Inspection Report

Date of Inspection: 22-23 February 2012
Purpose of inspection: Renewal of Treatment and Storage Licence
Length of inspection: 16 hours over two days
Inspectors: Wil Lenton (Lead); Andy Leonard; Paula Nolan; Cathy Hodgson (HFEA Audit); Siobhain Kelly (HFEA Audit).

Inspection details:
The report covers the pre-inspection analysis, the visit and information received from the centre between 20 January 2010 and 18 May 2012.

Date of Executive Licensing Panel (ELP): 1 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 Human Fertilisation and Embryology (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 ELP which makes the decision about the centre's licence renewal application.

Centre details

Centre name	St Mary's Hospital
Centre number	0067
Licence number	L0067/16/c
Centre address	The Department of Reproductive Medicine, Regional IVF and DI Unit, Whitworth Park, Manchester, M13 0JH, UK
Person Responsible	Dr Edmond Edi-Osagie
Licence Holder	Mr M Deegan
Date licence issued	21 September 2010
Licence expiry date	31 July 2012
Additional conditions applied to this licence	None

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Brief description of the centre and its licensing history:

St Mary's Hospital Manchester has been licensed by the HFEA since 1992. In the year ending 31 December 2011 the centre provided over 1500 licensed treatment cycles to NHS patients from Greater Manchester and surrounding areas. In order to promote elective single embryo transfer (eSET) the centre does not perform any three embryo transfers.

The present Person Responsible (PR) has been in post since September 2010 and is appropriately in compliance with the requirements of the Act. He has successfully completed the PR entry programme (certificate T/ 1169/8) and is familiar with all aspects of the service provided.

A NHS Trust Service Line Reporting review process took place during 2011, which assessed all aspects of the unit's service provision, funding, staffing and structure. Following this process, the unit was re-structured in order to be able to have enough suitably trained staff to safely deliver a maximum of 920 treatment cycles per year.

There have been no changes to the premises or facilities since the previous inspection on 20 January 2010.

Activities of the Centre:

Type of treatment	Treatment cycles 1 Jan - 31 Dec 2011*
In vitro fertilisation (IVF)	407
Intracytoplasmic sperm injection (ICSI)	620
Gamete intrafallopian transfer (GIFT)	0
Frozen embryo transfer (FET)	462
Donor insemination (DI)	43
Partner insemination**	46
Egg share provider (sharer)	0
Egg share recipient	0
Egg donation (non-egg share)	17

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

** Partner insemination data is for period 1 January to 31 December 2010

Outcomes*

For IVF/ICSI, HFEA held register data for the period 1 October 2010 to 30 September 2011 show the centre's clinical pregnancy rates are in line with national averages with the following exceptions:

- In women aged between 16-37 years undergoing IVF using their own eggs, the clinical pregnancy rate is lower than the national average at 21%.
- In women aged between 16-37 years undergoing ICSI using their own eggs, the clinical pregnancy rate is lower than the national average at 23%.

For the year 2010 the centre reported;

- 28 cycles of stimulated partner insemination with 3 pregnancies, which equates to a pregnancy rate of 11%.

- 21 cycles of un-stimulated partner insemination with 4 pregnancies, which equates to a pregnancy rate of 19%.

This is in line with national averages.

The PR provided information during the inspection concerning the implementation of a, 'live birth improvement strategy', which has been put into action in order to help improve the abovementioned IVF and ICSI clinical pregnancy rates, but it must be noted that the relatively poor clinical pregnancy rates for both IVF and ICSI have been a cause for concern since 2007.

The persistence of poor success rates may be indicative that a PR has failed to ensure that suitable practices are employed by a centre. Failure of a PR to ensure the use of suitable practices is a breach of S.17 (1d) of the Act and the Authority may revoke a licence where it is satisfied that a person responsible has failed to discharge their duty under section 17.

It is acknowledged that the present PR is recently appointed and has provided a commitment to the implementation of a programme of improvement. It is considered appropriate and proportionate however, that outcomes are monitored closely over the next twelve months, in order that improvements are documented. Should there be no evidence of improvement within this time-frame, this issue will need to be referred back to the ELP for further consideration (HF&E Act 17(1)(d)).

*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, except for the issues noted below, generally discharged their duty under Section 17 of the HF&E Act 1990 (as amended)
- the premises are suitable
- the practices are generally suitable, except for the issue mentioned below.
- 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 (ELP) is asked to note that at the time of the inspection there were a number of areas of practice that required improvement, including one critical area of non-compliance, six major areas of non-compliance and four other areas of non-compliance or areas of poor practice.

Since the inspection visit the PR has provided evidence that the following recommendations have been fully implemented;

Major areas of non compliance:

- Measures have been implemented to ensure that data is submitted to the Authority in an accurate and timely manner.
- All critical points in the laboratory process are now being double-witnessed.
- All equipment which comes into contact with licensed material is now appropriately documented for traceability purposes.
- A TPA for environmental monitoring is in place

Other areas of practice that require improvement:

- HTLV-1 screening is now in place for all gamete donors
- The reason(s) for double embryo transfers (DET) in elective single embryo transfer (eSET) eligible patients and the associated risks of multiple pregnancy are now being consistently recorded in patient records.
- The centre website and patient information has been reviewed and updated to include up-to-date centre-specific treatment outcome data
- Outstanding SOPs have been formulated and others reviewed as required. A timelime for the development of outstanding QI has been developed.

In his response to the draft report the PR has given a commitment to the following:

Critical areas of concern:

- **The PR should ensure that the laboratory and clinical practices are suitable to provide a good quality service to patients. This has been an issue for a number of years and the centre must make progress in this aspect of their quality of service.**

Major areas of non compliance:

- The PR should ensure that all critical equipment is validated.
- The PR should ensure that all critical processes are validated.

