Inspection Report

Date of Inspection: 6 & 7 March 2012
Purpose of inspection: Renewal of Treatment and Storage Licence
Length of inspection: 15 hours
Inspectors: Bhavna Mehta; Jason Kasraie; Gill Walsh; Susan Jolliffe (observing) and Siobhain Kelly

Inspection details:
The report covers the pre-inspection analysis, the visit and information received from the centre between 5 May 2009 and 30 April 2012.

Date of Executive Licensing Panel: 18 May 2012 & 7 June 2012

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

Centre details

Centre name	Centre for Reproduction & Gynaecology Wales (CRGW)
Centre number	0316
Licence number	L/0316/1/c
Centre address	Ely Meadows, Rhodfa Marics , Llantrisant, CF72 8XL,
Person Responsible	Dr Umesh Acharya
Licence Holder	Dr Amanda O'Leary
Date licence issued	09/07/10
Licence expiry date	08/07/12
Additional conditions applied to this licence	None

Contents

Report Executive Licensing Panel

Brief description of the centre and its licensing history:

Centre for Reproduction & Gynaecology Wales' (CRGW) was granted its first licence in July 2010. Since then, the centre's licence has been varied to change the name. It is situated in a science park to the north west of Cardiff city.. CRGW is approximately 100 metres from an acute hospital and has access to the hospital's emergency and inpatient services.

CRMW is located on two floors.

The centre is registered with the Healthcare Inspectorate of Wales' (HIW).

Activities of the Centre:

Type of treatment	Number of treatment cycles 01 Feb 2011 - 31 Jan 2012
In Vitro Fertilisation (IVF)	115
ICSI	196
GIFT	0
FET	53
DI	16
Partner insemination (2011)	71
Egg share provider (sharer)	8
Egg share recipient	10

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

Outcomes*

For IVF/ICSI, HFEA held register data for the period 01 Feb 2011 - 31 Jan 2012 shows that the Centre's success rates are in line with national averages.

For the year 2011 the centre reported 71 cycles of partner insemination with 17 pregnancies. This equates to a 24% pregnancy rate 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 / have not 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 Person Responsible (PR) is suitable and he has discharged his duty under section 17 of the HF&E Act 1990 (as amended)
- the premises are suitable
- the practices are suitable
- the centre has submitted appropriately completed documentation in accordance with General Direction 0008, in application for renewal of their licence
- the centre has submitted an application fee to the HFEA in accordance with requirements

The Executive Licensing Panel is asked to note that at the time of the inspection there were a number of areas of practice that required improvement, including four major areas of non-compliance and four other areas of non-compliance or areas of poor practice.

Since the inspection visit the PR has confirmed and/or provided evidence that the following recommendations have been fully implemented

Major areas of non compliance:

- Donor screening (SLC 52 a,b): The PR has confirmed that he will ensure that all staff follow the SOP for donor screening and meet the requirements the standard licence conditions.

Other areas of practice that require improvement:

- Suitable practices (SLC T2): The PR has confirmed that the centre retains the sterilization tracking tag within the patients' medical records to ensure traceability.

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

Major areas of non compliance:

- The centre should establish quality indicators (QIs for: provision of information, consent, counselling, Welfare of the child (WoC) assessments, submission of data to the HFEA register (SLC T35)
- The PR should ensure that information about storage of embryos (including cooling off periods) is given before patients give consent (SLC T58 (e)).
- If the centre's audit of submissions to the HFEA Register, find that the one critical error identified at inspection is a systematic failure, then the centre should liaise with the HFEA and implement corrective actions by 6 September 2012.

Other areas of practice that require improvement:

- The centre should have documented standard operating procedures (SOPs) for: provision of information, WoC assessments, confidentiality and privacy, submission of data to the HFEA (SLC T33(b)) and revise the Egg Share SOP to ensure that the terms of Directions 0001 are met.
- The centre should audit its practice for: provision of information, consent, counselling, WoC assessments, submission of data to the HFEA (SLC T36)

Recommendation to the Executive Licensing Panel

The inspection team considers that, overall there is sufficient information available to recommend the renewal of this centre's licence for a period of 4 years without additional conditions. In making this recommendation it is noted that the PR has responded to *all or most* recommendations made in this inspection report *and further improvement is required in only a few areas of practice.*

Details of inspection findings

1. Protection of patients and children born following treatment

Focus

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

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

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

What the centre does well.

The centre double checks the identification of gametes and embryos and the patient or donor to whom they relate at all critical points of the clinical and laboratory process - Standard licence condition (SLC T71). The electronic witnessing system (Matcher) is being trialled by the staff at the centre prior to its implementation in order to ensure that they were all comfortable with it and appropriately trained; and have risk assessed and validated the new system before use.

