Inspection Report

Date of Inspection: 6-7 February 2012
Purpose of inspection: Renewal of Treatment and Storage Licence
Length of inspection: 13 hours
Inspectors: Chris Hall and David Gibbon.
Auditors: Emer O'Toole and Ricky Gourd

Inspection details:
The report covers the pre-inspection analysis, the visit and information received from the centre between 9 December 2010 and 6 April 2012.

Date of Executive Licensing Panel: 20 April 2012

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

Centre details

Centre name	Sussex Downs Fertility Centre
Centre number	0015
Licence number	L0015-15-c
Centre address	BMI Esperance Hospital, Hartington Place, Eastbourne, East Sussex, BN21 3BG
Person Responsible	Dr David Chui
Licence Holder	Mrs Susan Mulvey
Date licence issued	5 July 2007
Licence expiry date	30 June 2012
Additional conditions applied to this licence	None

Contents

Page

Report to Executive Licensing Panel

Brief description of the centre and its licensing history:
The centre was established in 1991 and offers a range of licensed treatment services and is housed within the BMI Esperance Hospital in Eastbourne. The centre treats privately funded patients from the surrounding population in East Sussex (Hastings and Haywards Heath) and West Sussex (Brighton and Worthing) and provides approximately 220 NHS funded treatments via a contract with East Sussex PCT. The Person Responsible (PR) explained that patients are generally referred to the centre by their GP and that the split between private and NHS funded treatments is approximately 65% private and 35% NHS.

The centre is open 6 days per week 8:30am – 16:30pm Monday to Friday and 9:00am – 12pm on Saturdays. Egg collections are performed mainly on Monday and Tuesday.

Activities of the Centre:

Type of treatment	Number of treatment cycles for the period 01 Jan 2011 - 31 Dec 2011
In Vitro Fertilisation (IVF)	198
ICSI	165
GIFT	0
FET	51
DI	61
Egg share provider (sharer)	0
Egg share recipient	0
Egg donation (non-egg share)	1
IUI(P)	106

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

Outcomes**

For IVF/ICSI, HFEA held register data for the period 01 January 2011 to 31 December 2011 show the Centres success rates are in line with national averages.

For the year 2011 the centre reported 106 cycles of partner IUI with 15 pregnancies. This equates to a 14% pregnancy rate.

**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 he has discharged his duty under section 17 of the HF&E Act 1990 (as amended)
- the premises are suitable
- the practices are suitable
- the centre has submitted appropriately completed documentation in accordance with General Direction 0008, in application for renewal of their licence
- the centre has submitted an application fee to the HFEA in accordance with requirements

The Executive Licensing Panel is asked to note that there are seven areas of practice that require improvement, including two major areas of non-compliance and six other areas of non-compliance or areas of poor practice.

Since the inspection visit the PR has confirmed that the following recommendations have been fully implemented:

Major areas of non-compliance:

- The PR should ensure all critical equipment is validated;

Other areas of practice that require improvement:

- The PR should ensure complaints handling records detail whether, and if so how complaints are resolved and whether internal continuous improvement processes have been altered to prevent or reduce the likelihood of recurrence;
- The PR should ensure consenting for IVF and ICSI at the same time so that patients have adequate time to consider and ask questions in the eventuality that ICSI is indicated;
- The PR should ensure that: the embryo creation details submitted for surrogacy cases have not been duplicated for both the egg provider and the host; donor files are reviewed to ensure where pen portraits have been provided a copy is submitted to the Authority; and Data submission procedures are revised to reflect the requirements of form submission guidance.

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

Major areas of non-compliance:

- The PR should ensure third parties sign-off the agreements with the centre.

Other areas of practice that require improvement:

- The PR should ensure that success rate data published on the centre's website meets the requirements of the reflects the requirements of Chair's letter CH(11)(02);
- The PR should ensure trained and competent person audit activities authorised by the licence at least every two years;
- The PR should ensure that documents are version controlled in accordance with COP guidance;

The Inspection team recommends that the Executive Licensing Panel (ELP) requires that the PR complies with the following recommendations within the prescribed timeframes set out in the inspection report:

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

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. Contemporaneous witnessing is undertaken and recorded at each critical point of the clinical and laboratory processes by two members of staff to ensure patients receive treatment using the correct gametes or embryos. The witnessing record is retained in patient/donor files (Standard Licence Condition (SLC) T71). The centre has a documented standard operating procedure (SOP) describing the witnessing procedure for all relevant critical points specified in CoP Guidance 18.4 (SLC T33b). SOP compliant witnessing practice was observed for two inseminations on the day of inspection. Evidence of induction, training, and competence assessment for all staff performing witnessing steps is documented and was seen on inspection (SLC T15 (a)). Quality indicators (QIs) relevant to witnessing have been developed (SLC T35). Audits to ensure compliance with regulatory requirements and centre SOPs are performed. These include process audits of staff performing procedures and retrospective reviews of witnessing records in patient notes. The last patient notes audit performed identified no non-conformities (SLC T36 and CoP Guidance 18.7 (b)). Five sets of patient notes audited on inspection were found to include records of all required witnessing steps.
What the centre could do better. Nothing noted at the time of inspection.

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 in treatment based on the patient's medical history and therapeutic indications was seen to be documented in four sets of patient notes reviewed on inspection (SLC T49).