Recommendation to the ELP:

The inspection team acknowledge that the new PR and centre staff have undertaken a considerable amount of work since the last inspection, in an attempt to improve the systems and processes that underpin the clinical service and have more recently implemented a new live birth improvement strategy. The PR has also given a detailed response to the recommendations made in this report and made a full commitment to their implementation.

Nevertheless the inspection team are mindful that relatively poor clinical pregnancy rates for both IVF and ICSI persist and some of the issues required to be addressed at the previous inspection, such as, accurate and timely submission of data to the Authority and quality management system development, have still not been fully resolved.

The inspection team considers that, overall there is sufficient information available to recommend the renewal of this centre's licence for a period of three years without additional conditions, but also recommends on-going monitoring of issues such as patient outcomes, submission of data to the Authority and the validation of all outstanding critical equipment and processes over the next twelve months, with a view that an additional interim inspection be undertaken within the next twelve months to review progress made with the implementation of recommendations made within this report. Dependent on the findings of the interim inspection and the progress made by the centre in implementation of the recommendations made within this report, the Executive will then decide whether to refer any issues back to the ELP for further evaluation and/or regulatory actions.

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.

Witnessing

To ensure that patients receive treatment using the correct gametes or embryos, the centre double checks the identification of gametes and embryos against the patient or donor to whom they relate, at all critical points in the clinical and laboratory processes.

The centre has documented all the required witnessing checks, except for the one mentioned below, within standard operating procedures (SOPs) which describe the laboratory and clinical processes. These documents were last reviewed in January 2012 (SLC T33b). A review of four sets of patient notes indicated that witnessing was generally compliant with SLC T71, except for the issue noted below. The centre has a validated electronic witnessing system in place.

The centre undertakes an audit of witnessing practice at regular intervals. Generally ten sets of patient records are reviewed as part of each audit. The last audit took place on ninth January 2012 when fifteen records were reviewed. Any corrective actions are undertaken and the outcome of the audit and action points discussed at the next quality and governance or staff unit meeting (SLC T36).

Assessment and recording of staff competence when performing witnessing procedures is undertaken periodically (SLC T15a).

What the centre could do better.

Witnessing

Some witnessing steps are not being recorded as being double witnessed, for example the disposal of sperm samples (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
Justification for the use of gametes in treatment based on the patient's medical history and therapeutic indications was seen to be documented within the patient records reviewed during inspection (SLC T49).

Discussions with centre staff and review of results in patient records confirmed that laboratories undertaking patient investigative and diagnostic tests were accredited by the Clinical Pathology Accreditation UK limited (CPA).

Counselling
Through interviews with both the lead nurse and one of the counsellors it was established that access to counselling is offered to patients, which incorporates when required, both agreed fatherhood and agreed female parenthood (HF&E Act 1990 (as amended) Schedule 3, 3 (1) a and Schedule 3Z part 2). This was also seen to be part of the patient pathway checklist within patient records. Five sets of medical records were reviewed on the day of inspection and all found to have evidence that patients were offered access to counselling services (SLCs T60 and T61).

A counselling SOP is in place which meets regulatory requirements (SLC T33b).

Both counsellors at the centre hold recognised counselling qualifications, which include British Infertility Counselling Association (BICA) accreditation (AMBICA). Evidence of on-going training in the form of continued professional development (CPD) and clinical supervision. Periodic assessment of competence was reviewed and found to be compliant with current regulations (SLC T14 & T15).

Counselling practice is audited annually. The last audit, covering practice between 1 January and 31 December 2011, was seen to have been undertaken in January 2012 with any issues being discussed and action points identified. Patient support group surveys are also undertaken and assessed (SLC T36). Quality indicators (QI) have been established for counselling and were last evaluated during the above audit (SLC T35).

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 and review of donor records and documentation seen during the inspection, it was determined that the centre recruits, assesses and screens sperm donors in line with current regulations (SLC T52). The recruitment process is documented in a SOP (SLC T33b), is subjected to QI monitoring (SLC T35) and has been audited (SLC T36). Staff competence to recruit donors has been assessed as part of the clinical competency framework (SLC T15a).

The centre doesn't actively recruit egg donors, but does provide treatment to patients with a known egg donor. No payment is provided by the centre. The donor and the couple are assessed separately by the counsellor and clinical staff to ensure that there has been no coercion.

Screening tests are performed in a Clinical Pathology Accredited (CPA UK) laboratory (SLC T53a). Donated 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
Review of donor records and documentation seen during the inspection, and discussions with staff, enabled the inspection team to establish that payments to donors have been compliant with current regulations (SLC T69).

Donor assisted conception
Staff take time to talk through the importance of discussing the genetic background of any resulting offspring as soon as possible with those patients receiving treatment with donor gametes (SLC T63ab).

What the centre could do better.

Donor recruitment, assessment and screening
Extra laboratory screening for specific ethnic minorities is not documented in the SOP for donor recruitment and screening (SLC T33b).

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.

The centre follows good clinical practice**,** has suitable premises and equipment for the treatment services offered and maintains a quality management system (QMS) to continually improve the quality and effectiveness of the service it provides in accordance with good practice.

Quality management system
A new quality manager has been in post since April 2011. A quality manual, quality policy and quality objectives have been established (SLC T32). Except for the issues mentioned below most of the critical processes have documented SOPs in place (SLC T33b). Evidence was seen of audits undertaken during 2011-12 and also for those planned in 2012-13 (SLC T36). QI have been developed for most of the critical processes (SLC T35).

Each area of expertise such as clinical, laboratory and administration has its own quality lead who supports the quality manager to coordinate the QMS. The quality manager chairs weekly quality & governance meetings, which are structured, themed and minuted.

An annual QMS review process has been developed and a copy of the minutes from the latest meeting conducted during September 2011 was provided during the inspection (CoP G23.12 and 23.13).

