Inspection Report

Date of Inspection: 8 and 9 May 2013
Purpose of inspection: Renewal of Treatment and Storage Licence
Length of inspection: 12 hours
Inspectors: Wil Lenton (Lead inspector)
Susan Jolliffe (Clinical inspector)
Paul Knaggs (Scientific inspector)
Chris Hall (Audit)
Roup Kaur (Audit)

Inspection details:
The report covers the pre-inspection analysis, the visit and information received from the centre between 30 May 2013 and 05 July 2013.

Date of Executive Licensing Panel: 02 August 2013

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, 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 Licence Committee/ Executive Licensing Panel which makes the decision about the centre's licence renewal application.

Centre details

Centre name	Shropshire and Mid-Wales Fertility Centre
Centre number	0148
Licence number	L/0148/12/d
Centre address	Royal Shrewsbury Hospital, Mytton Oak Road, Shrewsbury, Shropshire, SY3 8XQ, UK
Person Responsible	Mr Jason Kasraie
Licence Holder	Dr Edwin Borman
Date licence issued	1 December 2008
Licence expiry date	30 November 2013
Additional conditions applied to this licence	None

Contents

Report to Executive Licensing Panel

Brief description of the centre and its licensing history:
The Shropshire and Mid-Wales Fertility Centre is part of The Shrewsbury and Telford Hospital NHS Trust, the centre has held a licence with the HFEA since 1994.

The centre provides a full range of fertility services, in relation to activity levels this is a medium-sized centre.

Dr Edwin Borman was appointed as the new Medical Director in April 2013, and takes the position as the Licence Holder (LH).

Activities of the centre:

Type of treatment	Number of treatment cycles for 01 May 2011 - 30 Apr 2012
In vitro fertilisation (IVF)	274
Intracytoplasmic sperm injection (ICSI	224
Frozen embryo transfer (FET)	137
Donor insemination (DI)	15
Egg share provider (sharer)	13
Egg share recipient	12
Egg donation (non egg share)	4

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

Outcomes*

For IVF and ICSI, HFEA held register data for the period October 2012 to March 2013 show the centres success rates are in line with national averages.

For the year 2010 the centre reported 11 cycles of partner insemination with no pregnancies, which is consistent with the national average.

*The data in the Register may be subject to change as errors are notified to us by clinics, or picked up through our quality management systems.

Summary for licensing decision

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

- the PR is suitable and 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 (ELP) is asked to note that there are a number of areas of practice that require improvement, including no critical areas of non-compliance, four major areas of non-compliance and five 'other' areas of non-compliance.

The ELP is also asked to note that the centre was proactive in addressing several of the areas of noncompliance highlighted on inspection soon after the inspection visit took place. An action plan addressing other areas of non-compliance was also provided.

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

Major areas of non compliance:

- The PR should ensure that the second cryo-store has a low oxygen monitoring sensor.
- The PR should ensure that the centre has effective consent for the storage of all cryopreserved gametes in store.

'Other' areas of practice that require improvement:

- The PR should ensure that there are Standard Operating Procedures (SOP) in place for;
  - the procedure to ensure traceability of gametes and embryos from procurement to patient treatment or disposal is required,
  - the procedure to obtain the relevant written records of consent to parenthood before treating a woman with donor sperm or embryos.
- The PR should consider the risks of not labelling the tubes used during egg collection. The HFEA should be informed of any actions taken to mitigate the risks of misidentification as a result of this practice.

The inspection team recommends that the ELP requires that the PR complies with the following recommendations within the prescribed timeframes set out in the inspection report:

Major areas of non compliance:

- The PR should review the workload and skill mix to determine how many cycles of treatment can be safely accommodated, taking into account the staff available.

- The PR should ensure the centre has audited how far Welfare of the Child (WOC) procedures complies with the HFEA requirements.

'Other' areas of practice that require improvement:

- The PR should ensure that the centre has established written agreements with all third parties who provide goods or services that influence the quality and safety of gametes and embryos.
- The PR should ensure that the centre's website meets the requirements of Chair's Letter CH (11)02.
- The PR should ensure that relevant staff are aware of the requirement to provide donor goodwill and pen portrait information to the HFEA and that such information is provided to the HFEA.

