Initial Licence Inspection Report

Date of inspection: 21 May 2013
Purpose of inspection: New Treatment (including embryo testing) and Storage Licence
Length of inspection: 8 hours
Inspectors: Sara Parlett, Andrew Leonard, Paula Nolan and Jenny Clifford

Inspection details:
The report covers the pre-inspection analysis, the visit and information received with the new licence application.

Date of Licence Committee: 11 July 2013

Purpose of the Inspection Report
The purpose of the inspection is to assess whether new centres will comply with the Human Fertilisation and Embryology (HF&E) Act 1990 (as amended), the HF&E Act 2008 and the Code of Practice (CoP), to ensure that centres will provide a quality service for patients. The report summarises the findings of the initial licence 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 which makes the decision about the centre's licence application.

Centre details

Centre name	Wales Fertility Institute
Centre number	0329
Licence number	No active licence
Centre address	Abertawe Bro Morgannwg University Health Board Neath Port Talbot Hospital Baglan Way Port Talbot SA12 7BX
Proposed Person Responsible	Mr Adnan Bunkheila
Proposed Licence Holder	Mr Pushpinder Mangat
Proposed date of licence issue	July 2013

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Report to Licence Committee

Brief description of the centre:

The HFEA received a new treatment and storage licence application from the proposed Person Responsible (PR) on 10 February 2013. The licence application is for a full range of activities, including embryo testing.

The proposed centre will provide treatment to NHS funded patients. The centre is designed to provide a maximum of 600 cycles of in vitro fertilisation (IVF) or intracytoplasmic sperm injection (ICSI) per annum. The PR plans a phased increase in treatment activity to this maximum level, starting with approximately eight treatment cycles per week in the first year.

Projected Activities of the Centre:

Type of treatment	Projected annual activity
IVF	600
ICSI	
Frozen embryo transfer (FET)	
Pre-implantation genetic diagnosis (PGD) and pre-implantation genetic screening (PGS)	50
Partner intrauterine insemination (IUI) / donor insemination (DI)	50

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

Summary for licensing decision

The Welsh Government has reviewed NHS-funded IVF services in Wales. This has resulted in all services being provided by NHS providers, principally in Cardiff (IVF Wales, centre 0049) and from Port Talbot (the subject of this licence application). As from 1 April 2013 management responsibility for IVF Wales (that is the accountability arrangements within the Welsh Government Health and Social Care system) was undertaken from Abertawe Bro Morgannwgg University Health Board (ABMU). Through the proposed new centre and IVF Wales, ABMU will manage all IVF services in South Wales. The Licence Committee is receiving a report of the performance of IVF Wales at this meeting.

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

- The proposed PR satisfies the requirements of Section 16 of the HF&E Act 1990 (as amended) necessary for a licence to be granted since:
  1. The proposed PR is currently PR at Swansea Reproduction Unit (HFEA licensed centre 0273). The proposed PR is considered suitable and to have discharged his duty in relation to his PR role at centre 0273. Centre 0273 was last inspected in December 2012 and the one major and two 'other' non-compliances noted have since been resolved. The minutes of the Executive Licensing Panel consideration of this interim inspection report are attached. Therefore, in agreement with the Head of Inspection, it was considered disproportionate to seek references to attest to the suitability of the character of the applicant to be PR at centre 0329.
  2. The proposed PR holds academic qualifications in the field of medicine and is registered with the General Medical Council (GMC). The proposed PR has more than two years' practical experience which is directly relevant to the activities to be authorised by the licence. The proposed PR's curriculum vitae has been submitted as part of the application.
  3. The proposed PR has previously completed a PR entry programme (certificate number: T/1121/7), but has also recently completed the new version of the programme (certificate number: T/1236/8).

- The licence application details the appointment of a Licence Holder (LH); the proposed LH's curriculum vitae has been submitted along with a letter confirming that he is willing to assume this role. Mr Pushpinder is also the LH at HFEA centre 0049.

- The premises and equipment are suitable, although one recommendation must be met before licensed activity is undertaken.

- The proposed practices and processes are considered to be suitable.

- The proposed PR has submitted documentation required to satisfy the requirements of General Direction 0008, with one exception. Two pieces of critical equipment are still in the process of being validated.

- The proposed PR has submitted an application fee to the HFEA in accordance with requirements.

The Licence Committee is asked to note that at the time of the inspection there were a number of areas of practice that required improvement, including five major areas of non-compliance and three 'other' areas of non-compliance or poor practice.