An audit of four sets of patient notes on inspection demonstrated that patients are screened for HIV, Hepatitis B and Hepatitis. Centre staff also confirmed that additional testing would be carried out where required (SLC T50 (c) and (d)).

Centre staff confirmed that laboratories undertaking diagnosis and investigation of patients are accredited by Clinical Pathology Accreditation (CPA) (UK) Ltd. Reports of test results, including blood screening tests and semen analysis, observed in patient notes reviewed on inspection were from CPA accredited laboratories (SLC T21).

Counselling is offered to those providing consent (SLC 58). The counsellor has recognised counselling qualifications and was awaiting British Infertility Counselling Association (BICA) accreditation at the time of inspection. The counsellor is able to refer patients for specialist counselling if required. The quality of the counselling service is monitored by patient questionnaires and attendance audits and the results of both were available at the time of inspection, the one issue raised has been addressed (SLC T35 and T36).

What the centre could do better.

Nothing noted at the time of inspection.

Donor recruitment, assessment and screening (Guidance Note 11)
Payments for Donors (Guidance Note 13)
Donor assisted conception (Guidance Note 20)
Only applicable to centres licensed to carry out treatment using donor gametes and / or embryos

What the centre does well.

In interviews, staff stated that the centre only uses gametes from identifiable donors in treatment. The centre provides treatment with donor sperm and occasionally with donor eggs.

There is a SOP for the process to be followed when recruiting and selecting donors (SLC T33b). A checklist is used as a QI of compliance with the SOP (SLC T35). Donor recruitment and selection audits are conducted and the results of the December 2011 audit were provided (SLC T36 and Schedule 3A (10) 2006/86/EC, Appendix 1F).

In interviews staff stated that donors are selected on the basis of their age, health and medical history (SLC T52a) and they are screened in accordance with the requirements of

SLC 52. Screening tests are conducted in a Clinical Pathology Accreditation (UK) (CPA) accredited laboratory (SLC T53a). Five sets of donors notes audited on inspection confirmed that appropriate screening had been conducted.

The centre records all treatments and outcomes and can therefore provide donors with information on the number of children born, their year of birth and their sex (HF&E Act 1990 (as amended) Section 31ZD(3)).

Payments to donors are restricted to travel expenses and loss of earnings with a £250 cap on the latter covering the whole period of donation. Additionally, receipts or other support for expense is sought to establish that expenses have actually been incurred (Direction 0001).

Patients receiving treatment with donated gametes are provided with patient information, documentation about informing any resulting child about their origins at an early age, and about the Donor Conception Network. The consultant and counsellor also discuss informing children about their origins with patients and partners (T63a & b).

What the centre could do better.

Nothing noted at the time of inspection.

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 quality management system (QMS) that the inspection team considered appropriate for the services provided. Documents were seen to include a quality manual and training and reference manuals (SLC T33 (a) and (d)). Critical procedures conducted at the centre are documented in SOPs. This is evidenced by the comprehensive Assisted Conception Unit (ACU) 'Policies and Procedures' and 'Laboratory Policies and Procedures' document indexes provided prior to inspection. A sample of the SOPs were reviewed on inspection (SLC T33 (b)).

Annual QMS reviews are conducted and a copy of the report of the review conducted during October 2011 was provided. The centre holds the International organisation for Standardisation ISO 9001:2008 Quality Management System Certification.

The output of the review is considered by senior management at 'Management review

Meetings'. The minutes of the 4 November 2011 meeting at which the QMS review was considered were reviewed on inspection along with the QMS review report which did not record any non-conformities.

The minutes of the November 2011 Management Review Meeting were submitted to the inspectorate prior to inspection and the QMS review report was reviewed on inspection. This detailed review included consideration of activity and staffing levels, TPAs, success rates and audits performed (CoP Guidance 23.12 and 23.13).

The centre's audit schedules for 2011 and 2012 and a sample of audit reports were reviewed on inspection. These included audits of laboratory and clinical procedures, laboratory cleaning, traceability, consent and WoC assessment. Findings and corrective actions to implement were also documented (SLC T36).

The fertility services manager explained that clinical pregnancy rates are reviewed on an annual basis and benchmarked against national data. The documented review of the centre's 2011 success rates was reviewed on inspection, documenting the completion of 24 IUI cycles with four pregnancies. The report concluded that outcomes were in line with the national average, as far as could be concluded with the small number of cycles performed, and that no changes were required (SLC T36).

Patient satisfaction is monitored by the centre via a BMI hospital-wide survey. The fertility services manager stated that positive feedback has been received, although very few completed surveys are returned. The Centre also uses 'in house' patient satisfaction surveys and these are reviewed at the QMS annual review. (CoP Guidance 23.12 (e)(ii) and 23.17). The HFEA has received just three patient questionnaires since the last inspection, which is not unusual for a small centre. Highly positive comments regarding the centre's services were noted.

Staff meetings are held regularly at the centre, including senior staff meetings and a BMI-wide 'fertility services steering and quality group'. The minutes of several of these meetings were reviewed and items discussed included audits performed, complaints, incidents and feedback from relevant external meetings including the British Fertility Society (BFS) and the Association of Clinical Embryologists (ACE).

The centre has a specific system for ensuring that any HFEA alert published is disseminated and acted upon. A record is maintained to indicate alerts are reviewed along with any action if required.