Recommendation to the Executive Licensing Panel

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.

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 following laboratory activities were observed in the course of the inspection: egg collection, sperm preparation and intracytoplasmic sperm injection (ICSI). All of the procedures observed were witnessed in accordance with HFEA requirements using a manual witnessing system.

The inspection team were able to review 10 sets of witnessing records and concluded that records of manual witnessing are maintained in accordance with Standard Licence Condition (SLC) T71.

There is a standard operating procedure (SOP) for witnessing procedures in place (SLC T 33 b).

An audit of compliance with witnessing requirements was performed in November 2011, the documentation, together with observation of practice demonstrated that corrective action had been identified and implemented (SLC T36).

What the centre could do better.

Nothing noted at the time of this 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.

Procuring, processing and transporting gametes and embryos: Guidance Note 15
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).

A sample of patient records seen on inspection demonstrated that patients are screened for HIV, Hepatitis B and Hepatitis C as required by SLC T50.

Laboratories undertaking diagnosis and investigation of patients are accredited by Clinical Pathology Accreditation (UK) Ltd. (CPA).

Counselling: Guidance Note 3
The centre advocates and offers counselling to all patients and partners prior to them consenting to licensed treatment (SLCs T60 and T61). The importance of counselling and how to access it are documented in patient information sheets and a verbal offer of counselling is made and documented in the medical notes (SLC T58f).

Counselling is provided by an experienced counsellor, who does not have a dedicated room, but has access to an adequate room which affords privacy and confidentiality to the session (SLCs T17 and T60). Patients interviewed at inspection were aware of the availability of counselling. The centre has SOPs which describe the counselling service processes (SLC T33b).The counsellor discussed outcomes of the most recent audit of the counselling services which indicate a high level of satisfaction with the service (SLC T36).

What the centre could do better.

Nothing noted at the time of this inspection.

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

What the centre does well.

Donor recruitment, assessment and screening: Guidance Note 11
A review of the relevant SOPs and discussions with staff, indicate that donor recruitment, screening and assessment practices are compliant with requirements. An audit of five donor records on the day of the inspection found that laboratory test results indicated that all required screening was conducted in accordance with current professional guidance CoP 11.21.

Payments for donors: Guidance Note 13
The reimbursements made to donors are restricted to expenses incurred in the UK. All claims are verified in accordance with the centre's protocol. This protocol and the patient information sheet regarding reimbursement were reviewed on inspection and were found to be compliant with the requirements of General Direction 0001.

Donor assisted conception: Guidance Note 20
All donated gametes used in treatment are from identifiable donors (SLC T54). Records of donor gamete usage are kept which allow the centre to provide donors with information, if requested, regarding the number of persons born as a result of their donation, their sex and their year of birth (HF&E Act 1990 (as amended), Section 31 ZD (3)).

What the centre could do better.

Nothing noted at the time of this 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 quality management system (QMS) that is accessible electronically and contains a quality manual and SOPs (SLC T33 a and b) which are regularly reviewed and document controlled (SLC T34).

The quality manual was recently updated; the quality manual is well organised and referenced in accordance with good practice. (SLC T33).

Quality indicators were seen, including those for the provision of information, consent, welfare of the child and submission of data to the HFEA (SLC T35).

Documentation provided demonstrated a comprehensive schedule of audits across key licensed activities against SOPs and regulatory requirements (SLC T36).

Traceability: Guidance Note 19
Procedures are in place to ensure the traceability of all gametes and embryos and the consumables, reagents and equipment that come into contact with them, with the exception noted below (SLC T99).

Containers used in the course of procurement and processing of gametes and embryos were observed on inspection to be marked with the full name of the patient and two further identifiers, with the exception noted below (SLC T101).

The Consultant Embryologist demonstrated the centre's database which is used to record consumable and reagent traceability data, including the supplier, product description and batch number (SLC T99).

The centre completed an audit of their traceability procedures in February 2012; the summary report did not identify any outstanding actions. (SLC T36).

Process validation: Guidance Note 15
The centre's critical processes have been validated in compliance with SLC T72.

Equipment and materials: Guidance Note 26
The Senior Embryologist provided documented evidence that all equipment that affects critical processing or storage parameters is subject to monitoring, alerts and alarms, with the exception noted below.