The centre has documented standard operating procedures (SOPs) describing the witnessing procedure for all critical points specified in CoP Guidance Note (GN) 18.4. Witnessing steps observed during the inspection were performed in accordance with CoP Guidance.

Observations of witnessing steps for patients undergoing treatment during the course of the inspection and an audit of seven sets of patient notes were found to include records of all required witnessing steps in GN 18.4, except the step to witness the disposal of

unfertilised oocytes (GN18.4(e)). Staff explained that the centre staff have risk assessed this and are satisfied that any risks are reduced. In addition only one treatment occurs at a time.

Evidence of comprehensive training and competence assessment for staff performing witnessing steps was seen on inspection (SLC T15 (a)).

The centre has established quality indicators (QIs) for witnessing and audits of compliance with witnessing requirements are performed annually. The report of the most recent audit, performed in February 2012, was reviewed on inspection and no corrective actions were required as no non-conformities were identified. (SLC T35 and T36).

What the centre could do better.

In one patient record audited at inspection, there was no evidence that the patient had been actively identified (SLC T71). The audit of witnessing practice, conducted in February 2012 did not identify this non-conformity, although the SOP states that a copy of the patient's photographic identity has to be kept in the patient's file. The Consultant Embryologist explained that this particular patient file may not have been included in the sample of ten patient records that they audited; and that the centre has an electronic database where patient records are held electronically. The Consultant Embryologist was able to demonstrate that in this case, on the electronic database that the patient file contained the patient's identity. Following the inspection, the Consultant Embryologist explained that when the patient's cycle is completed, all the manual notes are added to the electronic database and all the witnessing checks are audited again (SLC T71 & GN 18.17).

Patient selection criteria and laboratory tests

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

What the centre does well.

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

Centre staff confirmed that laboratories undertaking diagnosis and investigation of patients are accredited by Clinical Pathology Accreditation (UK) Limited (CPA). Reports of test results observed in patient notes reviewed at inspection were all from CPA accredited laboratories (SLC T21).

The laboratory Manager confirmed that he is working towards accreditation by CPA (UK) Ltd for the centre's laboratory (SLC T20). The centre provided evidence that the centre's laboratory is of a standard equivalent to that of CPA (UK) Ltd in that the centre has in place a quality management system, processes to assess the competence of individuals to perform and interpret tests; the appropriateness of tests; the reproducibility and accuracy

of tests and the capability of the testing laboratory to provide appropriate and accurate interpretation of the test result (the centre participates in NEQAS).

Counselling
From the evidence provided on inspection, the centre strongly advocates and offers counselling to all patients and partners prior to treatment (SLC T58). Counselling is provided in a comfortable and confidential environment by a fully qualified, BICA accredited and experienced counsellor. The number of sessions undertaken had been calculated by the PR.

Patient records reviewed on inspection showed that in all cases where gametes were donated, shared or received and where legal parenthood provision applied, counselling had been offered. SLC T60 and T61

What the centre could do better.

Counselling
The centre has not established QIs for counselling service (SLC T35)

The centre has not audited its counselling practice against compliance with the approved protocols, the regulatory requirements and quality indicators (SLC T36)

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

What the centre does well.

In interviews, staff stated that the centre only uses donated gametes from identifiable donors in treatment. The centre provides treatment with and recruits egg donors, egg sharers and sperm donors.

Donor recruitment, assessment and screening
Verbal and documentary evidence was provided that donors are selected on the basis of their age, health and medical history (SLC T52a) and are screened for all conditions required by SLC T52 with one exception, stated below. The screening tests are carried out in a CPA accredited laboratory (SLC T53a). Procedures are in place to identify when a donor may need additional screening and were described at inspection (SLC T52 (g) & (h)). Donor sperm is quarantined for a minimum of 180 days and then the donor is re-screened (SLC T53c).

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

There is a SOP for the process to be followed when selecting and recruiting sperm donors

(SLC T33b).

The centre has established QIs for selecting and recruiting sperm donors (SLC T36) and audits compliance with requirements annually. The report of the last audit, performed in December 2011, was reviewed on inspection and identifies that corrective actions have been taken.

When selecting and recruiting sperm and egg donors there is a checklist to ensure all screening and consent forms are completed.

Payments for Donors

The reimbursements made to donors are restricted to expenses incurred in the UK. The centre offers weekend appointments so as to avoid compensation for loss of earnings. The centre reimburses the actual expenses incurred where the donor provides receipts. The centre verifies car mileage claims by checking the distance to the centre using a motoring organisation's website. All other claims are verified in accordance with the centre's protocol. This protocol was reviewed at inspection and is compliant with the requirements of Direction 0001.