Traceability: Guidance Note 19

There is a documented SOP for the process to be followed for the traceability of all consumables, reagents and equipment that come into contact with gametes is assured. for traceability of patient/donors, gametes/embryos, equipment, media and consumables Evidence was seen on laboratory work sheets and in the traceability file (SLC T99).

QIs relevant to traceability have been established (SLC T35) and compliance with the SOP and against the QIs and regulatory requirements has been audited (SLC T36). The documented audit conducted on 10 December 2011 was reviewed on inspection, no corrective actions were required.(SLC t36)

The traceability competence file documents training and the review and signing- off of staff competence assessment in traceability procedures.

Containers used in the course of procurement and processing of gametes are labelled with the full name of the patient and partner and further identifiers (SLC T101). Evidence was seen during observation of an IUI procedure and denudation of embryos.

The SOP documents procedures for ensuring data necessary for traceability is retained for at least 30 years (SLC T103). Traceability records are stored securely in locked boxes off-site, records are retrieved by sealed box codes and not by record references.

Process validation: Guidance Note 15

Procurement processing are documented in a SOP (SLC T33b).

Procurement and processing SOP QIs have been established (SLC T35) and are audited against on a monthly basis (SLC T36), the audit and corrective actions are documented and are discussed at management meetings.

The centre's critical processes have been validated in compliance with SLC T72. Evidence was observed historical evidence based on validation files was.

The validation approach used includes reference to relevant published studies and confirmation that all consumables and reagents used are validated and traceable.

Equipment and materials: Guidance Note 26

Defined limits for the temperature of the refrigerator have been set. Records of the regular monitoring of these parameters demonstrated that these set ranges are achieved (SLC T24).

The centre has a planned preventive maintenance programme for critical equipment. Service records were reviewed on inspection (SLC T24).

Most critical equipment has been validated. Validation records for a selection of critical equipment, including the centrifuge, microscope, incubator, hood, dry shipper freezer and micromanipulators were reviewed on inspection (SLC T24).

Evidence was provided that critical measuring equipment, including the particle counter and thermometers, are calibrated against national standards (SLC T24).

The centre has instruction manuals documenting the procedures for operating critical equipment. The centre's 'procedure in the event of equipment failure' SOP documents the action to be taken in the event of equipment malfunction or failure (SLC T27).

The senior embryologist confirmed that consumables in use in the laboratory are all sterile and CE marked and this was found to be the case for a number of items seen on inspection in the laboratory (SLC T30).

Premises and facilities: Guidance Note 25

Activities authorised by the centre licence are carried out in the licensed premises (SLC T1) with blood tests performed by a Clinical Pathology Accreditation (UK) Ltd (CPA(UK)Ltd) accredited third party supplier (SLC T20).

The centre has a SOP for the monitoring of air quality, including the actions to be taken if the required air quality is not met (SLC T33 (b)). Monitoring is performed and includes both particle counts and microbiological sampling. The background air quality in the critical working environment, compliant with SLC T20.

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

Adverse incidents: Guidance Note 27

The centre has an adverse incident SOP, documenting the procedure to follow in the event of an incident, including HFEA reporting requirements (SLC T118).

The centre has reported adverse incidents to the HFEA since the last inspection in compliance with Direction 0011. Evidence of the implementation of corrective action was seen on inspection.

The centre has an adverse incident SOP (SLC T33(b)). It also maintains an adverse incident log which was examined at inspection and demonstrated that reportable incidents are appropriately reported to the HFEA.

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 with two exceptions, noted below (SLC T111) and has evaluated the ability of third parties to meet required standards (SLC T112).

A complete list of all TPAs is maintained (SLC T115) and it is a condition of the agreements that third parties will meet the requirements of relevant licence and the code of practice (SLC 116).

A sample of four TPAs were reviewed on inspection and found to be compliant with SLC T114.

QIs relevant to the performance of ICSI have been established (SLC T35) and audits of conformance with the QI, SOP and regulatory requirements have been conducted, are documented (T36).

Staff can provide documented evidence of the assessment of their competence in the performance of ICSI (SLC T15a).

What the centre could do better.

Not all critical equipment has been validated (SLC T24).

The signing of two third party agreements is outstanding. Evidence was seen on inspection of chasing up activity by the Fertility Services and Laboratory Manager, who has also provided regular updates to the HFEA on her chasing up activities (SLC T111).

Multiple Births (Guidance Note 7)

For the 2010/11 time period the centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 15.8%[1]

The centre's multiple clinical pregnancy rate for 2010/11 represents performance likely to likely to meet the target/ performance at a statistically significant level, unlikely to be due to random variation.

What the centre does well

On-going monitoring of the centres multiple clinical pregnancy rate suggests that the centre is not likely to exceed the 2011/12 multiple birth rate target of 15% (Standard Licence Condition T123).

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

What the centre could better

Nothing noted at the time of inspection.

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 provided. All staff, where appropriate, were seen to be registered with the relevant professional and/or statutory bodies (SLC T14). The Laboratory Manager and Senior Embryologist are Health Professions Council (HPC) registered clinical scientists (CoP Guidance 2.18 (c)).

Person responsible: Guidance Note 1

[1] A multiple clinical pregnancy rate of 25% is calculated as likely to result in a multiple live birth rate of 20%.