The centre has an on-call rota for responding to alarms out of hours. Further monitoring of critical equipment, including frequent temperature mapping of incubators and heated stages is also performed (SLC T24). Evidence was provided that critical measuring equipment, including thermometers, are calibrated against national standards (SLC T24).

The centre has documented procedures for the operation of all critical equipment (SLC T27) and a planned preventive maintenance programme has been established. Service records for a selection of critical equipment were reviewed and demonstrated that the selected equipment had all been serviced within the last year (SLC T24).

Critical equipment has been validated (SLC T28), the Consultant Embryologist confirmed that revalidation of equipment following repair is performed (SLC T25).

Staff were able to confirm that sterile instruments and devices are used in gamete and embryo procurement and processing procedures (SLC T28). All instruments and devices are CE marked (SLC T30).

Premises and facilities: Guidance Note 25
A tour of the centre confirmed that all activities are carried out on licensed premises. Patient records are stored securely in locked cabinets in rooms with restricted access for staff only (SLC T1).

Documented evidence was provided to demonstrate that the processing of gametes and embryos takes place in an environment of at least grade C air quality in the critical work area and a background air quality of at least grade D (SLC T20).

The premises were considered by the inspection team appropriate for the activities undertaken there, however it was noted that space was limited, and staff were commended on how well they worked in the confined area and used space in a way that did not appear to impact on the quality of care provided (SLC T17).

Adverse incidents: Guidance Note 27
The centre is compliant with HFEA requirements for incident reporting. The centre has an incident reporting SOP (SLC T33b) and discussions with centre staff indicated they understood the importance of reporting and investigating incidents appropriately (SLC T119). A review of the centre's incident log against HFEA records confirmed that all HFEA reportable incidents had been reported (SLC T118).

Third party agreements (TPAs): Guidance Note 24
The centre has developed TPAs where necessary with its suppliers, with the exception noted

below (SLC T111).

A list of TPAs was available on inspection (SLC T115) a sample of five TPAs were reviewed on inspection and found to be compliant with SLC T114 and SLC 116. .

What the centre could do better.

Traceability: Guidance Note 19
The centre does not have a SOP that identifies the procedure used to ensure that all gametes and embryos are traceable from procurement to patient treatment or disposal (SLC T33 (b)). See recommendation 5.

The tubes used during egg collection are not marked with patient identifiers. The tubes are used to transfer eggs within follicular fluid from the theatre to the laboratory; the aspirate is then transferred to dishes marked with the appropriate patient identifiers (SLC T101). See recommendation 9.

Equipment and materials: Guidance Note 26
The centre had two dedicated, secure cryostorage rooms used to store cryopreserved gametes and embryos. The main cryo-store has an effective oxygen monitor in use, but the second adjacent cryo-store in use does not have a low oxygen monitoring sensor. The PR has taken action to mitigate the risk associated with staff entering an oxygen depleted environment by ensuring that staff avoid entering the room without colleague support being present outside the room. A low oxygen monitor had been ordered prior to the inspection. See recommendation 3.

Third party agreements (TPAs): Guidance Note 24
The centre has not established written agreements with all third parties who provide services that influence the quality and safety of gametes and embryos. See recommendation 6.

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 25%[1]

The centre's multiple clinical pregnancy rate for 2010/11 represents performance likely to meet the 20% live birth rate target.

What the centre does well

Ongoing 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% (SLC 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

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

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 this inspection.

Staff engaged in licensed activity

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

What the centre does well.

Person Responsible: Guidance Note 1
The PR Mr Jason Kasraie has academic qualifications in the field of biological sciences as required by the HF&E Act 1990 (as amended) section 16(2)(c)(i) and (ii) and has more than two years of practical experience which is directly relevant to the activity to be authorised by the licence.

The PR has successfully completed the HFEA Person Responsible Entry Programme (PREP number T/1171/7).

Staff: Guidance Note 2
The centre has an organisational chart within the Quality Management System (QMS) which defines accountability and reporting relationships (SLC T11). Staff are appropriately accredited, qualified and registered where relevant (SLCs T12 and T14). The PR is the Consultant Embryologist for the centre, supported by a Senior Fertility Sister and Senior Embryologists (SLCs T14 and T16).