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

Major areas of non compliance

- The PR should ensure that all relevant safety certifications are submitted to the Executive before the first treatment occurs.
- The PR should ensure that the air quality is assessed and meets the requirements of Standard Licence Condition (SLC) T20 before the first treatment occurs.
- The PR should keep the Executive informed on the progress of the genetic testing laboratory, that will be used for the diagnostic analysis of biopsied material, towards Clinical Pathology Accreditation UK Ltd (CPA) accreditation.

'Other' areas of non compliance

- The PR should ensure that the standard operating procedure (SOP) for the use of the IVF chamber is in place before the equipment is used.
- The PR should ensure that quality indicators (QIs) for embryo biopsy are documented.

Since the inspection visit, the PR has either committed to fully implementing the following recommendations, or further information is required to demonstrate that the recommendations have already been completed:

Major areas of non compliance

- The PR should ensure that all critical equipment is installed and validated before the first treatment occurs.
- The PR should ensure that all third party agreements (TPAs) are in place with all suppliers and meet the requirements of SLC T114. Critical TPAs must be in place prior to commencing activity.

'Other' areas of non compliance

- The PR should review and revise the centre's multiple births minimisation strategy and multiple pregnancy rate QI to ensure they will be effective in meeting the 10% multiple live birth rate target.

The inspection team recommends that the Licence Committee requires that the PR complies with the recommendations above within the prescribed timeframes set out in the inspection report.

Recommendation to the Licence Committee

The inspection team considers that there is sufficient information available to recommend:

1. Granting a treatment and storage (including embryo testing) licence for a period of two years without additional conditions.

2. Appointment of the proposed PR.

3. Appointment of the proposed LH.

Details of inspection findings

1. Protection of patients and children born following treatment

Focus

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

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

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

What the centre does well:

The centre's proposed procedures for double checking the identification of gametes and embryos and the patient or donor to whom they relate are compliant with HFEA requirements (SLC T71).

The centre has installed an electronic witness system, but this is not yet validated. A manual witness system will be used initially and then in parallel with the electronic witness system as part of the validation process (SLC T24). The centre has a SOP for witnessing to ensure that no mismatches of gametes or embryos or identification errors occur and it was considered compliant with the requirements of Guidance Note 18.4.

What the centre could do better.

Nothing noted.

Patient selection criteria and laboratory tests

- Procuring, processing and transporting gametes and embryos (Guidance Note 15)
- Counselling (Guidance Note 3)

What the centre does well.

Procuring, processing and transporting gametes and embryos

Prior to the processing of gametes or embryos intended for use in treatment or storage, the centre will screen patients in accordance with SLC T50 in a CPA accredited laboratory (SLC T51). Diagnostic semen analysis will be performed by a laboratory which is considered by the HFEA to be accredited to a CPA-equivalent status (SLC T21).

If sperm is produced at home, the centre will record this in the gamete provider's records

(SLC T68).

Counselling
Counselling will be offered to those providing consent as required by Schedule 3 and 3ZA of the HF&E Act 1990 (as amended).

The centre will offer counselling to all patients and donors prior to consent to treatment or donation being sought. A SOP is in place for counselling (SLC T33b).

Where required there is provision in place for more specialist counselling to be made available (CoP Guidance 3.10).

QIs for counselling have been established and audits of the service are planned (SLC T35 and T36).

What the centre could do better.

Nothing noted.

Donor recruitment, assessment and screening

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

What the centre does well.

Donor recruitment, assessment and screening
The centre does not intend to recruit sperm or egg donors and is not planning to offer egg sharing initially. Treatment will be provided using imported sperm and known sperm and egg donors, for which SOPs are in place (SLC T33b). Proposed screening procedures are compliant with HFEA requirements and tests will be performed by a CPA accredited laboratory (SLC T52 and T53).

Payments for donors
Centre staff are aware of the regulatory requirements concerning donor compensation (General Directions 0001).

Donor assisted conception
Information will be provided to patients to ensure they understand the importance of informing any child at an early age that the child results from the gametes of a person who is not their parent; patients will be provided with information on how to tell the child (SLC T63).

What the centre could do better.

Nothing noted.

Good clinical practice

- Quality management system (Guidance Note 23)
- Traceability (Guidance Note 19)
- Validation (Guidance Note 15)
- Equipment and materials (Guidance Note 26)
- Premises – suitability of the premises and air quality (Guidance Note 25)
- Adverse incidents (Guidance Notes 27)
- Third party agreements (Guidance Note 24)
- Intracytoplasmic sperm injection (ICSI) (Guidance Note 21)

What the centre does well.

