Inspection Report

Date of Inspection: 25 and 26 April 2012
Purpose of inspection: Renewal of Treatment and Storage Licence
Length of inspection: 16 hours
Inspectors: Andrew Leonard; Paula Nolan; Sara Parlett Sheila Pike; Chris Hall; Roup Kaur.

Inspection details:
The report covers the pre-inspection analysis, the visit and information received from the centre between 14 April 2010 and 15 June 2012.

Date of Licence Committee: 30 August 2012

Purpose of the Inspection Report
The purpose of the inspection is to assess whether centres are complying with the Human Fertilisation and Embryology (HF&E) Act 1990 (as amended), the HF&E Act 2008 and the HFEA Standard Licence Conditions (SLCs) and 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 Licence Committee which will make the decision about the centre's licence renewal application.

Centre details

Centre name	IVF Wales
Centre number	0049
Licence number	L/0049/14/f
Centre address	University Hospital of Wales, Heath Park, Cardiff, CF14 4XW, UK
Person Responsible	Ms Arianna D'Angelo
Licence Holder	Dr Graham Shortland
Date licence issued	1 October 2010
Licence expiry date	30 September 2012
Additional conditions applied to this licence	Additional condition added on 16 December 2011 stating: 'For the remainder of the licence, and calculated over a three-month period, the Centre must limit the number of IVF or ICSI cycles provided to an average of twenty-four cycles per calendar month in total, and of frozen embryo transfers to an average of 8 per calendar month in total'.

Contents

Brief description of the centre and its licensing history:

IVF Wales has been licensed by the HFEA since 1992 and provides licensed fertility treatments to NHS and self-funded patients across South Wales. Opening hours at the centre are from 08:00 – 16:30 Monday to Friday; laboratory work is performed at the weekend as required. Licensed activities include the storage of eggs, sperm and embryos, in vitro fertilisation (IVF), intracytoplasmic sperm injection (ICSI), partner and donor intrauterine insemination (IUI), procurement and distribution of gametes and embryos, processing of gametes and embryos, treatment with donor gametes and embryos, and mechanical, chemical and laser assisted hatching. The centre also has a small egg donation programme.

The centre is part of the Cardiff and Vale University Health Board (CVUHB). The management of the centre was due to be transferred to Abertawe Bro Morgannwgg University Health Board (ABMU) on 1 April 2012 however the Person Responsible (PR) reported to the HFEA just prior to the inspection that this management change has been delayed until 1 September 2012.

The centre last underwent a renewal inspection on 14 & 15 April 2010 and it found one critical area of non-compliance, 22 major areas of non-compliance and 10 'other' areas of practice that required improvement. The Executive Licensing Panel (ELP) on 15 July 2010 awarded a treatment and storage licence for two years.

The centre historically performed approximately 400-500 treatments per year but this increased considerably in late 2010/early 2011 without matched resources being made available. This contributed to two grade B incidents which were reported to the HFEA in May/June 2011. The centre's licence was varied to approve a new PR by the ELP on 24 June 2011. Investigation of the incidents by an inspection team on 15 June 2011 led to a voluntary restriction of the centre's activity as well as other recommendations. A Licence Committee on 20 October 2011 endorsed the recommendations and placed an additional condition on the centre's licence formalising the activity restriction, which was revised on 16 December 2011 after representations by the PR to state: 'For the remainder of the licence, and calculated over a six-month period, the centre must limit the number of IVF or ICSI cycles provided to an average of twenty-four cycles per calendar month in total, and of frozen embryo transfers to an average of eight per calendar month in total.' This additional condition remains on the centre's licence.

The centre was inspected again in January 2012 to ensure that recommendations had been implemented. The inspection report noted the substantial amount of work performed by centre staff which enabled the PR to provide sufficient information that all the recommendations had been complied with or were in the process of being complied with; work on some corrective actions was on-going (e.g. liaising with patients regarding the use of inappropriately screened donor sperm; quality indicator monitoring and audit; validation; and accreditation of the andrology service). The report recommended the continuance of the centre's licence but without removing the additional condition. The Licence Committee on 26 April 2012 endorsed this recommendation. It also reserved the decision regarding the centre's next licence renewal application to the Licence Committee. Thus this inspection report will be present to the Licence Committee rather than the ELP.

The PR has been a consultant in Obstetrics and Gynaecology at IVF Wales since August 2007 and has occupied the PR role since June 2011. The PR works full-time at the centre and has completed the PR Entry Programme (T1190/8).

Activities of the Centre:

Type of treatment	Treatment cycles; 01/04/2011 – 31/3/2012*
Fresh IVF and ICSI	341
Gamete intrafallopian transfer (GIFT)	0
Frozen embryo transfer (FET)	110
Donor IUI (DI)	3
Partner IUI	89 (01/01/2011 – 31/12/2011)
Egg share provider	2
Egg share recipient	3
Egg donation (non-egg share)	8

Other licensable activities	✓ or Not applicable (N/A)
Storage of eggs	✓
Storage of sperm	✓
Storage of embryos	✓
Research	R0161 at centre 0319

*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.

Outcomes*

For fresh IVF and ICSI, FETs and DI, HFEA held register data for the period 1 January 2011 – 31 December 2011 show the centre's success rates are in line with national averages with the following exceptions:

- The clinical pregnancy rate for IVF in patients aged below 38 years is significantly below the national average.
- The clinical pregnancy rate for ICSI in patients aged below 38 years is significantly below the national average.

In 2011, the centre reported 89 cycles of partner insemination with nine pregnancies. This equates to a 10% pregnancy rate which is comparable to the national success rate for this treatment.

*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 the overall compliance of the centre, the inspection team considers that sufficient information drawn from documentation submitted by the centre prior to inspection and from observations and interviews conducted during the inspection visit was available to conclude that:

- the PR is suitably qualified for the role but, given the significant number of non-compliances found at this inspection, was not considered to have discharged her duty under Section 17 of the HF&E Act 1990 (as amended). The inspection team note that subsequent to the draft inspection report being provided to the centre, the PR has fulfilled her duty under Section 17 of the HF&E Act 1990 (as amended) and facilitated the implementation of corrective actions to ensure the centre's compliance.
- the premises are suitable.
- the practices were initially considered unsuitable, but corrective actions have been taken and they are now considered 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 Licence Committee is asked to note that at the time of the inspection there were a number of areas of practice that required improvement and led to recommendations for corrective actions being made, comprising six critical and eight major areas of non-compliance, and 24 'other' areas of non-compliance or poor practice.

The PR has subsequently provided evidence that the following recommendations have been fully implemented:

Recommendations to address critical areas of concern:

- **The PR should review the continued use of a potentially hazardous dewar and should ensure that the storage of sperm samples within it is safe (SLCs T23 and T24).**

Recommendations to address major areas of non compliance:

- The PR should ensure that all equipment is validated and that all non-conformities are addressed in a timely manner (SLC T24).
- The PR must ensure the low oxygen monitor and the dewar probes and alarm system, are periodically serviced to check their function and support their future reliability (SLCs T24 and T26).
- The PR must ensure that corrective actions are taken in a timely fashion in response to non-conformities which arise during equipment servicing. The issues identified with the dewar probes and air flow cabinet filter should be addressed (SLCs T24 and T26).
- The PR should review the monitoring of critical parameters and associated alarm systems to ensure they are appropriate and will guarantee that critical parameters are maintained within acceptable limits at all times (SLC T24).
- The PR must ensure that a validated air quality testing programme is reinstituted and that the centre's activities, where required, are undertaken in air of the required quality (SLC T20).

Recommendations to address other areas of practice that require improvement:

- The PR must ensure that all staff have time and opportunity to complete all modules required by their annual mandatory training programme (SLC T12 and T15a).
- The PR must ensure that all staff have time and opportunity to complete an annual appraisal (CoP Guidance 2.3).
- The PR must ensure the quality management system (QMS) is reviewed at least annually (CoP Guidance 23.13).
- The PR should ensure the documentation of all non-conformities, their investigation, the recommended corrective actions, the implementation of those actions and their subsequent impact (CoP Guidance 23.27).
- The PR should contact the third party commercial donor sperm banks and obtain assurance and evidence that compensation provided to sperm donors is compliant with General Direction 0001
- The PR should ensure that all witnessing is performed at the time of the process whenever possible. When it cannot be, the PR should risk assess practice and ensure it is as safe as possible (SLC T71).
- The PR should either ensure that plastic ware is appropriately labelled during egg collection, or should ensure the practice is risk assessed (SLC T71 and T101)
- The PR should ensure that the witnessing SOPs are reviewed and revised to be compliant with CoP requirements associated with witnessing checks. The validity of the reasons for using two witnessing SOPs should be reviewed and the SOPs should be amalgamated if necessary (CoP Guidance 31.6).
- The PR should review the transportation SOP against CoP requirements and revise it to ensure compliance with those requirements (SLC T33b and T109).
- The PR should ensure that the SOP for the use of embryos in training is revised to include the practices used to prevent any actual or perceived conflict of interest between the use of embryos in treatment and training (SLC T95).
- The PR should ensure that records of the cleaning, disinfection and sanitation of the premises and all critical equipment are documented (SLC T26).
- The PR must ensure that portable electrical appliance testing (PAT) is performed on the centre's equipment at an appropriate frequency (SLC T26).
- Several regulatory issues related to the protection of patient confidentiality were identified which led to the following recommendations
    - The PR should assess the confidentiality of the notes storage arrangements at the counsellor's home (SLC T43).
    - The PR should ensure that access to the centre's computers is appropriately controlled (SLCs T43 and T44).
    - The PR should ensure a secure and confidential telephone is provided for the counsellor (SLC T43).
    - The PR should ensure that actions are taken to protect the confidentiality of patient identifying information inside thank you cards displayed in the centre (SLC T43)
- The PR should ensure that all information displayed within the centre premises is up to date and should not potentially mislead patients (HF&E Act 1990 (as amended), Section 13 (6)).
- The PR should ensure the information provided to patients is reviewed against CoP requirements and is compliant with those requirements (e.g. CoP Guidance 7.7 a,b and 21.1a; SLC T58).

- The PR should ensure the information provided to oocyte donors and recipients is reviewed against CoP requirements. It should be updated so that the information is compliant with all requirements (HF&E Act 1990 (as amended), Section 13 (6)).
- The PR should ensure the information provided to egg share providers and recipients is reviewed against CoP requirements and is updated to be compliant with those requirements (e.g. CoP Guidance 20.11, 11.30 and 11.37).
- The PR should ensure the information about legal parenthood provided to couples using donated gametes, contains appropriate information about the mechanism by which they can withdraw their consent to be the legal second parent or their consent for their partner to be the legal second parent (SLC T61).
- The PR should review the mechanisms by which the consent to disclosure of identifying information to researchers is submitted through the EDI system to ensure that it is accurately submitted in the future (SLC T9e).
- The PR should take appropriate actions to meet the 28 day payment terms for HFEA invoices (SLC T9d).

The PR has provided evidence that corrective actions have been implemented in part and are on-going, regarding the following recommendations, and has given a commitment to fully implement them within the time frames stated in this inspection report:

Recommendations to address critical areas of concern:

- **The PR must ensure that gametes and embryos are stored only when valid consent for storage has been documented by the gamete providers (HF&E Act 1990 (as amended) Schedule 3, 8 (1) and 8 (2)).**
- **The PR must ensure that clinical activity is controlled so that the staff available can safely provide it. This includes that they are able to undertake all necessary corrective actions to regain and maintain regulatory compliance, which is essential if a safe service is to be provided (SLC T12).**
- **The PR should review the audit programme and procedures to ensure that all key activities are audited and audits of practice against the SOPs and regulatory requirements are conducted (SLC T36).**
- **The PR should review procedures for submission of information to the HFEA register to ensure that the centre's systems, processes and staff competence allow timely and accurate reporting of treatment data to the HFEA register. (SLC T9e; General Direction 0005).**
- **The centre should seek to obtain semen analyses from an appropriately accredited laboratory by progressing with the plan to obtain accreditation for the centre's semen analysis service (SLC T21).**

Recommendations to address major areas of non compliance:

- The PR should review the counselling provision and ensure that the counselling service is adequately resourced (SLC T12).
- The PR must ensure the completion of the process validation programme. The PR must also ensure that appropriate resources are available to implement the corrective actions required by the process validation report to address non-conformities (SLC T72).
- The PR should ensure that all critical consumables are validated to ensure their suitability (SLC T28).