Counselling is provided by a qualified and experienced counsellor, who has a Diploma in Counselling: she attended the British Infertility Counselling Association (BICA) introductory course, and is now working towards achieving accreditation with (BICA).

The counsellor works closely with the multi-disciplinary team (MDT), and has set QI's against the counselling SOP. She completed an audit of the counselling service in March 2012 and the findings were shared at the MDT meeting (SLC T36).

The centre has policies to support induction training and competence assessment, professional development and annual performance appraisal (SLCs T12 and T15). Nursing and laboratory staff provided evidence of an induction programme for new staff which included a corporate induction followed by a local induction. Nursing and laboratory staff records showed documented evidence of on-going assessment of core competencies and attendance at study days (SLC T12 and T15a).

What the centre could do better.

Staff : Guidance Note 2
The centre is not operating with a full complement of staff; in May 2012 a full time semenologist left and a part time embryologist commenced maternity leave, a second (part time) embryologist will leave in July to commence maternity leave, this equates to a shortfall of 2.2 whole time equivalent staff.

The PR has prepared a business case for the replacement of one member of staff (semenologist); the Trust Board has yet to approve the post. There is no plan at present to replace the 1.2 wte staff on maternity leave; therefore the PR has reviewed the workload and the number of cycles of treatment that the centre can provide to reflect the reduction in staff numbers.

The inspection team are concerned as to whether the reduced staffing will be sufficient to support treatment activity and implement corrective actions in response to the non-compliances in this report.(SLC T12).

The PR stated that the centre were keen to recruit new laboratory and clinical staff members to address these matters. See recommendation 1.

Welfare of the Child (Guidance Note 8)

What the centre does well.

The inspection team concluded that before providing treatment, the centre takes into account the welfare of the child (WoC) who may be born as a result of treatment and of any other child who may be affected by that birth (SLC T56).

This conclusion was based on a review of eight sets of patient records, all of which contained a WoC assessment (SLC T46e). The patient records showed that the WoC assessment process is documented, the centre has set QI's for WOC (SLC T56).

What the centre could do better.

The centre has not audited how far WOC procedures comply with the centre's own SOP. It is important for the centre to assure itself that before a woman is provided with treatment, account has been taken of the welfare of the child who may be born as a result of that treatment. See recommendation 2.

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) – *N/A*

What the centre does well.

Treating patients fairly: Guidance Note 29
The PR and staff reported that there are policies in place regarding the fair treatment of patients, which ensure that licensed activities must be conducted in a non-discriminatory manner and that careful consideration is given as to how the centre may meet the needs of individual patients and their circumstances.

Patient feedback from interviews, questionnaires and the centres own user satisfaction survey was very positive: the high quality of care was praised and staff were found to be very caring, friendly and informative.

Confidentiality and privacy: Guidance Note 30
A tour of the centre demonstrated that access to registers; data and patients records is restricted to authorised personnel. Key pad entry is used for access to non-patient areas in the centre. Areas where personal conversations and consultations may occur were seen to be private. The main medical record store room had a keypad lock and was considered by the inspection team to be appropriately secure (SLC T17).

Complaints: Guidance Note 28
Complaints are processed in a manner compliant with CoP Guidance Note 28. The centre has a complaints policy and record log. Information on how service users may make a complaint is available to patients (CoP Guidance 4.2k).

Provision of costed treatment plans: Guidance Note 4
Discussions with staff indicated that patients and their partners are provided with clear written information by the treating clinician about their proposed treatment and its anticipated costs (CoP Guidance 4.3). Detailed information regarding treatment costs is also provided.

Egg sharing arrangements: Guidance Note 12

The centre has an egg sharing scheme. All egg sharers are screened in accordance with legal requirements and are registered with the HFEA as donors. All egg sharers have provided the appropriate consents. The centre has appropriate agreements with both the egg sharers and the patients receiving treatment with the donated eggs. (Directions 0001)

What the centre could do better.

Nothing noted at the time of this 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) – N/A
- Information about legal parenthood (Guidance Note 6)

What the centre does well.