Traceability - Guidance Note 19
The electronic witnessing system is utilised to record all laboratory consumables which come into contact with gametes and/or embryos, thus ensuring that all critical materials are traceable from procurement to use in treatment and/or disposal. Batch/lot numbers, expiry dates and dates when individual stock items are first used are entered into the system. As the equipment also records patient cycle details, traceability data relating to any particular patient's treatment cycle can be retrieved upon demand. A written manual batch/lot number log for all consumables remains in place whilst the electronic system is being developed (SLC T99). The procedure for recording the traceability of any item which comes into contact with patient gametes and/or embryos is embedded within different laboratory processes (SLC T33b). Traceability audits are undertaken as part of the general patient records audit; records were available for audits in June and October 2011 (ten sets of notes on each occasion) and more recently in January 2012, when fifteen sets of notes were reviewed (SLC T36). QIs have been developed for traceability and are measured as part of the audit schedule (SLC T35). Staff competence in traceability processes is assessed as part of staff training (SLC T15a). Procedures are in place to ensure that

traceability data is stored for 30 years (SLC T103).

Process validation
Critical procurement and processing procedures have been documented in SOPs (SLC T33b). QI have been developed relevant to procurement and processing which are reviewed at different time intervals (SLC T35). Documented audits of practice are in place and include any corrective actions required (SLC T36). Documented evidence of the periodic assessment of staff competence when performing these processes was in place (SLC T15a).

Equipment and materials
There was documented evidence that some critical equipment had been validated (SLC T24). All critical equipment is monitored as part of the facilities monitoring system (FMS); staff are alerted via alarms if equipment parameters breach specified control 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 is used wherever possible (SLC T30).

Premises – suitability of the premises and air quality
Activities authorised by the centre's licence are carried out in the licensed premises (SLC T1) Diagnostic blood tests are performed by a CPA accredited third party laboratory (SLC T21).

The centre has a SOP for air quality monitoring, including actions to be taken if the required air quality is not met (SLC T33 (b)). Air quality monitoring is performed by laboratory staff (fortnightly) and also quarterly by a specialist third party. Monitoring includes both particle counting and settle plate microbiological sampling (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 (SLC T118).

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

Intracytoplasmic sperm injection (ICSI)
The centre has a SOP in place for performing ICSI (SLC T33b). QIs have been developed and are evaluated during the audit of practice which occurs every quarter (SLC T36 & T35). Quarterly QI monitoring is used as part of the documented periodic staff competence assessment to perform ICSI (SLC T15a).

What the centre could do better.

Quality management system
SOPs for both the taking of consent and the submission of data to the HFEA need to be documented (SLC T33b).

SOPs for witnessing, donor screening, transport of gametes and embryo and the use of embryos in training, need to be reviewed and amended in order to accurately describe current centre practices (SLC T33b).

Although audit of practice is occurring, audit methodology could be further developed to include raw data, audit trail evidence and not just results summaries. QI monitoring also needs to be further developed to encompass all centre activities (SLC T36 & T35).

Traceability
Some critical equipment that comes into contact with licensed material is not currently documented for traceability purposes, e.g. centrifuge (SLC T99b).

Process validation
Robust validation documentation covering all critical processes is not in place (SLC T72).

Third party agreements
The third party agreement with the environmental monitoring service provider was out of date (SLC T111).

Equipment and materials
Robust validation documentation covering all critical equipment is not in place (SLC T24).

Multiple Births (Guidance Note 7)

For the period, 1 April 2010 – 31 March 2011, the centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 18%. This multiple clinical pregnancy rate represents performance likely to meet the target multiple birth rate for that time period (as defined in General Direction 0003) which is unlikely to be due to random variation.

What the centre does well

Ongoing monitoring of the centre's multiple clinical pregnancy rate suggests that the centre is not likely to exceed the 2011/12 multiple birth rate target of 15% (SLC T123)

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 rates and subsequent multiple birth rates;
- staff at the centre have audited their strategy and protocols as part of the quality management audit programme;
- staff have maintained a log of women receiving double and triple embryo transfers who meet the criteria for single embryo transfer;
- staff have maintained a log which indicates the reasons for variation from the single embryo transfer policy

What the centre could better

The reasons for double-embryo transfers (DET) in patients who are eligible for eSET and the risks associated with multiple pregnancies that have been discussed with such patients, are not consistently recorded in the patient notes (General Direction 0003, 7(a)(b))

Staff engaged in licensed activity

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

What the centre does well.

Person Responsible
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 activities to be authorised by the licence.

The PR has successfully completed the HFEA Person Responsible Entry Programme (certificate T/1169/8).

Staff
The PR discussed a NHS Trust Service Line Reporting review process which took place during 2011, which assessed all aspects of the unit's service provision, funding, staffing and structure. Following this process, the unit was re-structured in order to be able to have enough suitably trained staff to safely deliver a maximum of 920 treatment cycles per year.

The centre provided an organisational chart that assigns responsibility and defines lines of accountability and reporting relationships (SLC T11). Following discussions with staff on the inspection, scrutiny of the aforementioned re-structuring process and review of the centre's latest annual management review (September 2011), it appeared that there was access to a nominated registered medical practitioner; workforce requirements had been assessed and that there were adequate staff presently in post to deliver the range of services provided by the centre (SLCs T16 and T12; CoP Guidance 25.10).

New staff undertake a NHS Trust structured induction process, together with unit-specific training which is documented and signed off by a mentor/manager. There is a staff competence assessment framework in place which allows section heads to record periodic assessments of staff competence. Assessments are reviewed as part of the annual staff appraisal scheme, during which any further training requirements are discussed and identified. Staff have access to on-going professional development (SLC T12 & T15).

What the centre could do better.

Nothing noted.

Welfare of the Child (Guidance Note 8)

What the centre does well.