What the centre could do better.

One known egg donor and 'matched' recipient set of records reviewed on inspection showed that donor screening for Syphilis or HTLV 1 as not conducted and the rationale as to why these tests were considered unnecessary was not documented. There was no evidence of the donor's medical history having been documented on which an assessment of donor suitability was made. (SLC 52 a,b). Staff were able to recall the particular circumstances of this patient and her donor and explained the rational for their decision. This was a deviation from the centre's protocol was based on their clinical judgement. Staff agreed to add this rationale to both sets of matched records.

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

The centre has a quality management system (QMS) and quality manual in place which encompasses training and reference materials (SLCs T32 and T33). The centre provided an index list of all QMS documents prior to inspection and individual documents were viewed as part of this inspection process.

Traceability

The centre's traceability SOP was reviewed and describes the process by which traceability of consumables and reagents which come into contact with gametes is ensured (SLC T33b) with one exception noted below.

The centre's logs of all reagents and materials used was reviewed on inspection and demonstrated that all relevant traceability data is recorded. A spot check of consumables in use in the laboratory against those recorded as being in use in the laboratory logs demonstrated that data is recorded accurately (SLC T102).

The centre has established QIs for traceability (SLC T36) and the audits of compliance with requirements are performed annually. The report of the last audit, performed in February 2012, was reviewed on inspection and identifies that the one corrective actions identified has been implemented.

Observations of practice in the laboratory provided evidence that the staff follow documented procedures and record traceability information as required by requirements (SLCs T12; T15 (a) and T102).

Validation
Evidence was provided on inspection that all critical processing procedures and equipment, new since the last inspection, used in these processes have been validated on the basis of published studies. The validation documentation was reviewed at inspection that demonstrated compliance with requirements (Act Schedule 3A (11) 2006/86/EC and SLC T24 and T72).

Equipment and materials
The laboratory staff have procedures to follow for the operation of all critical equipment, including information to direct actions in the event of failure or malfunction of the specified equipment (SLC T27). Instruction manuals for key equipment were also noted to be readily available to staff in the work area.

The scientific inspector observed that key equipment critical to the processing or storage parameters of gametes and embryos are subject to appropriate monitoring (scheduled preventative maintenance, regular calibration and parameter monitoring) and alarms which are maintained and tested regularly (SLC T24). Staff also provided a monthly log recording the regular cleaning and decontamination of equipment in the laboratory and clinical areas (SLC T26).

Staff were able to confirm that all disposable sterile equipment is CE marked (SLC T30).

Premises
A tour of the centre confirmed that all licensable activities are carried out on the licensed premises which are within the same building (Act S.12(1) and SLC T1). A copy of the centre's current licence was seen to be displayed in the main patient waiting area (SLC T5). Documented evidence of cleaning logs was available to review on inspection (SLC T26).

The centre monitors the air quality daily and the monitoring log was reviewed at inspection. Documented evidence was provide on the day of inspection that the processing of gametes and embryos takes place in an environment of at least grade C air quality in the

critical work area with a background environment air quality of grade D.

Adverse incidents
The centre is compliant with the HFEA requirements for incident reporting. A review of the centre's incident log confirmed that incidents reportable to the HFEA recorded at the centre correlate with those reported to the HFEA (SLC T118).
Third party agreements
The centre staff were able to demonstrate that there are third party agreements in place for all goods and services that influence the quality and safety of gametes and embryos and were available for review on the day of inspection (SLC T111). A complete list of all third parties is maintained by the centre and was seen to have been recently reviewed (SLC T115).

What the centre could do better.

Quality management system
The centre has not established QIs for: provision of information, consent, counselling, welfare of the child (WoC) assessments, submission of data to the HFEA register (SLC T35)

The centre has not audited its practice for: provision of information, consent, counselling, WoC assessments, submission of data to the HFEA (SLC T36)

The centre has not documented SOPs for: provision of information, WoC assessments, confidentiality and privacy, submission of data to the HFEA (SLC T33(b))

Traceability
It was noted when observing clinical procedures on inspection that the centre uses a small number of reusable surgical instruments. These instruments are decontaminated by the sterile services department of the neighbouring hospital using validated commercial standards. (SLC T29) However, it was noted that the 'peel and stick' decontamination and sterilization cycle tracking tag was not retained with the patient's primary medical record to ensure traceability.

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 target at a statistically significant level, unlikely to be due to random variation.

What the centre does well

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

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

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

What the centre could better

Nothing identified at this inspection.

Staff engaged in licensed activity

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

What the centre does well.