Information to be provided prior to consent : Guidance Note 4
The centre has an SOP for information provision to patients (SLC T33b). All prospective patients are invited to an initial consultation session to discuss any aspect of treatment. When treatment commences, patients are given an information pack containing all documentation relevant to their treatment pathway, including all required consent forms. Patients are asked to review the literature and to complete the relevant consent forms once discussed at the second consultation.

Patient information was reviewed on inspection and was found to be compliant with CoP requirements and to provide detailed information about the treatments available, their consequences and risks, consent, and the availability of counselling (SLCs T58 and T60).

Information about storage of embryos: including cooling off periods
Review of the written information indicated that patients are provided with appropriate information about gamete and embryo storage (SLCs T58 and T84; CoP Guidance 17.11, 17.12, 17.14). Information is also provided regarding the gamete provider's right to vary or withdraw their consent to storage and how this can be achieved (SLC T58).

Information about Intracytoplasmic sperm injection (ICSI) : Guidance Note 21
Discussion with staff and review of written patient information indicated that patients and their partners are given specific information about ICSI which discusses the process and the associated risks (CoP Guidance 21.1 and 21.2).

Information about legal parenthood: Guidance Note 6
The nursing staff and counsellor interviewed during the inspection demonstrated a good understanding of legal parenthood requirements (SLC T61 – T65). Information packs provided to recipients of donated gametes contain information about parenthood provisions (SLC T60 and T61).

What the centre could do better.

Information on the centre's website
The centre's website is not compliant with Chair's Letter CH (11)02 in the following areas;

- The live birth rate per treatment cycle is not shown.
- Data relating to activity, pregnancy rates and live birth rates was not less than three years old.
- National average was not shown for the same year, maternal age and treatment type by comparison.

See recommendation 7.

Consent

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

What the centre does well.

Consent to treatment, storage, donation, training and disclosure of information : Guidance Note 5
Staff at the centre provided evidence to demonstrate that appropriate written consent is obtained from patients by suitably qualified and competent staff before gametes or embryos are used in treatment or stored (SLC T57). Consent for the satellite patients is obtained at the satellite centre.

Consents are taken from patients in nurse consultations after written information has been provided and patients have been offered counselling and an opportunity to ask questions (SLC T57 and T58).

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).

The consent taking processes are described in clinical SOPs (SLC T33b). The centre has a QI for consent form completion which is audited (SLC T35 and T36). Assessment of staff competence to take consent has been documented (SLCs T12 and T15a).

A sample of five sets of medical records from patients and donors undergoing various treatments (IVF, FET, sperm donation, and DI), demonstrated that all contained correctly completed treatment and storage consent forms (SLC T57).

Consent to legal parenthood: Guidance Note 6
Information regarding legal parenthood is given to patients prior to treatment; Medical staff explain the process that would be followed if consent to parenthood was withdrawn (SLCs T64 and T65).

What the centre could do better.

Consent to legal parenthood :Guidance Note 6
The centre does not have an SOP to follow for taking consent to parenthood before treating a woman with donor sperm or embryos. See recommendation 5.

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.

Following a tour of the licensed centre premises, a review of documentation provided by the centre and discussions with staff, the inspection team consider that they have sufficient information to determine that all activities for which the centre is licensed are conducted within the premises to which that licence applies.

The inspection team consider that following discussions with centre staff and a review of documentation and records relating to imported gametes, no money or benefit is given or received for the supply of gametes except where authorised by the Authority. Donor compensation records indicated that compensation paid to donors is within the prescribed limits of General Direction 0001.

What the centre could do better.

Nothing noted at the time of this 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 T33b). The Senior Embryologist stated that storage audits are performed every two years, due next in June 2013, the last audit had been reviewed, and corrective action identified, and implemented (SLC T36).

What the centre could do better.

A review of the centre's records of consent to storage of gametes and embryos on inspection, showed that one embryo was being stored after the expiry of the consented storage period. The centre were in communication with the couple to resolve this.
See recommendation 4.

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 were reviewed and included details required by the General Direction 0006.

The centre had also imported donor sperm from America. 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 an SOP and checklists (SLC T110), Including the action to be taken if a recall of material is required.

What the centre could do better.

Nothing noted at the time of this inspection.

