Inspection Report

Date of Inspection: 17 and 18 April 2012
Purpose of inspection: Renewal of Treatment (including embryo testing) and Storage Licence
Length of inspection: 17 hours
Inspectors: Sara Parlett (Lead inspector)
Andrew Leonard (Scientific inspector)
Paula Nolan (Clinical inspector)
Cathy Hodgson (Operational audit)
Rosetta Wotton (Operational audit)

Inspection details:
The report covers the pre-inspection analysis, the visit and information received from the centre between 1 April 2010 and 15 June 2012.

Date of Executive Licensing Panel: 27 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	The Bridge Centre
Centre number	0070
Licence number	L/0070/18/c
Centre address	1 St Thomas Street, London Bridge London, SE1 9RY
Person Responsible	Dr Alan Thornhill
Licence Holder	Mr Paul Williams
Date licence issued	1 October 2010
Licence expiry date	30 September 2012
Additional conditions applied to this licence	None

Contents

Brief description of the centre and its licensing history:

The Bridge Centre is a privately run unit offering a wide range of assisted reproduction treatments, including pre-implantation genetic diagnosis (PGD) and pre-implantation genetic screening (PGS). An extensive network of satellite and transport centres feed into The Bridge Centre, enabling patients to undergo part of their treatment at a centre local to them. The centre has a UK-based egg sharing programme and three international programmes, offering treatment in Ukraine, Spain and America using donated eggs. The centre has carried out approximately 1800 cycles of licensed treatment in the last year.

The centre has been licensed by the HFEA since 1992 and a renewal inspection last took place on 31 March and 1 April 2010. The ELP which considered the centre's renewal application decided that a four year licence was not appropriate as a number of areas of non-compliance had also been seen at the previous inspection. The ELP decided to renew the centre's licence for a period of two years.

A change of Person Responsible (PR) from Professor Alan Handyside to Dr Alan Thornhill was approved by the ELP in December 2010. Dr Thornhill is a member of the Authority and has considerable experience in clinical embryology.

In January 2012, JD Healthcare Ltd entered into a management agreement to evaluate and restructure the organisation and management of the centre. The centre will continue to operate as a separate company. JD Healthcare also owns The London Women's Clinic (LWC) centres (HFEA licensed centres 0059, 0075, 0105 and 0301) and the London Sperm Bank (HFEA licensed centre 0011). The stated aim of the management agreement is to improve the quality, clinical effectiveness, regulatory compliance and financial security of the centre. Detailed plans to achieve these objectives are being implemented and were provided to the inspection team. There are also plans to refurbish several areas of the centre's premises which may necessitate an application to vary the licensed premises in the near future. The PR has been asked to keep the Executive fully informed at all stages of the reorganisation of both the centre's practices and premises.

Activities of the Centre:

Type of treatment	Number of treatment cycles for the period 1 April 2011 – 31 March 2012*
In vitro fertilisation (IVF)	834
Intracytoplasmic sperm injection (ICSI)	703
Frozen embryo transfer (FET)	372
Donor insemination (DI)	138
Partner insemination (IUI)	118
Egg share provider (sharer)	14
Egg share recipient	12
Egg donation (non-egg share)	13

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

Outcomes*

For IVF/ICSI, HFEA held register data for the period 1 January 2011 – 31 December 2011 show the centre's success rates are in line with national averages.

It should be noted however that the PR has not submitted 5% of required outcome information for this period to the register; as a result, this analysis may not be accurate. Please refer to page 32 of this report for further discussion.

For the year 2011 the centre reported 118 cycles of IUI with 15 pregnancies. This equates to a 13% clinical pregnancy rate (CPR) which is in line 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, with the exception of the areas of non-compliance identified in this report, discharged his duty under Section 17 of the HF&E Act 1990 (as amended).
- The premises are suitable.
- The practices are suitable.
- The centre has submitted appropriately completed documentation in accordance with General Direction 0008, in application for renewal of their licence.
- The centre has submitted an application fee to the HFEA in accordance with requirements.

The ELP is asked to note that at the time of the inspection there were a number of areas of practice that required improvement, including one critical area of non-compliance, ten major areas of non-compliance and six other areas of non-compliance or areas of poor practice.

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

Major areas of non-compliance

- To ensure either that the centre's standard operating procedure (SOP) is revised to remove the option for a sperm donor to provide recent or childhood photographs for recipients to view at the centre, or to document the centre's rationale for determining that a photograph is not identifying and submit this to the Executive.
- To validate the process for the use of pentoxyfilline.

Other areas of practice that require improvement

- To ensure that a full record is retained of the witness step to cross-check patient identifying information at the time of sperm collection.
- To submit the written agreement with one satellite centre to the Executive.
- To ensure that all dewars are within appropriate proximity of a low oxygen sensor.

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

Critical areas of non-compliance

- **To ensure that:**
    - **Appropriate consent is obtained for storage of the five sets of embryos referenced in this report** - evidence that this has been obtained for all embryos has been provided.
    - **Corrective action is identified and implemented to ensure that, prospectively, gametes and embryos are not stored without appropriately completed consent.**

Major areas of non-compliance

- To ensure that diagnostic semen analysis is performed in a laboratory accredited by Clinical Pathology Accreditation UK Ltd (CPA) or another body accrediting to an equivalent standard. To support this, the PR should ensure that satisfactory performance in the national external quality assessment scheme (NEQAS) for semen analysis is achieved and maintained.
- To ensure that the centre can provide accurate information to donors regarding the number, sex and year of birth of persons born as a result of their donation.
- To ensure that:
    - Prospectively, all donors are given the opportunity to provide a good will message and personal description.
    - A plan for retrospectively contacting donors who were not given the opportunity to provide a good will message and personal description is provided to the Executive.
- To ensure that:
    - Air quality procedures, including frequency of monitoring, are validated.
    - The centre's SOP reflects the air quality monitoring performed in practice.
- To ensure that:
    - The centre's systems, processes and staff competence and training allow timely and accurate reporting of treatment data to the HFEA register.
    - All outstanding early pregnancy outcome forms are submitted.
    - All errors and discrepancies noted in the audit are corrected.
    - All historic donor registration errors are resolved.
- To perform an audit of the consent to disclosure in patient records against the consent decisions which have been submitted to the HFEA.
- To ensure that:
    - The centre's website and patient information on success rates cover all requirements of Chair's Letter CH(11)(02).
    - The patient information is updated to provide accurate information.
- To review and revise procedures to ensure that fees are paid to the Authority within the required timescale.

Other areas of practice that require improvement

- To review and revise the SOPs referenced in this report. Four of the five SOPs referenced have been amended since the inspection.
- The PR has provided evidence post inspection that the centre's third party agreements (TPAs) with all companies carrying out diagnostic analysis include a description of how test/diagnostic results are relayed to the centre, including sign off and confirmation that the result applies to the correct sample. The PR should ensure that these revised TPAs are approved by the companies.

- To monitor the progress towards accreditation of two external laboratories used for diagnostic analysis of patient samples.

Thirty nine areas of non-compliance were identified at the last inspection and the majority of these non-compliances have been addressed. Material in storage without consent was an issue at the last two inspections. However, this area of non-compliance was previously caused by an inadequate bring forward system, which has now been improved.

Although there were a significant number of non-compliances identified at this inspection, overall the inspection team considers that the centre has made significant progress towards regulatory compliance since the last inspection.

The ELP is also asked to note that the centre was proactive in addressing several of the areas of non-compliance highlighted on inspection soon after the inspection visit took place and providing evidence of this to the Executive. An action plan addressing other areas of non-compliance was also provided. Further evidence demonstrating that a number of the remaining areas of non-compliance have been, or are in the process of being, addressed was provided with the PR's response to the report.

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

The centre will be subject to close on-going monitoring by the Executive and will be referred back to the ELP if the areas of non-compliance identified are not addressed within the timescales specified.

Details of inspection findings

1. Protection of patients and children born following treatment

Focus

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

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

▶ Witnessing and assuring patient and donor identification (Guidance Note 18)

What the centre does well.

The centre double checks the identification of gametes and embryos and the patient or donor to whom they relate at all critical points of the clinical and laboratory process (Standard Licence Condition (SLC) T71).

A radio frequency identification (RFID) electronic witnessing system is in use at the centre. The centre has identified the critical steps that must be witnessed manually; these include those required by CoP Guidance 18.4 and 18.33.

The centre has a documented SOP describing the witnessing procedure for all relevant points specified in CoP Guidance 18.4.

Witnessing steps observed during the inspection were performed in accordance with CoP requirements. Records of all required witnessing steps were seen in five sets of notes audited on inspection, with one exception detailed below.

Evidence of training and competence assessment for staff performing witnessing steps, including the use of the electronic system, was provided on inspection (SLC T15 (a)).

Quality indicators (QIs) have been established for witnessing and audits of compliance with witnessing requirements are performed regularly. A report of the last audit, performed in March 2012, was reviewed and included an analysis of the mismatches recorded by the electronic system and the corrective actions required and implemented. A review of all transport centre witnessing procedures was also performed recently (SLC T35 and T36).

What the centre could do better.

During the audit of five sets of patient records, it was noted that only the signature of one embryologist is recorded in the patient records for the witnessing step to cross-check

patient identifying information at the time of sperm collection. The laboratory manager explained that the patient witnesses this step and then signs the sperm receptacle label. The embryologist is then prompted to confirm and record on the electronic system that this step has been performed prior to processing the sample. However, the receptacle is discarded after the sperm is processed and a full record of this witness step is not retained in the patient's notes (SLC T71 and CoP Guidance 18.4 (b)).

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.

Justification for the use of gametes and embryos in treatment, based on the patient's medical history and therapeutic indications, was seen to be documented in the patient notes reviewed on inspection (SLC T49).

An audit of ten sets of patient notes on inspection demonstrated that patients are screened for HIV, Hepatitis B and Hepatitis C as required by SLC T50, with one exception detailed below. Screening results of satellite and transport patients are reviewed prior to treatment at the centre.

Hepatitis B screening

The audit of donor and patient notes on inspection demonstrated that screening for hepatitis B virus by serological testing for hepatitis B surface antigen (HBsAg) is performed. However, screening for hepatitis B core antigen antibody (anti-HBc) was not routinely performed before November 2011, non-compliant with SLC T50 and T52. Centre staff explained that they were not aware of this requirement prior to the release in October 2011 of information from the HFEA clarifying the screening tests required. Centre staff confirmed that screening for anti-HBc has been performed since then, as demonstrated in five sets of notes reviewed on inspection. A new SOP has recently been approved which documents the requirement to screen donors and patients for anti-HBc and includes the follow up actions required in the event of a positive result (SLC T33 (b)).

Laboratories undertaking diagnosis and investigation of patients are accredited by the CPA, with one exception detailed below. Reports of test results, including blood screening tests and hormone profiles, observed in patient notes reviewed on inspection were from an appropriately accredited laboratory, as demonstrated by the CPA certificates held by the centre for this laboratory (SLC T21).

What the centre could do better.

Additional testing

Centre staff confirmed that additional patient testing, including for HTLV-1, is carried out when required (SLC T50 (c) and (d)). However, the centre's 'initial assessment' SOP does not detail this requirement (SLC T33 (b)). Post inspection, the PR submitted a revised

SOP documenting the additional tests that are considered.

Semen analysis

Diagnostic semen analysis is performed at the centre to determine the treatment pathway but this semen analysis service is not accredited by CPA or another body accrediting to an equivalent standard (SLC T21).

CPA accreditation assesses an organisation's quality management system (QMS); the competence of individuals to perform tests; the appropriateness of tests; the reproducibility and accuracy of tests and the capability of the testing laboratory to provide an appropriate and accurate interpretation of the test result.

The PR stated that he considers that the centre meets these requirements through compliance with HFEA SLCs. However, CPA accreditation also requires participation in external quality assessment schemes to ensure the reproducibility and accuracy of tests. The centre participates in NEQAS for semen analysis but the laboratory manager explained that poor results have persistently been received for sperm morphology and sperm concentration assessments. A review has recently been conducted and a clear action plan documenting the corrective actions required was supplied to the inspection team (SLC T21 and CoP Guidance 23.23).