Person Responsible
The PR has academic qualifications in the field of medicine as required by the HF&E Act 1990 (as amended) section 16(2)(c)(i) and (ii) and has more than two years of practical experience which is directly relevant to the activities to be authorised by the licence. The PR has successfully completed the HFEA PR Entry Programme (PREP number T/1166/8). The PR is the nominated medical practitioner who oversees medical activities at the centre (SLC T16). He is registered with the General Medical Council (GMC) and is on the specialist register

Staff
The centre's second consultant, who is also the centre's Licence Holder, is registered with the GMC and on the specialist register for obstetrics and gynaecology.

The PR was able to confirm that staff working under the auspices of the licence are qualified and suitable persons to participate in the activities authorised by the licence (HF&E Act Schedule 17 (1) (a) and that all relevant staff have professional body registration and that all staff members participate in induction and on-going mandatory training. The centre has policies to support the staff professional development and performance appraisals (SLCs T12 and T14).

The PR stated that workforce requirements had been assessed within the last year and will continue to be monitored. At the time of inspection, it was reported that in this financial year, one member of nursing staff had left but confirmed that a new nurse has been recruited. The PR confirmed that the staff complement is sufficient in all disciplines (SLC T12).

From the documents reviewed at inspection, the staff were able to demonstrate evidence

of the assessment of the competence to perform their designated tasks (SLC T15 (a)). Staff competence was demonstrated during procedures observed on inspection including that for:

- Witnessing, the positive identification of gametes and embryos and the patients and partners to whom they relate
- information giving – verbal and written prior to, during and following the procedures observed
- positive identification of patients and partners verified against photo ID when checking consent prior to procedure
- maintenance of confidentiality, privacy and dignity during procedures
- record keeping and documentation
- traceability procedures

What the centre could do better.

Nothing identified at this inspection.

Welfare of the Child (Guidance Note 8)

What the centre does well.

From discussions with staff and review of information provided by centre staff, the inspectors conclude that before any woman is provided with treatment services proper account is 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 (SLC T56). The clinical staff were able to appropriately describe the process for conducting a welfare of the child (WoC) assessment and their actions in the event that matters of concern arise, giving examples of how this has been managed with specific case instances.

Five sets of patient records were audited on inspection. In each instance the file contained WoC questionnaires completed by the patient and partner and evidence of their review by a member of staff prior to the commencement of treatment. None of the completed questionnaires record that further information was sought and none of the questionnaire responses gave rise to concern.

Patients interviewed at inspection described their experience of undergoing the WoC assessment and reported having been given sufficient information and explanation as to why the assessment is required for all patients / partners having assisted conception treatments.

What the centre could do better.
The centre has not established QIs for WoC assessments (SLC T35)

The centre has not audited its practice for WoC assessments (SLC T36)

The centre has not documented SOPs for: WoC assessments (SLC T33(b))

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)

What the centre does well.

Treating patients fairly
Members of staff reported that there are policies in place on treating patients fairly, which ensure all licensed activities are conducted in a non-discriminatory manner (SLC T49) and that careful consideration is given as to how the centre may meet the needs of individual patients and their circumstances.

Confidentiality and privacy
A tour of the centre confirmed that all patient confidential information is stored securely with access restricted to authorised personnel only. Areas where conversations personal to individual patients and partners may occur were seen to be private and opportunities to be overheard reduced to a minimum.

All staff are asked to read and sign a confidentiality agreement on the maintenance of confidentiality (SLC T43). Maintaining confidentiality also forms part of the corporate mandatory induction and training (SLC T15 (a)). Documented measures to maintain data security safeguard against unauthorised data modifications, resolve data discrepancies and to respond to applications to access confidential records and correctly identify applicants (SLC T44).

Complaints
The centre's has a complaints policy. Information on how service users may make a complaint is displayed in patient areas. The centre's complaints log was reviewed at inspection and showed that there are not outstanding complaints.

Provision of a costed treatment plan

Detailed information regarding the cost of treatment is available to download from the centre's website. Self-funding patients and their partners are provided with clear written information regarding the anticipated costs of their treatment once the treatment pathway has been decided. This written information is then discussed during consultation, at which time costs and other implications of treatment or queries may be clarified. Discussion with the PR and the Licence Holder demonstrated compliance with the guidance.

Egg sharing arrangements
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.

What the centre could do better.

Nothing identified at 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) – *only applicable to centres licensed to carry out preimplantation genetic diagnosis and screening*
- Information about legal parenthood (Guidance Note 6)

What the centre does well.

All prospective patients are invited to an information evening to discuss any aspect of treatment and enable them to have a visit to the centre. This enables them to make an informed choice before committing to a consultation.

The centre's website and written information was also reviewed and found to be compliant with Chair's letter CH (11)02 and the CoP.