PR is a consultant obstetrician and gynaecologist and is registered with the General Medical Council (SLC T14).

The PR has the required medical and academic qualifications and more than two years of practical experience which is directly relevant to the activity to be authorised by the licence, as required by the HF&E Act 1990 (as amended) section 16(2)(c)(i) and (ii).

The PR has successfully completed the HFEA PR Entry Programme (certificate number: T/1010/7).

Staff: Guidance Note 2

Including the PR there are two nominated registered medical practitioners that are contactable by phone and pager by centre staff at any time (SLC T16).

The centre has provided an organisational chart that assigns responsibility and defines lines of accountability and reporting relationships (SLC T11).

The PR explained that staff recruitment and selection is managed centrally by BMI's human resources team. Suitability of character is assessed by interview, uptake of references, Criminal Records Bureau (CRB) checks and a probationary period, after which a performance review is held (HF&E Act 1990 (as amended), section 17(1)(a)).

The PR explained that the centre has a documented 6 month induction training procedure, comprising general orientation and support, mandatory training and specialist training. The fertility services manager explained that the induction process is monitored via the completion of a 'checklist for induction of fertility staff' form. The training folder for the newest member of staff was reviewed and appeared comprehensive, including manual handling, basic life support, infection control and training in confidentiality requirements (SLC T33 (b) and T15).

The senior nurse explained that the induction training for nurses is personalised and centred around competences and documented (SLC T12 and T15(a)). The documented competences for a lead nurse and an embryologist were examined on inspection. The Fertility Services and Laboratory Manager reviews and signs off competencies on an annual basis.

The PR explained that staff are encouraged to participate in continuing professional development (CoP Guidance 2.3). The PR said that staff attended the national conferences of the British Fertility Society (BFS), Association of Clinical Embryologists (ACE). In addition BMI have fertility groups for embryologists and nurses, and there is a one day update conference every other year.

The PR explained that workforce requirements are assessed on an on-going basis. A formal assessment covering the period July to December 2011 was provided. The PR confirmed that the centre is currently operating with a full staff complement (SLC T12). The PR anticipates that activity may rise by 50 to 70 cycles per annum and indicated staffing levels would be would be re-assessed in advance of this were it to happen.

What the centre could do better.

Nothing noted at the time of inspection.

Welfare of the Child (Guidance Note 8)

What the centre does well.

Before providing treatment services, the centre makes an assessment of the welfare of the child (WoC) who may be born as a result of licensed treatment and of any other child who may be affected by that birth.

The centre has a documented WoC SOP and the senior nurse confirmed that if patients had not been seen by centre staff for two years, or there had been a change in circumstances, the WoC assessment process would be repeated (SLC T33 (b) and CoP Guidance 8.6).

The assessment of staff competence to carry out WoC assessment is documented and the senior nurse's assessment was viewed on inspection (SLC T15a).

Five sets of patient notes reviewed on inspection demonstrated that WoC assessments had been completed by both patient and partner prior to the treatment date. None of these assessments resulted in further information being sought and in none did the question responses suggest that such action was indicated (SLC T56).

What the centre could do better.

Nothing noted at the time of inspection.

2. Patient Experience

Focus

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

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

Treating patients fairly

- Treating patients fairly (Guidance Note 29)
- Confidentiality and privacy (Guidance Note 30)
- Complaints (Guidance Note 28)
- Provision of costed treatment plans (Guidance Note 4)

What the centre does well.

A tour of the centre provided evidence that patients have treatment in suitable licensed premises.

From discussion with staff and observations made on inspection, the inspection team was assured that licensed activities are conducted in a non-discriminatory manner with proper respect for the privacy, confidentiality, dignity, comfort and well being of all prospective and current patients and partners (CoP Guidance 29.3).

The centre treats single sex couples, and staff provided examples of where use of interpreters, documentation translation and the use of deaf signers have been used.

Complaints

The centre has a procedure for dealing with complaints regarding the service (SLC T33 (b)). No complaints about the centre have been received directly by the HFEA.

Patients are provided with information on how to make a complaint in the patient information pack sent to them prior to treatment, and details are included on a notice board in the waiting room (CoP Guidance 4.2 (k) and 28.5).

Patient Surveys

The centre uses patient satisfaction surveys to ensure it is meeting patient needs and to facilitate identification of areas where improvements may be made. Review of the responses to the: the units own in-house survey; BMI Healthcare survey; and HFEA questionnaire indicate a high level of satisfaction with the service.

What the centre could do better.

Complaints

A review of onsite complaint records identified one that reviewed contained no details of

resolution action.

Information

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

What the centre does well.

The centre submitted a suite of patient information prior to the inspection, covering the requirements of the CoP. These include information about the nature of the treatment being offered, including the possible side effects, single embryo transfer, availability of counselling (SLC T58 and CoP Guidance 4.2 (g) and (j)).

A consultation checklist is kept in the notes to ensure patients are provided with appropriate information prior to providing consent. Patients are given the opportunity at consultations to ask questions and informed that counselling is available. A review of five patients records found completed checklists to be on file recording that patients were given appropriate information.

The centre has a SOP for the provision of information prior to obtaining consent an electronic version of the document was reviewed on inspection (SLC T33 (b)).

The centre uses is patient satisfaction as a method of monitoring whether patients fell they receive adequate information. Surveys reviewed at inspection indicate a high level of satisfaction.