Use of embryos for training staff (Guidance Note 22)

What the centre does well.

From discussions with staff and review of information, the SOP for research and training, and consents in patient records, the inspection team concluded that patients are: informed and consented regarding the use of their embryos in training (SLC T97); informed about the types of training undertaken and that they can withdraw consent at any time (SLC T97); advised regarding whether information will be fed back to them (SLC T97).

Processes documented in SOPs ensure that: embryos are only used in training when both gamete providers have consented to such use (SLC T94); embryos used in training are

not kept for or used in subsequent treatment (SLC T92); embryos are only used in training activities approved by the Authority (SLC T93). Laboratory staff keep a log of embryos used in training.
What the centre could do better. Nothing noted at the time of this 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 on inspection were clear, legible, well organised and complete (SLC T46). Each record was seen to include the patient's first name, surname, date of birth, age and sex.

Details of how the patient had been identified by staff were also evidenced in the records, with a copy of the passport as identification. Patient's notes included details of the services provided to them, a medical history and relevant documented consents, laboratory data and the results of tests carried out (SLC T46).

The centre has procedures in place to ensure that records are protected and are retained and readily retrieved (SLC T47). A system has been established to archive records for a minimum of 30 years (SLC T48).

To determine whether all licenced treatment activity is reported to the HFEA and within required timescales, a sample of treatments undertaken over a 12 month period and recorded within the centres laboratory records was compared to data submitted by the centre for inclusion on the register.

All 12 DI treatments and 131 IVF treatments within the audit sample had been reported to the HFEA as required by Direction 0005.

What the centre could do better.

The review of data seen in the patient records at the inspection, compared against data held on the HFEA Register, included five donor information form submissions. In each instance donors had provided additional information (pen portraits) which was found to be available on the donors file, but in three instances this information had not been forwarded to the HFEA. Page three and four of donor information forms potentially hold additional personal information (including: occupation; skills; reason for donating; goodwill message; pen portrait; religion or belief system) that is of great value to donor-conceived people.

The pages should be forwarded to the HFEA even if a donor has not completed these pages, so that the HFEA is able to respond to requests for information regarding the donor without needing to refer back to the clinic for information. See recommendation 8.

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

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

What the centre does well.

The PR provided all information required by the application process prior to inspection. Centre staff cooperated fully with the inspection team and all further information requested for the inspection was provided in a timely manner.

What the centre could do better.

Nothing noted at the time of this 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
Discussions with staff, a review of information submitted prior to inspection and a tour of the premises indicated that confidential patient information is not disclosed unless under circumstances permitted by law (SLC T43).

Disclosure of information, held on the HFEA Register, for use in research

To determine whether the register properly reflects the consent given by patients and their partners for the use of register information for research purposes, a sample of 22 completed patient and partner disclosure consents were reviewed against disclosure consent data supplied by the for inclusion on the register, no discrepancies were found between the patient and partner completed consent disclosure consents on patient files and consent information held on the register.

What the centre could do better.

Nothing noted at the time of this inspection.

5. Changes / improvements since the previous inspection on 30 May 2012.

Area for improvement	Action required	Action taken as evidenced during this inspection
The time of some procedures, specifically sperm preparation, frozen embryo transfer and removal of embryos from storage, is not recorded in the patient records, which is not compliant with guidance note 18.7(b) in the Code of Practice.	The PR should consider review of the record sheets to include the time of all procedures. If the PR amends the record sheets to include this information he should submit a copy of the amended sheet to the HFEA by 31 August 2012. If the PR decides not to amend the record sheet he should submit an explanation of his reasons to the HFEA by 31 August 2012.	The PR submitted copies of the amended sheets to the Executive on 16 July 2012. 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
1. **Staff** The PR informed the inspection team that the centre is not operating with a full complement of staff; the centre will have 2.2wte less staff in July 2013, due to maternity leave (1.1wte) and 1wte staff member leaving. (SLC T12).	The PR should review the workload and skill mix to determine how many cycles of treatment can be safely accommodated, taking into account the staff available. The PR must ensure that the clinical activity level continues to be controlled so that the staff available can safely provide and undertake all necessary activity associated with regulatory compliance. A copy of the workload review and findings should be submitted to the lead inspector by 09 August 2013.	We will be performing a workload review prior to the 9th August and will forward the results to the lead inspector by the 9th August. Subsequent to the inspection the Trust approved the replacement of the Seminologist post and interviews are taking place on the 28th June	The inspectorate is satisfied with the progress, and will monitor the workload review when it is received in August.