Welfare of the Child
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. Five sets of patient notes were reviewed during inspection and it was found that WoC assessments had been completed by both patient and partner prior to any treatment taking place (SLC T56).

The centre has a documented SOP in place for when staff undertake a WoC assessment and staff competence when performing a WoC assessment is periodically appraised and documented (SLC T33b & T15a).

QIs have been developed for WoC assessment (SLC T35). These were last evaluated during the review of patient consents within 50 sets of patient records, undertaken in June 2011, during which no major issues were found (SLC T36).

What the centre could do better.

Nothing noted.

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)

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 understood the need to maintain patient confidentiality, had received training in this area, and kept all such 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 within the patient waiting area.

Staff stated that the centre utilise the NHS Trust complaints procedure. They would always attempt to resolve any patient issues locally in the first instance by private discussion. If this wasn't possible the issue would be escalated in line with the complaints procedure (SLC T33b). The complaints log was reviewed and found it to be compliant with CoP Guidance 28.7.

Provision of costed treatment plans
The centre only provides treatment to NHS patients and the funding for such treatments is provided by various local Primary Care Trusts (PCTs) and not from individual patients. As such, there is no requirement for costed treatment plans. The centre do however provide prospective patients with information concerning the funding criteria for the different local PCTs together with advice on how to appeal if a funding request is declined (CoP Guidance 4.3).

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.

Information to be provided prior to consent
Patient information sheets were submitted pre-inspection and were found to provide information about the nature of the treatment, consequences and risks, analytical tests, confidentiality, consent, and the availability of counselling (SLC T58). Only senior clinical staff discuss treatment pathways and provide information to patients prior to taking consent. A checklist of information to provide to patients forms part of the patient care plan and was observed to be retained within patient records.

Assessment of staff competence to provide information to patients prior to taking consent has been documented (SLC T15a).

Information about legal parenthood
The counsellor discusses legal parenthood issues with any couple requiring treatment with donor gametes. Patient checklists seen within patient records refer to such information being provided to patients prior to consents being taken (SLC T60). Any patient or patient partner that wishes to withdraw their consent to legal parenthood is invited into the unit to discuss the issue in the first instance. If they wish to proceed with the withdrawal of consent they are asked to put such a request in writing. Any such request would then be discussed at the weekly senior management team meeting (SLC T64b).

A documented audit of patient records undertaken in October 2011 reviewed the provision of information to patients, with any corrective actions being implemented (SLC T36). QIs have been developed for the provision of information to patients and were evaluated as part of the abovementioned audit (SLC T35).

What the centre could do better.

Information provided to patients via centre website
The centre do not provide patients with up-to-date centre-specific live birth rate data on the centre website or in patient information (Chair's Letter CH(11)02)

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
Discussions with staff and a review of five sets of medical records, established that written consent is obtained from patients/partners and donors before any form of treatment is provided (SLC T57). Assessment of staff competence to take consent has been documented (SLC T15a). A documented audit of fifty sets of patient records undertaken in June 2011 reviewed the presence of patient consent, with any corrective actions being implemented (SLC T36). QIs have been developed for the taking of patient consent and were evaluated as part of the abovementioned audit (SLC T35).

The centre seeks patient consent to identifying information from the HFEA Register being disclosed to researchers. HFEA Register information demonstrated that 37% of all patients and partners who have been registered at the centre since October 2009 have consented to disclosure.

Staff demonstrated an awareness of the 'cooling off' period for embryos, when individual gamete providers may want to withdraw their consent for storage, and stated that the centre presently had no embryos being stored under the cooling off provision (CoP Guidance 5.35). The centre appeared to have written effective consent for all cryopreserved gametes and embryos currently in storage (HF&E Act 1990 (as amended), Schedule 3; 8(1)(2)).

What the centre could do better.

Consent to treatment, storage, donation, training and disclosure of information
Although staff could accurately describe how the process of taking consent is undertaken, there is currently no formal SOP in place (SLC T33b).

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.

During the inspection it appeared that only those activities authorised by the centre's licence are carried out at the premises specified in the licence (SLC T1).

Following discussions with centre staff on inspection, review of patient records and observation of practice it appeared that staff were aware of the special status of the embryo when performing their respective licensed activities.

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.

Storage of gametes and embryos
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 both gametes and embryos (SLC T33b). Staff competence when performing cryopreservation has been assessed and documented (SLC T15a). The most recent cryotank audit was undertaken in October 2011 during which eight errors were found and resolved successfully (SLC T36). QIs have been developed for cryopreservation (SLC T35).
All currently stored licensed material is within the statutory 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 statutory storage period (CoP Guidance 17.18). Before any material is stored the gamete providers are screened in accordance with current regulatory requirements, with the exception of the issue mentioned below (SLC T50). All screening tests are performed in a CPA (UK) Ltd accredited laboratory (SLC T51).

What the centre could do better.

Storage of gametes and embryos
HTLV-1 testing is not currently being performed if the gamete provider lives in or originates from high-incidence areas or has sexual partners originating from those areas or if their parents originate from those areas (SLC T50c).

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
Except for the issue mentioned below, the centre has procedures in place to ensure gametes and embryos are distributed under conditions that protect the safety and quality of the gametes and embryos (SLC T105; T106; T107 & T108). During the transport of licensed material between licensed centres, appropriate documentation is transferred with the gametes and embryos between the centres (SLC T109 & T110).

Import/export of gametes and embryos
The centre has not exported any licensed material in the last 12 months.

The centre has imported six sperm samples under General Direction 0006. Review of records for compliance collected by the centre indicated that the imports complied with the requirements of the Direction.

What the centre could do better.

Distribution of gametes and embryos
Although staff do ensure that all current requirements for the transport of licensed material between licensed centres are complied with, the SOP needs to be reviewed/amended to accurately capture present practice (SLC T33b).