Quality management system
A comprehensive quality management system (QMS) is in place (SLC T32), including a quality manual and associated documents (SLC T33 and T35). The centre plans to work towards ISO 9001:2008 certification of its QMS.

QIs have been established for all licensed activities, with one exception described on page 13 of this report (SLC T35). The centre has an appropriate audit schedule in place for regular audit of QIs and processes (SLC T36).

SOPs are in place for activities included in the licence application, and those activities that do not require a licence (SLC T33b). Where relevant, SOPs detail the specifications for critical materials and reagents to be used (SLC T31).

There will be an annual review of the QMS and benchmarking will be performed regularly with centre 0049, to facilitate continuous and systematic improvement (CoP Guidance 23.12 and SLC T32).

Traceability
There are documented procedures in place to ensure the traceability of all consumables, reagents and equipment that come into contact with gametes and embryos (SLC T99b).

Containers used in the course of procurement and processing of gametes and embryos will be labelled with the patient's full name, date of birth and hospital number (SLC T101).

Procedures are in place to ensure data required for traceability is stored for the necessary period of time (SLC T103).

Process validation
The centre will use established processes for critical procurement and processing procedures that have been validated by evaluation against published studies and clinical results from other centres. Further validation will take place via retrospective analysis of the centre's own data once treatment commences (SLC T72).

Equipment and materials
Activities will be carried out using equipment designed for the purpose (SLC T23). A number of pieces of critical equipment have been validated, including dewars, hoods and incubators. However, a number of items have either not yet been installed or are in the process of being validated, as detailed below (SLC T24).

The centre has documented procedures for the operation of critical equipment and procedures to follow if equipment malfunctions, with one exception detailed below (SLC T27).

Service agreements are in place for equipment. Equipment will be regularly inspected and maintained (SLC T24). Equipment with a critical measuring function is appropriately calibrated (SLC T24).

Sterile equipment and devices will be used for the procurement and processing of gametes and embryos (SLC T28). Wherever possible, CE marked consumables will be used (SLC T30).

Premises – suitability of the premises and air quality
The inspection team considered the premises to be suitable, with the exceptions detailed below (SLC T17). The main entrance has secure access arrangements and CCTV surveillance monitored by staff in the reception area. All areas in which patient records and gametes/embryos may be kept are secure and have controlled access.

There is an uninterrupted power supply that will provide power to critical equipment in case of unexpected power failure.

Particle count measurements performed to validate the air cleaning systems demonstrate that processing of gametes and embryos will take place in a background of at least Grade D air quality. Air quality in the critical work areas has also been measured via particle counting for validation purposes and has been shown to meet the requirements of SLC T20. Further air quality monitoring is required however, as detailed below.

Adverse incidents
Centre staff are aware of the requirements for reporting and investigating adverse incidents and a SOP for this is in place which is compliant with HFEA requirements (SLC T118 and T119).

Third party agreements
TPAs are not yet in place with all suppliers that provide goods or services that influence the quality and safety of gametes and embryos (SLC T111). Centre staff are aware of this requirement and noted that agreements are either awaiting signature by the third party or a decision as to which company to use has not yet been made.

The centre plans to conduct annual reviews to evaluate the ability of third parties to meet the required standards (SLC T112).

ICSI
The centre has a SOP (SLC T33b) and QIs (SLC T35) relevant to ICSI. Laboratory staff who will perform ICSI are appropriately trained and competent to perform the procedure (SLC T15).

What the centre could do better.

Equipment and materials
A small number of pieces of equipment have either not been installed or are not yet validated. These include the equipment monitoring system, the egg collection suction

pump and the micromanipulators. See recommendation 1.

The centre does not have a SOP for the use of the IVF chamber (SLC T33b). See recommendation 6.

Premises – suitability of the premises and air quality
Evidence of fire safety and health and safety certification has not been provided to the Executive, to demonstrate that the centre has suitable facilities to carry out licensed activities (SLC T17). See recommendation 2.

Although air quality has been tested, this was prior to installation of all laboratory equipment. A deep clean of the laboratory and treatment rooms will be performed once all equipment has been installed. Air quality monitoring will then be performed again, including bacteriological assessment via settle plates. See recommendation 3.

Third party agreements
TPAs are not yet in place with all suppliers that provide goods or services that influence the quality and safety of gametes and embryos (SLC T111).

A TPA is in place with one of the genetic testing laboratories that will be used for the diagnostic analysis of biopsied material. A template TPA for the second genetic testing laboratory was also reviewed on inspection. Neither of these include a description of how results will be relayed to the centre, including sign off and confirmation that the result applies to the correct sample (SLC T114f). See recommendation 4.