The inspection team consider that the centre's compliance with HFEA SLCs and the presence of experienced and competent laboratory staff to interpret results, will provide accreditation to an equivalent level as the CPA, once performance in NEQAS is at a consistently satisfactory standard.

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.

The centre has an active egg share programme and three international egg donor programmes. It also accepts known egg donors introduced by recipients and offers surrogacy treatment.

Centre staff confirmed that they are not currently recruiting sperm donors. Centre 0011 took over management of the centre's donor bank in 2011 and all unallocated donor sperm was transferred to that centre. The only donor sperm samples remaining at The Bridge Centre are those for sibling use or which have been imported for use by specific patients. There are plans to re-launch the sperm bank at centre 0070 under the management of centre 0011, towards the end of 2012.

The centre's donor procedures are supported by SOPs and checklists (SLC T33 (b)). Audit of three sets of egg donor medical records during the inspection provided evidence that:

- Donors are selected on the basis of their age, health and medical history provided in a questionnaire and in a personal interview with a qualified and trained medical professional (SLC T52 (a)).

- Donors are selected in accordance with the screening requirements of SLC T52 and relevant professional bodies, with one exception detailed on page 9 of this report[1].
- The laboratory tests required by SLC T52 have been carried out by a laboratory which is CPA accredited (SLC T53 (a)).

Centre staff demonstrated awareness of the requirement to quarantine donor sperm for six months (SLC T53 (c)) and confirmed that gamete providers in surrogacy arrangements are screened as donors. An audit of the registration of surrogates as egg donors, performed in April 2012, was reviewed and documented the corrective action identified and implemented (SLC T36).

The centre is aware that non identifiable donors can be used only in accordance with SLC T54 and a full audit of the registration status of donors was performed in 2010/2011 which documented the implementation of appropriate corrective actions (SLC T36 and T54).

The donor coordinator explained that they maintain a comprehensive donor database that alerts staff when the gametes of one donor have been used to create eight families, to ensure compliance with the ten family limit (CoP Guidance 11.44).

What the centre could do better.

Outcome information to donors

The centre maintains records to be able to provide donors with information regarding the number, sex and year of birth of persons born as a result of their donation. The PR explained however that it was not clear if these records could provide accurate information, as acknowledged in the response to the self-assessment question (SAQ) submitted prior to this inspection. The PR confirmed that a LWC member of staff had been identified to conduct a full audit of the centre's records. The inspection team is aware that as the majority of the donor bank has been relocated to centre 0011, this non-compliance is no longer the sole responsibility of the PR of centre 0070 (HF&E Act 1990 (as amended), Section 31ZD (3)).

Egg donor information form completion

The HFEA's donor information form includes the option for the donor to document additional information, including a good will message and a personal description. This non-identifying information can be given to the recipient and the donor conceived person at 16 years of age. The donor coordinator explained that an in-house egg donor information form is used at the centre, rather than the HFEA version. The centre's procedure is to ask the egg recipient if they want this additional donor information to be provided and if they do not, then the relevant sections of the donor information form are not given to the egg donor to complete (CoP Guidance 11.35 and 11.36).

Whilst there is no legal requirement for a good will message and personal description to be provided, the HF&E (Disclosure of Donor Information) Regulations 2004, Section 2 (2)(g)(h) clearly envisage that the type of information that may be contained in such

[1] The 2008 UK guidelines for the medical and laboratory screening of sperm, egg and embryo donors produced by BFS, BAS, ACE and RCOG.

descriptions should be disclosed to the donor-conceived, where available.

If donors at the centre are not being asked to provide this additional information, because the recipients do not require it, this undermines the HFEA's ability to discharge its subsequent statutory responsibilities towards the donor conceived. The inspection team consider this situation is non-compliant with General Direction 0005, which states that centres must use the donor information form to record information relating to donors and ensure that sections 1 to 20 are completed for each donor. Sections 21 to 27 (relating to religion, occupation, interests, skills, reasons for donating, good will message and pen portrait) must be submitted to the HFEA in paper format (HF&E Act 1990 (as amended), Section 13 (2)(f)).

Post inspection, the PR submitted several revised donor SOPs, documenting the requirement to discuss the option of providing a good will message and a personal description with all egg donors during their counselling session.

Donor identifying information

The centre's 'screening of sperm donors' SOP states "the donor should be asked if they are willing to provide a recent or childhood photograph which will be available for recipient viewing at the centre". Identifying donor information cannot be disclosed to recipients and photographs could be considered to be identifying (HF&E Act 1990 (as amended), Section 33A(1). The PR stated that this was not a procedure that was performed at the centre and that it would be removed from the SOP.

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 quality management system: Guidance Note 23

The centre has a comprehensive QMS that the inspection team considered appropriate for the services provided. Critical procedures conducted at the centre are documented in SOPs, a sample of which was reviewed on inspection and found to be comprehensive (SLC T33 (b)). The QMS is maintained by a quality manager and quality specialist (CoP Guidance 23.3 (a)).

The centre is ISO 9001:2008 certified and an audit of the QMS was last conducted by its certifying body in October 2011. A copy of the report documented two minor non-conformities. The quality specialist confirmed that appropriate corrective actions had been taken.

Annual QMS reviews are held and the minutes from the latest review in September 2011 were seen on inspection. They included consideration of quality objectives, third party audits and patient satisfaction (CoP Guidance 23.12).

QIs have been established for centre activities and are embedded in the centre's audit schedule. A broad range of QIs relevant to procurement and processing activities are regularly reviewed, including fertilisation rates, ICSI damage rates and CPRs. Process audits are also performed (SLCs T35 and T36).

The centre's audit schedules for 2011 and 2012 and a selection of audit reports were reviewed. These included audits of provision of information, consent, welfare of the child (WoC) assessment, donor screening and satellite and transport centre compliance. The audit scope and methodology appeared to have been planned carefully, demonstrating that audits are considered by centre staff to be an important tool for continuous improvement. Findings and the corrective actions identified and implemented were also documented (SLC T36).

Patient satisfaction is monitored closely by the centre via patient questionnaires. The nurse manager has introduced 'point of care' questionnaires which are provided to patients at critical treatment stages to complete immediately. The aim is to resolve any issues as they arise and evidence that corrective action was taken, where possible, was seen on inspection. The PR and nurse manager both stated that positive feedback has been received and this was confirmed by review of some of the patient questionnaires received and during interviews with patients.

The HFEA has received 21 patient questionnaires since the last inspection and very poor comments regarding the centre's services were noted. Based on this discrepancy between the information held at the HFEA and the findings on inspection, a further review of the HFEA held data was conducted post inspection. This demonstrated that the majority of the responses received by the HFEA were over a year old, suggesting that many of the issues raised have been satisfactorily addressed by the centre over the past year. The inspection team commends the staff for the work undertaken to improve the patients' experience at the centre.

The PR confirmed that staff meetings are held regularly, including senior staff, all staff and more frequent departmental meetings. The minutes of several recent meetings were reviewed and included detailed discussions of the new management agreement with JD Healthcare. Members of staff confirmed that other relevant information, including HFEA communications and incident alerts, are circulated to staff by the PR.

Process validation: Guidance Note 15

The centre's critical processes have been validated in compliance with SLC T72, with one exception detailed below. A selection of validation documents were reviewed on inspection, including those for sperm preparation, IVF, ICSI and storage procedures. The validation approach used includes a retrospective analysis of the centre's own data.

Traceability: Guidance Note 19

The centre ensures that the traceability of all consumables, reagents and equipment that come into contact with gametes and embryos is assured.

Containers used in the course of procurement and processing of gametes and embryos are labelled with the patient's full name and two further identifiers (SLC T101).

The traceability procedure for consumables and reagents is documented in a SOP (SLC T33 (b)). The laboratory manager demonstrated the centre's database used to record traceability data, including the supplier, product description and batch number (SLC T99).

Traceability audits are performed regularly, including physical audits of consumables in use in the laboratory against those recorded as being in use (SLC T36).

Third party agreements: Guidance Note 24

The centre has written agreements with third parties providing goods and services influencing the quality and safety of gametes and embryos (SLC T111). The quality specialist maintains a detailed spreadsheet of all third parties, including the goods/services supplied and when the TPAs are due for renewal (SLC T115).

A sample of five TPAs was reviewed on inspection and found to be compliant with SLC T114, with two exceptions detailed below.

Satellite and transport centre management: Guidance Note 24

Five satellite centres and four transport centres feed into The Bridge Centre. The PR stated that the ratio of centre patients to satellite/transport patients is approximately 45:55.

A report of an audit, conducted by the PR in November 2011, of the centre's largest transport centre was provided. The audit included a review of the QMS, communication between the centres, patient information, consent, competence assessment, equipment management and traceability procedures. Corrective actions required were documented. The inspection team considered that the report demonstrates significant and effective oversight of this transport centre. The PR plans to visit all transport centres on an annual basis to conduct similar reviews.

The PR explained that the success rates for satellite and transport patients are regularly audited. Meetings with satellite/transport centre staff are held frequently and HFEA inspection reports for HFEA licensed satellite and transport centres are reviewed and discussed. Evidence that incidents are followed up with site visits and thorough investigations was seen (CoP Guidance 24.6).

Three written agreements with satellite/transport centres were reviewed and covered the requirements of General Direction 0010.

Premises and facilities: Guidance Note 25

Air quality monitoring via particle counts was last performed in June 2011 by an external company and settle plate monitoring is carried out monthly. Records reviewed on inspection demonstrated compliance with the requirements of SLC T20.

Records of regular cleaning of both the premises and equipment were seen on inspection (SLC T26).

Equipment and materials: Guidance Note 26

The laboratory manager provided documented evidence that all equipment that affects critical processing or storage parameters is subject to monitoring, alerts and alarms. Defined temperature limits have been set and the centre's monitoring system for dewars and incubators will alarm if the measurements are outside of these limits. The centre has an on-call rota for responding to alarms out of hours. Daily monitoring of critical equipment is also performed (SLC T24).

Comprehensive service records were reviewed for a selection of critical equipment which included testing for electrical safety (SLC T24).

Critical equipment has been validated. Validation records were reviewed for the electronic witness system and a new incubator and were considered appropriate. Equipment qualification reviews, based on performance history, are in place for other pieces of critical equipment. The PR confirmed post inspection that the performance of critical equipment is re-assessed annually via QI monitoring. Evidence of revalidation following repair of a transport incubator was also provided (SLCs T24 and T25).

The centre has documented procedures for the operation of critical equipment and the procedure to follow if equipment malfunctions (SLC T27).

The specifications for critical reagents and consumables used are documented and the centre's process validation documents that all specifications meet the requirements for IVF use. Critical reagents and consumables are CE marked, where possible (SLC T30 and T31).

Adverse incidents: Guidance Note 27

The centre has reported adverse incidents to the HFEA since the last inspection. Reporting has been performed in a timely manner in compliance with SLCs T120 and T121 and General Direction 0011. Evidence of incident investigation and implementation of identified corrective actions was reviewed on inspection.

The centre has an adverse incident SOP and maintains an adverse incident register and a log of ovarian hyperstimulation syndrome (OHSS) cases. These were reviewed on inspection and demonstrated that reportable incidents had all been reported to the HFEA.

What the centre could do better.

Process validation: Guidance Note 15
The process for the use of pentoxyfilline has not been validated (SLC T72).

Traceability: Guidance Note 19

Although the critical equipment used in the processing of gametes and embryos is recorded, the centre's traceability SOP does not document this requirement. Post inspection, the PR confirmed that this requirement has been included in the centre's individual procedure SOPs. Two SOPs were submitted and confirmed this (SLC T99).