Information provided prior to consent
From information provided, discussions with staff on the day of inspection and from patient feedback received by the HFEA, the inspectors conclude that proper information is provided to patients and their partners prior to giving consent to treatment as required by Schedule 3 (1) (b) of the HF& E Act 1990 (as amended). Staff who are involved in the information giving process confirmed that prospective patients are sent all relevant consents and related written information regarding their proposed treatment. The proposed treatment and implications of that treatment are then discussed at separate one to one consultations with the clinician directing their treatment.

Information about storage of embryos (cooling off period)
From discussions with staff and from written information seen on inspection, the centre was able to demonstrate that patients and their partners are provided with information regarding the individual gamete provider's right to vary or withdraw their consent to continued storage of the embryos created with their gametes.

Information about ICSI
As part of the treatment information provided in writing and verbally during consultation, patients and their partners identified as likely to benefit from having ICSI are given specific information regarding this procedure and any associated risks. This was confirmed by discussion with staff, a review of written patient information and from information check lists seen in patient notes on inspection. (HF & E Act, Schedule 3,3(1) (b)).

Information about legal parenthood
Staff interviewed during the inspection demonstrated a good understanding of the requirements of legal parenthood legislation and stated that when required patients are provided with the relevant information. Staff were also able to appropriately describe the process to be followed in the event that one or other partner withdrew or varied their consent to legal parenthood. Written information for patients and their partners is available.

The centre has established QIs to the effect that the patient satisfaction survey responses are monitored for satisfaction with the amount and clarity of information provided prior to and throughout the treatment process (SLC T35). The provision of information has been audited as part of the patient satisfaction survey and the patient information audit most recently conducted in November 2011 which was seen on inspection (Schedule 3A (10) 2006/86/EC, Appendix 1 F and SLC T36). The audit identified the need for a documented procedure to follow when giving patient information and a draft of this was discussed at inspection.

A checklist for providing information was seen in a sample of five patient files reviewed at inspection which provided evidence of meeting the above requirements.

What the centre could do better.

Information about storage of embryos (including cooling off periods)
The PR and staff stated that patients would be provided with information about the cooling off provisions only if the patient contacts the centre to withdraw their consent in the event of a dispute between the patient and partner. This information is not given before patients give consent (SLC T58).

Staff described that, in the event of a dispute between gamete providers regarding the continued storage of their embryos, a 12 month ‘cooling off’ period will be instigated. In the event that a mutual decision cannot be reached, the embryo(s) will be allowed to perish one year from the date on which the centre was notified in writing that consent had been withdrawn by one of the gamete providers unless, the end of the statutory storage period is reached before this date. (Schedule 3 4A and Guidance (interpretation of mandatory requirements) 5H). However, patients interviewed at inspection were not aware of these provisions.

The centre has not established QIs for provision of information (SLC T35)

The centre has not audited its practice for provision of information (SLC T36)

The centre has not documented SOPs for provision of information (SLC T33(b))

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.

From discussions with staff, a review of documentation and practice observed at inspection, evidence was provided that written consent is obtained before gametes and embryos are used in treatment (SLC T57) and where legal parenthood provisions apply.

A review of a sample of medical records at inspection demonstrated that appropriate written consent, including consent to disclosure of information is taken and a copy kept in the records.

Patients and their partners interviewed on inspection said that they felt that when asked to give consent the implications of that consent and related required documentation was fully and clearly explained to them. Patients interviewed were also able to describe how the heightened confidentiality requirements under the HFE Act requires centre staff to seek consent to the disclosure of their personal and assisted conception treatment information before consulting other health care professionals outside of the centre team if required, such and the couple's general practitioner.

What the centre could do better.

The centre has not established QIs for consent (SLC T35)

The centre has not audited its practice for consent (SLC T36)

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, 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 precincts to which that licence applies. Embryos are only created, stored and used in treatment where permitted by law.

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

What the centre could do better.

Nothing identified at this inspection

Storage of gametes and embryos

- Storage of gametes and embryos (Guidance Note 17) – *only applicable for centres licensed to store gametes and / or embryos*

What the centre does well.
A review of the centre's storage records and discussion with staff confirmed that all material currently in storage at the centre has been appropriately screened (HFE Act Schedule 3A, SLC50 (b)). Staff were aware of the changes to the statutory storage periods for gametes and embryos and understood the provision for a 12 month cooling off

period if gamete providers are in dispute about what to do with stored embryos.

The audit of stored samples conducted in August/September 2011 reviewed at inspection, provided evidence that the centre performs audits annually, and all samples currently in store are stored with valid consent. No corrective actions were required.

Documented evidence was seen for one laboratory staff member of the assessment of competence in storing cryopreserved material (SLC T15a).

What the centre could do better.