Recommendations to address other areas of practice that require improvement:

- The PR should arrange the audit of all medical devices to ensure they are CE marked where possible (SLC T30).
- The PR should ensure that the SOP revision programme is completed (CoP Guidance 31.6), that patient information documents are all reviewed annually (CoP Guidance 31.6) and that an effective system of document control is established (SLC T34).
- The PR should ensure that appropriate SOPs for equipment operation are prepared and that they include the actions to take in the event of equipment failure (SLC T27).
- The PR should ensure that the plan, discussed on inspection, to review all third party agreements (TPAs) against CoP requirements, to revise them accordingly and to re-issue them, is progressed (T107, T114, T116 and T117).

Recommendation to Licence Committee

The list of recommendations detailed in this inspection report is extensive, reflecting significant non-compliance at this renewal inspection (6 critical; 8 major; 24 'other'). A similar situation was encountered at the last renewal inspection in April 2010, which resulted in the Executive Licensing Panel being concerned such that only a two year licence was provided. Some of these regulatory issues were reported to have been corrected but have recurred at the present inspection and therefore are now reported as 'critical' non-compliances. Two serious incidents also occurred in May/June 2011 which led to a targeted incident inspection on 15 June 2012, the report of which was considered by a Licence Committee on 20 October 2011. The present inspection found that some of the recommendations of the incident inspection report were still not fully implemented.

The HFEA team at the present inspection considered that the non-compliances identified are unlikely to contribute to an increased risk to patients, but that the inadequacies in the maintenance and validation of critical equipment and processes could pose a risk to the safety and quality of gametes and or embryos. The inspection team concluded that these failures constituted unsuitable practice. Also the scale of non-compliance with the Act, standard licence conditions and General Directions, led the team to conclude that the PR, having been responsible for the licence since June 2011, had not discharged her duties under Section 17 (1) (b,c,d,e) of the HF&E Act 1990 (as amended). These conclusions led the inspection team to recommend in the draft report that the centre's licence was not renewed unless significant improvements in the centre's compliance were made.

The PR has subsequently provided evidence of corrective actions which have fully implemented the report's recommendations to correct one area of critical non-compliance, five areas of major non-compliance and 20 'other' areas of non-compliance or poor practice. The PR has also provided evidence of continuing corrective actions which, when completed, will address five areas of critical non-compliance, three areas of major non-compliance and four 'other' areas of non-compliance or poor practice. The PR has committed to implement these outstanding recommendations within the timeframes stated in this report. The PR has not contested any of the non-compliances or failed to commence corrective actions in response to them.

The inspection team notes the improvement in the centre's compliance and has modified its assessment of the centre's practices and the PR's performance, which are both now considered to be suitable.

Regarding the renewal of the centre's licence and the period for which the licence should be renewed, the inspection team is mindful of paragraph 4.3 of the Indicative Applications Guide*. It cannot recommend the renewal of the centre's licence for four years because of the poor history of compliance at the centre and the current non-compliances in the storage of sperm beyond the consented storage period, the quality management system and the accurate submission of data to the HFEA. The inspection team has decided therefore to recommend the renewal of the centre's licence for a period of two years, subject to compliance with the recommendations made in this report being implemented within the prescribed timescales.

The inspection team notes the history of non-compliance at the centre but also that the PR, (only in the role since June 2011) and her staff, have provided evidence of multiple recent improvements at the centre. The inspection team expect these improvements to continue - the implementation of the remaining outstanding recommendations will be ensured by the Lead Inspector through the on-going monitoring system. It is also noted that Health Inspectorate Wales has indicated that IVF Wales will continue to be supported in the on-going development of improved governance and management systems: the HFEA will also liaise with HIW to support and monitor compliance of the centre going forward. Any indication that recommendations are not being fully implemented within the agreed timeframes or that non-compliances have recurred, will be reported to the Licence Committee for their consideration.

Regarding the additional condition on the centre's licence which limits the centre's activity: 'For the remainder of the licence, and calculated over a six-month period, the centre must limit the number of IVF or ICSI cycles provided to an average of twenty-four cycles per calendar month in total, and of frozen embryo transfers to an average of eight per calendar month in total.' The inspection team note the non-compliances which remain to be corrected including the staffing issues at the centre which have contributed to some of these non-compliances. Given these factors, the inspection team recommend that any licence issued to the centre should include the same additional condition. The condition should remain on the licence until such time as the centre has provided evidence which shows that all non-compliances have been addressed. The PR should then apply to have the licence varied to remove the additional condition.

*see http://www.hfea.gov.uk/docs/2009-08-21_Indicative_applications_guidance.pdf

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 has an electronic witnessing system which is not yet fully validated therefore manual witnessing of all required checks is performed and documented. Witnessing practices are generally compliant with the requirements of HFEA CoP Guidance Note 18, (with some exceptions noted below) which ensures that patients receive treatment using the correct gametes or embryos. This conclusion was supported by the inspection team's observations of electronic and manual witnessing in the laboratory and procedures room and review of: witnessed activities documented in six sets of patient records (SLC T71); the SOPs for witnessing (SLC T33b); and laboratory record sheets (SLC T71). The PR and Laboratory Manager (LM) discussed the quality indicator (QI) for witnessing which involves monthly retrospective audit of eight patient records for evidence of witnessing with a quality objective that 100% of witnessing checks are documented (SLC T35).

What the centre could do better.

The final dewar storage location for emergency oncology sperm freezes is sometimes witnessed retrospectively. This is non-compliant with SLC T71 which requires all witnessing to be performed at the time of the process. The LM noted however that witnessing guidance on the HFEA website allows retrospective witnessing of gamete storage where it is considered appropriate (see: http://www.hfea.gov.uk/docs/witnessing-protocols.pdf).

The tubes and dishes used during egg collection are not marked with patient identifiers (SLC T101). The tubes are used to transfer eggs within follicular fluid from the theatre to the laboratory. They are then emptied into unmarked dishes and eggs are identified and transferred to other dishes marked with patient identifiers and witnessing tags. Centre staff noted that the eggs spend little time in the unmarked tubes and dishes and there is no possibility of a mix up since: the tubes and dishes are all discarded after use; there are only one person's gametes in the critical work areas; and the critical work areas are emptied of all plastic ware and cleaned between each egg collection.

The centre has two SOPs for witnessing, which may be confusing to new staff. Neither discusses appropriate witnessing checks during sperm preparation or has been reviewed in the last year (CoP Guidance 31.6).

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 and embryos in treatment, based on the patient's medical history and therapeutic indications was seen to be documented in patient records reviewed on inspection (SLC T49). Review of patient records and discussions with staff indicated that all but one of the laboratories undertaking diagnosis and investigation of patients are accredited by CPA (SLC T21).

Patient couples are screened for HIV 1 and 2, and for hepatitis B and C prior to the procurement and processing of their gametes in accordance with SLC T50. Consideration is also given to the need for further testing dependent on risk factors such as their recent travel history.

Counselling
Evidence provided on inspection demonstrated that the centre offers counselling to all patients and partners prior to them consenting to licensed treatment (SLCs T60 and T61).

Counselling is provided in the out-patients' clinic or at the patient's home by a British Infertility Counselling Association (BICA) accredited counsellor (SLC T14; CoP Guidance 2.12). The importance of counselling and how to access it are documented in patient information sheets; a verbal offer of counselling is also made by nurses during information provision consultations and confirmation that counselling was offered was documented in the eight sets of patient records reviewed on inspection (SLC T58f). Nursing staff were said to continue to offer counselling during treatment, when appropriate, and if treatment fails. The centre has SOPs regarding information provision about counselling and counselling referral (SLC T33b). The counsellor provides therapeutic and implications counselling to patients, and counsels recipients of donor gametes about legal parenthood and telling the donor conceived about their origins (SLCs T60, T61 and T63). Arrangements have been established to ensure specialist counselling (e.g. genetics; gamete storage for fertility preservation) is available (CoP Guidance 3.10). Patient feedback regarding the counselling service is actively sought (CoP Guidance 23.17) and counselling QIs are monitored and reviewed (SLC T35). The Counselling Inspector suggested that BICA guidance on counselling QIs and audit should be considered by the PR to enhance the range of counselling QIs monitored.

What the centre could do better.

Procuring, processing and transporting gametes and embryos
The centre provides diagnostic semen analysis to patients and this service is not accredited by the CPA or another body accrediting to an equivalent standard (SLC T21).

This was an issue identified at the renewal inspection in April 2010 and the incident inspection and follow-up on the 15 June 2011 and 20 January 2012 respectively. The centre does not participate in the NEQAS scheme for semen analysis (SLC T21). Plans to obtain CPA accreditation were discussed on inspection with a senior CVUHB pathologist and a documented action plan, developed by an andrologist seconded to the centre from 1 June 2012 (who has obtained CPA accreditation at another centre) was subsequently provided. These plans seek to 'strengthen the andrology service' and obtain accreditation within 15-18 months.

Counselling
Audits of the counselling service are performed which are based on review of QI monitoring data however counselling practices have not been audited against the documented SOPs and the CoP requirements in the last two years (SLC T36).

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

What the centre does well.
The centre's sperm donor recruitment programme has been suspended since June 2011. The PR said it will remain so until the semen analysis service has attained CPA accreditation, or equivalent, and that the HFEA will be advised before the service re-commences. The centre's remaining sperm stocks are only used to create genetically related siblings to children already born as a result of treatment with the sperm. New patients needing donor sperm are treated using sperm imported from commercial donor sperm banks under TPAs.

The centre also accepts known egg donors introduced by recipients and egg sharers albeit both programmes are currently suspended.

A review of patient and donor records, relevant SOPs, TPAs with commercial donor sperm banks and discussions with staff, indicate that donor recruitment, screening, assessment and reimbursement practices, are generally compliant with CoP Guidance Notes 11 and 13 and General Direction 0001; some exceptions are detailed below.

When the centre receives donated sperm from third party commercial donor sperm banks, donor selection and screening records are included with the transfer. The centre's SOP requires this information is checked to verify donor recruitment and screening results are compliant. The centre has retrospectively audited the records to check that sperm sourced from third party procurers was appropriately recruited, screened and supplied (SLC T36).

Known egg donors are not compensated for their donation or expenses associated with it (General Direction 0001).

All donated gametes used in treatment are from identifiable donors (SLC T54). Records of donor use are kept which allow the centre to provide donors with information, if requested, regarding the number of persons born as a result of their donation, their sex and their year of birth (HF&E Act 1990 (as amended), Section 31 ZD (3)). Non-identifying information regarding sperm donors is made available to recipients (CoP Guidance 20.1b).

What the centre could do better.

One recently used known egg donor was 38 years old, i.e. above the upper age limit of 35 years in the joint professional body recommendations. The rationale for breaching the recommended upper age limit was not recorded in the medical records (CoP Guidance 11.3).

The PR could provide no specific evidence that compensation paid to donors by the third party commercial sperm banks was within the limits described in General Direction 0001 (SLC T69). One company had provided a certificate, dated November 2008, that all monies and other benefits provided to donors were in line with General Direction 2006/1. The inspection team did not consider this to be adequate evidence of the PR having taken reasonable steps to ensure that the requirements of General Direction 0001 have not been breached.

Good clinical practice

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

What the centre does well.

The inspection team considered that the centre follows good clinical practice and has premises and equipment to provide the treatment services which the inspection team considered to be generally suitable, with some exceptions. The centre has a QMS to continually improve the quality and effectiveness of the service, albeit improvements are needed, as discussed below.