Third party agreements: Guidance Note 24

The centre's TPAs with two companies carrying out diagnostic analysis do not include a description of how test/diagnostic results are relayed to the centre, including sign off and confirmation that the result applies to the correct sample. The PR confirmed post inspection that all TPAs have been reviewed for compliance with SLC T114 (f). An example of one revised TPA was submitted and was considered by the Executive to meet SLC T114 requirements.

Satellite and transport centre management: Guidance Note 24

The written agreement with one satellite centre was not available for review on inspection. The PR agreed to submit a copy for the inspector to review (General Direction 0010 (9)).

Premises and facilities: Guidance Note 25

The centre's SOP for the monitoring of air quality states that particle counts are performed quarterly or at a minimum frequency of biannually. Particle counts were last performed in June 2011.

Evidence was provided post inspection that an external company will commence particle count monitoring on a quarterly basis from May 2012.

The centre's air quality testing procedures, including the frequency of monitoring, have not been validated (SLC T72 and CoP Guidance 25.10).

Dewars storing licensed material are located in cryostores and the andrology laboratory, with low oxygen sensors relayed to alarms outside of these rooms. However, there is also one dewar situated in the main laboratory which did not appear to be in close proximity to a low oxygen sensor. Post inspection, the PR confirmed that a personal low oxygen monitor has been situated close to the dewar as an interim solution. Evidence was provided that a quotation for a fixed alarm has been provided and will be purchased and installed (CoP Guidance 25.15).

Multiple Births (Guidance Note 7)

For the 1 April 2010 – 31 March 2011 period the centre's multiple CPR for all IVF, ICSI and FET cycles for all age groups was 30%[2].

This multiple CPR represents performance unlikely to lead to a multiple birth rate significantly higher than the 2010/11 target multiple birth rate of 20%.

What the centre does well

The PR acknowledged in the SAQ submitted prior to inspection that the centre was unlikely to meet the 2011/2012 multiple birth rate target of 15%. Ongoing monitoring of the centre's multiple CPR suggests however that the centre is unlikely to significantly exceed this target (SLC T123). However, at the time of inspection 8% of the outcome information for the period 2011-2012[3] had yet to be reported to the HFEA Register.

The centre has a multiple birth minimisation strategy (MBMS) incorporating a detailed action plan for 2012. The MBMS documents how the centre identifies suitable cases for elective single embryo transfer (eSET), including criteria in relation to patient selection and embryo assessment (General Direction 0003, 5 (a)).

The PR has provided sufficient evidence to demonstrate compliance with HFEA Directions 0003 in that:

- Staff were able to describe their progress towards reducing their multiple pregnancy

[2] A multiple clinical pregnancy rate of 25% is calculated as likely to result in a multiple live birth rate of 20%.
[3] The proportion of missing early outcome forms for IVF/ICSI/FET for January 2011 – December 2011 is 5%. The centre's multiple CPR is calculated from April 2011 – March 2012 and the proportion of missing early outcome forms for this period is 8%.

rates and subsequent multiple birth rates;

- Staff have audited the MBMS as part of the QMS audit programme. Audits are conducted quarterly and the 2011 and first quarter 2012 audits were reviewed on inspection. The centre's audits are also missing the outcome information noted above (refer to page 32 of this report for further discussion);

  The PR explained that the centre will continue to review its eSET selection criteria to further reduce its multiple CPR. The centre also plans to initiate weekly clinical meetings to review all recent cases where patients meet the eSET criteria but have two embryos transferred. The intention is to improve patient eSET uptake by focusing on these individual decisions. In the first quarter of 2012, 83% of patients eligible for eSET had one embryo transferred;
- The centre maintains a log of women receiving multiple embryo transfers who meet the criteria for eSET, including the reasons for variation from the eSET policy and the pregnancy outcome. Evidence was seen in the patient records that discussions are held with patients regarding the risks associated with multiple pregnancy (General Direction 0003, 7);
- The centre maintains a summary log of cases in which three embryos have been transferred (General Direction 0003, 1 (b)). The log demonstrates that 11 patients have had three embryos transferred from 1 January – 13 April 2012 and that all were over the age of 40 (CoP Guidance 7.5 (b)). An audit of three embryo transfers, performed in April 2012, was reviewed and no issues were identified or corrective action required (SLC T36).

The PR explained that changes to the centre's MBMS policy are communicated and negotiated with the satellite and transport centres prior to full implementation.

The centre's patient information was reviewed and includes details of the risks of multiple pregnancy and gives reference to the One at a Time website (CoP Guidance 7.6).

What the centre could better

It should be noted that the PR has not submitted 8% of required early outcome information for 2011/2012 and, as a result, the analysis of the centre's multiple CPR for this period may not be accurate. Refer to page 32 of this report for further discussion.

Staff engaged in licensed activity

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

What the centre does well.

The centre has suitably qualified staff to carry out all of the licensed activities and associated services. All staff, where appropriate, are registered with the relevant professional and/or statutory bodies, with one exception (refer to page 22 of this report). The laboratory manager is a Health Professions Council (HPC) registered clinical scientist

and the nominated registered medical practitioner is registered with the General Medical Council (SLC T14 and CoP Guidance 2.19 (c)).

Person responsible: Guidance Note 1

Dr Alan Thornhill has held the position of PR at the centre since December 2010 and is a HPC registered clinical scientist. He has the required academic qualifications in the field of embryology and has held clinical embryology roles since 1996 (HF&E Act 1990 (as amended) Section 16(2)(c)(i) and (ii)). The PR has successfully completed the HFEA PR Entry Programme (PREP number T/1173/8).

Staff: Guidance Note 2

The centre has an organisational chart defining accountability and reporting relationships of all staff within the new JD Healthcare management structure (SLC T11).

The PR explained that staff recruitment is now managed centrally by the LWC Human Resources department. Suitability of character is assessed by interview, uptake of references and Criminal Records Bureau (CRB) checks, as documented in the centre's recruitment policy (HF&E Act 1990 (as amended), Section 17(1)(a)).

The centre has a documented induction training procedure, comprising general orientation and support, mandatory training and an overview of the centre and its departments. The induction folders for three members of staff were reviewed on inspection and were considered comprehensive. Evidence of up to date mandatory training for centre staff was also reviewed (SLC T15).

Evidence was provided that staff are competent in their designated tasks. The nursing competence assessment framework is based on the Royal College of Nursing specialist competencies for fertility nurses and two training files were reviewed and considered comprehensive.

Laboratory staff competence assessments include semen analysis, ICSI and storage of gametes and embryos. The PR confirmed that the laboratory has also signed up to the NEQAS embryo grading scheme and is currently developing an in-house quality assurance programme (CoP Guidance 23.23).

Centre staff explained that a more formal competence framework for doctors was in the process of being introduced. This was reviewed on inspection and covered conducting WoC assessments and the management of OHSS (SLC T15 (b)).

Centre staff are given the opportunity to participate in continuing professional development, including attendance at external workshops and journal clubs held at the centre. The PR also explained that staff appraisals are held annually and the appraisal process includes a re-assessment of staff competence (SLC T12 and CoP Guidance 2.3).

Workforce requirements are regularly assessed by the centre. The PR confirmed that the centre is currently operating with a full staff complement and new members of staff from LWC will soon be joining, including consultants, a nurse manager, a quality assurance co-ordinator and a register officer. It appeared at the time of inspection that personnel are available in sufficient numbers for the present activity and workload (SLC T12).

What the centre could do better.

Nothing noted at the time of this inspection.

Welfare of the Child (Guidance Note 8)

What the centre does well.

The centre has a detailed WoC SOP and staff interviewed were able to demonstrate a full understanding of WoC requirements. The centre's WoC patient information also clearly describes the assessment process and includes details of when the assessment would be repeated (CoP Guidance 8.6).

The nurse manager explained that satellite and transport centres carry out WoC assessments, in compliance with The Bridge Centre's SOP. A checklist is used to ensure the assessment has been performed prior to treatment.

Six sets of patient notes reviewed on inspection demonstrated that WoC assessments had been completed appropriately prior to treatment (SLC T56).

What the centre could do better.

Nothing noted at the time of inspection.

Embryo Testing

- Preimplantation genetic screening (Guidance Note 9)
- Embryo testing and sex selection (Guidance Note 10)

What the centre does well.

The centre is licensed for embryo testing and offers both PGD and PGS. The centre's embryo biopsy procedures are documented in SOPs (SLC T33 (b)).

QIs have been established for embryo testing, including embryo damage rates, diagnosis rates and live birth rates. The report of an audit performed in April 2012 was reviewed and no issues were identified or corrective action required. The laboratory manager explained that each case is also individually reviewed on completion for potential learning opportunities (SLC T35 and T36).

An audit of cycles performed in 2010-2011 was reviewed and demonstrated that PGD testing was only performed for genetic conditions that have been authorised by the Authority (SLC T89).

The laboratory manager confirmed that no sex selection for social reasons is conducted at the centre (SLC T88 (b)). An audit of embryos biopsied in 2011 was conducted in April 2012 and demonstrated that no biopsied and non biopsied embryos were transferred in the same cycle (CoP Guidance 9.2).

Evidence of detailed competence assessment for staff performing embryo and polar body biopsy was reviewed on inspection (SLC T15 (a)).

The biopsy procedures used have been validated via retrospective evaluation of the centre's results. External laboratories undertake the analysis of material for PGD and PGS and centre staff explained that the centre's PGD consultant has assisted in developing the

testing methodologies in use at these laboratories (SLC T72).

The centre has TPAs with the external laboratories used for the diagnostic analysis of blastomeres and polar bodies for embryo testing. One was reviewed on inspection and is compliant with requirements, with one exception (refer to page 15 of this report) (SLC T111 and T114).

What the centre could do better.

Three external laboratories are used for the diagnostic analysis of blastomeres and polar bodies for embryo testing. One is CPA accredited and one is in the process of obtaining CPA accreditation. The centre is kept informed of the progress of this laboratory towards CPA accreditation. Centre staff interviewed on inspection were not aware of the accreditation status of the third laboratory. Evidence was provided post inspection that it is in the process of obtaining ISO 15189 accreditation, which is considered equivalent to CPA accreditation (SLC T21).

2. Patient Experience

Focus

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

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

Treating patients fairly

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

What the centre does well.

Evidence was provided on inspection that patients have treatment on suitable licensed premises.

From discussion with staff and patients and observations made on inspection, the inspection team was 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 donors and patients (CoP Guidance 29.3).

The PR stated that all patients attending the centre are considered equally for treatment and the centre has a medical advisory committee used to consider any complex medical and ethical issues.

Counselling: Guidance Note 3

A new counsellor has recently started at the centre. The centre also has a genetic counsellor who assesses all patients prior to commencing treatment.

The centre has a counselling SOP which includes the process for implications, support and therapeutic counselling (SLC T33 (b)). Counselling for recipients of donated gametes includes the importance of informing any resulting child that they are donor conceived (CoP Guidance 20.8). The counsellor confirmed that legal parenthood provisions are also discussed, where appropriate (SLC T60 and T61).

Satellite and transport patients are given the option of having counselling via the secondary centre or at centre 0070.

Patients and donors are made aware of the offer of counselling at the initial consultation

and a patient information leaflet regarding the counselling service is provided. Evidence that counselling had been offered was documented in the patient notes reviewed on inspection.

Counselling QIs, based on the British Infertility Counselling Association (BICA) recommended indicators (SLC T35), have been established and monthly patient satisfaction surveys are also conducted. An audit performed in April 2012 testing the compliance of the provision of counselling with SOPs and regulatory requirements, was also reviewed on inspection (SLC T36).

The counsellor is a member of BICA and evidence was provided demonstrating that she is working towards BICA accreditation (SLC T15(a) and CoP Guidance 2.12 (b)).

Complaints: Guidance Note 28

A new complaints officer has been in post since October 2011. Patients can directly contact the complaints officer and the centre's policy is to resolve complaints immediately where possible. If the issue is more serious, patients are asked to put the complaint in writing to initiate an investigation. Complaints are discussed at team meetings to ensure that learning is shared with all appropriate staff members.