Use of embryos for training staff (Guidance Note 22)

What the centre does well.

Use of embryos for training staff
Through discussions with staff, documentation review and observation of practice it was established that embryos are only used for authorised training activities when consent has been obtained from the gamete providers and that any embryos used in training are not subsequently used for patient treatment (SLC T92; T93 & T94). Prior to providing consent for use of embryos in authorised training, gamete providers are provided with all required regulatory information by an appropriately trained member of staff (SLC T97 & T98). Centre staff ensure that clinical and training roles are separated (SLC T95).

What the centre could do better.

Use of embryos for training staff
Although centre practices were found to be compliant with current regulations the embryo training SOP needs to be reviewed/amended to capture all authorised training activities (SLC T33b).

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.

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

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

Treatment cycle data is submitted to the HFEA by different personnel within the centre. Procedures are in place for the submission of data to the HFEA from the laboratory (SLC T33b).

An audit of treatment data concerning ten patient cycles submitted to the HFEA was undertaken in September 2011 and indicated that all necessary corrective actions were implemented (SLC T36).

What the centre could do better.

Record keeping and document control
Although nursing staff knew how to submit relevant treatment cycle data to the HFEA, the procedure has not been formulated into a SOP (SLC T33b).

QIs need to be developed for the submission of data to the HFEA (SLC T35).

Legal requirements [HF&E Act 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 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 (SLC T4).

The PR stated that due to problems with the centre's patient information database which is used to interface with the HFEA Electronic Data Interface (EDI) system, a new database has been commissioned. It will be designed and developed by the local NHS Trust IT Department and should be ready for use by the end of 2012. The PR considers that this change is likely to significantly improve the accuracy and timeliness of data submission to the HFEA.

What the centre could do better.

There are still issues relating to the accurate and timely submission of data to the Authority.

Licensed Treatment Reporting

To determine whether all licensed treatments are reported to the Authority as required, a sample of licensed treatments undertaken by the centre between 1/1/2011 and 31/12/2011 was reviewed. The sample was drawn from the centre's records and was reviewed against an extract of the Authority's statutory register.

During the review of 178 treatments (i.e. 138 IVF and 40 DI treatments) it was found that;

- 15 (38%) of the DI treatments had not been reported to the HFEA.
- 31% of the treatment cycles in the audit sample were not reported to the HFEA within 5 working days of treatment (24% for IVF cycles).

Data Quality

To ascertain the quality of the data submitted by the centre for inclusion on the statutory register, 108 assorted data forms submitted to the Authority between 1/1/2011 and 31/12/2011 were reviewed against source documentation held on patient and donor files. A small number of minor errors were found together with one critical error: A donor code had been incorrectly entered on a DI form. The audit sample was too small to conclusively determine whether the errors identified were due to system/process problems, or simply due to input faults. Given that the centre also has a considerable proportion of missing DI treatments, this suggests that the procedure for the inputting of DI forms is non-compliant and should be reviewed (HF&E Act 1990 (as amended) Section 17 (1) d,e; General Direction 0005; SLCs T9(e), T2 and T39).

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 (Guidance Note 30)
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 is kept confidential and 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.

Disclosure of information, held on the HFEA Register, for use in research
A sample of consents to the disclosure of personal information held on the HFEA Register was reviewed on inspection. Half of the consents, recorded in six sets of patient records, were found to be have been incorrectly submitted to the HFEA. Three patients who had agreed to consent to disclosure of information for research purposes having been recorded as not consenting (HFE Act 1990 (as amended) Section 17 (1) d,e; General Direction 0005; SLCs T9(e), T2 and T39)

5. Changes / improvements since the last inspection on 20 January 2010

Area for improvement	Action required	Action taken as evidenced during this inspection
Failure to maintain emergency crash trolleys in line with professional body guidelines	Revision of nurse management, training and practices in order to prevent further failures concerning the emergency crash trolleys	Resuscitation equipment in the centre is now checked daily. All staff are now trained by Trust in the use of all 3 types of defibrillators on site. No further action required
The present practice of storing the low oxygen cryo-alarm mute key within the cryostore is potentially lethal.	Revision of staff policy and practices when storing and accessing the low oxygen cryo-alarm mute key.	This issue was resolved in 2010. No further action required
The continued storage of an embryo beyond the statutory storage period, which involved the loss of patient records	Submission of an incident report concerning the continued storage of an embryo beyond statutory storage period, which involved the loss of patient records	This issue was resolved in 2010. There are presently no embryos in storage without appropriate consent being in place. No further action required
Accurate and timely submission of data to the Authority (HFE Act S17 (1)(d)(e); D0005; T9(e)(f); T2; T39)	The PR must resolve regulatory issues concerning the accurate and timely submission of data to the Authority as a matter of urgency.	Reporting of data to the HFEA is much improved but problems still remain as indicated on pages 24 and 25 of this report. The main issue appears to be a continuing problem with the centre's ACUBase database. The Trust has commissioned a replacement database to be installed by the end of 2012. **Further action required**
Observed practice of drugs cabinet keys being left in situ and patient notes left unattended within a patient treatment room. (HF& E Act S17 (1) (a); (d); S33A;T2; T12; T15; T33b; T43)	Revision of nursing staff training practices which would prevent the recurrence of drug cabinets keys being left in situ during the inspection	This issue was resolved in 2010. No further action required