The centre's clinical pregnancy rates for 1 January 2011 – 31 December 2011 are, in general, comparable to the national averages, except for IVF and ICSI in those aged <38 years which were significantly lower than the national averages. This was due to poor results in the first half of 2011; results have improved in the latter half of 2011 subsequent to the incident inspection in June 2011.

The centre has a QMS which was ISO 9001:2000 accredited but that accreditation has now lapsed because the QMS has not been inspected recently. Evidence provided on inspection indicated that the QMS is well-developed, albeit non-compliant in several ways discussed below (SLC T32). It consists of a quality manual which is currently being updated (SLC T33a), quality policy, SOPs with document control features for key activities (SLCs T33b; T34), training and reference manuals (SLC T33d) and patient information (SLC T58). SOPs are in the process of being revised to bring them up to date with current practices and regulatory requirements. Those which have been reviewed were considered to be well written and compliant with CoP requirements, for example the materials to be used in laboratory processes are referenced (SLC T31). QI monitoring of key practices is performed (SLC T35) based on the retrospective analysis of laboratory data and patient

records. QI data is presented in a dashboard format at the monthly management team meeting and also at the monthly all staff meetings.

Traceability
Laboratory sheets in the patient records, the consumables traceability log, witnessing records and the traceability and witnessing SOPs were all reviewed by the inspection team. This evidence indicated that systems are in place, with some exceptions detailed below, to ensure all gametes and embryos are traceable (SLC T99a) and appropriate information is recorded regarding all media, consumables and equipment that could influence their quality and safety (SLC T102). The PR understands that this information must be retained for 30 years (SLC T103). The centre has established a QI for traceability (SLC T35). All gamete and embryo containers are appropriately labelled (SLC T101) except at egg collection as discussed in 'Witnessing and assuring patient and donor identification' in this section.

Validation
A validation programme has recently been implemented by an external supplier which has included a thorough equipment validation exercise (SLC T24). This has been completed and has documented multiple non-conformities. Evidence provided on inspection and immediately thereafter indicates that some non-conformities are being addressed by appropriate corrective actions, e.g. a new fridge has been ordered; dry shippers have been marked as 'out of service until validated'; incubator areas known to be below temperature limits have been marked and will not be used (SLC T24).

Equipment and materials
Instruction manuals are present for the operation of most items of critical equipment and must be read by staff before they use the equipment; staff know through training the actions to take in the event of failure or malfunction (SLC T27). Evidence reviewed on inspection indicated that most equipment is regularly serviced and records of this are maintained (SLC T26); exceptions are discussed below. Repaired equipment is re-validated before being returned to service (SLC T25). Equipment is generally subject to appropriate monitoring, alerts, alarms and corrective actions through manual monitoring and recording of key parameters (SLC T24), albeit the inspection team had some concerns regarding the dewar and incubator alarm systems, discussed below. Equipment with a critical measuring function has been calibrated against a traceable standard (SLC T24). Staff were able to confirm that sterile instruments and devices are used in the procurement of gametes (SLC T28).

Premises
A tour of the centre confirmed that all licensed activities are carried out on the licensed premises which are within the same building (SLC T1). The out-patients' clinic premises were considered generally appropriate, being spacious, private and appropriately equipped (SLC T17) with some exceptions discussed below. These premises are located close to the centre's treatment corridor on which the rooms are located in which all licensable activities occur. The treatment corridor was considered by the inspection team to be also appropriate for the activities undertaken there (SLC T17). All sensitive areas within the out-patients' clinic and the treatment corridor are card key protected, restricting access to personnel authorised by the PR (HF&E Act (1990) as amended, Section 33A (1)). Patient records are stored in appropriately secure locations in the out-patients' clinic (long term storage) or on the treatment corridor in the administration office (SLC T45). The

inspection team consider that patients are provided with an acceptable level of privacy and comfort throughout the centre.

Adverse incidents
The centre is compliant with HFEA requirements for incident reporting. The centre has an incident reporting SOP (SLC T33b) and discussions with staff indicated they understand the importance of reporting incidents and investigating them appropriately (SLC T118). The SOP for managing patients with ovarian hyperstimulation syndrome (OHSS) discusses reporting such cases as incidents to the HFEA (SLC T118). The centre has responded appropriately to incidents since the last renewal inspection in April 2010.

Third Party Agreements
The centre has developed TPAs where necessary with its suppliers and a list of TPAs was available on inspection (SLCs T111 and T115). The quality manager (QM) reported that legal advice is being sought from CVUHB lawyers regarding the composition of TPAs and, when this is provided, all TPAs will be revised and re-issued.

Intracytoplasmic sperm injection
The ICSI process is documented in a SOP (SLC T33b). QIs have been established for ICSI fertilisation, degeneration and clinical pregnancy rates for the laboratory and for each ICSI practitioner and are reviewed monthly (SLCs T35). Staff competence to perform ICSI is assessed via QI monitoring and by observations of practice (SLC T12).

What the centre could do better.

Quality Management System
Audits of all key practices against the SOPs and regulatory requirements have not been performed in the last two years (SLC T36). This issue was also highlighted in the incident inspection report in June 2012 and at the last renewal inspection in April 2010. Audit reports for 2011 were wide-ranging but were, in all but one case, based on retrospective review of patient or laboratory records for evidence of compliance. Only one audit of practice against the SOP has been performed (for egg collection) in the last two years, and no audits of practices or SOPs against the regulatory requirements, contrary to SLC T36. A programme of audits of key practices has been prepared and will be implemented from May 2012 but it seemed to the inspection team that under the current plans, activities not documented in the patient records will not be effectively audited as no practice audits are planned. Such key activities include patient confidentiality and privacy; counselling; information provision to patients and egg donors/recipients; laboratory and clinical practices; gamete and embryo transport and import/export; research and training uses of oocytes and embryos; the QMS; TPAs; and incidents and complaints (SLC T36).

SOPs are in the process of being reviewed but this programme is progressing slowly and a number of SOPs have not been reviewed in the last year (55 of 101 listed SOPs and other documents), including the SOPs for witnessing, storage, traceability, ICSI, responding to emergency alarms and air quality monitoring (CoP Guidance 31.6). The large number of SOPs which are out of date suggests that document control processes at the centre are dysfunctional (SLC T34).

As reported in Section 2, Patient experience: Information; a significant proportion of the patient information documents have not been reviewed in the last year (CoP Guidance

31.6).

The centre does not consistently document non-conformities (e.g. in QI monitoring), their investigation, the recommended corrective actions and their implementation and subsequent impact (T36; CoP Guidance 23.27). Thus non-conformities can be seen in QI monitoring data but no evidence of their investigation and the implementation of corrective actions is available.

The performance of the QMS has not been reviewed in the last year (CoP Guidance 23.13).

Traceability
Traceability processes have not been audited in the last two years against the SOP and regulatory requirements (SLC T36). The only audit performed in that time has been a retrospective review of traceability data in one set of patient records in January 2012. It is the centre's own policy that a review is performed monthly as a QI for traceability and the centre are not adhering to this (SLC T35).

The SOP describing traceability processes has not been reviewed since 2009 and does not discuss the processes which facilitate equipment traceability, which have been introduced in the last year (SLC T33b).

Validation
The recent equipment validation exercise found a significant number of non-conformities: e.g. lack of servicing of the dewar alarm system; temperatures above defined limits in a reagent fridge and below defined limits in some incubator locations; new incubators not yet calibrated; absence of air quality monitoring data for air flow cabinets; absence of user SOPs; absence of electrical safety testing. Some non-conformities have been addressed by the implementation of corrective actions but most have not. The LM provided a list of 18 corrective actions which were discussed at a meeting with the centre's CVUHB managers on 21 February 2012. Only one action had been implemented by the time of the inspection and plans to implement the other corrective actions were not yet in place. The LM stated that this was because the CVUHB managers had not approved the implementation of the actions because of the impending transfer of the unit to the ABMU health board. She also stated that limitations in staffing numbers in the laboratory made the implementation of actions difficult (SLC T24).

The centre's processes were included in the validation exercise but the validation report has not yet been delivered (SLC T72). The validation programme has overrun the deadline for completion (mid-February 2012) discussed in the follow up inspection report in January 2012. The LM stated that the process validation will now be completed by the end of May 2012. She accepted that the contracting of the external supplier to undertake the validation exercise has delayed the validation, but considers that the thoroughness and assurance provided by the supplier makes the delay worthwhile. The inspection team accept the validity of this point of view.

Consumables which may influence the quality and safety of the gametes and embryos have not yet been validated to ensure their suitability. The LM informed the inspection team that this is being completed as part of the process validation (SLC T28).

Equipment and materials

The centre has not documented procedures for the operation of all items of equipment albeit equipment operating manuals are available for most of them (SLC T27). The actions to take in the event of equipment failure are not documented for all items of equipment (SLC T27).

The oxygen monitoring system and dewar probes and alarm system have not been serviced since 2009; both systems are well beyond their normal service intervals (SLCs T24 and T26). The LM provided evidence that the centre was establishing a contract with a third party supplier who would perform the necessary servicing activities. The risk caused by the lack of servicing of the dewar probes and alarms is reduced by weekly testing by disconnecting each probe from the alarm circuit to check the alarm activates. The level of liquid nitrogen in each dewar before filling is also monitored weekly and this data is analysed to check for incipient dewar failure. It should be noted however that the 'probe disconnection' test checks the integrity of the alarm but not the probe function.

At the last dewar service it was noted that two probes were 'incorrectly calibrated'; no evidence was available of subsequent corrective actions (SLCs T24 and T26). A similar situation was observed regarding a filter on the down flow of an air flow cabinet which failed the last service but has not been replaced (SLCs T24 and T26). The LM was advised by the engineer that the fault should not compromise air quality however the absence of air quality monitoring makes it difficult to validate this opinion.

The report of an external survey of the centre's dewars in January 2010, stated that multiple dewars were aged and needed replacement. This was highlighted by the renewal inspection in April 2010 and the centre was required to renovate the cryostorage facilities. The Lead Inspector was advised that this had been completed and that all defective dewars had been replaced. On this inspection one dewar, described in the January 2010 report as 'very old and neck cork broken' was seen to still be in use and contained sperm samples from four patients. The inspection team consider this is hazardous to staff and poses a risk to the quality and safety of the sperm samples (SLCs T23 and T24).

The centre has not performed a PAT testing programme since 2010 (SLC T26).

The incubator carbon dioxide meters are not connected to a dial-out alarm system to summon assistance if carbon dioxide levels fall below defined limits, neither is the carbon dioxide manifold supplying the incubators so connected (SLC T24).

The temperature probe on the incubators is integral to each unit and connected to an automatic dial out system. The inspection team had some concerns whether the temperature probe had an independent power supply and would function and activate the alarm system if the electrical supply to the incubator failed (SLC T24).

The LM believes that all instruments and devices used in the centre's activities are CE marked but agreed that this has not been recently audited so cannot be said with certainty (SLC T30). The validation of the centre's processes, soon to be completed, will accomplish this.

Equipment in the laboratory and clinical areas appeared to be clean but the centre does not record the regular cleaning and decontamination of equipment (SLC T26).

Premises
The centre has no documented air quality testing data for the critical work areas and laboratory background air since July 2010 and therefore cannot confirm that air quality in these areas has been compliant with HFEA requirements since that time (SLC T20).

The premises and laboratory appeared clean however documented records of the cleaning of the clinical areas and laboratory are not maintained (SLC 26).

