulatory requirements within the last two years (SLC T36)

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.

Consent to treatment, storage, donation, training and disclosure of information.
An audit of five patient / donor records conducted on inspection confirmed that written consent is obtained prior to the patient / couple's gametes being used in treatment, storage or donation. Where applicable, consent to disclosure of information was also seen to be present. There is a SOP in place to direct the consent process which appeared to be clear and comprehensive (SLC T33(b)).

Documented evidence of the assessment of competence for a staff member to seek valid consent was seen (SLC T15(a)).

The quality indicator that 100% of records audited contain all required consent documentation, appropriately completed, has been agreed by the centre (SLC T35). The most recent audit of consent for donors was conducted in September 2011 and was available to see on inspection. There where no non-conformities noted (SLC T36).

Consent to legal parenthood.
The senior nurse described that the legal parenthood information giving and consent process is managed within the nursing team and the consent SOP guides this (SLC T33(b)). The senior nurse was also able to confirm that there are procedures in place to ensure no treatment would be provided to a woman where the nominated second parent has withdrawn their consent to legal parenthood until the woman being treated is informed of this and also where the woman being treated withdraws or varies her consent to the nominated second parent until that person is informed of the change (SLCs T64 and T65)

What the centre could do better.

Consent to treatment, storage, donation, training and disclosure of information.
Patient consent procedures and documentation have not been audited for compliance with approved protocols, regulatory requirement and quality indicators in the last two years (SLC T36).

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
- 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.

A tour of the centre confirmed that the centre's premises are suitable for the licence activities and that all activities to which the centre's licence applies are conducted on the licensed premises (SLC T1).

No money or other benefit is given or received in respect of the supply of gametes unless authorised by the Authority.

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.

There is a SOP to direct the procedure for storing gametes which was reviewed on inspection and appeared to be comprehensive (SLC T33(b)). Storage procedures have been validated (SLC T72). The centre audits their storage procedures annually and the last audit was conducted in October 2011; no non-conformities were recorded in the report seen (SLC T36). The centre operates a 'bring forward' system to provide staff and gamete providers with sufficient notice of the end of the consented or statutory storage period of gametes held (CoP Guidance 17.18). All material currently stored at the centre was demonstrated to be stored with the valid consent of the gamete provider and to be within the statutory storage period (HF&E Act 1990 (as amended), Section 14(1)(c)). Confirmation was provided that all gamete providers had been subjected to appropriate screening tests prior to storage (SLC T50).

Staff were able to provide documented evidence of the assessment of their competence in storing and handling cryopreserved gametes (SLC T15(a)).

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.

A SOP (SOP 019) is in place which details the circumstances, responsibilities and procedures for the release of stored material before distribution including the labelling and documentation requirements to meet SLC T107 (SLC T33(b)).

From observation and documentation seen, it was confirmed that the centre ensures that gametes are packed and transported in a manner that is secure, minimises the risk of contamination of the gametes and persons transporting them and preserves their biological function (SLC T105 and T108).

Transport and shipping vessels used by the centre to distribute gametes to other licenced centres are provided by the recipient centres, which will be responsible for validating them (SLC T108).

Centre staff were able to demonstrate that there is a documented procedure to ensure and record that the requirements of General Directions 0005 (Collecting and recording information for the HFEA) and 0006 (Import and export of gametes and embryos) has been met (SLC T33b). The centre has not imported any gametes since the last inspection and has exported one patient's own gametes under Special Directions.

What the centre could do better.

SOP 019 does not specify the transport conditions required to ensure the safety of gametes in transit, including the temperature and time limits for transport (SLC T107).

The centre does not have a specific procedure that defines the responsibilities and actions required when a gamete distribution is recalled, for handling returned gametes or for the investigation of any recall as an adverse incident (CoP interpretation of mandatory requirements 15C; SLC T122).

Use of embryos for training staff (Guidance Note 22)

This centre does not use, store or create embryos.

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.

All patient/partner and donor records seen at the time of inspection were seen to be clear, legible and well organised. Each record was seen to include: patient/donor first name, surname, date of birth, age, sex, details of how the patient/donor had been identified (passport/driving licence), the treatment provided; a medical history; welfare of the child assessment; relevant documented consents and clinical and laboratory data and the results of tests carried out (SLC T46). Procedures are in place to ensure records are protected from unauthorised amendment; are retained and can be retrieved from in house storage or approved off site archives throughout the designated retention period (SLC T47).

Documents submitted to the HFEA as part of the renewal application and viewed on inspection were seen to be controlled, recording the history of document reviews and systems are in place to ensure that only the current version is in use and accessible to staff (SLC T34).

What the centre could do better.

Nothing noted.