Multiple Births (Guidance Note 7)

What the centre does well

The centre has a multiple births minimisation strategy comprising of criteria for a single embryo transfer and the requirement to record information on the number of embryos transferred and to provide information to patients requesting multiple embryo transfer on the risks of multiple pregnancies (General Direction 0003).

What the centre could better

The centre's multiple births minimisation strategy states that "HFEA guidance requires all IVF clinics to decrease the numbers of multiple births as a result of assisted conception treatment cycles to 10% over the next few years". The 10% multiple live birth rate target has been active since 1 October 2012 (General Direction 0003).

The centre has established a QI for multiple pregnancy rates that requires no more than 20% of pregnancies be multiples. This is unlikely to meet the 10% multiple live birth rate target (SLC T123). See recommendation 7.

Staff engaged in licensed activity

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

What the centre does well.

Person Responsible
The PR holds academic qualifications in the field of medicine and has more than two years of practical experience which is directly relevant to the activities to be authorised by the licence (HF&E Act 1990 (as amended) section 16(2)(c)(i) and (ii)).

The PR has successfully completed the HFEA PR Entry Programme (PREP number T/1236/8).

The PR plans to work full time at the new centre as soon as it is licensed and to relinquish the role of PR at centre 0273 at some point in the next year. The PR is confident that he can manage the role of PR at both centres in the interim.

Staff
Recruitment of staff is currently on-going. However, based on discussions at the time of inspection, the current staff numbers are likely to be sufficient for the projected initial activity level of eight cycles of IVF/ICSI per week (SLC T12).

Staff appointed to work at the centre are appropriately registered with professional and/or statutory bodies (SLC T14 and T16).

There are four consultants who are all registered with the GMC. The lead nurse is registered with the Nursing and Midwifery Council. The centre has access to a suitably qualified counsellor who is working towards accreditation with the British Infertility Counselling Association (CoP Guidance 2.12).

The individual responsible for the clinical embryology laboratory is Health and Care Professions Council (HCPC) registered (SLC T14).

There are documented induction and training procedures for all staff and these were provided to the inspection team (SLC T15). Arrangements for competence assessments are in place and processes have been established for all staff to participate in continuing professional development and have regular appraisals (CoP Guidance 2.3).

What the centre could do better.

Nothing noted.

Welfare of the Child (Guidance Note 8)

What the centre does well.

Account will be taken of the welfare of any child who may be born as a result of treatment and of any other child who may be affected by the birth, before treatment is provided (SLC T56). The centre has a SOP for conducting welfare of the child assessments and appropriate QIs have been developed. Welfare of the child assessments form part of the

audit schedule (SLC T36).

What the centre could do better.

Nothing noted.

Embryo Testing

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

What the centre does well.

The PR has applied for an embryo testing licence and considers that the centre will be in a suitable position to offer PGD and PGS immediately.

The centre has two embryologists competent to carry out embryo biopsy (SLC T15a).

Embryo biopsy protocols have been documented and the template laboratory worksheets include the requirement for witnessing at all stages of the biopsy procedure (SLC T33b and T71). The biopsy procedures have been validated in compliance with SLC T72.

Centre staff are aware of the genetic conditions for which embryo testing can be carried out. No embryo will be tested unless it meets the statutory tests (SLC T89).

The laboratory manager confirmed that any information derived from tests will not be used to select embryos of a particular sex for social reasons and this is also documented in the patient information leaflets (SLC T88b).

The information that will be provided to patients regarding PGD and PGS meets the requirements set out in the CoP.

What the centre could do better.

The genetic testing will be conducted by two external laboratories, one of which is not currently accredited by CPA (SLC T21). The laboratory is in the process of obtaining CPA accreditation and is due to be inspected in August 2013. The laboratory manager considers that this information and the laboratory's experience and international reputation mitigates the risks of non-compliance with SLC T21. See recommendation 5.

QIs for embryo biopsy were described on inspection but have not yet been documented (SLC T35). See recommendation 8.

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)
- Complaints (Guidance Note 28)
- Provision of costed treatment plans (Guidance Note 4)
- Egg sharing arrangements (Guidance Note 12)
- Surrogacy (Guidance Note 14)

What the centre does well.

Treating patients fairly
The centre's policies and procedures appeared to ensure that patients will be treated fairly.

Complaints
There is a complaints policy in place, and a log of complaints will be maintained and discussed at team meetings (CoP Guidance Note 28).

Patient feedback
Patient satisfaction will be monitored closely by the centre via patient questionnaires.