Third party agreements
The content of five TPAs was reviewed. The inspection team considered that in many agreements the nature of the service provided was not clear (SLC T114a) nor was it stated that the third party should meet the requirements of the relevant licence conditions and HFEA CoP guidance (SLC T116). Most agreements also did not contain: a summary of the responsibilities of the third party and the agreed procedures to be used (SLC T114d); specified criteria that the service must meet, particularly in relation to quality and safety (SLC T114e); a description of how any test/diagnostic results should be relayed to the centre, including sign off and confirmation that the result applies to the correct sample (SLC T114f). For example, an agreement with a transport agent did not state the critical parameters to be maintained during the transport of gametes and embryos (SLCs T107 and T114e) and two agreements with third party sperm procuring agents did not include that they should provide a procurement report compliant with SLC T117 and that donor compensation should be compliant with General Direction 0001. TPAs were said by the QM to have not been recently reviewed to ensure they are accurate and compliant with CoP requirements. The QM also reported that legal advice is being sought from the CVUHB lawyers regarding the composition of TPAs and, when this has been provided, they are all to be reviewed and re-issued.

The centre has not recently assessed the ability of third parties to comply with relevant licence conditions and the terms of their TPAs (SLC T112). The QM said this will be annually assessed in future for a subset of the TPAs.

Intracytoplasmic sperm injection
The ICSI process is documented in a SOP but that SOP was last reviewed in March 2010 (SLC T33b).

The ICSI process has also not yet been validated, though it has been included in the process validation currently being performed (SLC T72).

The centre has not recorded the response and corrective actions triggered by breaches of control limits detected by monthly ICSI QI monitoring (SLC T36).

Multiple Births (Guidance Note 7)

The centre's multiple clinical pregnancy rate for the time period from 1 April 2010 to 31 March 2011 was 25%. This indicates performance in 2010/11 that is not likely to be significantly different from the multiple live birth rate target rate of 25%[1].

The centre's multiple clinical pregnancy rate for the time period from 1 April 2011 to 31 March 2012 was 23%. This indicates performance in 2011/12 that is not likely to be significantly different from the multiple live birth rate target rate of 15% (SLC T123).

What the centre does well.

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

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

What the centre could do better.

A three embryo transfer was performed in a patient aged less than 40 years (CoP Guidance 7.4b). The PR had documented in the patient records a discussion with the patient of the risk of multiple pregnancy and the clinical rationale for transferring more than two embryos (age 39.4 years; non-optimal embryo quality and recurrent implantation failure). The case resulted in a singleton pregnancy which is on-going. The inspection team consider that no further action is required.

Staff engaged in licensed activity

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

What the centre does well.

The inspection team note the information provided by the PR and her staff before, during and after the inspection and the engagement of the centre's staff with the inspection process.

Person Responsible

The PR has academic qualifications in the field of medicine and has more than two years

[1] The HFEA use a conversion factor of 1.27 to convert the multiple live birth rate (MLBR) target to a multiple clinical pregnancy rate (MCPR) target. The 2010/11 MLBR target of 20% is calculated as equivalent to a MCPR of 25%: the 2011/12 MLBR target of 15% is calculated as equivalent to a 19% MCPR.

of practical experience directly relevant to the licensed activities, as required by the HF&E Act 1990 (as amended), Section 16(2)(c)(i) and (ii). The PR has successfully completed the HFEA PR Entry Programme (certificate number T/1190/8). The PR is registered with the General Medical Council (GMC) and is on the specialist register for Obstetrics and Gynaecology (SLCs T14 and T16).

Staff

The centre has an organisational chart within the QMS which describes the management structure and staffing of the centre (SLC T11).

The PR confirmed that all staff working under the auspices of the licence are qualified and suitable persons to participate in the licensed activities (HF&E Act 1990 (as amended), Section 17 1a). All staff are subjected to Criminal Record Bureau and professional body registration checks during recruitment and references are also obtained (SLC T14). Employment contracts require criminal offences to be reported to the CVUHB. All staff reviewed by the inspection team were appropriately registered, accredited and qualified, (SLCs T12 and T14). The centre has an accredited consultant who oversees medical activities and is registered with the GMC and is on the specialist register for Obstetrics and Gynaecology (SLCs T14 and T16).

The centre has, in nearly all cases, policies to support induction training and competence assessment, professional development and annual performance appraisals (SLCs T12 and T15). Nursing and laboratory staff provided evidence of detailed induction programmes and all staff could provide evidence of on-going competence assessment (SLC T12 and T15a). The PR is confident of the competence of all staff which can be evidenced through the completion of competence assessment frameworks, QI monitoring, their registration with appropriate bodies and completion of continual professional development programmes (SLC T12).

The centre's activity level and staffing resources are discussed during the monthly centre management meetings to ensure they are matched. In mid-May 2012, the LM and a non-HPC registered embryologist will leave the centre and a laboratory assistant will go on six weeks sick leave. The laboratory staff will then consist of two HPC registered scientists, one laboratory assistant and one andrologist. Clinical and nursing staffing levels are also much reduced from the normal staffing levels at the centre. The PR has controlled treatment activity in response to these staffing changes, reducing it to four IVF cycles per week from 1 April 2012. The centre has also advertised to recruit a consultant, a trainee embryologist and three nurses and, subsequent to the inspection, the PR advised the Lead Inspector of the recruitment of a new LM.

What the centre could do better.

Gametes are currently being stored after the gamete providers' documented consent to storage has expired (HF&E Act 1990 (as amended), Schedule 3, 8 (1) and 8 (2)). There are also many other non-compliances with SLCs and General Directions, some of which have been highlighted by previous inspection reports. The inspection team conclude therefore that the PR has not carried out the duties required by the HF&E Act 1990 (as amended).

The LM reported that laboratory staffing is inappropriately low given the activity (capped at 24 cycles of ICSI/IVF per month but reduced from 1 April 2012 to 16-18 cycles per month)

and the back log of regulatory compliance work. In her opinion, treatment has been safely provided but the laboratory staff did not have time to address all the regulatory issues. The inspection team are concerned whether the reduced staffing will be sufficient to support treatment activity and implement corrective actions in response to the non-compliances in this report, which are required to ensure the safe operation of the centre (SLC T12). The PR stated that the centre were in the process of recruiting several new laboratory and clinical staff members to address these matters.

The counsellor is contracted for six sessions per week. The Counselling Inspector was concerned that this may not be enough time given the number of counselling referrals has almost doubled in the last year with no increase in counselling staff resources. There is also no cover if the counsellor is on leave so the counselling service is suspended. This situation is potentially non-compliant with SLC T12.

Some staff have not completed all modules of their annual mandatory training (SLC T12 and T15). Some staff have not been provided with an annual appraisal within the last year (CoP Guidance 2.3).

Welfare of the Child (Guidance Note 8)

What the centre does well.

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

This conclusion was based on a review of eight sets of patient records which all contained a WoC assessment (SLC T46e). The PR confirmed that the WoC assessment process is documented and is applied to all patients, including all those participating in surrogacy arrangements (SLCs T33b and T56). WoC assessments are performed by the clinical and nursing staff. If there are concerns, the counsellor will see the patients and feed relevant information, with the patients' consent, back to the centre's 'Social Issues Group' which decides on difficult WoC cases.

The WoC assessment process is subjected to QI monitoring through retrospective audit of patient records (SLC T35 and T36). Clinical and nursing staff competence to perform WoC assessment has been assessed (SLC T12).

What the centre could do better.

No issues were identified at this inspection.

Embryo Testing

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

What the centre does well.

The centre is not licensed to provide treatment which involves pre-implantation genetic screening or diagnosis, therefore this theme was not relevant at this inspection.

What the centre could do better.
Not relevant at this inspection.

2. Patient Experience

Focus

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

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

Treating patients fairly

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

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 (CoP Guidance 29.1 – 29.3).

Confidentiality and privacy

A tour of the centre and discussions with staff demonstrated that confidential information is generally stored securely and access to it is restricted to authorised personnel (SLC T45), with some exceptions discussed below. Areas where conversations and consultations may occur are private (CoP Guidance 25.7), with one exception discussed below.

Patient confidentiality is protected by clauses in staff employment contracts, induction training on the subject and the centre's confidentiality SOP (SLCs T15a, T33b and T43). Access to the centre's server and patient information database is password protected (SLC T45). Documented processes are in place to maintain data security and safeguard against unauthorised data modifications, to resolve data discrepancies and to respond appropriately to applications to access confidential medical records (SLC T44).

Complaints

Complaints are processed in a manner compliant with CoP Guidance Note 28. The centre has a complaints policy and log. Information on how service users may make a complaint is displayed in some patient areas and in written information provided to patients (CoP Guidance 4.2k). Complaints can be made verbally to all staff members who attempt immediate resolution. More significant complaints are directed to the centre's complaints manager (the QM) who responds, investigates and ensures that corrective actions are taken. Formal written complaints can be directed to the Women's Health Directorate complaints manager who is also on the centre's licence.

Provision of a costed treatment plan
The centre has treated no self-funded patients since June 2011, therefore no costed treatment plans have been prepared recently. Documentation is however still available to provide to self-funded patients if they are treated in the future (CoP Guidance 4.3). Staff related that a copy of the treatment plan and its costs would be placed in the patient's records.

Egg sharing arrangements and Surrogacy
The centre does not have an egg sharing scheme at present but does treat patients in surrogacy arrangements. Gamete providers in surrogacy arrangements are screened as donors in accordance with SLC T52 and are registered as donors (General Direction 0005). All participants in surrogacy arrangements are subjected to WoC assessment (SLC T56). The counsellor sees all participants and can, if the commissioning couple and surrogate consent to it, input information to the multi-disciplinary team which considers the provision of treatment and WoC issues (SLC T56).

What the centre could do better.

Confidentiality and privacy
Processes associated with confidentiality and privacy have not been audited in the last two years, contrary to SLC T36.

The centre displays a board of 'thank you' cards from patients who have had a child after treatment at the centre. These cards are in a public area, contain the patients' names and are not sealed shut, which allows persons not subject to a HFEA licence to identify persons who have had licensed treatment and have not consented to disclosure of their identifying information. This situation risks non-compliance with the HF&E Act 1990 (as amended), Section 33A.

The inspection team found in an area open to patients, a computer containing patient identifying information which was unsupervised by staff and could be operated by the inspection team. The inspection team considered that this may allow unlicensed persons to access patient identifying information (SLCs T43 and T44).

The counselling room in the centre's temporary outpatient clinic is comfortable and private but does not have a telephone or computer connections. This means that the counsellor has to call clients from a telephone at the nurses' station which has limited confidentiality given the flow of patients and staff in this area (SLC T43).

Some counselling notes are stored in the home of the counsellor. Discussions with the counsellor indicate that the storage arrangements are probably appropriate however the PR has not assessed the confidentiality of the storage arrangements (SLC T43).

Information

- Information to be provided prior to consent (Guidance Note 4)
- Information about storage of embryos (Guidance Note 17)
- Information about Intracytoplasmic sperm injection (Guidance Note 21)
- Information about legal parenthood (Guidance Note 6)

What the centre does well.

Review of information sheets and patient records, and discussions with staff, indicate that the centre has, with some exceptions, reliable materials and processes for providing patients with appropriate information well before they complete HFEA consent forms (SLC T58 and T60).

The patient satisfaction survey includes questions regarding the quality and usefulness of information about treatment and whether patients have had opportunities to ask further questions. This survey is performed every six months and functions as a QI for information provision (SLC T35 and T36). Staff competence to provide information to patients prior to taking consent has been documented (SLCs T12 and T15a).

The centre has an SOP for information provision. SOPs for taking consent to treatment, consent to donation to research, consent to use in training and consent to egg donation, also include the provision of information before the taking of consent (SLC T33b).

Information provided prior to consent

Written information about treatment is contained in an 'information brochure' given to patients at the start of the treatment pathway (SLC T58). This brochure is supplemented with a 'day-to-day guide to treatment' and also relevant information leaflets selected from the centre's detailed portfolio of patient information sheets. Amongst these are sheets with information about more specialised areas of treatment. Information is also provided verbally during the initial consultations with medical and nursing staff and in the injection teaching session; these sessions provide patients an opportunity to ask questions (CoP Guidance 5.6). Patients are informed about consent to disclosure of identifying information in the nurse consultation using the consent form itself as an information aid (CoP Guidance 5.26a-e).

Written information provided to patients was reviewed and was found to be generally compliant, with some exceptions noted below, and to provide detailed information about the treatments available, their consequences and risks, analytical tests, consent, and the availability of counselling (SLCs T58 and T60).