Costed treatment plans

Patients are provided with information regarding the cost of their treatment before it commences. A price list is provided on the centres website and an annotated price list is used to detail and personalise the main elements of the treatment proposed and the cost of that treatment for patients (CoP Guidance 4.3).

Patient information

What the centre could do better.

Patient information

The centre's website was reviewed prior to inspection. The inspection team considers that information provided on the site does not meet that recommended in Chair's Letter CH(11)(02) in relation to the following:

- The data is not less than three years old.
- The live birth rate per treatment cycle is not provided.
- The website does not provide the national rate and like for like comparisons (the same year, maternal age, treatment type, etc.).

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.

Consents

The centre has a documented SOP that describes the procedures for taking effective consent (SLC T33 (b)), has established QIs relevant to consenting (SLC T35) and conducts annual audits of consenting (SLC T36).

A copy of the SOP, QIs and the June 2011 audit report were reviewed on inspection.

Audit findings are documented and implemented (SLC T36) and a follow-up audits used to confirm implementation.

Documented evidence of the assessment of staff competence to take consent was provided on inspection (SLC T15a).

Consultants and nurses take treatment, storage and disclosure consent and embryology staff check that appropriate consents have been provided on prior to a procedure and record their check on a lab sheet. Embryology staff consent donors.

Centre staff explained that photographic evidence of patient/partner identity is used to verify patient identity when required. Copies of photographic identification were seen in the patient notes reviewed on inspection (CoP Guidance 5.10). Names and numbers are also checked.

Five sets of patient records were reviewed on inspection. All had appropriately completed consent forms on file. In each case the consent forms bore dates prior to the date of first treatment date.

An audit of cyro-preserved gametes in store was reviewed on inspection, this recorded that no material in storage was identified out of consent at the audit date (Human Fertilisation and Embryology Act 1990 (as amended), Schedule 3, 8(1)).

The Laboratory Manager explained that embryos may be used for vitrification practice where both gamete providers have consented to use of their gametes for such training (SLC T94).

Legal Parenthood

The senior nurse explained that all unmarried couples and same sex couples not in civil partnerships being treated with donor gametes are provided with patient information on legal parenthood (SLC T60) and all patients having donor gametes are required to see the counsellor.

The centre's SOP indicates that treatment must not be provided where the second parent withdraws their consent without informing the patient they have withdrawn it (SLC T64(b)). If the patient withdraws their consent for the nominated second parent being the legal parent or consents to a different person being the second parent, the SOP records that nominated parent is to be notified in writing.

What the centre could do better. **Consent** Consent may occasionally be obtained on the day of procedure when it is considered that ICSI is indicated) and this may restrict the opportunity of patients to receive proper counselling about the implications of the procedure for which they are being asked to provide consent (CoP 5B).

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
A tour of the centre demonstrated that the activities authorised by the centre's licence are carried out at the premises specified in the licence (SLC T1).

Staff interviewed, displayed in their responses, appropriate respect for the special status of the embryo when carrying out licensed activities.

Based on our interview of staff, review and audit of patient and donor records, and our observation of practice, all gametes and embryos are procured and used in a lawful manner, with appropriate consent.

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 a documented standard operating procedure (SOP) describing the procedures for storing gametes and embryos. A copy was reviewed on inspection (SLC T33b).

Quality indicators relevant to storage have been developed (SLC T35) and bi-yearly audits are planned to ensure compliance with regulatory requirements and centre SOPs (SLC T36).

Documentary evidence of competence assessment in storage procedures for all laboratory staff was observed in the competency file (SLC T15a).

The centre has a documented standard operating procedure (SOP) describing the bring-forward system to ensure adequate advance notice of the end of consented storage periods is given. A copy was reviewed on inspection (SLC T33b).

What the centre could do better.

The last completed audit of stored material was in during December 2009 and no errors were found. At the time of inspection the centre was two-thirds the way through the subsequent audit (SLC T36).

Distribution and / or receipt of gametes and embryos

- Distribution of gametes and embryos (Guidance Note 15) – *only applicable for centres that has distributed or exported gametes and / or embryos*
- Export of gametes and embryos (Guidance Note 16) – *only applicable for centres that has exported gametes and / or embryos*
- Receipt of gametes and embryos (Guidance Note 15) – *only applicable for centres that has received gametes and / or embryos*
- Import of gametes and embryos (Guidance Note 16) – *only applicable for centres that has imported gametes and / or embryos*

What the centre does well.

The centre has not imported or exported gametes or embryos under General Directions in the last 12 months (Direction 0006).

The centre has a documented SOP describing the procedure for the transfer of gametes and embryos to other licensed centres and a copy was provided in advance of the inspection for review (SLC T33b).

Transport conditions including temperature and next day delivery are specified (SLC T107) and dry shippers have been validated (SLC T108)

Shipping containers are appropriately labelled (SLC T107) and all required information provided when distributing material (SLC T110).

Gamete and embryo packaging and transportation arrangements were reviewed on inspection and considered to be secure and appropriate to prevent damage and/or contamination and meet the requirements of SLC T105 and T108.

A record is made in the notes of gamete providers when sperm is produced at home. One patient record was checked on inspection to confirm SOP adherence (SLC T68). Photo identification is used and a declaration is obtained from the gamete provider that the sample is theirs and has not been interfered with.