Nothing identified at this inspection.

Distribution and / or receipt of gametes and embryos

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

What the centre does well.

The centre has processes and procedures in place to ensure gametes and embryos are only sent to other licensed centres in conditions that protect the safety and quality of the gametes and embryos.

Distribution of gametes and embryo
The centre has a SOP describing the procedure for the distribution of gametes and embryos, including the required labelling of the shipping container (SLC T33 (b) and T107). The centre does not, at present, distribute gametes and embryos.

Import of gametes and embryos
Between March 2011 and January 2012 the centre has imported 42 vials of donor sperm samples and 40 donor egg samples. The staff confirmed that the samples were received with the appropriate documentation to satisfy the PR that the requirements of HFEA Direction 0006 had been met. A review of the supporting documentation confirmed that the requirements of General Direction 0006 had been complied with.

What the centre could do better.

Nothing identified at 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/partner and donor records seen at the time of inspection were seen to be clear, legible and well organised. Each record reviewed was seen to include: patient/donor first name, surname, date of birth, age and sex. Details of how the patient/donor had been identified (passport/driving licence): the treatment provided; a medical history; welfare of the child assessment; relevant documented consents and clinical and laboratory data and the results of tests carried out.

What the centre could do better.

Nothing identified at this inspection.

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

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

What the centre does well.

Obligations and reporting requirements of centres
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.

Licensed Treatment Reporting
To determine whether all licensed treatments are reported to the Authority as required by Direction 0005, a sample of licensed treatments undertaken by the centre between 01/02/2011 and 31/01/2012 was reviewed. The sample was drawn from the centres records and was reviewed against an extract of the Authority's statutory register.

The sample comprised 119 IVF and DI treatments and was drawn from system generated

print-outs. Nine (9%) of the IVF treatments and 2(11%) of DI treatments in the audit sample were found to be unreported at the time of inspection.

On average 42% of the treatment cycles in the audit sample were reported to the HFEA within 5 working days of treatment as required by Direction 0005. The figure for IVF treatments was 48%.

Data Quality

To ascertain the quality of the data submitted by the Centre for inclusion on the statutory register, the audit team reviewed 56 assorted data forms submitted to the Authority between 01/02/2011 and 31/01/2012 against source documentation held on patient and donor files.

The centre has not been collecting baby NHS numbers to date. It was suggested that the outcome form that the centre uses should be amended to include a field for this data to ensure that this information is routinely collected.

Other systemic errors, though minor, include missing middle names on registration and donor information forms.

No errors were found in a critical field that could affect the Authority's ability to fulfil statutory obligations to offspring (e.g. failure to indicate the use of donor gametes in an IVF treatment).

The audit team have provided a record of the audit work to the centre so that where appropriate corrections to submitted data can be made.

The centre has not established QIs for submission of data to the HFEA register (SLC T35)

The centre has not audited its practice for submission of data to the HFEA (SLC T36)

The centre has not documented SOPs for submission of data to the HFEA (SLC T33(b))

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

Discussions held with staff, a review of information submitted for the inspection and a tour of the premises indicated that information about patients is not disclosed unless under circumstances permitted by law (SLC T43)

What the centre could do better.

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

The consent to disclosure to researchers reported to the HFEA did not match the consent contained in the patient file on six registration forms (three patient and corresponding partner registrations). Whilst only one of the errors is critical (i.e. consent has been submitted to the Register when the patient/partner does not want the HFEA to release data to researchers),.

Confidentiality
The centre has not documented SOPs for the requirements for confidentiality and privacy, (SLC T33(b)).

5. Changes / improvements since the previous inspection on 5 May 2010

Area for improvement	Action required	Action taken as evidenced during this inspection
Premises. T20 In premises where the processing of gametes and embryos exposes them to the environment, the processing must take place in an environment of at least Grade C air quality, with a background environment of at least Grade D air quality as defined in the current European Guide to Good Manufacturing Practice (GMP_ Annex 1 and Directive 2003/94/EC). It must be demonstrated and documented that the chosen environment achieves the quality and safety required	The centre must show evidence to the inspection team, that the air quality in the laboratory, cryostore and procedures rooms has been re-tested and meets, at least, Grade C in gamete/embryo 'processing' area with Grade D background, before commencing licensed treatments.	Documents provided to the HFEA demonstrated compliance with Action required. See body of this report for update findings at this inspection.

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
Donor screening At inspection, one known egg donor medical records showed that the donor was not screened for Syphilis or HTLV 1, and there was no evidence that the donor's suitability had been assessed (SLC 52 a,b).	The PR should ensure that all staff follow the SOP for donor screening which is complaint with current requirements. In this case the PR must ensure that the donor and 'matching' recipient medical notes are updated to include the rationale for not screening and for not assessing the suitability of the donor. The PR should confirm that this action has been completed by the time he responds to this report.	This case has been discussed at our review meeting. Both patients did not want testing and we should have documented this. The notes of these patients have been updated.	The PR's comments are noted. No further action required.