Patients are provided with information on how to make a complaint, including contact details and the timescale for acknowledging and responding to complaints (CoP Guidance 4.2 (k)). The centre's complaints log was reviewed on inspection and demonstrated that the target response times are being met.

What the centre could do better.

Nothing noted at the time of inspection.

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 preimplantation genetic testing (Guidance Notes 9 & 10) – *only applicable to centres licensed to carry out preimplantation genetic diagnosis and screening*
- Information about legal parenthood (Guidance Note 6)

What the centre does well.

Several patients were interviewed on inspection and all gave positive feedback about their experience at the centre. They considered that they were given sufficient time to discuss their proposed treatment plan prior to giving consent, had sufficient opportunity to ask questions and said that staff were approachable and knowledgeable.

The centre has a SOP for the provision of information prior to obtaining consent for treatment (SLC T33 (b)). The nurse manager explained that patients have an initial consultation regarding treatment and possible costs with a clinician, followed by

information sessions with a nurse, prior to consent being obtained.

The centre submitted a suite of patient information prior to the inspection, covering the majority of the requirements of the CoP. Centre staff confirmed that the specific information not provided in these leaflets is provided verbally, prior to obtaining consent, with one exception (refer to page 11 of this report). Evidence of the provision of patient information was documented in the patient notes reviewed on inspection.

The centre's satellite and transport centres' websites were reviewed prior to inspection. The inspection team considers that appropriate and accurate information is given (Chief Executive's letter (10)(05)). The centre's own website was also reviewed prior to inspection and was considered to provide appropriate information, with the exceptions detailed below.

Costed treatment plans

Patients are provided with information regarding the cost of their treatment before it commences. A costed treatment plan is generated prior to each treatment cycle and a copy of this is given to the patients (CoP Guidance 4.3).

What the centre could do better.

A number of errors or areas of concern were identified during the patient information audit conducted prior to the inspection, as detailed below. The findings were discussed with the quality specialist on inspection and full details were provided post inspection. The PR explained that centre staff recognised the need for review and consolidation of the patient information leaflets. However, it has not yet been decided if the JD Healthcare re-structuring will include the use of LWC patient information leaflets. Therefore a full review of patient information is being postponed until this decision has been made.

Out of date contact information

The centre's 'use of discarded IVF samples for training purposes' patient information was considered comprehensive and invites patients to contact the centre if they have any questions or concerns. However, the contact details given are those of the previous laboratory manager.

The centre's 'welfare of the child assessment' patient information gives the HFEA's previous address.

Post inspection, updated patient information leaflets were submitted by the PR.

Screening requirements

The centre's 'IUI with donor sperm (DI)' recipient information states that it is a HFEA requirement for screening tests to be performed within the previous 12 months for the female patient. SLC T50 states that screening must be performed prior to the processing of patient gametes or embryos, intended for use in treatment or storage. Screening of the female patient prior to DI is not a mandatory requirement, although it may be considered good practice by the centre.

Post inspection, the PR submitted an appropriately revised patient information leaflet.

Success rates

The centre's patient information describing its success rates does not cover all of the requirements of CoP Guidance 4.2 (e). For example, CPRs for 2007-2010 for IVF/ICSI and 2008 for DI are referenced.

The centre's website does not satisfy all of the requirements of Chair's Letter CH(11)02. For example, success rates are not less than three years old and live birth rates are not provided. The website does provide a link to the HFEA's website for success rates, but this is on a separate page to the centre's results.

The website has been revised since the inspection to provide CPRs for 2010 only. The PR also confirmed that a clear link to the HFEA website will be added.

The centre's IUI and DI patient information leaflets state that its results are "significantly above the national average". HFEA data analysis demonstrates that the centre's current results are consistent with the national average.

The centre's website gives information on its 'mind and body programme' and states "70% of course attendees get pregnant". This was raised as an issue at the last inspection and the PR confirmed on this inspection that he would review the accuracy of this statement.

The website has been revised since the inspection and this statement has been removed.

Fees

The centre's 'recipient programmes schedule of fees' and 'egg sharing information for donors' refer to the previous HFEA IVF treatment fee of £104.50. The IVF treatment fee was reduced to £75 on 1 October 2011.

Revised patient information leaflets, reflecting the current treatment fee, were submitted by the PR after the inspection.

Donor information

The centre's 'freeze and share' information for donors implies that it is a legal requirement to have counselling. The HF&E Act 1990 (as amended), Section 13(6), (6A) and Section 13A(3) require that a suitable opportunity to receive proper counselling has been given. The PR has confirmed post inspection that this reference has been removed.

Several of the centre's donor and recipient patient information leaflets and the centre's website state that:

- Donor-conceived children born as a result of treatment prior to 1st April 2005 cannot know the identity of their donor. It does not explain that this is possible if the donor has since re-registered as identifiable (CoP Guidance 11.36).
- Limited information can be made available to donor conceived children at the age of 16, if they are getting married. It does not include the availability of information if the person proposes to enter into an intimate physical relationship (HF&E Act 1990 (as amended), Section 31ZB, (2)(c)).

Post inspection, evidence has been provided that some, but not all, of the patient information leaflets have been updated.

The centre's website includes articles written by donors describing their experience at the centre. One article states "everything is done anonymously and I will never know who

receives my eggs or even if a pregnancy results". The HF&E Act 1990 (as amended), Section 31ZD allows for information regarding the number, sex and year of birth of donor conceived children to be given to donors. The website has been revised since the inspection to remove this information.

Disclosing information

The centre's website suggests that the centre can disclose identifying information to General Practitioner's and debt collection agencies without patient consent. The HF&E Act 1990 (as amended), Section 33A places strict restrictions on the disclosure of patient identifying information without patient consent.

The centre's website states that patients need to 'opt out' if they do not want identifying information to be released to researchers. The HFEA's consent to disclosure form (Part 2 – research purposes), must be completed by all patients[4].

Storage of licensed material

The centre's 'information for men wishing to store sperm samples for the future' patient information refers to extending storage up to the age of 55 years. The HF&E (statutory storage period for embryos and gametes) Regulations 2009 allows for storage, in certain circumstances, of 55 years. This patient information was revised post inspection.

The centre's 'storage terms and conditions' patient information states that if one gamete provider withdraws consent to the storage of embryos, by law the embryos must be removed from storage and allowed to perish. It does not include the provision of a one year cooling off period, not extending beyond the end of the statutory storage period, where one gamete provider withdraws consent (HF&E Act 1990 (as amended), Schedule 3, (4A)).

Embryo testing

The centre's 'PGD for aneuploidy by array CGH' patient information leaflet states that HFEA regulations allow a maximum of two embryos to be transferred, even over the age of 40, if PGD has been performed. This is not a requirement of the current CoP. Appropriately revised patient information was submitted post inspection.

The centre's 'PGD' patient information states that the purpose of an application to the HFEA for the testing of a novel condition is to confirm that testing is suitable and to ensure that the test itself is accurate and reliable. When considering an application, the Authority does not take into account the accuracy and reliability of the test, this is the responsibility of the PR. This information has since been appropriately revised.

Treatment abroad

The centre's 'Bridge UK and international egg recipient programmes' patient information leaflet states that "the HFEA has advised patients against booking treatment overseas without the support of a licensed centre in the UK" and "Bridge works in partnership to prepare and support patients who wish to travel to Spain for treatment. This is in accordance with advice given by the HFEA". The HFEA has given no such advice. This was raised as an issue at the last inspection but this one reference was found to remain.

[4] Exception: This form is not completed by gamete/embryo donors or by patients using donated gametes/embryos.

ICSI

The centre's 'ICSI' patient information states that "egg damage happens in less than 5% of injected eggs". The centre's QI threshold for damage rates is 15%, although evidence was seen that the centre is considering reducing this threshold to 5%. The centre's 2012 data demonstrated a 6% damage rate.

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.

Centre staff provided evidence that written consent is obtained from patients prior to treatment (SLC T57) and the centre has a documented SOP for obtaining consent (SLC T33 (b)).

The nurse manager explained that consent is obtained by a nurse, usually at a second patient information session. Nurses have received legal training in the requirements for consenting patients (SLC T15 (a)).

Consent for satellite and transport patients is obtained by the secondary centre. Checklists are used at centre 0070 to ensure appropriate consent is in place prior to treatment.

Photographic identification is used to verify patient identity. Copies of photographic identification were seen in the patient notes reviewed on inspection (CoP Guidance 5.10).

Six sets of patient notes, including those of transport patients, were reviewed on inspection. Appropriate consents were in place in all cases, including consent to the disclosure of identifying information.

Legal parenthood: Guidance Note 6

The nurse manager stated that information regarding legal parenthood is given to patients prior to treatment and explained the process that would be followed if consent to parenthood was withdrawn (SLCs T64 and T65). If patients require more in depth advice regarding parenthood provisions, they are advised to seek their own legal advice.

Five sets of records of patients who had undergone treatment using donor sperm were reviewed. Consent to legal parenthood was obtained appropriately in all cases.

What the centre could do better.

Refer to page 28 of this report for storage consent issues.

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.

Premises and facilities: Guidance Note 25

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

Donor compensation: Guidance Note 13

Following discussions and a review of documentation, the inspection team consider that no money or benefit is given or received for the supply of gametes or embryos, except where authorised by the Authority. Donor compensation records indicated that compensation paid to donors was within the prescribed limits of General Direction 0001, version 2. The report of an audit of reimbursements to egg donors in 2011 was reviewed on inspection and demonstrated full compliance with the requirements of General Direction 0001, version 2.

The centre has not recruited sperm donors for over one year and the donor coordinator stated that compensation is not given to known sperm donors.

The donor coordinator explained that the centre's procedures regarding donor compensation are currently being updated to comply with the new requirements of General Direction 0001, version 3. Egg donors will now be compensated a fixed sum of £750, but will not be provided any excess expenses.

What the centre could do better.

Nothing noted at the time of inspection.

Storage of gametes and embryos

- Storage of gametes and embryos (Guidance Note 17)

What the centre does well.

The centre has SOPs detailing the procedures for storing gametes and embryos (SLC T33 (b)).

A checklist is used to ensure that consent to storage is in place prior to treatment and is kept in the patient notes.

The centre has revised it's bring forward system since the last inspection. It is clearly documented and the embryologist responsible for its management described the system in use. Contact is initiated with patients one year prior to the expiry of the consented storage period. Audit reports provided on inspection demonstrated that all licensed material in storage is currently within the consented storage periods, with some exceptions noted below (SLC T79 and CoP Guidance 17.17). Material in storage past its consented period has been raised as an issue at the last two inspections and the inspection team is satisfied that the bring forward system now in place is fit for purpose and is appropriately managed.

A complete donor sperm storage audit was performed in 2010 and a further representative sample audit was performed in 2011 prior to the relocation of the donor sperm bank to centre 0011. The audit report was reviewed on inspection and demonstrated that no issues were identified. The embryologist explained that due to the risk of material being damaged by repeated removal from dewars for a physical audit, ongoing audits are now performed at the time that material is removed from storage either for use in treatment or to allow to perish. Paper audits of a proportion of the material in storage are however carried out monthly and include a detailed review of the storage consent forms to ensure that they have been completed appropriately (SLC T36 and CoP Guidance 17.17).

What the centre could do better.

The centre's March 2012 embryo storage audit report of 129 freeze events was reviewed on inspection. This identified six sets of embryos that were in storage either without valid consent or with incomplete consent. The issues identified ranged from consent forms not being present, the storage sections of consent forms not being completed and consent forms not being dated.

Post inspection, the PR provided information demonstrating that appropriate consent has been obtained for one set of embryos and that action is being taken in relation to the other sets of embryos.

Further corrective actions, including a review of the procedures for checking appropriate consent is in place prior to storage and staff training, are also to be implemented (HF&E Act 1990 (as amended), schedule 3, (8)(1) and (2)).