Provision of costed treatment plans
Only NHS patients will be treated at the centre initially and therefore costed treatment plans are not required.

Egg sharing arrangements
The centre does not plan to facilitate egg sharing arrangements.

Surrogacy
The centre has procedures in place that require that gamete providers in surrogacy arrangements be screened as donors, and that sperm will be quarantined for a minimum of 180 days prior to repeat testing (SLC T52 and T53c).

What the centre could do better.

Nothing noted.

Information

- Information to be provided prior to consent (Guidance Note 4)
- Information about storage of embryos (including cooling off periods)
- Information about Intracytoplasmic sperm injection (Guidance Note 21)
- Information about preimplantation genetic testing (Guidance Notes 9 & 10)
- Information about legal parenthood (Guidance Note 6)

What the centre does well.

There is a SOP for providing information to patients (SLC T33b).

A suite of patient information has been reviewed by the inspection team against SLC T58 and the relevant CoP guidance notes. It was considered to be comprehensive and compliant with requirements.

The centre did not have a dedicated website at the time of inspection for assessment of compliance with Chair's Letter CH (11)02. The PR confirmed that he would inform the HFEA when the website is active.

What the centre could do better.

Nothing noted.

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.

The centre will take consent before gametes or embryos are used in treatment or storage (SLC T57). There is a SOP for taking consent (SLC T33b) and audits are planned (SLC T36). The identity of the person providing consent will be appropriately verified (CoP Guidance Note 5.10).

Consent to legal parenthood will be obtained where required and centre staff understand the requirements in relation to legal parenthood. Centre staff were able to describe mechanisms to ensure that where a patient or second parent withdraws consent, the second parent or patient will be informed and in the case of the patient this will be before treatment takes place (SLC T64 and T65).

What the centre could do better.

Nothing noted.

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.

The centre will be conducting the activities essential to the provision of licensed activities at the licensed premises only (SLC T1).

Only permitted embryos will be used in the provision of treatment services. Embryos will not be selected for use in treatment for social reasons and will not be created by embryo splitting. Centre staff are aware that embryos must only be created where there is a specific reason to do so and the clinician responsible for the patient will document the justification for the use of gametes and embryos based on the patient's medical history and therapeutic indications (SLC T49).

Staff are aware of the requirements of General Direction 0001 for compensation of gamete and embryo donors.

What the centre could do better.

Nothing noted.

Storage of gametes and embryos

- Storage of gametes and embryos (Guidance Note 17)

What the centre does well.

SOPs (SLC T33b) and QIs (SLC T35) are in place for storage related activities and the process and related equipment have been validated (SLC T24 and T72).

Patients and donors will be appropriately screened before their gametes or embryos are

stored (SLC T50 or T52 as appropriate).

Based on a description provided during inspection, the process to ensure that gametes and embryos are not stored beyond their consented storage period is likely to be compliant with CoP Guidance 17.18.

There is a process in place to manage the 'cooling off' period where required (CoP Guidance 5.35).

What the centre could do better.

Nothing noted.

Distribution and / or receipt of gametes and embryos

- Distribution of gametes and embryos (Guidance Note 15)
- Export of gametes and embryos (Guidance Note 16)
- Receipt of gametes and embryos (Guidance Note 15)
- Import of gametes and embryos (Guidance Note 16)

What the centre does well.

SOPs are in place for the distribution, receipt, and recall of gametes and embryos (SLC T105, T106, T107, T108, T109 and T110).

Donor sperm will be purchased from a European sperm bank. The centre has a detailed SOP to ensure that the requirements of General Direction 0006 are met prior to import.

What the centre could do better.

Nothing noted.

Use of embryos for training staff (Guidance Note 22)

What the centre does well.

The centre intends to use embryos in training. Embryos will only be used for the purposes of training staff in embryo biopsy and embryo storage. These are both activities that have been expressly authorised by the Authority (SLC T93). Prior to giving consent, each gamete provider will be provided with information on the nature of the training, and informed that their decision will not affect their treatment (SLC T97).

Procedures are in place to ensure that embryos appropriated for training staff are not used for treatment, that they are only used where both gamete providers have consented to this purpose and that there is no actual or perceived conflict of interest between the use of embryos in training and the use of embryos in the provision of treatment services (SLC T93, T94 and T95).

What the centre could do better.

Nothing noted.

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.

Documents reviewed on inspection were controlled, with version numbers and review dates (SLC T34).

The content of patient records as required by SLC T46 was discussed with the centre staff who confirmed that the required elements will be retained in their electronic records management system.