Review of written information provided to egg donors indicated that it was compliant with the requirements of CoP Guidance 4 and 11 with the exception of the issues stated below. Those receiving treatment with donated gametes are provided with written information which includes the importance of informing any resulting child at an early age that they were conceived using donated gametes and also regarding how this can be achieved (SLC T63). The information also satisfies the other information requirements of CoP Guidance Note 20, with the exception of the issues stated below.

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

Information about storage of embryos, including the 'cooling off' period
Discussions with staff and review of written information indicated that patients are provided with information about most aspects of gamete and embryo storage (SLCs T58; CoP Guidance 17.11, 17.12, 17.14). The information states that the centre recommends storing embryos initially for five years but that storage for 55 years is possible. It also discusses a gamete provider's right to vary or withdraw their consent to gamete or embryo storage (SLC T58) and the implementation of a 'cooling off' period in the event that consent to embryo storage is withdrawn, albeit more detail is required as discussed below.

Information about ICSI
Discussion with staff and review of written patient information indicated that patients and their partners are given specific information about ICSI which discusses the methodology and the associated risks, with one exception (CoP Guidance 21.1 and 21.2).

Information about legal parenthood
Written information provided to recipients of donated gametes contains information about parenthood provisions as well as an offer of counselling (SLC T60 and T61). Users of donated gametes are also provided with verbal information about legal parenthood issues by nursing staff and by the counsellor if they choose to see her. Staff interviewed during the inspection demonstrated a good understanding of legal parenthood requirements (SLC T61 – T65).

What the centre could do better.

Information provided prior to consent
A significant proportion of the patient information documents have not been reviewed in the last year (CoP Guidance 31.4 and 31.6).

The written information provided to IVF and ICSI patients was audited against CoP requirements after inspection and it was found to not include discussion regarding:

- The recording and protection of personal data and confidentiality by Section 33 of the HF&E Act 1990 (as amended) (SLC T58d).
- A person's right to vary the conditions of their consent and the procedure by which this can be achieved (SLC T58e; Interpretation of Mandatory Requirements 5B).
- A person's right to vary or withdraw an existing consent and the procedure by which this can be achieved (SLC T58e; Interpretation of Mandatory Requirements 5B).
- Multiple pregnancies: the increased risk of complications which are serious and life threatening to the future mother and baby and lead to miscarriage, still birth and perinatal infant death (CoP Guidance 7.7 a,b).
- Gamete and embryo storage: the possible deterioration or loss of viability resulting from storage (CoP guidance 17.12a); the statutory storage periods and the regulations for extending the statutory storage period (CoP guidance 17.12b); in the event of a withdrawal of embryo storage consent by one gamete provider, the provision of a 'cooling off' period of one year or until the statutory storage period expires, whichever is shorter, and the actions taken by the centre to inform the other gamete provider and facilitate resolution of the conflict (CoP 17.12b).

Written information provided to recipients of oocyte donors and recipients was last reviewed in 2005, is non-compliant with multiple CoP requirements and does not satisfy

the requirement of the HF&E Act 1990 (as amended), Section 13 (6) that patient receive 'such relevant information as is proper' before consenting to treatment.

Information provided to egg share providers and recipients was audited against CoP requirements even though the egg share programme was said to be currently suspended. Written information provided to egg share providers was found to not include discussion regarding:

- The scope and limitations of the genetic testing that will be done and the implications for the donor and their family (CoP Guidance 11.30c);
- What information about the donor must be collected by the centre and held on the HFEA Register (CoP Guidance 11.30h);
- The importance of supplying up-to-date contact information so that the donor can be informed if and when disclosure of identifiable information will be made (CoP Guidance 11.30k);
- The procedure for donors to withdraw consent for the use of their gametes, or embryos created with their gametes (CoP Guidance 11.30n);
- The fact that if the donor is an egg donor who is not a patient, she is free to withdraw from the donation process after preparation for egg recovery has begun without incurring a financial or other penalty (CoP Guidance 11.30o);
- That anyone born as a result of their donation will have when they are 16 years old access to each specific item of the non-identifying information provided by the donor stated by CoP Guidance 11.35 a-m.

Written information provided to egg share recipients does not state:

- That when any donor-conceived child is 16 years old, they will have access to each item of non-identifying information about the donor specified by CoP Guidance 20.11 a – m.

It is noted that the information requirements above are not satisfied by the written information however, given the audit was performed after inspection, it could not be determined whether they are satisfied through verbal communications between centre staff and the patients.

Information about ICSI

Written information about ICSI does not discuss the risk that damage caused by the ICSI procedure may reduce the number of eggs/embryos available for treatment (CoP Guidance 21.1a).

Information in the outpatient clinic

The outpatients' clinic has some out of date information displayed on the wall which is not considered 'proper' information (HF&E Act 1990 (as amended), Schedule 3, 3 1b) due to the inaccuracies within it, specifically:

- An academic poster from 2007 reporting treatments at the centre and success rates, some of the treatments being now no longer provided and the success rates are out of date;
- An ISO 9001:2000 accreditation certificate for the QMS which is no longer valid.

Information about legal parenthood

Information provided to couples using donated gametes who are not married or in a civil partnership, does not contain information about the mechanism by which they can

withdraw their consent to be the legal second parent or their consent for their partner to be the legal second parent (SLC T61).

Consent

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

What the centre does well.

Staff at the centre provided evidence to demonstrate that appropriate written consent is obtained from patients by suitably qualified and competent staff before gametes or embryos are used in treatment or stored (SLC T57).

Consent to treatment, storage, donation and training
Consents are taken from patients in nurse consultations after written information has been provided, and patients have been offered counselling and an opportunity to ask questions (SLC T57 and T58). The consent provider's identity is verified against a copy of a photographic form of identification held in the patient record when consent is provided and also at the time of treatment; this practice was observed on inspection (CoP Guidance 5.10 and 5.11). The centre has SOPs for taking consent to treatment, to research and to training (SLC T33b). The centre has a QI for consent which involves reviewing the consent forms in one randomly selected patient record every week. The findings are reviewed and logged, then compiled into an annual summary (SLC T35). Assessment of staff competence to take consent has been documented (SLCs T12 and 15a).

An audit of eight sets of records from patients undergoing treatment demonstrated that all contained correctly completed treatment and storage consent forms (SLC T57). Identity checks performed when the consents were taken and at treatment were also documented (CoP Guidance 5.10 and 5.11). Consent to disclosure forms were also present in all eight patient records reviewed.

Discussions with staff indicated that consents for egg storage or ICSI may be taken on the day of treatment. This happens very rarely and only if sperm is unexpectedly absent or of low quality on the day of egg collection. All patients are provided with information on ICSI and egg storage well before treatment and the counsellor and embryology staff are available to discuss concerns before the consents are taken. The inspection team considers there are no regulatory issues associated with this area of practice.

Gamete or embryo storage consent is taken from patients initially for five years, then can be extended for a further five years to give the statutory ten years storage period. Information is provided to patients before they consent which discusses the possibility of extended storage to 55 years (SLC T58). The centre operates a bring-forward system to ensure that consent for storage is present for all stored embryos (CoP Guidance 17.18 and 17.20). A recent audit found that all stored embryos were accounted for and that consents for storage were in place for all but one set which had passed the consented storage period (HF&E Act (1990) as amended, Schedule 3, 8(2)).

Staff understood that if one gamete provider wants to withdraw their consent for storage but the other does not, the centre can provide a 'cooling off' period of one year or until the

statutory storage period expires, whichever is shorter. Staff advised that the centre presently has no embryos being stored under this provision (CoP Guidance 5.35).

Consent to legal parenthood

The centre collects consent for legal parenthood in an appropriate manner (SLCs T60-T65). The centre has a SOP which documents the process to obtain written consent to legal parenthood (SLC T33b); this is rarely used at present because the centre provides little treatment with donor sperm. The centre has a compliant process to follow if consent to legal parenthood is withdrawn (SLCs T64 and T65). Completion of a legal parenthood consent and/or its subsequent withdrawal, is noted on the patient pathway check list in the patient record; a valid legal parenthood consent must be in place for treatment with donor sperm to progress (SLC T64 and T65). Records of recipients of donor gametes seen on inspection all contained appropriately completed legal parenthood consents (SLC T57).

What the centre could do better.

Consent to storage

The LM stated that staff have not had time to review and audit the stored sperm samples in ten dewars against the storage records and consents. The centre has also not maintained a bring-forward system for these sperm samples (CoP Guidance 17.18 and 17.20). It is likely therefore that numerous sperm samples are in storage even though their consented storage period has expired, contrary to HF&E Act 1990 (as amended) Schedule 3, 8 (1). However, because the storage term for many of the samples has been calculated from when the storage consent was signed, rather than from when samples were placed into storage, the extent of this non-compliance is not known.

A robust bring-forward system is in place for stored embryos however one patient couple has indicated that they wish to extend their storage consent but have repeatedly failed to provide an updated consent form. The centre has kept this one set of embryos in storage even though the consented storage period expired on 7 September 2011 (HF&E Act 1990 (as amended) Schedule 3, 8 (2)).

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 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 licensed activities are conducted within the licensed premises (SLC T1).

Following a review of patient records and discussions with the PR and centre staff, the inspection team have concluded that embryos are only created, stored and used in treatment at the centre when specifically authorised by the centre's licence (SLC T2).

The PR stated that embryos are not produced by embryo splitting nor is embryo testing provided at the centre so can not be used to select the sex of an embryo for social reasons (SLC T88). No evidence of these activities was seen in patient records.

Donor compensation is discussed in 'Section 1; Protection of patients and children born following treatment'.

What the centre could do better.

Nothing identified at this inspection.

Storage of gametes and embryos

- Storage of gametes and embryos (Guidance Note 17)

What the centre does well.

After review of the storage facilities, patient records and documentation provided on inspection, and discussions with centre staff, the inspection team conclude that gamete

and embryo storage at the centre is compliant with HFEA CoP requirements, with several significant exceptions discussed below and elsewhere in this report.

There are documented SOPs for the processes to be followed when storing gametes and embryos which include the cryopreservation processes and the bring-forward system for embryos (SLC T33b). QIs for storage and thawing are monitored based on FET clinical pregnancy rates for the laboratory and for individual embryologists (SLC T35). QI monitoring data and laboratory induction and training logs are used to evidence staff competence to perform cryopreservation processes (SLC T12 and T15a).

The centre has a dedicated, secure room for the 14 dewars used to store cryopreserved gametes and embryos; several of the dewars have been recently purchased. The cryostore is equipped with a low oxygen monitor which alarms inside and outside the room (SLC T17; CoP Guidance 17.2a). Appropriate safety signage was displayed, as was the safe system of work used by staff when working in the room. The room has a boost extractor fan which is switched on by an infrared detector when persons are in the cryostore and also by the low oxygen monitoring alarm when activated. A ventilation grill has also been installed in the main door to allow the entry of 'fresh' air into the room.

The dewars are fitted with liquid nitrogen depth probes connected to an alarm system which sounds in the cryostore and has an auto-dial facility to the hospital switchboard (SLCs T24 and T75). The switchboard has an SOP for responding to the alarm, ensuring it is relayed to the on-call centre staff. Dewars are filled up manually every week and the depth of liquid nitrogen before filling is logged and reviewed against past data to check for incipient dewar failure.

The centre provides storage facilities to oncology and other patients requiring long-term storage for preservation of fertility potential. Samples are divided between two storage dewars (CoP Guidance 17.7). A spare dewar is kept filled with liquid nitrogen and ready for use as a back-up in case of dewar failure (CoP Guidance 17.6).

Discussions with staff and review of SOPs and the patient records indicated that before gamete and embryo storage, patients and partners are screened for HIV 1 and 2, and for hepatitis B and C in accordance with SLC T50; The centre does not have facilities to store samples from patients who have screened positive during these tests and the patients are directed to centres which are able to provide such facilities. The embryologists check screening test results are in place before cryopreserving samples. The embryologists also ensure appropriate consent is in place before cryopreserving or thawing samples (SLC T57).