The PR described accurately the procedure that would be used for invoking the cooling off period for embryo storage (HF&E Act 1990 (as amended), schedule 3, paragraph 4A (4))

however, this is not documented in a SOP (SLC T33 (b)).

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.

The centre has imported and exported sperm and embryos since the last inspection. The notes of two sets of patients who had samples exported in March 2012 were reviewed and included the details required by General Direction 0006.

The centre has also imported donor sperm from America and Denmark. Written confirmation that the requirements of General Direction 0006, Schedule 3 were satisfied for the import of sperm from America was reviewed and found to be comprehensive.

The centre's procedures for the distribution of gametes and embryos using transport incubators and dry shippers are supported by a SOP and checklists (SLC T33(b)).

A system is in place to ensure that consents and relevant screening test results are in place prior to the processing of transport patients' gametes.

Site visits to the transport centres have recently taken place to review their transport procedures, including maintenance and monitoring of the transport incubators. The records of two transport patients were reviewed and demonstrated that the data required by SLC T117 is provided to the centre, including traceability data and the temperature of the incubator at the start of transport. The centre plans to fit data loggers to the transport incubators to allow for the continuous monitoring of temperature during transit.

What the centre could do better.

The centre's SOP for the distribution of licensed material describes the actions to take if a recall of gametes/embryos is required. However, it does not define the procedure for handling returned material, including their reacceptance into the inventory, or document the requirement to investigate any recall of licensed material as an adverse incident (SLC T33 (b) and CoP Interpretation of Mandatory Requirements 15C).

Use of embryos for training staff (Guidance Note 22)

What the centre does well.

Embryos are used for staff training at the centre. The laboratory manager explained that once gametes and embryos have been designated as not for treatment purposes, the training consent is checked and material is moved to a dedicated training incubator (SLC T92).

Embryologists interviewed demonstrated a clear understanding of the purposes for which embryos could be used for training purposes (SLC T93).

The report of a recent training consent audit was provided and demonstrated that appropriate consent had been obtained prior to the use of embryos for the purpose of training staff to biopsy (SLC T36 and T94).

The centre's patient information clearly describes how gametes and embryos will be used to train staff and covers the requirements of SLC T97.

What the centre could do better.

The centre's SOP for the use of embryos for training does not document:

- The process by which it is assured that embryos appropriated for training purposes are not used in treatment services (SLC T92).
- The specific training purposes for which embryos are used (SLC T93).
- The procedure to ensure there is no actual or perceived conflict of interest between the use of embryos in training and the use of embryos in the provision of treatment services (SLC T95).

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 records reviewed during the inspection were seen to be clear and legible and satisfied all of the requirements of SLC T46. Records are kept either as paper notes or on the centre's electronic database.

Centre staff are currently in the process of reviewing all SOPs and implementing a new format to ensure both conciseness and usefulness. The staff are focusing on the laboratory SOPs initially and several SOPs using the revised template were reviewed on inspection and appeared very clear.

Centre documents are version controlled and reviewed on an annual basis (CoP Guidance 31.6). All documents reviewed on inspection were within their review period. There are plans to implement an electronic database which will automate the management of the document review process.

The centre's 'control of health records' SOP documents the requirement to maintain patient records for thirty years. The centre's new SOP template also lists all records associated with each procedure and their retention period requirements (SLC T48).

What the centre could do better.

Based on the number of issues highlighted in the patient information audit (see page 23 of this report), the inspection team was concerned that the annual review of centre documentation was not being performed thoroughly (CoP Guidance 31.6).

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

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

What the centre does well.

After the last renewal inspection in 2010, information requested from the centre was not always provided in a timely manner. However information requested throughout this inspection process was provided promptly. The Executive acknowledges this significant improvement and requests that the PR continues with the timely submission of requested information.

The PR has indicated on the renewal application form that in vitro maturation and non-invasive assessment activities are new processes by which the centre will conduct licensed activities. The PR confirmed that there was no intention to introduce in vitro maturation in the near future and it has not yet been validated. The PR is reminded to notify the Authority via the clinic portal when this process is introduced (General Direction 0008 (18)).

Non-invasive assessment activities have recently been introduced, using an incubator with integrated time-lapse photography function to assess embryo development. Validation records for this incubator were reviewed on inspection (SLC T24 and T72).

Licensed treatment reporting

The centre has a SOP for the submission of data to the HFEA (SLC T33 (b)) and has established QIs for the submission of data. Audits performed in April 2012 were provided and included a review of the registration status of all egg sharers and egg donors treated in 2011. Corrective action was seen to be documented and implemented (SLC T35 and T36).

Centre staff explained that data submission reports are regularly generated via the electronic data interface (EDI) to the HFEA Register, to ensure the timely correction of errors. Only nine recent errors are currently outstanding. This is a significant improvement in data quality compared to that found in the last two inspections.

What the centre could do better.

Licensed treatment reporting

Five per cent of early pregnancy outcome forms have not been submitted to the HFEA within the timeframe required by General Direction 0005. The Executive performs monthly cumulative sum (CUSUM) analysis of register data to allow on-going assessment of CPRs at individual centres. CUSUM analysis of CPRs for ICSI in the below 38 years age group at the centre demonstrated a dip in success rates in August and September 2011. This was discussed with centre staff on inspection and it is considered likely that the missing early pregnancy outcome forms is impacting negatively on the CUSUM analysis.

The PR explained that these forms had not been submitted because their transport

centres had not provided the required information, despite extensive prompting. It was further explained that the largest transport centre had recently lost two nurses who were responsible for providing this information. There are plans for a new member of staff to spend three days a week at the centre to manage the treatment reporting procedures and ensure their compliance.

To determine whether all licensed treatments are reported to the Authority as required by General Direction 0005, a sample of licensed treatments undertaken by the centre between 1 March 2011 and 29 February 2012 was reviewed on inspection. The sample was drawn from the centre's records and was reviewed against an extract of the Authority's statutory register.

The sample comprised 277 treatments (136 IVF and 141 DI treatments). Three of the 136 IVF treatments and one of the 141 DI treatments in the audit sample were found to be unreported at the time of inspection.

12% of the treatment cycles in the audit sample were not reported to the HFEA within five working days of the treatment as required by General Direction 0005.

Data Quality

To ascertain the quality of the data submitted by the centre for inclusion on the statutory register, 87 assorted data forms submitted to the Authority between 1 March 2011 and 29 February 2012 were reviewed against source documentation held in patient and donor files.

A number of errors were found where information on the donor files had not been submitted correctly. Details of these errors have been supplied to the centre so that corrective actions can be taken.

The centre currently submits 'intention to treat' (ITT) forms for DI treatments. These are required only for treatment cycles involving the collection of eggs.

There were a number of errors identified in the centre's gamete movement forms. The errors were due to a naming inconsistency which prevented the forms linking to the appropriate donor records.

An inter-departmental HFEA team has recently focussed on the large number of errors in the centre's donor registration forms, non-compliant with General Direction 0005. These errors place the HFEA at risk of not being able to provide donors and donor conceived people with information from the register. The PR was asked to ensure that these issues are resolved by 4 June 2012. The Registry Department has confirmed that the number of errors is being actively reduced and further EDI data entry training has also been provided to relevant staff by the register team since the inspection.

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

Access to the centre is restricted to licensed staff and a tour of the centre confirmed that patient identifying information is stored securely (SLC T43).

A sample of staff records reviewed on inspection included training in confidentiality requirements as part of the induction programme (SLC T15 (d)).

The centre's detailed SOPs for the control of health records were reviewed on inspection and include procedures for the secure maintenance of paper and electronic patient records, the appropriate use of email to send patient identifying information and the procedure for arranging access to patient records (SLC T44).

What the centre could do better.

Consent to disclosure of identifying information to researchers

An audit of patient and partner consent to identifying information from the HFEA register being disclosed to researchers, against that recorded on the HFEA register, was performed. In one of the twelve registration forms reviewed, a discrepancy was noted where a patient had consented to identifying information being released but this consent decision was not correctly entered on the HFEA register.

5. Changes / improvements since the previous inspection on 31 March and 1 April 2010

Area for improvement	Action required	Action taken as evidenced during this inspection
Embryos used for the validation of equipment and processes. A treatment licence cannot be granted for the activities stated above and the activities contravene the HF&E Act 1990 (as amended), schedule 2 (1) (3), which states “A licence under this paragraph cannot authorise any activity unless it appears to the Authority to be necessary or desirable for the purpose of providing treatment services”. HF&E Act 1990 (as amended), schedule 2 (1) (3).	The PR should ensure that only activities authorised by a treatment licence are carried out.	Confirmation was received after the last inspection from the previous PR that embryos would not be used for validation purposes. No further action is required.
The centre’s SOPs and patient information do not include the requirement for HTLV-1 antibody testing. SLC T52 (g).	The PR should ensure that the centre’s practice and documentation is revised to include the requirement for testing as per SLC T52 (g).	The centre’s donor SOPs submitted prior to this inspection document the requirement for HTLV-1 antibody testing. The quality specialist explained this test was rarely indicated for the centre’s patient population and therefore it is not included in all of the patient information leaflets. However, during the initial patient consultation, the clinician would determine if this test was required and would then give information verbally to the patient. Refer to page 9 of this report for HTLV-1 antibody testing of patients prior to processing of gametes or

		embryos for treatment or storage. No further action is required**.**
Blood samples for screening tests for donors not taken at the time of donation. SLC T53 (b).	The PR should ensure that blood samples for screening tests for donors are obtained at the time of donation.	The centre's egg donor SOPs state that blood samples for screening tests must be taken within six months of the time of donation. In the three sets of egg donor records reviewed on inspection, screening tests were performed two to three months prior to egg collection. The PR explained that screening was performed early in the donor assessment stage, because a positive result would prevent the donor from being accepted. This assessment stage can be some months before donation occurs. Post inspection, the PR provided evidence that re-testing at the time of down-regulation of the egg donor via nucleic acid amplification will now be performed. No further action is required.
QIs have not been set for all areas of centre practice. SLC T35.	The PR should ensure that QIs are set for all areas.	QIs have been established for all areas of centre practice. No further action is required.
Recording of the name and status of the practitioner and witness for all witnessing steps. SLC T71.	The PR should ensure that the name, status and signature of both practitioner and witness are	The name and status of the practitioner and witness at each witness step is recorded on the centre's electronic witnessing system.

	recorded in the patient records.	No further action is required.
TPAs are required with the hospitals used when a female patient's BMI is 40 or over, and with the laboratory equipment servicing company. SLC T111 (a).	The PR should put in place TPAs.	After the last inspection the centre submitted the TPA with the laboratory equipment servicing company. The PR confirmed that other hospitals are not being used currently for the purpose of egg collection. However, the centre's patient information does refer to other hospitals being used on occasion. **Further action is required.**
The centre's third party list is not up to date. SLC T111 (b).	The PR should ensure that the list of TPAs is complete.	The centre's TPA list was seen to be up to date. No further action is required.
The centre's TPA with a sample courier firm refers to the requirements of the 7th CoP. SLC T116.	The PR should ensure the agreement is updated to refer to the requirements of the 8th CoP.	The centre submitted a revised TPA with the courier company after the last inspection, referring to the requirements of the 8th CoP. No further action is required.
Two of the satellite centres on the list of transport/satellite centres submitted by the centre are not included on the HFEA held list. General Direction D0010 (section 3).	The PR should ensure that the centre submits its agreement and patient information to the HFEA prior to the start of any new service.	The centre submitted written agreements with the two satellite centres after the last inspection. The details of the centre's current satellite and transport centres submitted as part of this renewal application are included on the HFEA held list, with one exception. The PR explained that this satellite arrangement was no longer going to proceed. No further action is required.