Documented procedures are in place to ensure records are secure at all times and that systems are in place for maintaining data security. The centre has procedures for arranging for patients to access their records (SLC T43 and T44).

The centre has documented procedures to ensure that patient records will be maintained for at least thirty years (SLC T48).

What the centre could do better.

Nothing noted.

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

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

What the centre does well.

There is a SOP for submitting data to the HFEA (SLC T33b). Staff confirmed that they are familiar with submitting data to the HFEA and the PR is satisfied with the competence of staff (SLC T15a).

Staff are aware of the requirements of General Direction 0005.

What the centre could do better.

Nothing noted.

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.

The inspection team considered that there is good provision for maintaining the confidentiality and privacy of patients. The centre has a range of SOPs in place to ensure that all information is kept confidential and only disclosed in circumstances permitted by law (SLC T43).

Access to areas where confidential identifying information can be seen or obtained will be restricted and authorised by the PR (Section 33A(1) HF&E Act 1990 (as amended)).

What the centre could do better.

Nothing noted.

Areas of practice requiring action

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, or a significant shortcoming from the statutory requirements. 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 noted.			

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. **Equipment** Not all pieces of critical equipment have been installed and/or validated. These include the equipment monitoring system. SLC T24.	The PR should ensure that all critical equipment is installed and validated before the first treatment occurs. The lead inspector should be informed when the validation has been completed. A sample of validation documents will then be requested for submission before the first treatment occurs.	The suction pump is installed and document validation attached. Remains: the anti-vibration table with the micromanipulators already installed. The wireless monitoring system is being installed. All are now being validated. A further sample of validation documents will be sent to lead inspector before start of first treatment.	Evidence of validation of the suction pump has been submitted. The PR's response is noted and it is requested that evidence of validation of the two remaining pieces of equipment is submitted before the first treatment occurs.
2. **Suitability of premises** Evidence of fire safety and health and safety certification has not been provided to the Executive, to demonstrate that the centre has suitable facilities to carry out licensed	The PR should ensure that all relevant safety certifications are provided to the lead inspector before the first treatment occurs.	All requested premises certifications are attached.	Evidence of a health and safety and fire safety review has been submitted. No further action is required.

activities. SLC T17.			
3. **Air quality** Although air quality has been tested, this was prior to installation of all laboratory equipment. A deep clean of the laboratory and treatment rooms will be performed once all equipment has been installed. Air quality monitoring will then be performed again, including bacteriological assessment via settle plates. SLC T20.	The PR should ensure that the air quality is assessed after deep cleaning and that it meets the requirements of SLC T20. The results of the assessment should be forwarded to the lead inspector before the first treatment occurs.	The Laboratory air quality was assessed after deep clean of the laboratory and all meet requirements. Assessment results (particle and plates) in addition to the validation document are attached.	Evidence has been submitted that the air quality has been assessed, by particle counts and bacteriological assessment, following a deep clean of the laboratory and treatment rooms. Air quality meets the requirements of SLC T20. No further action is required.
4. **Third party agreements** TPAs are not yet in place with all suppliers that provide goods or services that influence the quality and safety of gametes and embryos. A TPA is in place with one of the genetic testing laboratories that will be	The PR should ensure that TPAs are in place with all suppliers. The PR should revise the TPAs with the genetic testing laboratories to include the requirements of SLC T114f and submit copies to the lead inspector.	A new TPA that meet all the criteria with an alternative CPA accredited genetic testing laboratory is now established and attached. A TPA with an alternative genetic testing laboratory is being updated, this lab will be used if they achieve CPA accreditation by December	The TPA with the CPA accredited genetic testing laboratory has been submitted. It appears that the result reporting requirements are documented in an appendix to the TPA that was not submitted. The lead inspector cannot therefore determine if the TPA complies with the requirements of SLC T114(f). It