QMS-QI The centre has not established QIs for: provision of information, consent, counselling, Welfare of the child (WoC) assessments, submission of data to the HFEA register (SLC T35)	The centre has not established QIs for: provision of information, consent, counselling, Welfare of the child (WoC) assessments, submission of data to the HFEA register (SLC T35) As not all activities and processes are listed on the centre's audit schedule, it is likely that the centre will not meet this requirement. It is recommended that the PR adds QIs for all outstanding activities and processes to the audit plan and confirm this to the lead inspector. By the time the PR responds to this report.	As seen during the inspection we are establishing Quality standard File which covers all aspects of HFEA inspection (we are using HFEA code of practice as our quality standard) and will ensure that the following will be amongst the next set of QS we undertake and hence fulfil this requirement. • provision of information, • consent, • counselling, • Welfare of the child (WoC) assessments, • submission of data to the HFEA register (SLC T35) Some of these have already been done e.g. Copy of welfare of child included with this submission	The lead inspector confirms that the centre's new system for monitoring quality was demonstrated at inspection. The addition of the outstanding licensed activities to the plan for monitoring quality should conform to the CoP requirements. The PR's comments confirming that some of the recommendations following inspection have been implemented are noted. Further action required.
Information about storage of embryos (including cooling off periods) The PR and staff stated that patients would be provided with information about the withdrawal of consent only if the patient contacts the centre	The PR should ensure that prior to giving consent, gamete providers must be provided with information about the right to withdraw or vary their consent. By the time the PR responds	This is mentioned in our Consent booklet (version 5 nov 2010) page 5 and also in IVF/ICSI information (version 2 – Jan 2010 page 8 paragraph 5). I hope this fulfils the requirements asked for.	The PRs comments are noted. The information in the booklets received with the PRs response has been reviewed; this does not mention the requirements for variation and withdrawal of consent. The PR

to withdraw their consent in the event of a dispute between the patient and partner. This information is not given before patients give consent (SLC T58 (e)).	to this report		is referred to the CoP, Guidance note 5: Variation and withdrawal of consent. Further action and confirmation required by 20 June 2012.
Disclosure of information, held on the HFEA Register, for use in research The consent for researchers does not match the consent form contained in the patient file on six registration forms (three patient and corresponding partner registrations). Whilst only one of the errors is critical (i.e. consent has been submitted to the Register when the patient/partner does not want the HFEA to release data to researchers), it is essential that extra care is taken to submit this information correctly going forwards (Direction 0005)	The PR should liaise with the HFEA Register/Audit team to ensure that action is taken to correct any errors identified. By 6 September 2012	The team has taken corrective action about this with Emma Jones who deals with all these forms checking the forms that they are correct. She will get in touch the HFEA Register/Audit team to check any outstanding ones. Emma has e-mailed Cathy Hogson without success so we will ask our inspector to provide us with a name of person to liaise with.	The PR's comments are noted. If the centre's audit of submissions to the HFEA Register, find that the one critical error identified at inspection is a systematic failure, then the centre should liaise with the HFEA and implement corrective actions by 6 September 2012. The lead inspector has emailed the PR as requested regarding the register team's contact details. Further action required by 6 September 2012.

Licensed Treatment Reporting On average 42% of the treatment cycles in the audit sample were reported to the HFEA within 5 working days of treatment as required by Direction 0005. The figure for IVF treatments was 48%.	The PR should ensure all licenced treatments are notified to the Authority in accordance with the requirements of Direction 0005 To be monitored by the lead inspector (see also action required for QI and audits).		

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
Suitable practices (SLC T2) It was noted when observing clinical procedures on inspection that the centre uses a small number of reusable surgical instruments. These instruments are decontaminated by the sterile services department of the neighbouring hospital using validated commercial standards. (SLC T29) However, it was noted that the 'peel and stick'	The PR should consider retaining the sterilization tracking tag within the patients' medical records to ensure traceability (if not sterile then this could be a risk to the patient). By 6 September 2012	Staff already doing this since the inspection.	The PR's comments are noted. No further action required.