2. Welfare of the child The centre had not audited how far WOC procedures comply with the approved protocols, the regulatory requirements and quality indicators in the last two years (SLC T36).	The PR should audit how far WOC procedures comply with the approved protocols, the regulatory requirements and quality indicators in the last two years. A copy of the audit findings and any corrective actions should be submitted to the lead inspector by 09 August 2013	This audit is due to be performed prior to the 9th August. A copy of the findings will be forwarded when complete. A draft audit tool is enclosed for your perusal.	The draft audit tool has been seen, and the findings of the audit will be monitored in August.
3. Equipment and materials The second cryo-store does not have a low oxygen monitoring sensor (CoP Guidance 25.15),	The PR should inform the lead inspector of the timescale for the installation of the oxygen monitor in the secondary cryo-store and provide confirmation when it is installed.	An oxygen monitor has now been installed in the secondary cryostore.	No further action required.
4. Storage of gametes and embryos The centre had one embryo in storage after the expiry of the consented storage period. HF&E Act, as amended, Sch 3 para 8 (1)	The PR must ensure that communication with the couple is followed through as a matter of urgency. The lead inspector to be informed of the outcome.	This embyro has now been discarded as per protocol	No further action required.

Other areas of practice that requires improvement

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
5. An SOP is required for; **Consent to legal parenthood** The centre does not have an SOP to follow for taking consent to parenthood before treating a woman with donor sperm/embryo (T33b). **Traceability** The centre does not have a SOP that identifies the procedure used to ensure that all gametes and embryos are traceable from procurement to patient treatment or disposal (T33b).	The PR should ensure that the SoP's are written and shared with staff. A copy of the two SOP's should be submitted to the lead inspector by 09 August 2013.	SOP for legal parenthood exists and has done for some time. It is called the 'Protocol for parental responsibility' and is enclosed. The traceability of embryos is covered in several protocols already- embryos are traceable. Protocol and practice have been updated following discussions with the inspection team to clarify the situation. Embryos are now logged into and out of training for disposal. See enclosed form A46E. Embryos are signed into training on the main laboratory record and their disposal from training is documented on the log form	The protocol for parental responsibility has been received, thank you. The embryo disposal record has been seen, thank you. No further action required.
6. Third party agreements The centre does not have written agreements with all third parties who provide goods or services that influence the quality and safety	The PR should ensure that all TPA's are agreed between those third parties who provide goods or services that influence the quality and safety of gametes and embryos.	An audit of third party agreements will be undertaken and forwarded to the HFEA by the 9th August. It is important for the HFEA to	The inspectorate appreciates the difficulty in obtaining a third party agreement with some suppliers, and is satisfied with the planned audit expected by August.

of gametes and embryos (SLC T111).	The PR should ensure that all TPA's are in place, by completing an audit, a copy of the summary report should be sent to the lead inspector by 09 August 2013	understand the difficulties encountered with some third party suppliers in obtaining a TPA.	
7. Website The centre's website was not compliant with Chair's Letter CH (11)02.	The PR should ensure that the centre's website satisfies the requirements of the Chair's Letter CH (11)02 by 09 August 2013.	On the day of the inspection the website link to our success rates was broken. An old news article relating to success rates in 2009 has now been removed as it was more than 3 years old. We have updated the 'success rates' section of the website to better reflect the Chair's letter and provided permanent links to the HFEA website. The link to our own data is still dead and we are investigating this with our web content provider. We would highlight to the HFEA that other Centres locally and nationally are not compliant with the content of CH(11)02.	The website has been improved since the inspection, it is now showing; • Data relating to activity, pregnancy rates and live birth rates that is less than three years old. Local data is still not available, and this will be followed up by the lead inspector by August.
8. Record keeping and document control The HFEA register team reviewed submission forms against information held on patient and donor files, this	The PR should ensure that relevant staff are aware of the requirement to provide donor goodwill and pen portrait information to the HFEA and that such information is	All staff have been reminded of the necessity. This appears to have been the result of human error. Forms have now been forwarded to the HFEA.	The outstanding information has been sent to the register team at the HFEA. A summary report of corrective action should be sent to the