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 required by the application process prior to inspection. All members of staff cooperated fully with the inspection team and all further information requested was provided in a timely manner.

The PR has responded to the recommendations of previous inspections. There is one recurring issue which required review at this inspection.

Evidence provided demonstrates that the centre has documented procedures for data submission to the HFEA (SLC T33b). Staff competence in the submission of data has been assessed (SLCT15(a)).
What the centre could do better. The centre has not established quality indicators for the submission of data to the HFEA (SLC T35) or audited how far procedures for the submission of data to the HFEA comply with approved protocols, regulatory requirements and quality indicators (SLC T36).

Disclosure of information • Disclosure of information, held on the HFEA Register, for use in research
What the centre does well. **Disclosure of information held on the HFEA Register for use in research.** This centre provides partner IUI and donor treatment only therefore consent to disclosure of information considerations does not apply.
What the centre could do better. Nothing noted.

5. Changes / improvements since the previous inspection on 2 December 2009

Area for improvement	Action required	Action taken as evidenced during this inspection
Staffing SLC T12	The PR should monitor the centre's activity to ensure appropriate staff are in place to accommodate the current and anticipated workload. Consideration should be given to the realisation of anticipated appointments and especially at the point at which the practice of the specialist fertility nurses begins to extend to encompass ultrasonography. The PR should monitor the professional accountability lines for nursing staff now in place to ensure that appropriate job evaluation, performance appraisal and appropriate clinical professional development is planned and undertaken.	**Further action required** Staffing issues were addressed and additional recruitment was arranged, however due to changes in the workforce due to resignation, sickness and maternity leave, the centre has struggled to maintain acceptable senior nursing staff levels and has reduced patient numbers to try to manage this.
Premises and facilities The cryostore flooring was cracked and uneven which represents a significant risk to staff safety from trips and in the movement of cyro preservation dewars.	Repairs or replacement of the flooring in this area should be addressed as a matter of some urgency to ensure compliance with Health and Safety requirement and to ensure the safety of gametes in store.	No further action required. This was raised as a risk with the Trust and application was made for repair which was approved and has been undertaken.
Quality indicators The centre has not established quality indicators relevant to: Information provided prior to consent and consent procedures. SLC T35	Quality indicators should be established and agreed by the centre and incorporated into the audit schedule.	No further action required. The centre has established quality indicators relevant to the provision of information.

Area for improvement	Action required	Action taken as evidenced during this inspection
Counselling The centre has not established quality indicators or objectives relevant to the provision of counselling. SLC T35	The centre should establish quality indicators relevant the provision of counselling.	No further action required. Quality indicators have been established.
Equipment The centre cannot provide documented evidence of regular cleaning and the decontamination of equipment. SLC T26.	The centre should maintain a record of when routine (or exceptional) cleaning and decontamination of equipment takes place.	No further action required. Current and historical logs of regular cleaning and decontamination of equipment were seen on inspection.

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
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
Equipment – alarms and monitoring Four cryostorage dewars containing approximately 300 stored samples are not subject to the required alarms and monitoring of the critical storage parameters to alert staff to a malfunction and a possible threat to the viability of the samples. SLC T23 and T24.	The PR must ensure that the equipment used to store gametes is subject to appropriate monitoring and alarms to ensure the safety of the gametes. The PR is to report the progress of the centre's application to the Trust for the capital to purchase the necessary monitoring equipment to the centre's inspector by 24 April 2012 and thereafter provide a timeline plan for the installation of the required monitoring system. The centre should be able to provide evidence that the system is installed and	This has been an on-going issue that is still going through the Directorate Management Team. The issue will be discussed on Thursday 26th April and funding hopefully will be agreed. I will inform the HFEA of the outcome of the Trusts deliberations. The Fertility Unit team have been pressing for some time (over one year) to get this addressed. We have put in place safety	The PR has provided confirmation that the purchase and installation of an appropriate alarm system is now in progress and will inform the centre's inspector when this is in place. No further action required.

	running by 24 July 2012. Any deviation from the anticipated route of purchase and installation of this equipment by this date should be communicated to the centre's inspector without delay whereby this information by be presented to an ELP of the HFEA for further consideration.	measures to minimise risk as best we can. The Trust have been warned that if the alarms are not replaced the storage of gametes will need to cease and that they are transferred to another centre for storage. Meeting today 26th April received from Trust commitment to fund new alarms a detailed time line will be forwarded asap	
Staffing Due to changes to the workforce due to resignation, sickness, maternity leave and constraints imposed on recruitment, the centre has struggled to maintain acceptable senior nursing staff levels and has reduced patient numbers to try to manage this. Despite this certain key staff areas have been depleted and the on-going provision of treatment is often only possible	The PR should monitor the centre's activity to ensure appropriate staff are in place to accommodate the current and anticipated workload. If the anticipated restoration of acceptable staff levels with the return of key staff does not happen, activity levels must be managed to ensure that there is sufficient staff available to conduct treatment and staff are able to take allocated rest days and scheduled leave.	A third nurse has now been appointed. The nurse previously covering maternity leave has taken up the post. With the return of our senior nurse from maternity we have been able to work to competencies. I am happy that at present we are adequately staffed for the workload, this has allowed our senior nurse to take leave.	The centre's inspector is satisfied that workforce issues are being addressed. Staffing resources relative to the activity of the centre will be reviewed as part of the on-going monitoring process.