There is a third party agreement in place that documents the conditions required to be

maintained during distribution of gametes and embryos (CoP 15C). The records of five transfers in from other licensed centres and five transfers out of the centre to other licensed centres were reviewed on inspection along with the third party agreement and shipper validation records.
What the centre could do better. Nothing noted at the time of inspection.

Use of embryos for training staff (Guidance Note 22)
What the centre does well. Prior to giving consent for the use of embryos in training nurses inform gamete providers of the nature of the training in which embryos will be used and whether information will be fed back to them and that the decision to donate or not will not affect their treatment; and that they may withdraw their consent at any point prior to use (SLC T97).
What the centre could do better. Nothing noted at the time of inspection.

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, legible and well organised and to meet the requirements of SLC T39 and T46.

The centre's 'retention of records' SOP documents the requirement to maintain patient records for thirty years. It further states that no records are to be disposed of without the express permission of the PR or fertility services manager (SLC T48).

Centre documents are version controlled and are reviewed by the Quality Manager annually. A selection of documents examined on inspection, were reviewed within the last twelve months (CoP Guidance 31.6).

What the centre could do better.

Record keeping and document control

Version control does not extend to the including of page numbers and total number of pages; authority for issue; and author identification on all the documents reviewed on inspection (CoP Guidance 31.4(ii) (iii) (iv)).

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

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

What the centre does well.

All members of staff cooperated fully with the inspection team and information requested throughout the inspection process was provided in within the required timeframe (SLC T4).

Treatment data is provided to the Authority in a timely manner and the centre submitted its 2010 annual IUI return within the timeframe required by General Direction 0005.

Except for those matters recorded below, the auditors assessed the quality of data submitted to the Authority as good.

What the centre could do better

Reporting Requirements
A sample of treatments recorded in the centre's laboratory records was compared to data submitted by the centre for inclusion on the statutory register. One of 158 treatments in the audit sample that had not been reported to the Authority in accordance with Direction 0005.

A review of the quality of data submitted to the Authority against source data held in patient and donor files found;

- duplication of embryo creation details in surrogacy treatments (i.e. embryo creation treatment forms are completed for the individual providing eggs and the individual receiving the embryo transfer); and

- donor pen portraits provided by donors are not always provided to the Authority in accordance with form guidance.

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

A tour of the centre confirmed that access to all confidential information is restricted to authorised personnel (SLC T43).

In-house BMI training on data protection, Caldicott Principles and confidentiality is undertaken as part of the new staff induction programme (SLC T15 (d)).

The centre's confidentiality policy includes procedures for the control of access to health data and records and the appropriate disposal of records. The SOP also documents the prohibition on moving records off site and the use of data storage devices (SLC T44).

Patient and partner disclosure consents reviewed against data submitted to the Authority was reviewed by auditors. All consents matched data supplied to the Authority in relation to disclosure of information held of the HFEA register for use in research.

What the centre could do better.

Nothing noted at the time of inspection.

5. Changes/improvements since the previous inspection on 9 December 2010

Area for improvement	Action required	Action taken as evidenced during this inspection
There are 12 written agreements outstanding with third parties who provide goods or services that influence the quality and safety of gametes and embryos. Examples of outstanding agreements include other laboratories and courier services. Standard Licence Condition T111	The PR should ensure that all outstanding third party agreements are completed and provide evidence of this to the inspectorate. Until all agreements are completed, provide monthly reports to the inspectorate outlining actions taken and progress made with completing each agreement. By 9 March 2011	All suppliers for whom there is an outstanding third party agreement have been contacted. The first update report will be sent to the HFEA on 06.02.11. Quarterly updates received: 2 TPA's outstanding as at 10/11/2011 **Further action is required.**
Dishes and tubes containing gametes and embryos are labeled with only the patient's surname and unique identifier. This practice accorded with written procedures. Standard Licence Condition T101	The PR should ensure that all samples of gametes and embryos are labeled with at least the patient's or donor's full name and a unique identifier. By 9 March 2011	Effective immediately, all dishes, tubes and containing gametes and embryos are labeled with patients forename and surname as well as hospital number. No further action required.
The processes for cleaning of the laboratory and laboratory equipment have not been validated. Standard Licence Condition T72	The PR should ensure that the laboratory cleaning processes is validated By 9 June 2011	A report detailing the validation of cleaning procedure will be sent to the HFEA by 09.06.11. Received 14/06/2011. No further action is required.
Validation of critical equipment has been identified but is not yet complete. Standard Licence Condition T24	The PR should ensure that the validation of critical equipment is completed. By 9 June 2011	The validation of all critical equipment will be completed by 09.06.11 and a report will be sent to the HFEA providing evidence of compliance by the specified deadline. Received 14/06/2011. No further action is required.