What the centre could do better.

The cryopreservation processes have not been validated (SLC T72).

The SOPs for gamete and embryo cryopreservation and storage have not been reviewed in the last year (SLC T33b).

Concerns regarding storage consents are discussed in 'Section 2: Patient Experience; Consent'

Concerns about the equipment used in gamete and embryo storage are discussed in

‘Section 1. Protection of patients and children born following treatment; Good Clinical Practice; Equipment.

Distribution and / or receipt of gametes and embryos

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

What the centre does well.

The centre has documented processes which ensure that gametes and embryos are only sent to other licensed or appropriately accredited centres within the UK and overseas, under conditions that protect their safety and quality.

Import/export of gametes and embryos

In June 2011 – March 2012, the centre performed 20 imports of sperm from Denmark and nine imports of sperm from the USA, all under General Direction 0006. One sperm sample was exported to Trinidad and Tobago under Special Directions. No oocytes or embryos have been imported. Discussions with the PR and staff and review of patient and other records indicated that samples are imported with appropriate documentation regarding the gamete provider(s) (SLC T110) and the compliance of the source with the requirements of General Direction 0006, with one exception regarding the reimbursement of donors discussed earlier in this report.

Distribution of gametes and embryo

The centre has a SOP describing the processes for the import and export of gametes and embryos which is also used for transferring gametes and embryos between centres within the UK (SLC T33b). Review of the SOP and discussions with staff indicated that the centre’s transport and distribution processes were compliant with CoP requirements with minor exceptions discussed below. Packaging and transportation arrangements are secure and will prevent damage and/or contamination (SLC T105 and T108). The centre only uses dry shippers provided by other centres at present as the centre’s dry shipper has not been validated. The centre ensures that the dry shippers used for transporting cryopreserved materials are validated (SLC T108) and are enclosed in a protective casing to prevent damage (SLC T105). Distributed packages are appropriately labelled (SLC T107) and the information required by SLC T110 is included in the package. The centre has a documented recall procedure which includes the actions to take on receipt of the recalled material and the reporting of the recall as an adverse incident (CoP interpretation of mandatory requirements, 15B and 15C).

What the centre could do better.

Distribution of gametes and embryo

The SOP for import and export of gametes and embryos is also used for transferring samples between centres in the UK, but this use is not clearly stated within the SOP (SLC T33b).

The SOP also states that recalled material should be placed back into its original storage

location. Such material should in fact be placed into quarantine until investigation of the recall has been completed and it has been confirmed that the material is safe and compliant with requirements (SLC T109).

Use of embryos for training staff (Guidance Note 22)

What the centre does well.

From discussions with staff and review of patient information, the SOP for the use of embryos in training, training logs and consents in patient records, the inspection team concluded that patients are: informed and consented regarding the use of their embryos in training (SLC T97); informed about the types of training undertaken and that they can withdraw consent at any time (SLC T97); advised regarding whether information will be fed back to them (SLC T97). Processes documented in SOPs ensure that: embryos are only used in training when both gamete providers have consented to such use (SLC T94); embryos used in training are not kept for or used in subsequent treatment (SLC T92); embryos are only used in training activities approved by the Authority (SLC T93). The report of a training consent audit performed in January 2012 was provided and demonstrated that appropriate consent had been obtained prior to the use of embryos in training (SLC T36 and T94).

Laboratory staff members each keep a training log in which embryo use in training is documented and when interviewed demonstrated a clear understanding of the purposes for which embryos could be used in training (SLC T93).

What the centre could do better.

The SOP for the use of embryos in training does not state that roles involved in the clinical and training uses of embryo should be clearly separated to prevent any actual or perceived conflict of interest (SLC T33b); appropriate working practices to achieve this have not been implemented (SLC T95).

The SOP for the use of embryos in training has not been recently reviewed (SLC T33b).

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.

Record keeping and document control

All patient records reviewed on inspection were clear, legible, well organised and complete. Each record reviewed was seen to include the patient's first name, surname, date of birth, age and sex. Details of how the patient had been identified by staff were also evidenced. Patient notes also included details of the service provided to them, a medical history, relevant documented consents, laboratory data and the results of tests carried out (SLC T46). The centre has procedures in place to ensure that records are protected from unauthorised amendment and are retained and readily retrieved in this condition throughout their specified retention period (SLC T47).

What the centre could do better.

As reported elsewhere in this report (Section 1: Protecting patients and children born following treatment: Good clinical practice; What the centre could do better; QMS and Section 2, Patient experience: Information) a significant proportion of the SOPs and patient information documents have not been reviewed in the last year (CoP Guidance 31.4).

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

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

What the centre does well.

Obligations and reporting requirements

The PR provided all information required by the application process prior to inspection. Centre staff cooperated with the inspection team and further information requested was generally provided in a timely manner. The PR has responded fully to many recommendations made after previous recent inspections, but recommendations have not been fully implemented.

In the 2011/2012 financial year, the centre took an average of 71 days to pay HFEA invoices issued. The PR should note that the terms of payment of HFEA invoices are that payment should be received within 28 days, and that the PR is obliged under Licence Condition T9d to do this. The HFEA Finance Department also reported however that there has been a significant recent improvement and of late the centre is paying invoices within 28 days'. Delayed payment of HFEA invoices was an issue at the last renewal inspection in April 2010.

Licensed treatment reporting
Relevant QIs for data entry have been developed and are monitored (SLC T35).

What the centre could do better.
To assess the completeness and timeliness of submission of information to the HFEA register, the reporting of 152 treatments (i.e. 129 IVF and 23 DI treatments) from between 1/12/2010 and 30/11/2011 was reviewed. The register audit found that eight IVF treatments (6%) and 15 (65%) DI treatments were not on the HFEA register at the time of the inspection. 114 (75%) of the 152 treatments reviewed had not been reported within five days of treatment (General Direction 0005). Of eight early outcome forms reviewed, none had been submitted to the HFEA within eight weeks of the cycle completion date (General Direction 0005).

To ascertain the accuracy of register data submission, the content of 47 assorted data forms (submitted between 1/12/2010 and 30/11/2011) was reviewed against source documentation in patient and donor medical records. Systematic error was identified within the sample of 47 forms which impacts the integrity of the register data set, non-compliant with SLC T9e. Some patient and partner registration form data fields were found to be completed with "Not Stated" or "Not Available" either because the data had not been obtained from the patient or, when captured and readily available in the record, it had not been supplied in the form. The dates of donor gamete first use on donor information forms was also found either not to be completed, or to be completed with the date of import. The QM has been provided with the relevant patient numbers, form numbers and error and omission details so that corrections can be made where necessary.

A register audit inspector observed staff submitting EDI data and noted that they did not check whether earlier forms have been submitted prior to input and did not use the input mechanism introduced to part pre-populate forms The latter would: highlight whether forms that need to be linked had not previously been inputted; reduce the likelihood of input error; and improve the efficiency of the data entry process. This highlighted obvious training needs (SLC T12 and T15a). The same conclusion can be drawn from the errors seen in forms related to surrogacy and in the register audit described above. Indeed, the training of persons to submit data through the EDI system was said by the QM to be inconsistent, because it had been cascaded down from one person to the next (SLC T12 and T15). The QM also stated that the SOP for data entry through the EDI system was not in use and needed revision (SLC T33b) and that a full audit of the processes for EDI data submission has not been performed for more than two years (SLC T36). Finally, there is no formal assessment of staff competence to perform EDI data submission (SLC T12 and T15a). The centre recognises some of these non-compliances and corrective actions are planned: The QM related that a process to identify training needs was to be introduced imminently; the 'Simple guide to EDI' was being updated; and an EDI process

audit was planned. Despite these proposed corrective actions, these non-compliances are of concern given the timeliness and quality of data submitted to the HFEA was an issue of non-compliance highlighted in the incident inspection report in June 2011 and at the last renewal inspection in 2010, and continues to be so (General Direction 0005; SLC T9e).

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
This subject is discussed in Section 2: Patient Experience.

Disclosure of identifying information to researchers
Consent to disclosure forms were seen to be present in all eight patient records reviewed on inspection and included consent to disclosure of identifying information from the HFEA register to researchers (Chair's Letter CH(10)05).

What the centre could do better.

Consent to disclosure of identifying information to researchers
The operational audit inspectors audited 18 forms in the medical records recording consent to disclosure to researchers of identifying information from the HFEA register, against the consenting decision recorded on the HFEA register. In seven (39%) of the 18 forms audited, the register did not reflect the fact that the patient or partner had provided a consent to disclosure in their medical records. Thus the centre's data submission to the HFEA had been inaccurate (SLC T9e). These discrepancies mean that the consent expressly given by patient and partners cannot be acted upon and the pool of data available to researchers is reduced.

5. Changes/improvements since the renewal inspection on 14/15 April 2010 and the post-incident inspection on 15 June 2011 and follow-up inspection on 20 January 2012.

The centre underwent a renewal inspection on 14/15 April 2010. The renewal inspection report cited one critical area of non-compliance, 23 major areas of non-compliance and 10 other areas of practice that required improvement. When evidence for corrective actions, provided by the PR at that time, was reviewed on 17 December 2010, it was determined that corrective actions had been implemented to address nearly all the non-compliances. Those remaining comprised: one critical area of non-compliance (the safety of the cryostore, where a major programme of renovation and re-equipment was on-going and was completed in early 2011); three major non-compliances (two regarding TPAs, which were being corrected as agreements were renewed; one concerning the semen assessment service not being accredited); and one 'other' area of non-compliance concerning the audit and minimisation of embryos used in training.

The incident inspection on 15 June 2011 investigated the likely causes of two serious incidents. It highlighted non-compliances (seven critical and four major) in several areas of practice, some of which had been found lacking at the renewal inspection on 14/15 April 2010 albeit for different reasons in some cases. These areas included: the accreditation of the semen assessment service; the matching of treatment activity to staff resources; donor recruitment and screening; QI monitoring and audit of practices; validation; recruitment of an effective QM; and inaccurate EDI data entry. Other issues identified included declining success rates and whether suitable practices were being used; and witnessing errors.

A follow up inspection on 20 January 2012 assessed the implementation of recommendations made in the report of the incident inspection on 15 June 2011 to address the non-compliances that had been noted. The report stated: 'at the time of this inspection the PR was able to provide evidence that all the recommendations in the inspection report have been complied with or are in the process of being complied with, as work on some corrective actions is on-going (e.g. liaising with patients regarding the use of inappropriately screened donor sperm; audits and quality indicator monitoring; validation; accreditation of the andrology service)'.

In summary, those areas for improvements identified in the table below for investigation at this inspection are: those related to non-compliances identified by the renewal inspection on 14/15 April 2010 which were not confirmed as resolved by 17 December 2010; and those related to non-compliances identified by the incident inspection of 15 June 2011 where actions were on-going and not confirmed as resolved by the follow up inspection on 20 January 2012. Also included were the non-compliant areas identified at the renewal inspection on 14/15 April 2010, which were said to be resolved after that inspection but which the incident inspection on 15 June 2011 found to remain non-compliant. Though the follow up inspection on 20 January 2012 found these areas to be subject to completed or on-going corrective actions, it was thought prudent to include them as they may represent areas which the centre finds hard to maintain continually compliant.