due to the good will of the senior nurse as described in the staff section of this report. SLC T12	The PR is to update the centre's inspector as to staffing and activity levels, including and significant sickness or absence that affects the centre's ability to provide the number of treatments planned by 23 May 2012 and quarterly thereafter if staffing problems persist.	A meeting is planned for the 26th of May to address leave, staffing and workload with the Directorate Management team. Reports on workload and assessment of quality are being worked on.	
Traceability Consumables batch records held by the centre currently record when a new batch is received but not the date from which that batch is used in patient treatment which may prevent the full traceability of that product's use. SLC T99	The PR should ensure that all relevant data about anything coming into contact with gametes is traceable. Actions to be completed by 23 May 2012	SOPs have been written for traceability and an audit will be carried out as part of the QMS.	No further action required.
Transport conditions for gametes The centre's SOP 019 which details the responsibilities and procedures for the release of stored material before distribution does not specify	SOP 019 should be reviewed to ensure that the transport conditions and time limits for the safe transport of gametes is specified. Actions to be completed by 23	Gametes are not transported by the unit. We will write into our third party agreements that centres providing transport dewars and couriers have an SOP in place for monitoring temperature on receipt of the	This is now in place. No further action is required.

the transport conditions required to ensure the safety of gametes in transit, including temperature and time limits for transport. SLC T107.	May 2012	gametes.	

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
Quality management system The centre has not established quality indicators for the following areas of practice: • Welfare of the child • Traceability • Data submission to the HFEA SLC T35 The centre has not audited the following areas of practice within the last two years: • Welfare of the child • Traceability • Information given to patients consenting to treatment • Consent procedures • Data submission to the HFEA	The PR should ensure that the quality indicators are established for these areas of practice. Actions to be completed by 23 May 2012 The PR should ensure that the areas of practice described are audited. Actions to be completed by 23 August 2012	New SOPs have been written for WOC/tracebility and an audit will be carried out as part of the QMS We are looking at a way of assessing quality in terms of data submission to the HFEA. Audits will be drawn up and a report sent by the required time. With our new quality manager we will establish an ongoing audit programme that will cover areas that we are deficient in.	The PR has provided a copy of the SOPs required. Progress with audits will be reviewed as part of the on-going monitoring process. No further action required.

SLC T36 The centre does not have a SOP in place for: • Provision of information to patients giving consent to treatment SLC T33(b)	A SOP for the provision of information to those giving consent to treatment should be documented and the content of that SOP communicated to staff who provide information to patients giving consent to treatment. Action to be completed by 23 May 2012	An SOP has been written that has links to the COP and will be placed into the QMS, with an Audit plan and a quality indicator.	
Recall of transported gametes The centre does not have a documented mechanism in place to manage the recall of gametes distributed, the receipt of recalled gametes and the investigation of any gamete recall as an adverse incident. CoP mandatory requirements 15B and 15C	The PR should ensure that a mechanism is established to manage the recall of gametes and subsequent actions in the event that this is required. Once agreed, this procedure must be communicated to all staff involved in the distribution of gametes. Action to be completed by 23 May 2012	I have discussed this with Dr Tomlinson and we will be writing an SOP to cover this eventuality.	This is now in place. No further action required.
Confidentiality The centre's complaints policy	The PR should there is a nominated person to whom complaints should be directed	Complaints procedure has been amended, so that additional information is given	No further action required.

and patient / donor information on how to make a complaint directs the complainant to the Trust patient liaison service (PALS) which is not part of centre licence. Dependant of the treatment type of the individual making the complaint, the information communicated to the PALS may constitute the disclosure of information protected by section 33 of the HFE Act. SLC T43	within the centre and review the patient information offered and the mechanism for individual service users is clear and does not present the potential for the accidental disclosure of treatment or donor information to persons not covered by the centre's HFEA licence. Actions to be completed by 23 May 2012	to patients to make them aware of the Trust complaints policy and also the Units HFEA complaints policy.	