used for the diagnostic analysis of biopsied material. A template TPA for the second genetic testing laboratory was also reviewed on inspection. Neither of these include a description of how results will be relayed to the centre, including sign off and confirmation that the result applies to the correct sample. SLC T111 and T114f.	The PR should review the TPAs required and ensure those which are critical (e.g. with testing laboratories, media supply companies and gamete/embryo couriers) are in place prior to commencing activity. Confirmation of this should be provided to the lead inspector. All other TPAs should be in place by 1 November 2013.	2013. Await TPA signature from only few suppliers. TPAs for all critical areas will be in place prior to commencing licensed treatments. All other TPAs will be complete by the due date specified.	is requested that the PR submits the TPA appendices. The PR's response regarding all other TPAs is noted. It is requested that confirmation that all critical TPAs are in place is submitted to the HFEA prior to commencing activity.
5. **CPA accreditation** One of the genetic testing laboratories that will be used for the diagnostic analysis of biopsied material is not CPA accredited. SLC T21.	The PR should keep the Executive informed on the laboratory's progress towards CPA accreditation, including confirmation that the CPA inspection scheduled for August 2013 has been conducted. If CPA accreditation is not achieved by December 2013, the PR should assess whether this laboratory should continue to be used for diagnostic analysis. A report of this assessment should be	The HFEA Executive will be kept informed of the progress of the genetic laboratory CPA inspection scheduled for August 2013. WFI will review the use this particular genetic laboratory, if the inspection is not conducted by August 2013 or CPA accreditation is not achieved by December 2013.	The inspector notes the PR's response and awaits an update following the scheduled CPA inspection in August 2013.

	provided to the centre's inspector by 1 January 2014.		

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
6. **SOPs** The centre does not have a SOP for the use of the IVF chamber. SLC T33b.	The PR should ensure that this SOP is in place before the equipment is used.	This equipment is not essential and its use is deferred. An SOP will be in place with validation documentation before the IVF chamber is used.	The PR's response is noted. No further action is required.
7. **Multiple births** The centre's multiple births minimisation strategy states that "HFEA guidance requires all IVF clinics to decrease the numbers of multiple births as a result of assisted conception treatment cycles to 10% over the next few years". The centre has established a QI for multiple pregnancy rates that requires no more than 20% of pregnancies be multiples. This is unlikely to meet the 10% multiple live birth rate target.	The PR should review and revise the centre's multiple births minimisation strategy to ensure it reflects the 10% multiple live birth rate target, active from 1 October 2012. The PR should review and revise the multiple pregnancy rate QI to ensure it will be effective in monitoring the centre's compliance with the 10% multiple live birth rate target. Evidence of completion to be forwarded to the centre's inspector by 21 August 2013.	The multiple pregnancy rate QI corrected. Copy of revised QI attached.	The PR has revised the established QI for multiple pregnancy rates to require that no more than 10% of pregnancies be multiples. The PR is asked to confirm that the multiple births minimisation strategy has also been suitably revised.

General Direction 0003, SLC T123 and SLC T35.			
8. The centre has not documented QIs for embryo biopsy. SLC T35.	The PR should ensure that embryo biopsy QIs are documented. A copy of the revised QIs should be submitted to the centre's inspector by 21 August 2013.	Embryo biopsy QIs are now documented. Copy of revised QIs attached.	The PR has submitted documented QIs for embryo biopsy. No further action is required.

Reponse from the Person Responsible to this inspection report

HFEA Licence Committee Meeting

11 July 2013

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

Minutes – Item 3

Centre 0329 (Wales Fertility Institute) – Initial Inspection Report

Members of the Committee:	Committee Secretary:
Sally Cheshire (lay) Chair Bishop Lee Rayfield (lay) Debbie Barber (professional)	Lauren Crawford Legal Adviser: Stephen Hocking, DAC Beachcroft

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

The following papers were considered by the Committee

- Initial inspection report
- Application form
- CV of the proposed PR
- Two references for the proposed PR
- CV of proposed LH
- Confirmation letter from the proposed LH
- Committee minutes :8 February 2013 Interim Inspection report of Centre 0273

The Committee also had before it

- HFEA Protocol for the Conduct of Licence Committee Meetings and Hearings
- 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); and
- 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 Directions 0000 – 0012
- Guide to Licensing
- Compliance and Enforcement Policy
- Policy on Publication of Authority and Committee Papers

Background

1. The Committee noted that an initial enquiry was received by the HFEA from the proposed PR of Wales Fertility Institute in February 2013, regarding licensing requirements for a treatment and storage (with embryo testing) licence.

2. The Committee noted that the Welsh Government has reviewed NHS-funded IVF services in Wales. This has resulted in all services being provided by NHS providers, principally in Cardiff (IVF Wales, centre 0049) and from Port Talbot (the subject of this licence application). As from 1 April 2013 management responsibility for IVF Wales (that is the accountability arrangements within the Welsh Government Health and Social Care system) was undertaken from Abertawe Bro Morgannwgg University Health Board (ABMU). Through the proposed new centre and IVF Wales, ABMU will manage all IVF services in South Wales.