Area for improvement	Action required	Action taken as evidenced during this inspection
14/15 April 2010: Critical 1 There are multiple non-compliances in the cryostore facility related to: a) The alarm system is potentially non-compliant with Guidance 26.4c b) The cryostore has failed a Health and Safety Inspection, thus its continued use is contrary to CoP Guidance 25.7 c) There is inadequate spare storage space to enable transfer of samples if a dewar fails, contrary to CoP Guidance 26.4d. The suitability of the cryostore for licensed activity is thus questionable (Licence Condition T17)	The PR must ensure the safety of the cryostore for staff and stored samples, and ensure compliance with CoP Guidance 26.4c, 26.4d and 25.7. Assurances were provided on inspection of the Health Board's commitment to quality and safety and to compliance with regulatory requirements. Thus it is expected that all assistance required by the PR to ensure the safety of the service will be provided. These actions should be immediately initiated and completed as quickly as possible.	Email exchanges with the centre during 2010/2011 and review of the cryostore on inspection on 15 June 2011 and 20 January 2012 indicate this recommendation had been implemented. Observations during this inspection confirmed the completion of a significant amount of work to correct the deficiencies in the cryostore. Non-compliances were however observed (see Section 1, Protecting patients and children born following treatment: Good clinical practice; What the centre could do better; Equipment and materials). Further actions are required.
14/15 April 2010: Major 1 A list of all suppliers of goods and services which impact on the quality and safety of gametes and embryos was submitted to the HFEA. The centre does not have transport or satellite centres. TPAs are in place with some but not all suppliers, non-compliant with Licence Condition T111.	The PR should ensure that TPAs, compliant with Licence Conditions, are in place with all suppliers of goods or services which could impact on the quality and safety of gametes and embryos, as well as with the centre providing contingency service, as required by Licence Condition T111. This should be completed by 1 October 2010.	On this inspection it was seen that agreements were present for all third parties listed under SLC T111. No further action is required to implement this recommendation. It was also noted however that the content of the TPAs is not compliant, as discussed in Section 1, Protecting patients and children born following treatment: Good clinical practice; What the centre could do better; TPAs. Further actions are required.

14/15 April 2010: Major 2 The compliance of third parties with HFEA requirements has not been evaluated, non-compliant with Licence Condition T112, nor is compliance with the HFEA CoP a stated requirement of the TPAs already in place, non-compliant with Licence Condition T116.	TPAs should be revised at the next opportunity, to include that the third party should comply with all relevant HFEA requirements. The PR should take action to evaluate the compliance of third parties with HFEA requirements. This should be completed by 1 April 2011.	The content of TPAs was not compliant with CoP requirements, as discussed in Section 1, Protecting patients and children born following treatment: Good clinical practice; What the centre could do better; TPAs. Further actions are required.
14/15 April 2010: Major 3 The andrology laboratory provides testing services for the centre's patients but is not accredited by an appropriate body, contrary to Licence Condition T21.	An action plan has been developed for CPA accreditation of the andrology service. The PR should implement this as quickly as possible and appropriate accreditation should be obtained for the andrology service by 1 January 2011.	No significant progress had been made regarding this non-compliance prior to this inspection. On this inspection, credible plans to obtain CPA accreditation within 15-18 months were presented, as discussed in Section 1, Protecting patients and children born following treatment: Patient selection criteria and laboratory tests; What the centre could do better; Procuring, processing and transporting gametes and embryos. Further actions are required.
14/15 April 2010: Other 1 The SOPs for consenting for the use of sperm, oocytes and embryos in training, provide no commitment or mechanism to ensure that the number of embryos used is minimised to those needed for adequate training (Licence Condition T96). Furthermore, there is no documented audit of embryo use in training, to ensure they have been	Minimising embryo usage in training to that required for the training purpose, and auditing embryo usage, should be included in procedures, to comply with Licence Condition T96. The inspectorate also suggests that a QI and objective be developed regarding documenting the training purposes for which embryos are used and ensuring all such embryos are used effectively.	The requirement to minimise embryo use in training has been removed from the CoP. On this inspection it was noted that embryos are currently not used in training and that the centre has carried out an audit of its past embryo use in training. See Section 3, Protection of gametes and embryos: Use of embryos in training staff for details. No further actions are required.

appropriately and effectively used (i.e. Licence Condition T96 has been complied with). No embryos have however been used in training so this has not caused a breach of Licence Condition T36.	These actions should be completed by 1 August 2010.	
15 June 2011: Critical 1 The inspection team take the view that the centre has been non-compliant with SLC T12 in recent months, in that the centre could not undertake both the treatment of patients and all the other activities necessary to support the compliance of the centre, for example work supporting the QMS and EDI data entry, with the staffing resources available.	To allow the centre to function efficiently and effectively with the reduced staffing resources and to undertake the corrective actions to comply with their regulatory requirements, the inspection team consider that the number of cycles performed should be controlled. The inspection team propose that the centre should limit the number of IVF or ICSI cycles provided to six cycles per week in total, and of frozen embryo transfers to two per week in total, until all corrective actions described in this inspection report are completed. This activity limit should be immediately implemented. Once corrective actions have been completed, the PR should ensure that activity only increases to a level at which the staffing resources available can safely provide the treatment	During the inspection on 15 June 2011, the new PR stated that activity had been reduced to six egg collections, two FETs and two IUIs per week. The inspection team formally recommended these limits to the Licence Committee and that the activity limits be averaged. On the 15 December 2011, the Licence Committee placed an additional condition on the centre's licence stating: 'For the remainder of the licence, and calculated over a six-month period, the centre must limit the number of IVF or ICSI cycles provided to an average of 24 cycles per calendar month in total, and of frozen embryo transfers to an average of 8 per calendar month in total.' The follow up inspection on 20 January 2012 noted that the QI dashboard includes activity levels and is reviewed monthly by the PR to verify activity is controlled. The booking of patients into the treatment pathway is controlled by the Lead Nurse. The centre also has a risk assessment for the impact of staffing resources on treatment activity which is used to maintain activity at a safe level. The inspection team considered the centre had implemented the recommendation.

	services and simultaneously maintain regulatory compliance.	On this inspection, the inspection team confirmed that the activity control measures seen on 20 January 2012 remain in place. They also reviewed the past activity levels and found no evidence that activity has exceeded the limits stated in the additional licence condition. It also became apparent that staffing losses in recent months may have impacted on the centre's regulatory compliance. These issues are discussed in Section 1, Protecting patients and children born following treatment: Staff engaged in licensed activity; What the centre could do better; Staff. The PR related the centre's plans to recruit several new laboratory and clinical staff members to address these matters. No further actions are required to implement the recommendations but continuing action is needed to ensure that activity is set at a level at which the staffing resources can safely provide the treatment services and maintain regulatory compliance.
15 June 2011: Critical 2 The disposal of some pre-2007 stored samples was undertaken without effective identification and witnessing, SLC T71 and SLC T99a.	The contents of the two dewars used for pre-2007 samples, now in a single new dewar, should be audited against the storage log to determine which patients' samples have been discarded. Patients will need to be advised about the accidental discard of their stored material. The PR should provide the Executive	The follow-up inspection on 20 January 2012 found that the contents of the dewar used for storing pre-2007 partner sperm had been audited. Missing samples had been identified (one straw from each of three patients) and appropriate corrective actions taken. A report of the audit was provided to the inspection team who concluded that the centre had fully complied with the recommendation. This issue did not need to be specifically followed up on this inspection but it was found that the sperm samples in another 10 dewars have not been recently audited and

	with an action plan, by 5 August 2011, regarding this audit of samples and, if necessary, how sperm providers will be approached if it is found that their samples were inappropriately allowed to perish.	some were thought to be passed the expiry of storage consent (HF&E Act 1990 (as amended) Schedule 3, 8 (1)). This is discussed further in Section 2, Patient Experience: Consent to storage. No further actions are required to implement the recommendation but action is needed to ensure the compliance of sperm storage at the centre.
15 June 2011: Critical 3 Donor screening and laboratory testing has been non-compliant with SLC T52 and SLC T53c. The donor recruitment programme at the centre should be suspended until actions are taken to support its safe resumption.	The contents of the two dewars used for donor samples should be audited against the storage log to ensure that all samples are stored in the correct dewar. Donor records should also be audited to ensure donor samples released for use have been appropriately released, i.e. quarantined for 180 days and released after review of the required set of screening test results. Where donor gametes have not been appropriately released, further screening results should be sought or tests commissioned, to determine the degree of risk to users of those gametes. The risk to users of donated gametes in general should also be considered if inappropriately released donated gametes are likely to have	Monitoring after the incident inspection on 15 June 2011 and subsequent review during the follow up inspection on 20 January 2012 and thereafter, provided strong evidence that the centre had implemented these recommendations. This issue did not need to be specifically addressed at this inspection but relevant observations are discussed in Section 1, Protecting patients and children born following treatment: Donor recruitment, assessment and screening. No further actions are required.

	transferred pathogens into the 'in use' dewar. If significant risk to donated gamete users is detected, the centre should inform those patients of the risk and arrange appropriate testing, counselling and clinical care. The PR should provide the Executive with an action plan, by 5 August 2011, regarding this audit of samples and how the users of the donated samples will be approached if they are considered to be at risk.	
15 June 2011: Critical 4 The PR should ensure an effective QI monitoring programme is established and maintained for all critical activities and processes within the centre (SLC T32 and T35).	The PR should review the centre's documented QI monitoring programme against the HFEA guidance regarding QIs. When an appropriate set of QIs has been defined and documented, the PR should ensure that: mechanisms for monitoring them are present *and* operational; quality objectives or control limits are established for each QI, QI data review frequencies and responsibilities are defined; and mechanisms for taking corrective actions are present.	The follow-up inspection on 20 January 2012 reported that 'the QIs reviewed at the centre are wide-ranging and monitor all key activities and processes. The centre has implemented this recommendation and no further actions are required beyond the continued monthly preparation, review and response to the dashboard QIs.' The relevant observations on this inspection are reported in Section 1, Protecting patients and children born following treatment: Good clinical practice; QMS. No further actions are required.

	The HFEA Executive should be provided with a monthly update on progress and the action should be completed by 30 September 2011.	
15 June 2011: Critical 5 The PR should establish an effective procedural audit programme to verify that critical practices and processes at the centre adhere to the documented SOPs and that those SOPs comply with regulatory requirements. Mechanisms should also be in place to review those audits, and to document corrective actions and their implementation (SLC T36 and T32). To initiate this action, the PR should review the centre's documented audit programme and ensure all critical processes and practices are included, notably witnessing and donor recruitment, screening and release. The PR should ensure adequate resources are available to perform those audits, to review the audit reports, and to implement any corrective actions necessary. The HFEA Executive should be	The PR should establish an effective procedural audit programme to verify that critical practices and processes at the centre adhere to the documented SOPs and that those SOPs comply with regulatory requirements. Mechanisms should also be in place to review those audits, and to document corrective actions and their implementation (SLC T36 and T32). To initiate this action, the PR should review the centre's documented audit programme and ensure all critical processes and practices are included, notably witnessing and donor recruitment, screening and release. The PR should ensure adequate resources are available to perform those audits, to review the audit reports, and to implement any corrective actions necessary. The HFEA Executive should be provided with the revised audit	The follow-up inspection on 20 January 2012 reported that the PR had provided an audit plan for 2012 and nominated a clinician as audit coordinator. The Lead Inspector made recommendations regarding the activities to be audited and the need for practice audits. The PR presented a revised audit plan and the inspection team concluded that the centre had implemented this recommendation. No new actions were required beyond those already being progressed, i.e. the implementation of the audit plan. The relevant observations on this inspection are reported in Section 1, Protecting patients and children born following treatment: Good clinical practice; What the centre could do better; QMS. Further actions are required to implement this recommendation.

provided with the revised audit programme by 5 August 2011.	programme by 5 August 2011.	
15 June 2011: Critical 6 Changes in processes and practices at the centre should be validated before implementation (SLC T24 and T72). This validation must be documented. At the renewal inspection on 14/15 April 2010 the centrifuges had not been validated.	The PR should review changes made in the last year to the centre's practices and processes and ensure a documented validation process is in place for each significant change. This action should be completed by 5 August 2011.	The validation of equipment and processes is discussed in Section 1, Protecting patients and children born following treatment: Good clinical practice; Validation. Further actions are required.
15 June 2011: Major 1 Donor screening, storage and release processes and SOPs, as well as all documentation relating to donor storage, screening and release, have not been recently audited, reviewed or revised to ensure their compliance with HFEA CoP requirements (SLC T36; T52; T53).	While donor recruitment at the centre is currently suspended, donor screening, storage and release processes and SOPs, as well as all documentation relating to donor storage, screening and release, should be audited immediately to ensure their compliance with HFEA CoP requirements. One expected issue will be the use of a blood test instead of a urine nucleic acid amplification test to screen for chlamydia (SLC T52; T53; T36). Any non-compliances should be corrected, and should also be reviewed to determine whether the non-	All donor screening, storage and release processes and SOPs, as well as documentation relating to donor storage, screening and release, were reviewed in response to the incident inspection on 15 June 2011. They were provided to the Lead Inspector and after some revisions by the centre were compliant, thus no further actions were required. No further actions are required to implement this recommendation.