Competence assessments have not been completed for all members of staff for all critical processes. Not all competencies are re-evaluated after the initial assessment. **This was an issue at the previous inspection.** SLC T12.	The PR should ensure competence assessments are completed and re-evaluated at regular intervals.	The competence of all staff was seen on this inspection to have been appropriately assessed. No further action is required.
The centre's OHSS log was seen at inspection to include four hospital admissions in 2009. These were not reported to the HFEA. SLC T118. CoP Guidance 27.1.	The PR should ensure all previous and future cases of OHSS that require hospital admission and have a severity grading of severe or critical are reported to the HFEA.	The four cases of OHSS were reported to the HFEA after the last inspection. The centre's 'OHSS' SOP includes the requirement to report severe cases to the HFEA (SLC T33(b)). The report of a recent audit was reviewed on inspection and demonstrated that all OHSS admissions in 2011 had been reported to the HFEA (SLC T36). No further action is required.
The centre's "control of records" policy does not include all requirements of SLC T44, including preventing unauthorised disclosure of information whilst guaranteeing the traceability of gamete, embryo or tissue (cell) donations. SLC T44.	The PR should ensure that the centre's policy for control of records includes all requirements of SLC T44.	Refer to page 34 of this report. No further action is required**.**

The centre is licensed to provide gamete intra-fallopian transfer (GIFT), but the centre's MBMS does not include a section regarding GIFT. The current MBMS describes the centre's 2009 plan for its strategy. General Direction 0003.	The PR should decide whether to either apply for the removal of GIFT as a licensable activity or to add the appropriate section to the MBMS. The PR should update the centre's MBMS.	The centre submitted an updated MBMS after the last inspection. The centre does not provide GIFT treatment. No further action is required.
There is no summary log of cases in which multiple embryos have been transferred to a patient who meets the criteria for eSET and details are not recorded in the patient notes General Direction 0003 (3 (c) and 7).	The PR should ensure a summary log is kept and details are recorded in the patient notes.	Refer to page 17 of this report. No further action is required.
The scientific director confirmed that PGD is being carried out only for those genetic conditions expressly authorised by the Authority. No evidence of this was seen at inspection. The scientific director agreed at inspection to submit the centre's PGD log. This has not yet been submitted, therefore the inspectorate is unable to assess compliance with the Licence Condition. SLC T89.	The PR should ensure that the centre's PGD log for 2009/2010 is submitted to the inspectorate.	The centre submitted its PGD log, demonstrating compliance with SLC T89, after the last inspection. No further action is required.
The "transport of gametes and embryos nationally and internationally" SOP does not	The PR should revise the SOP to include all points of SLC T107.	The centre submitted evidence demonstrating compliance with SLC T107 after the last inspection.

include the requirement to label the shipping container “Tissues and Cells” or to record the date and start time of transport. SLC T107.		No further action is required.
The centre’s staff confirmed that the centre has information regarding the validation of ICSI, biopsy, PGS and PGD processes, but that this information has not been collated into validation documents and therefore could not be assessed by the inspectorate. SLC T72.	The PR should ensure that all critical processing procedures are validated as per SLC T72.	Process validation has been completed, with one exception. Refer to page 15 of this report. **Further action is required.**
Transport incubators are the property of transport centres and the laboratory manager stated that the maintenance of the incubators is their responsibility and was not aware if servicing was performed regularly. SLC T109 (a). CoP Guidance 24.6.	The PR is reminded that the centre retains overall responsibility to ensure that treatment arranged at another centre complies with all relevant legal requirements, quality and safety considerations and CoP Guidance. The PR should ensure that the centre is informed of the maintenance and servicing of the incubators. It is recommended that the transport/satellite pathway is reviewed to ensure the quality and safety of games, as per SLC T109	Refer to page 29 of this report. No further action is required.

	(a).	
Sperm from 1 patient and embryos from 49 patients are in storage without consent. **This was an issue at the previous inspection.** HF&E Act 1990 (as amended), schedule 3 (8) (1).	An action plan was provided to the inspectorate by the centre at inspection. The PR should ensure the action plan is followed and the Executive is kept informed. Considering that this was also an issue at the last inspection, it is recommended that six monthly storage audits are carried out for at least two years and the results submitted to the Executive and that the centre reviews its storage procedures.	The centre provided evidence that the storage of material without consent referenced in the last report had been resolved. The inspection team is satisfied that the bring forward system now in place is fit for purpose and is appropriately managed. However six sets of embryos were in storage either without valid consent or with incomplete consent at the time of this inspection. Refer to page 28 of this report. **Further action is required.**
A random check of two items of laboratory consumables showed that the batch number of one item did not match that recorded as in use on the electronic spreadsheet. SLC T99 (b).	The PR should ensure that all relevant data relating to anything coming into contact with gametes or embryos is appropriately recorded so as to ensure traceability from procurement of gametes to patient treatment or disposal and vice versa. The inspectorate recommends that traceability audits are carried out at the centre every three months for at least one year and the results submitted to the Executive.	Traceability audits were submitted to the Executive as requested after the last inspection. Refer to page 13 of this report. No further action is required.

A “monthly temperature monitoring chart” from December 2009 was seen. Measurements were recorded and corrective action where measurement was not in the specified range was seen in some cases, but not all (see section below). Acceptable limits were defined as 37.0^{o}C +/- 0.5^{o}C. The laboratory SOP states that if the equipment is out of acceptable limits, corrective action should be taken. Some cases corrective action was recorded where out of range, but one stage measured at 38.1^{o}C at start of measuring and 37.9^{o}C after 10 minutes, but corrective action taken was not documented. SLC T24.	The PR should either review and revise the acceptable limits defined for critical parameters, define when corrective action should be taken, or ensure that corrective action is taken where critical parameters fall outside of acceptable limits.	The PR confirmed that laboratory staff had been reminded of the need to take corrective action when critical parameters fall outside of acceptable limits, after the last inspection. Refer to page 14 of this report. No further action is required.
The centre’s “transport of gametes and embryos nationally and internationally” states that on arrival of the transport incubator, a note is made of the temperature and time of arrival. At inspection it was observed that a record is made of the reading on the temperature display, but it is not measured using an independent probe (SLC T24). Independent monitoring is carried out on a monthly basis. The inspectorate was concerned that for a critical piece of equipment, more frequent monitoring with equipment calibrated against a traceable standard is required. SLC T24.	The PR should review the frequency of independent monitoring of the transport incubators.	Evidence was provided that the temperature of the transport incubator is verified using a calibrated thermometer upon arrival at the centre. No further action is required.

The centre's "Temperature monitoring" SOP states that all equipment used for temperature monitoring is serviced and calibrated at least annually. The laboratory manager explained that there is no formal schedule for calibration because the equipment regularly malfunctions and calibration is routinely carried out at the time of repair by an external company. SLC T24.	The PR should ensure that all critical equipment and technical devices are regularly inspected and maintained in accordance with the manufacturer's instructions. The inspectorate considers that a formal schedule is required to ensure critical devices are regularly inspected and maintained.	The centre submitted evidence demonstrating that measuring equipment is calibrated annually after the last inspection. No further action is required.
Clinical drug refrigerators are monitored frequently and the temperature record log for 2009 was seen. However, the thermometer used for measuring is not calibrated against a traceable standard. SLC T24.	The PR should ensure that all equipment with a critical measuring function is calibrated against a traceable standard if available.	The PR confirmed that monitoring of the clinical drug refrigerators using thermometers calibrated against a traceable standard would be performed after the last inspection. No further action is required.
There are no specific equipment SOPs and no written procedures for action to be taken in the event of a malfunction. SLC T27.	The PR should ensure that procedures for the operation of each piece of critical equipment are established and document the action to be taken in the event of malfunctions or failure.	Refer to page 15 of this report. No further action is required**.**
There is not a SOP for equipment cleaning. SLC T33 (b).	The PR should ensure SOPs are in place for all activities authorised by this licence and other activities carried out in the course of	The centre submitted an equipment cleaning SOP and checklist after the last inspection. Clear documentation of equipment cleaning was seen

	providing treatment services that do not require a licence.	on this inspection. No further action is required**.**
Various document control issues were observed during the inspection. These included: documents past their review date and documents with no version control. In the suite of patient information provided by the centre prior to inspection, different versions of the same information were provided for some documents. The adequacy of the review of documents to ensure they remain fit for purpose was lacking for the centre's "Surrogacy" SOP. SLC T34. CoP Guidance 31.4 and 31.6.	The PR should ensure that: • The document control procedure ensures that only current versions of documents are in use. • All documents are controlled. • Documents are reviewed, revised and reapproved at a frequency that ensures they remain fit for purpose. The maximum interval between reviews should be 12 months.	Refer to page 31 of this report. **Further action is required.**
The average payment time for treatment fees for the 12 months to 6 March 2010 was 78 days. The centre has not met the 28 day timescale for any invoice during this period. **This was an issue at the previous inspection.** SLC T9 (d).	The PR has responsibility for ensuring fees are paid to the Authority within the timescale specified in Directions or in writing. The HFEA requires payment of fees for treatment cycles no later than 28 days from the date on the Authority's invoice. The PR is in talks with the PCTs regarding payment of fees.	The average payment time for treatment fees for the 12 months from 01/04/2011 to 31/03/2012 was 88 days. The HFEA's Director of Finance and Facilities wrote to the PR in December 2011 to set out the action that would be taken in future if late payment recurred, including: 1. The issue of a Chief Executive's letter for the next late payment, regardless of duration; 2. Referral of the matter to a Licence Committee if

		there is a subsequent recurrence. 3. Consideration of other applicable sanctions, including complaints to relevant professional bodies. The January and February fees and the renewal fee were not paid within the required 28 day timescale and consequently the Chief Executive's letter was issued on 23 April 2012. All outstanding fees were subsequently paid on 27 April 2012. No evidence was seen on inspection that financial issues have impacted on the quality and safety of gametes and embryos. The PR assured the inspection team that appropriate funds were available for all critical activities (e.g. equipment servicing and liquid nitrogen deliveries). Post inspection, the PR confirmed that the centre has developed new processes to streamline the payment of fees. Payments will be made an organisational priority and will be paid according to payment terms. **Further action is required.**
There continues to be problems with data submissions to the HFEA. The centre is in breach of General Direction 0005 with HFEA form submission errors not cleared within two months. **This was an issue at the previous**	The PR should ensure that data submissions comply with HFEA Directions.	Since the last inspection, the centre has dedicated significant resources to error clearing, resulting in a significant improvement. No further action is required.

inspection.		
The centre has not submitted appropriately completed documentation in application for renewal of the licence, as per General Direction 0008, paragraph 16. SLC T4.	The PR must submit the outstanding information in support of the renewal application. The PR should ensure in future that documentation is provided to the Authority within 28 days of a request.	The centre submitted the required documentation after the last inspection. All requested documentation for this renewal inspection was submitted in a timely fashion. No further action is required.
The centre's donor SOPs do not include the requirement for testing for gonorrhoea for egg donors. CoP Guidance 11.16.	The PR should ensure that donors are screened in accordance with current professional guidance.	The centre's revised donor SOPs include the requirement for testing for gonorrhoea for egg donors. Three sets of egg donor records reviewed on inspection demonstrated that testing for gonorrhoea was performed. No further action is required.
The centre's "donating your embryos" patient information does not include reference to the uncertain legal status of men donating embryos to single women. CoP Guidance 11.25.	The PR should revise the patient information.	The centre's revised patient information references the uncertain legal status of men donating embryos to single women. No further action is required.
The witness step of eggs received from transport centre only includes checking the patient's surname and date of birth. CoP Guidance 18.5.	The PR should ensure that the witness step checks the patient's full name and their unique identifying code.	The centre's witness step now includes the requirement to check the patient's first name, surname and date of birth. No further action is required.