Quality indicators relevant to witnessing have not been formalised. Standard Licence Condition T35 and T36	The PR should ensure that the quality indicators for witnessing are documented and audit against these accordingly. By 9 June 2011	The policy for witnessing has been updated. All quality indicators for witnessing are documented and an audit report will be sent by the specified deadline. Received 14/06/2011. No further action is required.
Written procedures for screening did not include the requirement for HTLV testing (where relevant). Standard Licence Condition T52 (c)	The PR should ensure that written procedures for screening of donors includes the requirement for HTLV-1 antibody testing where relevant, prior to storage. By 9 February 2011	Procedure has been updated to include screening of donors for HTLV-1 antibody testing where relevant prior to storage. PR's response is satisfactory. No further action required.
The laboratory manager has not undergone competency assessments in the performance of her designated tasks. Standard Licence Condition T15	The PR should ensure that the laboratory manager undergoes competency assessments and results documented. By 9 June 2011	The laboratory manager has contacted peer state registered embryologists within the BMI group to complete and document competency assessments for her designated tasks. All competency assessments for the laboratory manager will be completed by the specified deadline, and evidence of compliance will be submitted to the HFEA. Received 14/06/2011. No further action is required.
There are no written procedures for carrying out external, physical examinations on sperm donors to assist in the detection of sexually transmitted infections. UK guidelines for the medical and laboratory screening of sperm, egg and embryo donors (2008)	Review procedures to make provision for external physical examinations of sperm donors to assist in the detection of sexually transmitted infections. 9 February 2011	Procedure has been updated to include an external physical examination of sperm donors prior to donation and after completion of the donation period. PR's response is satisfactory. No further action required.
Legal parenthood: the written	Include arrangements for	Procedure has been

procedures for obtaining written effective consent do not include arrangements for dealing with anyone who withdraws or varies their consent. Guidance Note 6.8 - 6.9	dealing with anyone who withdraws or varies their consent in written procedures. By 9 February 2011	amended to include arrangements for dealing with anyone who withdraws or varies their consent. PR's response is satisfactory. No further action required.

Areas of practice that require the attention of the Person Responsible

The section sets out matters which the Inspection Team considers may constitute areas of non-compliance. These have been classified into critical, major and others. Each area of non-compliance is referenced to the relevant sections of the Acts, Regulations, Standard Licence Conditions, Directions or the Code of Practice, and the recommended improvement actions required are given, as well as the timescales in which these improvements should be carried out.

Critical area of non compliance

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
None.			

Major area of non compliance

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

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
Not all critical equipment has been validated (e.g. suction pump) (SLC T24). Progress has been made in validating critical equipment since the time of the previous inspection.	The PR should ensure all critical equipment (technical devices) are validated by 7 May 2012.	The suction pump has now been validated.	The PR's comments indicate the recommendation has been implemented. No further action is required on this matter.
The signing of two third party agreements is outstanding (e.g. EDGH Pathology and EME and Ferring Pharmaceuticals (SLC T111). Evidence was seen on inspection of chasing up activity by the Fertility Services and Laboratory Manager,	The PR should ensure third parties sign-off the agreements with the centre by 7 May 2012.	Pathology and EME are part of EDGH and there is a an existing agreement in place with The Esperance Hospital for all services provided. The Fertility Services Manager will ensure that this agreement incorporate the requirements by the authority included in the SDFC third party agreement	The PR's comments indicate the recommendation will be implemented. This issue will be reviewed as part of the on-going monitoring process to confirm implementation.

since the time of the last inspection. Regular progress on sign-off and continuing chasing activity has been provided to the HFEA.		and that it will be in place by 07.05.12. Notification has been sent to Ferring, and the urgency of returning this agreement stressed to them.	

Other areas of practice that requires improvement

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
Quality Management Complaints: One of the five complaints records reviewed contained no details of resolution action taken. (Complaint No. 26 received 03/07/2011) Guidance Note 23.12 (e)(ii)	The PR should ensure complaints handling records detail whether, and if so, how complaints are resolved and whether internal continuous improvement processes have been altered to prevent or reduce the likelihood of the source of the complaint reoccurring by the 7 May 2012.	All complaints are investigated and where applicable processes reviewed to prevent the likelihood of a re-occurance. Complaint 26 was fully resolved and action was taken to prevent a re occurance (documented in the complaints record) The section on the summary complaint form advising of action/resolution was not completed, despite full resolution. This has been rectified immediately.	The PR's comments indicate that this matter has been addressed. No further action is required.
Patient information The centre's website was reviewed prior to inspection. The inspection team considers that information provided on the site does not meet the recommended information set out within Chair's Letter CH(11)(02) in relation to the	The PR should ensure that success rate data published on the centre's website meets the requirements of the reflects the recommended information contained within Chair's Letter CH(11)(02) by 7 August 2012.	Work has already commenced with GHG IT department to ensure that the website information for the SDFC is up to date and reflects the recommendation information within the Chairs letter CH(11)(02). This will be	The PR's comments indicate the recommendation will be implemented. This issue will be reviewed as part of the on-going monitoring process to confirm implementation.

data being more than 3 years old; the absence of the live birth rate per treatment cycle; data not being broken down by maternal age and if appropriate treatment type; and the absence of the national rate for a like for like comparison.		completed by 07.08.12	
Consent Consent may occasionally be obtained on the day of the procedure (e.g. ICSI is considered to be indicated) and this may restrict the opportunity of patients to receive proper counselling about the implications of the procedure for which they are being asked to provide consent (CoP 5B).	The PR should ensure consenting for IVF and ICSI at the same time is introduced so that patients have adequate time to consider and ask questions, in the eventuality that ICSI is indicated at the time of egg collection, by 7 May 2012.	All patients undergoing IVF or IVF with ICSI are now given written information on the subject of ICSI at the time of their initial consent counselling and required to complete their consent at this time. This allows sufficient time to consider the implications of the procedure prior to egg collection.	The PR's comments indicate the recommendation has been implemented. No further action is required on this matter.
The last completed audit of stored material was in during December 2009 and no errors were found. At the time of inspection the centre was two-thirds the way through the subsequent audit (SLC T36).	The PR should ensure trained and competent person audit activities authorised by the licence at least every two years by 7 may 2012.	Physical audit is on going however completion expected by 01.05.12. A report will be submitted on or before 07.05.12	The PR's comments indicate the recommendation will be implemented. This issue will be reviewed as part of the on-going monitoring process to confirm implementation.