Potential for breach of patient confidentiality due to the practice of the records store door being left open. (HF& E Act S17 (1) (a); (d); S33A; T2; T15; T33b; T43)	Revision of staff practices when using the new patient records store to prevent the door from being left open with the potential for a breach of confidentiality	This issue was resolved in 2010. No further action required
Lack of management, training and competency assessment within the nursing department (HF& E Act S17 (1) (a); (d); T12; T15)	Review of the management of nursing staff, to include resourcing, training and competency issues	Nurse competence assessment framework now in place. Annual staff appraisals. Any training issues highlighted are dealt with via on-going training and development. A lead nurse has been appointed. No further action required
There was a lack of both assessment and recording of staff competence throughout the centre (HF& E Act S17 (1) (a); (d); T12; T15a)	Review and implementation of periodic staff competence assessment and recording	Staff competence assessment framework now in place. Annual staff appraisals. Any training issues highlighted are dealt with via on-going training and development. No further action required
The quality management system had not been maintained appropriately during the absence of the quality manager. Systems and processes had not been reviewed/ audited. There had been no annual review. (HF& E Act S17 (1) (a); (d); T32; T35; T36)	Review of the quality management system to assess areas where quality indicators are not currently in place and audits not being performed	New quality manager in post since April 2011. Improvements have been made to the QMS, with audit schedules in place, audits undertaken and QI developed. Further development of the system is however still required as discussed on page 10 of this report. **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
IVF and ICSI outcomes for patients <38 years are below the national average. (HF&E Act S17(1)(d))	The PR should ensure that the laboratory and clinical practices are suitable to provide a good quality service to patients. This has been an issue for a number of years and the centre must make progress in this aspect of their quality of service. The PR should provide reassurance to the Executive that this area of practice is being rigorously reviewed in order to provide better outcomes for service users. This situation will be monitored closely	The PR wishes to reassure the Executive that this area of practice is being rigorously reviewed in order to provide better outcomes for service users. This centre has in place an ongoing programme of improvements and this is a particular focus in 2012. We welcome the plan by the Executive to monitor this situation closely over the next year and we would be delighted to work closely with our Inspector in this	The PR is actively addressing this issue and will work with the inspector by forwarding quarterly updates concerning measures of patient outcomes. **Inspector to monitor quarterly patient outcome data and to review progress made over the next twelve months before deciding whether any further regulatory actions are required.**

	by the Executive and referred back to the ELP if no improvements are seen within the next twelve months.	regard over the period. The PR will forward 1st-Quarter-2012 treatment cycle, laboratory and early outcome KPIs to the Inspector when all outstanding outcomes are available. See full details on page 39 below.	

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
Accurate and timely submission of data to the Authority. (HFE Act S17 (1)(d)(e); D0005; T9(e)(f); T2; T39)	The PR should ensure that issues concerning the accurate and timely submission of data to the Authority are resolved as a matter of urgency. This was an issue at the previous inspection and has still not been successfully resolved. The PR should provide details about how this issue is to be resolved by 3 May 2012.	The PR acknowledges and regrets that this centre has had problems with accurate and timely submission of data to the Authority over several years. His investigation of this issue has determined that these problems have largely been caused by two unrelated issues: ▪ An inadequate database (ACUBase) which is to be replaced ▪ Lack of a designated individual with responsibility for managing the Centre's data issues and interfacing with the Authority. The centre has therefore taken the decision to appoint a Data Management Officer to work alongside the Quality Manager to deal with all data handling issues. The advert for this post is	Issue being addressed by the PR. **On-going monitoring of this issue by the inspector to ensure that a designated individual is in post to ensure accurate and timely data submission.**

		currently being developed.	
Some witnessing steps are not being recorded as being double witnessed, for example the witness check at the disposal of sperm samples (SLC T71)	The PR should ensure that all critical points in the laboratory process are double-witnessed, including when any semen samples are disposed of. The PR should forward a revised witnessing SOP and undertake an audit of recently completed treatment cycles in order to ascertain whether critical processes are being witnessed in line with current regulatory requirements. Audit results and revised SOP to be forwarded to inspector by 3 May 2012	The PR can confirm that the Laboratory witnessing SOP and documents have been revised to ensure that all critical points in the laboratory process are double-witnessed, including when any semen samples are disposed of. An audit of recently completed treatment cycles is in progress to ascertain whether critical processes are being witnessed in line with current regulatory requirements. The PR will forward the revised witnessing SOP and audit results to the Inspector by 3 May 2012.	The PR forwarded a patient notes audit which referenced the revised witnessing SOP. Issue resolved.

Some critical equipment has not been validated (SLC T24)	The PR should ensure that all critical equipment is validated. Evidence of validation of any outstanding critical equipment to be forwarded to the inspector by 3 May 2012	The PR regrets that this Centre did not have a robust system of validation of critical equipment in place at the time of the recent inspection. Following the inspection, the PR commissioned a team (including the Quality Manager, Laboratory Manager and Nurse Team Lead) to investigate ways of achieving this objective. This Team has since reported back to the PR with a recommendation to utilise the British Andrology Society recommended system of validation and this has now been commissioned for this Centre. This is a robust but labour intensive system of validation that will take some time to work through; that work has commenced already. The PR requests that the Authority acknowledges that whilst this process is acceptable it will take time to deliver. The PR will forward evidence of the new critical equipment validation system to the Inspector by 3 May 2012.	The PR forwarded documentation giving details of critical equipment validation plans. **PR to forward progress made by centre on validation of critical equipment as part of PR quarterly update.**

Some critical processes have not been validated (SLC T72)	The PR should ensure that all critical processes are validated. Evidence of validation of any outstanding critical processes to be forwarded to the inspector by 3 May 2012	The PR regrets that this Centre did not have a robust system of validation of critical processes in place at the time of the recent inspection. Following the inspection, the PR commissioned a team (including the Quality Manager, Laboratory Manager and Nurse Team Lead) to investigate ways of achieving this objective. This Team has since reported back to the PR with a recommendation to utilise the British Andrology Society recommended system of validation and this has now been commissioned for this Centre. This is a robust but labour intensive system of validation that will take some time to work through; that work has commenced already. The PR requests that the Authority acknowledge that whilst this process is acceptable it will take time to deliver. The PR will forward evidence of the new critical processes validation system to the Inspector by 3 May 2012.	The PR forwarded documentation giving details of critical processes validation plans. **PR to forward progress made by centre on validation of critical processes as part of PR quarterly update.**