It is recommended that a counselling leaflet is provided to patients, including information giving the name of the qualified counsellor, explaining their role, when they are available and how to access the service. CoP Guidance 3.2.	The PR should provide a counselling leaflet including the information stated in CoP Guidance 3.2.	The centre's counselling leaflet includes all requirements of CoP Guidance 3.2, with the exception of the name of the counsellor. The PR explained that one counsellor has just left the centre and another has recently joined and therefore the name was removed during this transition phase. The counsellor explained that she will be revising this leaflet and adding her details to allow patients to contact her directly. No further action is required.
The counsellor explained that all members of centre staff have access to the counsellor's electronic diary, including patient names. During the patient records audit carried out at inspection, counselling notes were observed to be filed with the clinical notes. CoP Guidance 3.12.	The PR should ensure that information obtained during counselling is confidential. The written records of the professional counsellor should be kept in a secure place.	All counselling records were observed to be stored securely on inspection. No further action is required**.**
The centre charges £63 for copying patient notes for patients who have not attended the clinic for over twelve months. The maximum fee allowable is £50. Data Protection Act 1998 (fees and miscellaneous provisions) Regulations 2001. CoP Guidance 30.8.	The PR should revise the charges for copying of patient notes.	The centre provided evidence demonstrating that the fee had been revised to £50 after the last inspection. No further action is required.
Patient information on the centre's website	The PR should ensure that patient	Improvements have been made to the centre's

requires revision.	information on the centre's website is reviewed and revised, as documented in the main body of the report.	website, but some issues remain (refer to page 23 of this report). The PR explained that it was difficult to navigate through the large number of pages on the website to revise all of the requested information. There are plans to redesign and re-launch the centre's website in August 2012. **Further action is required.**
Patient information leaflets referring to previous statutory storage periods. CoP Guidance 17.12 (b).	The PR should ensure that all patient information referring to previous statutory storage periods are updated.	After the last inspection, the centre submitted revised information, referencing current statutory storage periods. During the patient information audit prior to this inspection, one leaflet was found to continue to refer to previous statutory storage periods. This patient information was revised post inspection No further action is required.
Patient information states that donors are 'free to modify or withdraw consent at any time until the eggs are used'. CoP Guidance 5.22 (a).	The PR should ensure that relevant patient information is revised in line with CoP Guidance.	The centre submitted appropriately revised patient information after the last inspection. No further action is 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
1) Embryos in storage without valid consent Six sets of embryos were in storage either without valid consent or with incomplete consent at the time of inspection. Evidence was provided post inspection that consent has been obtained for one set of embryos and that action is being taken in relation to the other sets of embryos. HF&E Act 1990 (as amended), Schedule 3, (8) (1) and (2).	The PR should ensure that appropriate consent is obtained for the storage of the remaining five sets of embryos. The PR should ensure that the identified corrective action is implemented by 18 July 2012, to ensure that prospectively, gametes and embryos are not stored without appropriately completed consent forms. Details of the implementation of this corrective action should be	The six sets of embryos identified at the time of inspection without valid consent or with incomplete consent documentation have been updated and corrections made. All embryos have valid consent and complete consent documentation. A completed action plan has been provided to the inspector with this report	The PR has submitted evidence demonstrating that appropriate consent has been obtained for the remaining five sets of embryos. The Executive will continue to monitor progress with respect to implementation of further corrective action.

	submitted to the Executive.		

Major area of non compliance

A major area of non compliance is a non critical area of non compliance:

- which poses an indirect risk to the safety of a patient, donor, embryo or to a child who may be born as a result of treatment services
- which indicates a major shortcoming from the statutory requirements;
- which indicates a failure of the Person Responsible to carry out his/her legal duties
- a combination of several "other" areas of non-compliance, none of which on their own may be major but which together may represent a major area of non-compliance.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
1) Diagnostic semen analysis Diagnostic semen analysis is performed in the centre's laboratory. The PR considers that the centre meets the requirement of SLC T21 to be accredited by a body accrediting to an equivalent standard as the CPA, through its HFEA licence and compliance with HFEA SLCs. CPA accreditation requires the participation in external quality assessment schemes to ensure the reproducibility and accuracy of tests. The centre participates in NEQAS for semen analysis. However, poor results have persistently been received for sperm morphology and	The PR should ensure that the action plan is implemented by 18 July 2012. The results of the next NEQAS assessment should be provided to the Executive within one week of the centre receiving them. The PR should also inform the Executive if the centre fails a NEQAS assessment or receives a negative NEQAS report at any time.	The action plan is in progress and implementation will continue to completion by 18th July 2012 NEQAS distribution 73 (11th June 2012) has been completed by the centre and results will be provided to the inspector one week from the centre receiving them. NEQAS distribution 74, 75, 76 (13/08/2012: 12/11/2012/ 11/02/2013 respectively) will be completed and results provided to the inspector one week from receipt.	The Executive is satisfied with the PR's response and will continue to monitor progress. The inspection team consider that the centre's compliance with HFEA SLCs and the presence of experienced and competent laboratory staff to interpret results, will provide accreditation to an equivalent level once performance in NEQAS is at a consistent and satisfactory standard.

sperm concentration assessments. A review has recently been conducted and a clear action plan documenting the corrective actions required was supplied to the inspection team. SLC T21 and CoP Guidance 23.23.			
2) Outcome information to donors The centre maintains records to be able to provide donors with information regarding the number, sex and year of birth of persons born as a result of their donation. However, the PR explained that it was not clear if these records could provide fully accurate information. The inspection team is aware that as the majority of the donor bank has been relocated to centre 0011, this non-compliance is no longer the sole responsibility of this centre's PR. HF&E Act 1990 (as amended), Section 31ZD (3).	Post inspection, the PR confirmed that a sample audit has been undertaken to estimate the resources required for a full review of the centre's records to ensure that accurate information regarding the number, sex and year of birth of persons born as a result of their donation can be given to donors. Further resources have since been allocated and a full action plan will be submitted to the Executive by 18 May 2012. The PR should also ensure that processes are in place by 18 July 2012 to ensure that accurate information is collected prospectively.	A donor usage/outcome action plan has been developed and being implemented. The action plan has been provided to the inspector with this report. An SOP will be provided to the inspector by the 18 July 2012.	The centre has submitted a detailed action plan, due for completion by 31 July 2012. The Executive is satisfied with the PR's response and will continue to monitor progress.

3) Egg donor information form completion Whilst there is no legal requirement for a good will message and personal description to be provided, the HF&E (Disclosure of Donor Information) Regulations 2004, Section 2 (2)(g)(h) clearly envisage that the type of information that may be contained in such descriptions should be disclosed to the donor-conceived, where available. Some donors are not being asked to provide this information, which undermines the HFEA's ability to discharge its statutory responsibilities towards the donor-conceived. HF&E (Disclosure of Donor Information) Regulations 2004 Section 2 (2)(f)(g)(h). CoP Guidance 11.35 and 11.36.	Post inspection, the PR submitted several revised SOPs, documenting the requirement to discuss the option of providing a good will message and a personal description with all egg donors during their counselling session. The PR should ensure, prospectively, that all required sections of the donor information form are submitted to the HFEA, whether completed by the donor or not. This action should be implemented immediately. The PR should evaluate the options for retrospectively contacting donors who were not originally given the opportunity to provide this information and where either donor-conceived children have been born as a result of the donation, or where embryos created using their gametes are in storage. The PRs proposed plan should be submitted to the Executive by 18 July 2012, prior to contacting any donors.	All SOPs are part of our Quality Management System and will be reviewed and audited as part of our audit schedule. All sections of the donor information form will be submitted to the HFEA whether completed by the donor or not. Although the requirement for a good will message is not a mandatory requirement the centre will evaluate the options for retrospectively contacting donors, develop a plan and submit to the inspector by the 18th of July 2012.	The Executive is satisfied with the PR's response and will continue to monitor progress.

4) Donor Identifying information The centre's 'screening of sperm donors' SOP states "the donor should be asked if they are willing to provide a recent or childhood photograph which will be available for recipient viewing at the centre". Identifying donor information cannot be disclosed to recipients and photographs could be considered to be identifying. HF&E Act 1990 (as amended), Section 33A (1)).	The PR should ensure that either: • The SOP is revised to remove the option of a donor providing recent or childhood photographs. • If the SOP is not revised, the centre's rationale for deciding that a recent or childhood photograph is not identifying should be documented and submitted to the Executive. The selected action should be completed by 18 July 2012.	In practice donor photographs have not been requested or stored. Practice has been at variance to the SOP. Sperm donors are no longer recruited or screened via the Bridge centre. All recruitment and screening is carried out by the London Sperm Bank (LSB) SOPs relating to recruitment have been provided to the inspector with this report. LSB Recruitment manual:1964 05/04/2012 The records for sperm donor samples transferred to the LSB do not contain potentially identifying photographs.	The Executive is satisfied with the PR's response. **No further action is required.**
5) Process validation The process for the use of pentoxyfilline has not been validated. SLC T72.	The PR should ensure that the process for the use of pentoxyfilline is validated by 18 July 2012.	The use of pentoxyphylline has been validated and the validation report has been provided to the inspector with this report.	The centre has submitted evidence demonstrating that the process has now been validated. **No further action is required.**

6) Air quality The centre's SOP for the monitoring of air quality states that particle counts are performed quarterly or at a minimum frequency of biannually. Particle counts were last performed in June 2011. The air quality procedures, including frequency of monitoring, have not been validated. SLC T72 and CoP Guidance 25.10.	Evidence was provided post inspection that an external company will commence particle count monitoring on a quarterly basis from May 2012. The PR should confirm to the Executive by 1 June 2012 that this has been performed and that the results meet the requirements of SLC T20. The PR should ensure that the air quality testing procedures, including the frequency of monitoring, are validated by 18 October 2012.	The Bridge Centre has carried out further air quality testing (07/06/2012) which demonstrates compliance with regulatory requirements as described on page 1 of the attached report. The documented results have been provided to the inspector with this report. The Bridge Centre will follow the validated JD Healthcare air quality testing procedures. Documented evidence will be submitted by 18 October 2012.	The centre has submitted evidence demonstrating that particle count monitoring was performed on 7 June 2012 and that air quality meets the requirements of SLC T20. The Executive is satisfied with the PR's response regarding validation of the air quality testing procedures and will continue to monitor progress.
7) Treatment data submission to the HFEA **Licensed treatment reporting** Five per cent of required early pregnancy outcome forms have not been submitted to the HFEA within the timeframe required by General Direction 0005. The HFEA Register audit found that from a sample of 136 IVF and 141 DI treatments, three IVF treatments and one DI treatment were unreported at	The PR has confirmed post inspection that processes have been reviewed and staff training has been provided by the HFEA, to ensure the timely and accurate reporting of treatment data to the HFEA register. The PR should ensure that all outstanding early pregnancy outcome forms are submitted to	The Bridge Centre is committed to providing timely data submissions to the HFEA; however, we have experienced a number of technical IT errors in this submission process. As a result we are working with the HFEA to install new EDI terminals and an improved IT connection with the HFEA to ensure that all submissions are completed accurately.	CUSUM analysis of the centre's data for the period March 2011 – February 2012 was reviewed by the Executive on 13 June 2012. The number of missing early pregnancy outcome forms for this period has been significantly reduced and the data shows the centre's success rates continue to be in line with the national average.

the time of inspection. Twelve per cent of the treatment cycles had not been reported within 5 days, as required by General Direction 0005. **Data quality** The HFEA Register audit identified a number of errors where information on the paper donor records had not been correctly submitted to the HFEA. There were errors with gamete movement forms where the forms were not linking to appropriate donor records because of the name used on the 'Gamete Movement In' (GI) form. The centre currently submits 'intention to treat' (ITT) forms for DI treatments. These are required only for treatment cycles involving the collection of eggs. **Donor registration errors** The centre had a large number of	the HFEA. The Executive will review the centre's outcomes, including multiple CPRs, based on the submission of this data. Any areas of concern will be followed up with the centre. The PR should ensure that all errors and discrepancies noted in the HFEA Register audit are corrected. Details of all audit findings have been provided to the centre. These actions should be completed by 18 July 2012. The PR should ensure that all historic donor registration issues	The centre will ensure that outstanding early pregnancy outcome forms are submitted to the HFEA. The centre will ensure that corrections are made by the 18th July 2012 The donor registration error corrections have been submitted to the HFEA	Analysis performed on 13 June 2012 demonstrated that the centre continues to be unlikely to significantly exceed the 2011/2012 multiple birth rate target of 15%. The HFEA registry team has confirmed that only seven donor registration errors remain. These may be genuinely missing donors, rather than data submission errors, and will be followed up as part of a different registry process. The Executive is satisfied with the PR's response and will continue to monitor progress.