included five donor information forms. In each instance donors had provided additional information which was found to be available on the donors file but in three instances this information had not been forwarded to the HFEA (SLC T9(e). T41 Direction 0005).	provided. An audit of record keeping should be completed to ensure that all information is submitted to the HFEA in line with Directions 0005. A summary report of corrective action should be sent to the lead inspector by 09 August 2013.	An audit will be performed and corrective actions detailed to the HFEA prior to the 9th August	lead inspector by August.
9. Labelling containers At egg collection not all containers (dishes, vials, ampoules, tubes etc) used during the procurement of eggs are labelled with the patient's/donor's full name and a further identifier (SLC T101).	The PR should either ensure that the plastic ware is all appropriately labelled during egg collection, or should ensure the practice is risk assessed and that the laboratory SOP for egg collection states that only one person's gametes should be in the critical work area at a time and that the air flow cabinet must be emptied of all plastic ware and cleaned between each egg collection. The lead inspector should be informed of any actions taken to mitigate the risks of misidentification as a result of this practice by the time this report is considered by the ELP.	The centre does not undertake more than one egg collection procedure at a time and does not process material from more than one individual in a cabinet at a time. Witnessing procedures are robust- all aspirate tubes are examined and any eggs collected are witnessed into appropriately labelled dishes and placed in incubation before another egg collection begins. The cabinet is checked and reset before the next egg collection begins. No aspirate tubes remain in the cabinet at this time. The treatment room is cleaned and reset before the next egg collection begins. No aspirate tubes remain in the treatment	The protocol for oocyte collection has been sent by the PR, the protocol states that only one person's gametes should be in the critical work area at a time and that the air flow cabinet must be emptied of all plastic ware and cleaned between each egg collection. The risk has been assessed to reduce the possibility of misidentification, and practice and protocols reflect the findings of the risk assessment. No further action required.

		room from the previous egg collection at this time. Protocols C038 and E004 (enclosed) have been updated to better reflect this practice. Thus there is no possibility of a misidentification event with current practice- which has been designed with this issue in mind. Risks are already mitigated.	

Additional information from the Person Responsible

HFEA Executive Licensing Panel Meeting

2 August 2013

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

Minutes – Item 1

Centre 0148 – (Shropshire and Mid-Wales Fertility Centre) – Renewal Inspection Report

Members of the Panel:	Committee Secretary:
Mark Bennett – Director of Finance and Facilities (Chair) Nick Jones – Director of Compliance and Information Rachel Hopkins – Head of HR	Rebecca Loveys

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 is a medium-sized centre which has held a Treatment and Storage licence with the HFEA since 1994. The Panel noted that the centre provides a full range of fertility services.

2. The Panel noted that the centre has a five year licence due to expire in November 2013 and that the inspection took place on 8 and 9 May 2013.

3. The Panel noted that, from October 2012 to March 2013, the centre's success rates for IVF and ICSI were in line with national averages.

4. The Panel noted that, at the time of inspection, four major and five other areas of non-compliance were identified.

5. The Panel noted that, since the inspection, two major and two other areas of non-compliance have been addressed by the PR.

6. The Panel noted that the inspectorate recommended a licence be granted for four years; also that recommendations to address the remaining areas of non-compliance are to be implemented within the timescales stated in the report.

Decision

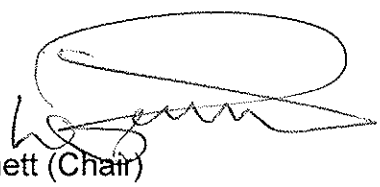
7. The Panel had regard to its decision tree. It was satisfied that the appropriate application and fee had been submitted and that the application contained the supporting information required by General Directions 0008.

8. The Panel was satisfied that the qualifications and character of the PR are such as is required for the supervision of the licensed activities.

9. The Panel was satisfied that the licence application concerned treatment or non-medical fertility services related to gametes intended for human application.

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

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

Signed: 
Mark Bennett (Chair)

Date: 7 August 2013