3. The Committee noted that Wales Fertility Institute is located at:

   Abertawe Bro Morgannwg University Health Board
   Neath Port Talbot Hospital
   Baglan Way
   Port Talbot
   SA12 7BX

4. The Committee noted that at the time of the inspection, the Inspectorate reported that there were a number of areas of practice that required improvement, including five areas of major non-compliance and three ‘other’ areas of non-compliance or poor practice.

5. The Committee noted that since the inspection the Person Responsible (PR) has provided evidence to the Inspectorate that the all ‘major’ areas of non-compliance and two of the ‘other’ areas of non-compliance have been completed, with the exception of one additional follow up report which is to be received by the inspectorate by the 5 September 2013.

6. The Committee noted the Inspectorate’s recommendation to grant the centre’s licence for a two year period without additional conditions and to also appoint the proposed PR and Licence Holder (LH).

Discussion

7. The Committee referred to its decision tree. It was satisfied that the appropriate application and fee had been submitted, and noted that the executive had received the supporting information required by General Direction 0008.

8. The Committee noted that the PR plans to work full time at the new centre as soon as it is licensed and to relinquish the role of PR at centre 0273 at some point in the next year. The PR is confident that he can manage the role of PR at both centres in the interim.

9. The Committee noted that the proposed PR holds academic qualifications in the field of medicine and is registered with the General Medical Council (GMC). The proposed PR also has more than two years' 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). He has successfully completed the HFEA PR Entry Programme .

10. The Committee noted the PR is suitable and will discharge his duty under section 17 of the HF&E Act 1990 (as amended). The proposed PR is currently PR at Swansea Reproduction Unit (HFEA licensed centre 0273). The proposed PR is considered suitable and to have discharged his duty in relation to his PR role at centre 0273. Centre 0273 was last inspected in December 2012 and the one major and two 'other' non-compliances noted have since been resolved. Therefore, in agreement with the Head of Inspection, it was considered disproportionate to seek references to attest to the suitability of the character of the applicant to be PR at centre 0329.

11. The Committee was satisfied regarding the suitability of the proposed LH, Mr Pushpinder Mangat.

12. The Committee was satisfied that the licence application concerns treatment, storage or non-medical fertility services which relate to gametes or embryos intended for human application.

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

14. The Committee noted that the application is for a full licence with all activities including embryo testing. The Committee note the clinic has suitably qualified staff and premises to undertake PGD. Furthermore, the inspector is satisfied that the centre is able to perform PGD and the 3rd party labs will get CPA accreditation.

15. The Committee noted that the application includes the use of embryos for training and noted the information provided in regards to the use of embryos for training purposes. The Committee referred to their decision tree for the use for embryos in training and were not entirely satisfied that the information currently provided was appropriate for this activity to be

licenced. The Committee could not be sure that the proposed activity was "necessary" as the Act requires. In particular, the Committee would have wished to see some evidence dealing with how many persons might be trained at this centre in a given period, and a protocol explaining how their training would be conducted so as to reduce the use of human embryos (as opposed to animal embryos, simulations, and other techniques) to the minimum reasonably necessary for proper training. In the absence of such evidence the Committee did not feel able to make a decision on this activity.

16. The Committee were minded to grant the licence but not to include the activity 'Using embryos for the purpose of training persons in embryo biopsy, embryo storage or other embryological techniques' pending further information.

17. The Committee noted and considered that the current licencing framework does not allow for activities to be removed from licences and that in order temporarily to restrict the activities on this licence that a condition would need to be added to it.

18. The Committee 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.

19. The Committee noted the Inspectorate's recommendation for a two year licence, without additional conditions, subject to the proposed PR providing evidence of compliance with the one remaining non-compliance detailed in the report.

Decision

20. The Panel agreed to appoint Mr Adnan Bunkheila as the Person Responsible for Wales Fertility Institute (Centre 0329) with immediate effect, in accordance with section 18A of the HFE Act 1990 (as amended).

21. The Panel agreed to appoint Mr Pushpinder Mangat as the Licence Holder for Wales Fertility Institute (Centre 0329) with immediate effect.

22. The Committee agreed to grant the centre's licence for a period of two years with the additional condition that the '**Use of embryos for the purpose of training persons in embryo biopsy, embryo storage or other embryological techniques' is not to be undertaken by this centre until it provides further information on the training techniques and methods to be used'**. (This would be acceptable in the form of an SOP or QMS document.) The Committee stresses that it has merely deferred a decision on this activity, its decision is not that the activity is not

necessary. Further the Committee stresses that there is no censure or criticism of the Centre implied by the imposition of this condition.

Signed: Date: 30/07/2013

Sally Cheshire (Chair)