donor registration errors. It was required to address the issue and has taken corrective action. This has reduced the scale of the problem to 31 errors on 08/05/2012.	are resolved by 4 June 2012.	Due to an error in the electronic interface between the centre and the HFEA were not submitted by the 4 June (see solution described above).	
8) Consent to disclosure of identifying information to researchers In one of the twelve registration forms audited on inspection, a discrepancy was noted where a patient had consented for research, but this consent decision was incorrectly entered on the HFEA register. General Direction 0005.	The PR should ensure that the discrepancy noted on inspection is corrected on the HFEA register. The PR should conduct an audit of a representative number of consent to disclosure forms (completed since October 2009) in the patient records against the consent decisions that have been submitted to the HFEA. The findings of the audit and any relevant corrective actions should be documented and a copy provided to the Executive by 18 July 2012. If the audit findings indicate a systemic problem, a full audit of all consent to disclosure forms completed since October 2009 may be required. The PR should ensure that, in future, all data submitted regarding consent to disclosure of identifying	An audit of the consent to disclosure of identifying information to researchers consent forms has begun. (30/05/2012) A representative sample by year has been identified for 2010, 2011, and 2012. The results and any corrective actions will be provided to the inspector by 18 July 2012.	The Executive is satisfied with the PR's response and will continue to monitor progress.

	information from the HFEA register, is entered accurately and is supported by the patient record.		
9) Patient information The centre's website and patient information leaflets provide information on success rates, but do not cover all requirements of Chair's letter CH(11)(02). A number of errors/areas of concern were found during the patient information audit, including a review of the centre's website, as detailed and referenced in the body of the report.	Post inspection, the PR provided evidence that several of the patient information leaflets and sections of the centre's website have been revised. The PR should ensure that the centre's website and patient information on success rates cover all requirements of Chair's letter CH(11)(02). The PR should ensure that the remaining patient information is updated to provide accurate information. The PR should ensure that future annual reviews of centre documentation include a review of the accuracy and compliance of the patient information given. These actions should be implemented by 18 July 2012.	The centre's success rates are published on the website in line with the requirements of CH (11) (02) i.e. within 3 years. Patient information reviewed as a result of the inspection has been updated to provide accurate information. Patient information regarding sperm and egg donation are being updated as the service develops. These will be provided to the inspector on completion prior to 18 July 2012. The centre's annual review of documentation will include a review of the accuracy and compliance of the patient information given.	The Executive recommends that further revision to the centre's website is considered to comply with all of the requirements of the Chair's Letter, including live birth rates and details of the national success rates. The Executive is satisfied with the PR's response and will continue to monitor progress.

10) Fee payment The centre took an average of 88 days to pay invoices from 01/04/2011 to 31/03/2012. A further late payment of fees will result in the matter being referred to a Licence Committee. SLC T9 (d).	Post inspection, the PR confirmed that the centre has developed new processes to streamline the payment of fees. Payments will be made an organisational priority and will be paid according to payment terms.	N/A	The Executive is satisfied with the PR's response and will continue to monitor progress.

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
1) Witnessing The signature of the patient, witnessing the cross-checking of patient identifying information at the time of sperm collection, is not retained in the patient's records. SLC T71 and CoP Guidance 18.4 (b).	The PR should ensure that a full record of the witnessing step to cross-check patient identifying information at the time of sperm collection is retained in the patient's records. This action should be implemented by 18 July 2012.	The signature of the patient, witnessing the cross-checking of patient identifying information at the time of sperm collection, will be retained in the patient's records. An updated SOP 9 Witnessing and laboratory recording sheet has been provided to the inspector with this report.	The centre has submitted documentation demonstrating that a full record of this witnessing step will now be retained in the patient's records. **No further action is required.**
2) SOPs a) The centre's 'initial assessment' SOP does not detail the requirement for additional patient testing, including for HTLV-1, where appropriate. b) The centre's traceability SOP does not document the requirement to record the critical equipment used in the processing of gametes and embryos.	Evidence was provided post inspection that the requirements at a) and b) are now documented in centre SOPs. The PR should ensure that the other SOPs referenced in this report are also reviewed and revised appropriately. This action should be implemented by 18 October 2012.	c) The procedure that would be used for invoking the cooling off period is described on page 6 of the Storage review of frozen gametes and embryos LABSOP 2. This was submitted to the inspector on the 11/05/2012. d) This SOP will be provided to the inspector by 18 October 2012.	The centre has submitted its revised 'storage review of frozen gametes and embryos' SOP and its 'storage terms and conditions' patient information. The Executive is satisfied with the PR's response and will continue to monitor progress.

c) The procedure that would be used for invoking the cooling off period for embryo storage has not been documented. d) The centre's SOP for the distribution of licensed material describes the actions to take if a recall of gametes/embryos is required. However, it does not define the procedure for handling returned material, including their reacceptance into the inventory, or document the requirement to investigate any recall of licensed material as an adverse incident. e) The centre's SOP for the use of embryos for training staff does not include the requirements of SLCs T92, 93 and 95. SLC T33 (b).		e) The training SOP has been revised to clarify which gametes/embryos can be used in training and for what purposes. LABSOP 18 training, professional development Patient information has been clarified to ensure patients are fully informed. INF 961 Use of discarded IVF samples for use in training. A training log has been introduced to ensure that all training/disposal is recorded LABSF10 Training material log	
3) Third party agreements The centre's TPAs with two companies carrying out diagnostic analysis do not include a description of how test/diagnostic results are relayed to the centre, including sign	The PR confirmed post inspection that all TPAs have been reviewed for compliance with SLC T114 (f). An example of one revised TPA was submitted and was considered by	The PR will inform the inspector by 18 October 2012 when the revised TPAs have been approved by the companies.	The Executive is satisfied with the PR's response and will continue to monitor progress.

off and confirmation that the result applies to the correct sample. SLC T114 (f).	the Executive to meet the SLC requirements. The PR should inform the Executive by 18 October 2012 when the revised TPAs have been approved by the companies.		
4) Written agreement with satellite centre The written agreement with one satellite centre was not available for review on inspection. The PR agreed to submit a copy to the inspector for review. General Direction 0010 (9).	The PR should ensure that the written agreement is submitted for review. This action should be implemented Immediately.	The Bridge Centre no longer has an agreement with the identified satellite centre.	The Executive is satisfied with the PR's response and will update the HFEA's records accordingly. **No further action is required.**
5) Low oxygen sensor and alarm One dewar, situated in the centre's main laboratory, did not appear to be in close proximity to a low oxygen sensor. CoP Guidance 25.15.	Post inspection, the PR confirmed that a personal low oxygen monitor has been situated close to the dewar as an interim solution. Evidence was provided that a quotation for a fixed alarm has been received and the sensor will be purchased and installed. The PR should ensure the sensor is fitted as soon as is practical and should advise the Executive when this has been completed.	A new O2 sensor has been ordered and a copy of the purchase order has been provided to the inspector. The PR will inform the inspector once completed.	The Executive is satisfied with the PR's response and will continue to monitor progress.

6) Accreditation Three external laboratories are used for the diagnostic analysis of blastomeres and polar bodies for embryo testing. One is CPA accredited and one is in the process of obtaining CPA accreditation. The centre is kept informed of the progress towards CPA accreditation of this laboratory. Centre staff were not aware of the accreditation status of the third laboratory. Evidence was provided post inspection that it is in the process of obtaining ISO 15189 accreditation. SLC T21.	The PR should ensure that the centre is kept informed of the progress towards accreditation of the two external laboratories. The PR should inform the Executive when accreditation has been achieved.	The PR will inform the inspector when accreditation has been achieved	The Executive is satisfied with the PR's response and will continue to monitor progress.

Additional information from the Person Responsible

HFEA Executive Licence Panel Meeting

27 June 2012

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

Minutes – Item 1

Centre 0070 – (The Bridge Centre) – Renewal Inspection Report

Members of the Panel:	Committee Secretary:
Mark Bennett, Director of Finance & Facilities (Chair) Rachel Fowler, Policy & Information Manager Dave Moysen, Head of Information	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 and the last renewal inspection took place on 31 March and 1 April 2010.

2. The Panel noted that it had granted a two year licence following the renewal inspection in 2010.

3. The Panel noted that a change of Person Responsible (PR) had been approved at a meeting in December 2010 . The Panel also noted the PR is a Member of the HFEA.

4. The Panel noted that, in January 2012, JD Healthcare Ltd entered into an agreement to evaluate and restructure the organisation and management of the centre. The Panel noted that the centre will continue to operate as a separate company.

5. The Panel noted that JD Healthcare also owns the London Women's Clinic (LWC) centres (HFEA licensed centres 0059, 0075, 0105 and 0301) and the London Sperm Bank (HFEA licensed centre 0011).

6. The Panel noted that there will be an application in the future to vary the centre's licensed premises, and that the PR has been asked to keep the Inspectorate informed at all stages of the reorganisation of both the centre's practices and premises.

7. The Panel noted the outcome data for IVF/ICSI during 1 January– 31 December 2011 show the centre's success rates are in line with national averages, with a caveat regarding incomplete receipt of data by the HFEA.

8. The Panel noted the centre's multiple birth rate for 1 April 2010 – 31 March 2011 for all IVF, ICSI and FET cycles for all age groups was 30%.

9. The Panel noted that the Inspectorate is satisfied that the centre has appropriate systems for witnessing, and incidents and has a quality management system in place.

10. The Panel noted that, at inspection, there was a number of areas of practice that required improvement, including one critical, ten major and six other areas of non-compliance or areas of poor practice.

11. The Panel noted that, since the inspection, the centre has provided evidence that two major and three other areas have been addressed.

12. The Panel noted that the PR has given a commitment to fully implement the other areas identified within the report within the timescales indicated. The Panel was reassured by reports of the

constructive engagement of the PR to the inspection and its recommendations.

13. The Panel noted that all but six of thirty-nine areas that had been identified at the previous renewal inspection in 2010 had been assessed as implemented. The Panel particularly noted that late payment of fees had been such a serious issue in 2011 and early 2012 that the HFEA had sent both Director of Finance and Chief Executive warning letters to the centre. The co-operation of the PR and the recent prompt payment of invoices had, so far, avoided the need for further action.

14. The Panel noted that the patient donor information and the transfer of information to the HFEA needs to be improved, and urged the PR to work with the Inspectorate to implement this.

15. The Panel noted that the Inspectorate recommended that the centre's licence be renewed for four years with no additional conditions, subject to the recommendations made in this report being implemented within the prescribed timescales.

16. The Panel noted that the Inspectorate also recommended close monitoring of progress and supported this.

Decision

17. 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.

18. 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.

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

20. 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.

21. The Panel noted that the application does involve the use of embryos for training purposes and that the improvements in procedures required had already been done.

22. 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 for a period of up to four years where the evidence before it reveals no concerns in the matters specified in paragraph 4.3.

23. The Panel considered that the report showed significant progress had been made and continued to be made to improve compliance at the centre. Therefore, it agreed that it had no major concerns based on the evidence before it.

24. However, the Panel agreed patient donor information and the transfer of information to the HFEA needs to be improved, and urged the PR to work with the Inspectorate to implement this and remaining recommendations as set out in the report. The Panel considered the close monitoring proposed by the Inspectorate should identify serious slippage in progress and enable timely action to be taken, including referral back to the Panel if appropriate.

25. The Panel endorsed the Inspectorate's recommendation and agreed to renew the centre's licence for a period of four years with no additional conditions.

Signed: Date: 12 July 2012
Mark Bennett (Chair)