Record keeping and document control Version control does not extend to the including of page numbers and total number of pages; authority for issue; and author identification on all the documents reviewed on inspection (CoP Guidance 31.4(ii) (iii) (iv)).	The PR should ensure that by 7 August 2012 documents are version controlled in accordance with COP guidance.	Any outstanding documents not adequately version controlled, are currently being amended, for completion by 07.08.12.	The PR's comments indicate the recommendation will be implemented. This issue will be reviewed as part of the on-going monitoring process to confirm implementation.
Reporting Requirements A of sample of treatments recorded in the centre's laboratory records was compared to data submitted by the centre for inclusion on the statutory register. One of 158 treatments in the audit sample that had not been reported to the Authority in accordance with Direction 0005. A review of the quality of data submitted to the Authority against source data held in patient and donor files by register auditors found; • duplication of embryo	The PR should ensure that by 7 May 2012: • the embryo creation details submitted for surrogacy cases have not been duplicated for both the egg provider and the host. • Donor files are reviewed to ensure that where pen portraits have been provided a copy is submitted to the Authority. Data submission procedures should be revised to reflect the requirements of form submission guidance.	• This has been rectified and the information is now correct • If provided by the donor, all pen portraits will be submitted to the Authority by 31.04.12	The PR's comments indicate the recommendation has been implemented. No further action is required on this matter.

creation details in surrogacy treatments (i.e. embryo creation treatment forms are completed for the individual providing eggs and the individual receiving the embryo transfer); and • donor pen portraits provided by are not always provided to the Authority in accordance with form guidance.			

Additional information from the Person Responsible

HFEA Executive Licence Panel Meeting

20 April 2012

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

Minutes – Item 4

Centre 0015 – Sussex Downs Fertility Centre – Renewal Inspection Report

Members of the Panel:	Committee Secretary:
Mark Bennett, Director of Finance & Facilities (Chair) Hannah Darby, Senior Policy Manager David Moysen, Head of IT	Lauren Crawford Observing: Paula Robinson, Head of Business Planning Rachel Fowler,

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 the centre had applied for the renewal of its treatment and storage licence and that an inspection of the centre had taken place in February 2012.

2. The Panel noted that the centre was established in 1991, offers a range of treatment services to privately funded patients and is housed within the BMI Esperance Hospital in Eastbourne.

3. The Panel noted that, at the time of the inspection, the centre's success rates for IVF/ICSI were in line with the national average, and that the treatment cycle figures for partner IUI in 2011 was 106 with 15 pregnancies.

4. The Panel also noted the centre's multiple clinical pregnancy rate suggests that the centre is not likely to exceed the year 3 multiple birth rate target of 15%.

5. The Panel noted that, although the centre is licensed to use embryos for training purposes and there is mention in the inspection report, the application form does not include the use of embryos for training as a proposed activity. Nevertheless, it is a permitted activity to be included on the new licence.

6. The Panel noted that, at the time of the inspection, there were eight areas of practice that required improvement, including two major areas of non-compliance and six other areas of non-compliance or poor practice.

7. The Panel noted that, since the inspection, the Person Responsible (PR) has provided evidence that one major and three other recommendations have been fully implemented and given a commitment that the remaining one major and three other areas will be addressed.

8. The Panel was disappointed to note that the remaining major recommendation relates to signing-off some third party agreements which had also been identified in the previous inspection of December 2010.

9. The Panel noted the Inspectorate's recommendation to renew the centre's licence for a four year period with no additional conditions.

10. The Panel confined its consideration to the evidence before it.

The Panel's Decision

11. The Panel referred to its decision tree. It was satisfied that the appropriate application and fee had been submitted, and contained the supporting information required by General Direction 0008.

12. The Panel was satisfied that the qualifications and character of the PR is such as is required for the supervision of the licensed activities and that the PR will discharge the duties under section 17 of the HF&E Act 1990 (as amended).

13. The Panel noted that the PR is a consultant obstetrician and gynaecologist and is registered with the General Medical Council. The PR has successfully completed the HFEA PR Entry Programme.

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

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

16. The Panel referred 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 [The Executive Licensing Panel] will normally only grant a renewal licence for treatments/ storage non-medical fertility services licence for a period of up to four years where the evidence before it reveals no concerns in the matters specified in paragraph 4.3.

17. On the basis of the PR's responses to the inspection report and the recommendations identified, the Panel agreed that it had no concerns. The Panel agreed to renew the centre's licence for a period of four years with no additional conditions.

18. The Panel urged the new PR to address the outstanding recommendations, and to provide the information requested by the Inspectorate, within the agreed timeframes.

Signed ..... Date 10/5/12

Mark Bennett (Chair)