Some equipment coming into contact with licensed material is not being recorded (SLC T99)	The PR should ensure that all equipment which comes into contact with licensed material is appropriately documented for traceability purposes. The PR should ensure that any such equipment that comes into contact with licensed material is appropriately documented immediately and inform the inspector that this action has been completed.	The PR can confirm to the Authority that all equipment which come into contact with licensed material are now appropriately documented for traceability purposes. The PR has commissioned an audit of recent treatment cycles to ascertain that this is being done and will forward the results of that audit to the Inspector by 3 May 2012.	The PR forwarded a patient notes audit which referenced the revision of Traceability SOP INS/49. Issue resolved.
The TPA concerning environmental monitoring has not been renewed (SLC T111)	The PR should ensure that the TPA for environmental monitoring has been renewed by 3 May 2012.	The PR can confirm that the TPA for environmental monitoring is being renewed and will forward the renewed document to the Inspector by 3 May 2012.	PR stated that this TPA is now in place Issue resolved.

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
HTLV-1 antibody testing is not currently being performed if the gamete provider lives in or originates from high-incidence areas or has sexual partners originating from those areas or if their parents originate from those areas (HF&E Act Schedule 3A(11) – 2006/17/EC; SLC T50C)	The PR should risk assess whether HTLV-1 antibody testing is to be performed if the gamete provider lives in or originates from high-incidence areas or has sexual partners originating from those areas or if their parents originate from those areas. PR to provide evidence that the risk assessment has been undertaken by 3 May 2012.	The PR has risk assessed whether HTLV-1 antibody testing is to be performed if the gamete provider lives in or originates from high-incidence areas or has sexual partners originating from those areas or if their parents originate from those areas. The Centre has taken the decision to perform HTLV-1 antibody testing on all gamete donors attending this Unit in future irrespective of their origins. The PR will forward evidence of the revised viral screening protocol to the Inspector by 3 May 2012	The PR forwarded a revised donor screening SOP which included HTLV-1 testing for all gamete donors. Issue resolved.
The reasons for double embryo transfers (DET) and the associated risks of multiple pregnancy in elective single embryo transfer (eSET) eligible patients are not being	The PR should ensure that both; • the reasons for a multiple embryo transfer in patients who are eligible for an elective single embryo transfer	The PR can confirm that the Centre's Embryo Transfer (ET) policy has been revised to ensure that the following are consistently recorded in medical records:	The PR forwarded a revised embryo transfer policy. Issue resolved.

consistently recorded in medical records D0003: 7(a)(b)	• and the discussion of the associated risks of multiple pregnancy with the patient are consistently recorded in medical records. The PR to provide evidence that this action has been instigated to the inspector by 3 May 2012.	▪ the reasons for a multiple embryo transfer in patients who are eligible for an elective single embryo transfer ▪ and the discussion of the associated risks of multiple pregnancy with the patient The following measures were also employed to disseminate and monitor the change in practice: ▪ notice displayed clearly in theatre with clear instructions to clinicians who undertake ET ▪ compliance to be audited by Quality Manager after 6 months The PR will forward the revised ET policy to the Inspector by 3 May 2012.	
Centre website and patient information does not include up-to-date centre-specific outcome data (CH(11)02)	The PR should ensure that both the centre website and patient information includes up-to-date, centre-specific outcome data. To be forwarded to the inspector by 3 May 2012.	The PR can confirm that the patient information booklet has been amended to include centre-specific clinical pregnancy and live birth rates. The centre website is currently	The PR forwarded a revised patient information guide which included centre-specific outcome data

		being rebuilt and the finalised version would display centre-specific outcome data. The PR will forward the revised patient information booklet to the Inspector by 3 May 2012.	Issue resolved
The quality management system requires further development (SLC T33b; G23.12 e(iv) & T35;)	The PR should ensure that; SOPs are formulated for: • Taking consent • Submission of data to the HFEA SOPs need to be reviewed and amended concerning: • Witnessing • Donor screening • Transport of gametes and embryo • The use of embryos in training QI need to be developed and evaluated for all critical activities PR to ensure that SOPs are in place and an action plan with time-line for the further development of QI is forwarded to the inspector by 3 May 2012.	The PR can confirm that SOPs have been developed for the following: ▪ Consent taking ▪ Submission of data to the HFEA The PR can also confirm that the following SOPs have been reviewed and amended: ▪ Witnessing ▪ Donor screening ▪ Transport of gametes and embryos ▪ The use of embryos in training The PR can confirm that a timeline for the further development of QI for all critical activities has been developed and is being progressed. The PR will forward the new	The PR forwarded evidence that all required SOPs had been formulated and/or revised. A timeline for QI development has also been received. Issues resolved.

		and revised SOPs as well as the time-line for the further development of QI to the Inspector by 3 May 2012.	

Additional information from the Person Responsible

IVF and ICSI outcomes for patients <38 years are below the national average.
The PR confirms to the Executive that he is satisfied that the laboratory and clinical practices within the Unit are suitable to provide a good quality service to patients. He acknowledges that poor outcomes has been an issue for a number of years but feels confident that the measures that are being introduced to the Unit over recent months will help to address those concerns.