Additional information from the Person Responsible
I am sorry that the reply is a bit late. We had a meeting scheduled with the Directorate Management Team last Thursday but Matt was unable to attend due to a traffic incident. This was reconvened this week and I am pleased to say the DMT gave the go ahead for getting the alarms sorted. Matt has been in touch with the chosen supplier and has asked for a time line for installation which will be forwarded to you as soon as possible. I have put together the SOPs required for the QMS and we will be establishing an audit programme to look at the areas we are weak in. Attached is the reply part of the report. We are committed to putting in place changes that will benefit the nurses and help with patient care. Thank you for your help and for sending the notebook, it will be very useful in planning our audits and making sure we are squeaky clean at our next inspection and will help further develop the QMS.

HFEA Executive Licensing Panel Meeting

15 June 2012

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

Minutes – Item 3

Centre 0162 – (Queens Medical Centre Fertility Unit) – Renewal Inspection Report

Members of the Panel:	Committee Secretary:
Juliet Tizzard, Head of Policy & Communications (Chair) Rachel Hopkins, Head of Human Resources Hannah Darby, Senior Policy Manager	Joanne McAlpine

Declarations of Interest: members of the Panel declared that they had no conflicts of interest in relation to this item.

The Panel also had before it:

- HFEA Protocol for the Conduct of Meetings of Executive Licensing Panel
- 8th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- Decision trees for granting and renewing licences and considering requests to vary a licence (including the PGD decision tree)
- Guidance for members of Authority and Committees on the handling of conflicts of interest approved by the Authority on 21 January 2009.
- Guidance on periods for which new or renewed licences should be granted
- Standing Orders and Instrument of Delegation
- Indicative Sanctions Guidance
- HFEA Direction 0008 (where relevant), and any other relevant Directions issued by the Authority
- Guide to Licensing
- Compliance and Enforcement Policy
- Policy on Publication of Authority and Committee Papers

Consideration of Application

1. The Panel noted that this centre was first established in 1992 and provides a service for the diagnosis and treatment of sub-fertility and insemination with partner or donor sperm.

2. The Panel noted that between 1 July 2010 and 31 June 2011 the centre carried out 252 cycles of partner insemination, resulting in 39 pregnancies, three of which were twin and one triplet pregnancy. The Panel noted that this equates to a 15% pregnancy rate which is consistent with the national average across all age ranges treated.

3. The Panel noted that there has been no substantial change to the centre since the last inspection on 2 December 2010, although the sperm production room was undergoing refurbishment at the time of the inspection.

4. The Panel noted that the Person Responsible (PR) informed the HFEA that he has been given notice that the Trust intends to reconfigure the footprint of the neonatal unit which sits alongside the centre and therefore the centre will need to move premises within the next year.

5. The Panel noted that at the time of the inspection the Inspectorate identified four major areas of non-compliance and three other areas of practice that required improvement.

6. The Panel noted that since the inspection the PR has provided evidence that some of these areas of non-compliance have been implemented and has given a commitment that the other areas will be implemented within the appropriate timescales highlighted in the report.

7. The Panel endorsed the Inspectorate's recommendations and timescales, noting in particular the non-compliance relating to staffing, which was also identified on the previous inspection. The Panel encouraged the PR to ensure that this recommendation is implemented, along with the alarm monitoring of key equipment, as promptly as possible.

8. The Panel noted that the Inspectorate recommended the renewal of the centre's licence for a period of four years with no additional conditions, subject to compliance with the recommendations made in the report being implemented within the prescribed timeframes.

Decision

9. The Panel had regard to its decision tree. It was satisfied that the appropriate application and fee had been submitted and that the application contained the supporting information required by General Directions 0008.

10. The Panel was satisfied that the qualifications and character of the PR are such as is required for the supervision of the licensed activities and that the PR will discharge the duties under section 17 of the Act.

11. The Panel was satisfied that the licence renewal application concerns treatment or non-medical fertility services which relate to gametes intended for human application.

12. The Panel was satisfied that the premises to be licensed were suitable for the conduct of licensed activities based on the evidence provided within the report.

13. The Panel noted that the application does not involve the use of embryos for training purposes.

14. The Panel had regard to 'Guidance on periods for which new or renewed licences can be granted'. The Panel took into account matters set out in paragraph 4.3 and noted paragraph 4.4 of the guidance which states that the Executive Licensing Panel will normally grant a renewal licence for treatment/storage/non-medical fertility services licences for a period of up to four years where the evidence before it reveals no concerns in the matters specified in paragraph 4.3.

15. The Panel endorsed the recommendations made by the Inspectorate within the report. The Panel agreed to renew the centre's licence for a period of four years with no additional conditions, and encouraged the PR to implement the recommendations made in the report within the prescribed timescales, with staffing and the monitoring of alarms and key equipment being the priority.

Signed: Tizzard. Date: 25 June 2012

Juliet Tizzard (Chair)