decontamination and sterilization cycle tracking tag was not retained with the patient's primary medical record to ensure traceability.			
QMS The centre has not documented SOPs for: provision of information, WoC assessments, confidentiality and privacy, submission of data to the HFEA (SLC T33(b)) QMS – SOP to be revised: Egg Share SOP be revised to ensure that the terms of Directions 0001	The PR must develop SOPs for all licensed activities. The PR should provide an action plan and a timeline to meet these requirements to be completed by 6 September 2012. By the time the PR responds to this report.	This is been actioned with our QS plan and for these 4 actions • provision of information, • WoC assessments, • confidentiality and privacy, • submission of data to the HFEA (SLC T33(b)) We submit an action plan which will meet the requirements by the stated date of 6/9/2012. See below action plan.	The PR's comments are noted. The PR should confirm by 6 September 2012 that SOPs for all licensed activities have been developed and are in use. Further action required.
QMS- audits The centre has not audited its practice for: provision of information, consent, counselling, WoC assessments, submission of data to the HFEA (SLC T36)	As not all activities and processes are listed on the centre's audit schedule, it is likely that the centre will not meet this requirement to audit every two years. It is recommended that the PR adds all outstanding activities and processes to the audit	Again these 4 areas: • provision of information, consent, • counselling, • WoC assessments, • submission of data to the HFEA (SLC T36) are a part of our QS file and will have audits undertaken regularly. We also envisage	The PR's comments are noted. However, to ensure that the PR will meet the requirement of SLC T36, the audits need to be conducted before the centre's licence in renewed. Further action required.

	plan and confirm this to the lead inspector. By the time the PR responds to this report.	having completed all this by 6/9/12	

Additional information from the Person Responsible

HFEA Executive Licence Panel Meeting

18 May 2012

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

Minutes – Item 1

Centre 0316 – (Centre for Reproduction & Gynaecology Wales (CRGW)) – Renewal Inspection Report

Members of the Panel:	Committee Secretary:
Mark Bennett, Director of Finance & Facilities (Chair) Danielle Hamm, Senior Policy Manager Rachel Hopkins, Head of Human Resources	Joanne McAlpine

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

The Panel also had before it:

- HFEA Protocol for the Conduct of Meetings of Executive Licensing Panel
- 8th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- Decision trees for granting and renewing licences and considering requests to vary a licence (including the PGD decision tree)
- Guidance for members of Authority and Committees on the handling of conflicts of interest approved by the Authority on 21 January 2009.
- Guidance on periods for which new or renewed licences should be granted
- Standing Orders and Instrument of Delegation
- Indicative Sanctions Guidance
- HFEA Direction 0008 (where relevant), and any other relevant Directions issued by the Authority
- Guide to Licensing
- Compliance and Enforcement Policy
- Policy on Publication of Authority and Committee Papers

Consideration of Application

1. The Panel noted that this is a medium-sized IVF centre that was first granted a licence in July 2010, since when the licence has been varied to change the centre's name.

2. The Panel noted that the centre carried out 71 reported treatment cycles of partner insemination with 17 pregnancies during 2011, which equates to a 24% pregnancy rate which is consistent with the national average. The centre's success rates for IVF/ICSI are also in line with national averages.

3. The Panel noted that during 2010/11 the centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 25%. This represents performance likely to meet the target.

4. The Panel noted the Inspectorate identified four major areas of non-compliance and four other areas of poor practice that require improvement.

5. The Panel noted that, since the inspection, the Person Responsible (PR) has provided evidence that one major and one other area of non-compliance has been implemented.

6. The Panel noted that the PR has given a commitment to implement the outstanding areas of non-compliance, within the recommended timescales highlighted within the report.

7. The Panel noted that the Inspectorate recommended the renewal of the centre's licence for a period of four years with no additional conditions.

Decision

8. 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 Direction 0008.

9. The Panel was satisfied that the qualifications and character of the PR are such as is required for the supervision of the licensed activities and that the PR will discharge the duties under section 17 of the Act.

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

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

12. The Panel noted that the inspection report did not comment on the use of embryos for training. Further, the minutes of the Licence Committee of 24 June 2010 awarding the initial licence were clear that the application 'did not concern... the use of embryos for training purposes' (Consideration paragraph 5). However, the Panel noted that the type of licence applied for includes the use of embryos for training, in principle. Also, the application form from the clinic indicates that there is, and will be, some use of embryos for training (Form: end of 5 of 18).

13. Therefore, the Panel was not clear from the evidence in the papers whether this activity is, or is to be, performed and whether the Inspectorate should report on it. The Panel recognised the form could have been incorrectly completed but considered the risk was too great of making an incomplete renewal decision in the absence of more information on training.

14. The Panel agreed to adjourn its decision pending clarification of whether the clinic uses embryos for training and whether it will do so in future. The Panel requested the Inspectorate to report accordingly.

15. The Panel requested this information as soon as possible as it appreciated the centre's current licence is due to expire on 8 July 2012.

Signed: Date: 28 May 2012
Mark Bennett (Chair)