The PR wishes to reassure the Executive that this area of practice is being rigorously reviewed in order to provide better outcomes for service users. This centre has in place an ongoing programme of improvements and this is a particular focus in 2012. Examples of recent and planned developments include:

- Treatment outcomes are now monitored and audited monthly and discussed in monthly Staff meetings.
- Treatment KPIs are reviewed weekly at Quality meetings at which all cycles not achieving ET are scrutinised to find reasons and explore potential solutions. This uses the document INS/DRM/QMS/012 newly developed in January 2011.
- Consultants triage all referrals and decide on ovarian stimulation regimes taking into consideration AMH, AFC, FSH and BMI.
- A new ovarian stimulation protocol was introduced in November 2011 with the objective of achieving >90% ET and <5% cycle cancellation due to excessive response. Early indications are that the protocol appears to be achieving these objectives.
- A new ET protocol was introduced at the end of 2011 with the expectation of achieving >40% positive hCG/ET. Early indications are that this protocol has made a significant difference but its impact is being monitored.
- Other strategies planned for implementation in 2012 include:
  - Hysteroscopy before IVF (being implemented)
  - DHEA for poor responders (being implemented)
  - Introduction of an embryoscope to assist embryo grading and selection for transfer (being assessed for implementation)
  - IMSI procedure for patients requiring ICSI (being assessed for implementation)
  - Assisted hatching for repeated implantation failure (planned for future implementation)

We wish to remind the Authority that St. Mary's Hospital is an exclusive NHS Unit and the only centre in the UK that does not carry out private or fee paying treatment cycles. The patients who attend this Unit are essentially childless and would have endured years of subfertility before becoming eligible for NHS funding. As a result we treat an institutionally (NHS) selected poor prognosis group of patients, many of whom have unexplained subfertility. Our audit of AMH assays demonstrated that 50% of all the patients we treat have AMH levels less than 20pmol/l, i.e. they have low ovarian reserve. Based on pure logic, our results are likely to trend

below the national average, as this is calculated across all patient groups. Therefore, whilst we continue to strive to improve outcomes it is important that the basis for comparison between our data and the national database is fully understood and acknowledged by the Authority.

We are currently implementing the next phase of our multiple births minimisation plan and can foresee conflicts with other ongoing developments. Whilst we anticipate that the programme of improvements highlighted above would increase implantation rates per embryo transferred, the drive to carry out more eSETs will inevitably limit the overall impact of any improvements in overall success rates in 2012.

We welcome the plan by the Executive to monitor this situation closely over the next year and we would be delighted to work closely with our Inspector in this regard over the period.

The PR will forward 1st-Quarter-2012 treatment cycle, laboratory and early outcome KPIs to the Inspector when all outstanding outcomes are available.

HFEA Executive Licence Panel Meeting

1 June 2012

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

Minutes – Item 3

Centre 0067 – (St Mary's Hospital) – Renewal Inspection Report

Members of the Panel:	Committee Secretary:
Juliet Tizzard, Head of Policy & Communications (Chair) Mark Bennett, Director of Finance & Facilities Paula Robinson, Head of Business Planning	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 has been licensed by the HFEA since 1992. In the year ending 31 December 2011, the centre provided over 1500 cycles of licensed treatment to NHS patients from Greater Manchester and the surrounding areas.

2. The Panel noted that the centre's IVF/ICSI data for 1 October 2010 to 30 September 2011 show that the majority of the centre's clinical pregnancy rates are lower than national averages.

3. The Panel noted that the current Person Responsible (PR) was appointed at the end of 2010 and that he has given a commitment to implement a programme of improvement in this area, in particular a 'live birth improvement strategy'. However, the relatively poor clinical pregnancy rates have been a cause of concern since 2007.

4. The Panel noted that an NHS Trust service line reporting review process took place during 2011, which assessed all aspects of the unit's service provision, funding, staffing and structure.

5. The Panel noted that following this process, the unit was re-structured in order to be able to have enough suitably trained staff to safely deliver a maximum of 920 treatment cycles per year.

6. The Panel noted that, at the time of the inspection, there were one critical, six major and four other areas of non-compliance or practice that required improvement.

7. The Panel noted that, since the inspection, the PR has provided evidence to the Inspectorate that four major and four other areas of non-compliance have been addressed.

8. The Panel noted that the PR has given a commitment to implement the one critical and two major areas of non-compliance that remain outstanding within the prescribed timeframes highlighted in the report.

9. The Panel noted that the Inspectorate recommends that the centre's licence is renewed for three years with no additional conditions, but also recommends on-going monitoring of issues such as patient outcomes, submission of data to the Authority and the validation of all outstanding critical equipment and processes over the next twelve months, with a view that an additional interim inspection be undertaken within the next twelve months to review progress made.

10. The Panel noted the email update from the Inspectorate that had been tabled for this meeting informing the Panel of its rationale for recommending renewal of the licence for a three year period.

11. The Panel noted that the centre had implemented the majority of the recommendations made from the previous inspection, and noted that the centre has since appointed a new Quality Manager and a new PR.

Decision

12. 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.

13. 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.

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

15. 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.

16. The Panel noted that the application does involve the use of embryos for training purposes.

17. 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.

18. Whilst the Panel had no major concerns, it agreed that relatively poor clinical pregnancy rates for both IVF and ICSI persist and some of the issues required to be addressed at the previous inspection, such as accurate and timely submission of data to the Authority and quality management system development, have still not been fully resolved.

19. The Panel was concerned that 38% of the centre's donor cycles had not been reported accurately to the Authority. The Panel wished to remind the PR that failure to report donor information in a timely and accurate manner undermines the Authority's statutory duty to respond to requests for information from parents and donor-conceived people.

20. The Panel agreed with the Inspectorate's recommendations made in the report and endorsed the recommendations. The Panel agreed to renew the centre's licence for a period of three years with no additional conditions.

21. The Panel urged the PR to work closely with the Inspectorate in order to improve performance with regard to patient outcomes, submission of data to the Authority and the validation of all critical equipment and processes.

22. The Panel endorsed the Inspectorate's recommendation that an interim inspection visit should take place in the next twelve months.

Signed: Date: 19 June 2012

Juliet Tizzard (Chair)