	compliance may have implications for the safety of users of donor gametes. This action should be completed by 5 August 2011.	
15 June 2011: Major 2 The QM has not been provided with appropriate training for the role and has not enough time scheduled in her job plan to support the role on a permanent basis (SLC T12).	To facilitate the development of the QMS so that it can effectively monitor the centre's activities and prevent non-compliant and potentially unsafe operation, the PR should ensure that the QM is provided with appropriate training for the role and has enough time scheduled in her job plan to support the role on a permanent basis (SLC T12). This action should be completed by 31 August 2011.	The QM attended a three day course of quality management training in early December 2011 and has two days per week allocated to the QM role. The development of the QMS suggests the QM has time to undertake her role and the inspection team considers that this recommendation has been implemented. Some non-compliances remain within the QMS however (see Section 1, Protecting patients and children born following treatment: Good clinical practice; What the centre could do better; QMS) and must be addressed by the PR, the QM and centre staff. No further actions are required to implement this recommendation. .
15 June 2011: Major 3 It was noted by the inspection team that the andrology laboratory has made no progress with attaining accreditation from the CPA, despite this being a corrective action recommended by the report of the renewal inspection in April 2010 (SLC T21).	If the andrology service is to be continued, the PR must ensure that it obtains CPA accreditation at the earliest opportunity. The PR must provide monthly updates until this process is complete.	No significant progress had been made regarding this non-compliance prior to this inspection. On this inspection, credible plans to obtain CPA accreditation within 15-18 months were presented, as discussed in Section 1, Protecting patients and children born following treatment: Patient selection criteria and laboratory tests; What the centre could do better; Procuring, processing and transporting gametes and embryos.

		Further actions are required.
15 June 2011: Major 4 Early outcome forms have not been submitted within 8 weeks of the end of the treatment cycle, as required by General Direction 0005. Note that EDI data submission was also an area of non-compliance at the renewal inspection on 14/15 April 2010.	Actions to ensure that early outcome forms are submitted within 8 weeks of the end of the treatment cycle, as required by General Direction 0005, should be implemented by 31 August 2011.	The centre corrected nearly all inaccuracies in the centre's data set in response to the report of the incident inspection on 15 June 2011. On this inspection however, the non-compliance was seen to have returned since the operational audit team observed problems related to the timeliness and accuracy of EDI data entry, including in the timeliness of early outcome form submission. The compliance of the EDI data entry is discussed in Section 4, Good governance and record keeping: Legal Requirements. Further actions are required.

Areas of practice that require the attention of the Person Responsible

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

Critical area of non compliance

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
Critical 1): At the time of inspection, the centre had not recently audited stored sperm samples and the bring-forward system was not in operation. It is likely therefore that the centre had sperm samples in storage beyond their consented storage period, contrary to HF&E Act 1990 (as amended) Schedule 3, 8 (1). One set of embryos was also being stored after consent for storage had expired, contrary to HF&E Act 1990 (as	The PR must ensure that sperm and embryo samples are stored only when valid consent for storage has been documented by the gamete providers. The PR should review the centre's bring-forward system, the staffing resources available to manage it, the disposal arrangements at the expiry of storage consent and the	The Centre's bring-forward system arrangements have been reviewed and are implemented as follows; Embryos - a brought forward system is in place and embryo recall undertaken by AS. The 1 set of embryos still being stored beyond the consented storage period is subject to a legal dispute	9 July 2012: The PR provided evidence that the one set of embryos stored beyond the consented storage period were subject to legal dispute between the gamete providers. Evidence was also provided that the centre has taken legal advice on the matter which has led to the embryos being retained in storage at present. An audit report of the records of sperm in storage was also provided which stated that of 1143 sperm samples stored before October 1st 2009 currently in storage: 61 are stored beyond storage consent expiry;

amended) Schedule 3, 8 (2).	written information provided to patients regarding storage consent. The PR should provide an action plan to the Lead Inspector by 25 July 2012, stating how the centre will progress to address this non-compliance. The Lead Inspector should be updated monthly regarding progress in implementing corrective actions. All corrective actions should be completed by 25 October 2012.	between the donor couple, which supersedes the current consented storage period (see attached email). Sperm - a recall protocol is in place. Sperm banking audit system implemented and audit undertaken in June 2012 and an appropriate action plan is being drafted to address the audit results (audit attached). The audit highlighted an incident reported verbally to the HFEA on the 27/06/2012. Further investigation has been undertaken by the PR and incident formally reported to the Health Board on the 06/07/2012 and the HFEA on the 09/07/2012. To support ongoing compliance an MLA post will be advertised shortly to	584 do not have all their consent forms complete; 851 are stored without proof of virology screening; 108 are stored without compliant witnessing; and 150 are stored with valid storage consent, compliant witnessing and virology screening tests filed. These audit results have led to an incident report being filed with the HFEA, which was also provided. The report also noted that a physical audit of the stored sperm is still required. 25 July 2012: The PR provided recently revised SOPs for embryo/oocyte and sperm, recall which describe thorough 'bring-forward' systems to ensure these licensed materials are not stored beyond the expiry of their consented storage period. Template letters to be sent to those storing embryos and/or gametes were also provided which make clear that material can only be stored with the providers' consent. A job specification for an embryology practitioner and an internal application to allow the vacancy to be filled were also provided, in evidence of the on-going recruitment of further staff to support an effective bring-forward system.

		assist with the tasks highlighted by the audit. Monthly update reporting system is implemented. Updates will be forwarded to the inspector monthly as requested.	The PR also provided an update regarding sperm stored without consent and the centre's plans to correct the situation. These plans were reviewed by the Lead Inspector and were considered suitable. The PR has indicated a completion date of December 2012 which is reasonable given the scale of the problems indicated by the audit of the records of stored sperm. The inspection team consider that the PR has initiated appropriate corrective actions to address embryos and gametes being stored without consent. These corrective actions are in the process of being completed and their continued implementation will be monitored via the monthly reports to be submitted by the PR to the Lead Inspector. 3 August 2012: The PR stated that the audit of stored sperm samples and associated corrective actions might be completed by the 25 October 2012, as required by the inspection report. The action plan was updated to reflect this revised completion date. 14 August 2012: The Lead Inspector

			advised the PR that because of the significant amount of activity required to bring sperm storage at the centre into compliance, the timeframe for completion could be extended until 31 December 2012. The PR should supply the Lead Inspector with monthly updates on the implementation of the action plan to correction of this non-compliance.
Critical 2): The LM reported that laboratory staffing is inappropriately low to allow laboratory staff time to address the regulatory issues. The inspection team also considers that the reduced staffing level impacts on the centre's compliance. Staffing levels were an issue at the incident inspection in June 2011.	The PR must ensure that the clinical activity level continues to be controlled so that the staff available can safely provide it and can also undertake all necessary activity associated with regaining and maintaining regulatory compliance. This action should be addressed immediately.	The PR can confirm that this non compliance was actioned a year ago after the inspection in June 2011. Since June 2011 all activity levels have continued to have been controlled by the PR. Activity levels reduced in line with the principles below; Week where only 1 embryologist available - no treatments are booked [below current licence restrictions]	25 July 2012: The PR provided in evidence of compliance a detailed risk assessment for staffing and activity level, which the centre has used since July 2011, and a spreadsheet on which the weekly treatment activity booked and actually performed is monitored. The risk assessment describes activity levels which can be safely performed with various clinical, embryology and nursing staffing resources, justified using data from a study of centres across the UK. The activity monitoring sheet provides evidence that the centre adheres to the risk assessed weekly activity levels and to the addition condition on the centre's licence. The Lead Inspector believes this evidence shows that the centre has made significant efforts since the incident inspection in June

		Week when 2 embryologists and trainee available only 4 treatments are booked [below current licence restrictions] Week when 2 embryologists, trainee and locum head of embryology available [full team] 6 cycles planned [within current licence restrictions] To enable the unit to address and maintain regulatory compliance, the PR can confirm that action has been taken to increase staff levels as follows; Interim Head of Embryology appointed until service transfer to ABM at end of Sept 2012. New single service Head of Embryology for the new South Wales service will be appointed 13/07/2012. Advertisement for additional	2011 to control activity at a safe level. However the level of non-compliance and the LM's comments on inspection lead the inspection team to be concerned that longstanding non-compliances at this centre, which take considerable resources to address, mean that more staff are needed to maintain a set activity level than would be required in an "average" centre with a history of on-going compliance The PR should consider this possibility and amend the activity/staff risk assessment if necessary. The Lead Inspector is assured that this issue is being addressed as the PR has stated 'To enable the unit to address and maintain regulatory compliance, the PR can confirm that action has been taken to increase staff levels'. She also provided evidence of the appointment of an interim Head of Embryology, another embryologist and an andrologist. A state-registered embryologist, a medical laboratory assistant, a new consultant clinician, a fertility nurse and an administrative assistant are also in the process of being recruited. Telephone discussion with the PR on the 3 August 2012 confirmed these plans are progressing.

		Band 7 embryologist post was unsuccessful at first attempt. Post readvertised, shortlisting to be completed w/c 16/07/2012 - interview dates will be arranged early August. Band 6 trainee embroyologist appointed - commenced post 07/07/2012. MLA (Band 4) post to be advertised in July 2012. Transfer to a single service in October 2012 will support increased further recruitment and staffing cover. Prior to this, in order to provide sufficient staff time to undertake regulatory compliance actions, the lab work will be reduced through outsourcing to 'buddy' unit in Bristol as appropriate.	The Lead Inspector considers that corrective actions are on-going to correct this non-compliance and will be progressed by the PR as quickly as possible.

Critical 3): Audits of all key practices against the SOPs and regulatory requirements have not been performed in the last two years (SLC T36). This issue was also highlighted in the incident inspection report in June 2011 and at the last renewal inspection in April 2010. (SLC T36).	The PR should review the audit programme and procedures and implement corrective actions to ensure that all key activities are audited and audits of practice against the SOPs and the regulatory requirements are conducted. A summary report of the review and any corrective actions and a revised audit programme should be provided to the HFEA by 25 July 2012. Any delays in the implementation of the audit programme should be reported to the HFEA.	The PR can confirm that audits of all key practices against SOPs have been undertaken for all nursing and medical staff in 2010 and repeated in 2012. Audit of key practices for embryology staff will be undertaken by LM and will be completed by 25/07/2012. The updated audit plan, documented practical audit papers, and any resulting corrective actions will be forwarded to the Inspector as requested by the 25/07/2012.	25 July 2012: The PR provided evidence of competence assessments of nursing, embryology and medical staff which include audits of some practices against the SOPs. Audit of embryology, medical, nursing and administrative practices against the SOPs is now included in the revised audit schedule for 2012/13, which was provided to the Lead Inspector. The PR provided template documents for use in the audit of processes. It is also apparent that QI monitoring data can contribute to practice audits in many areas. The Lead Inspector considers that some corrective actions have been taken to implement the specific recommendation. The fine detail of the schedule for practice audits has not yet been documented however and the PR was advised on this matter on 6 August 2012. Many of the actions taken in response to this report's recommendations will be recorded in the centre's SOPs and evidence of their implementation can be obtained by the audit of practices against the SOPs. The results of the audit of practices will also contribute to the process validation documents. The PR must therefore ensure the audit plan is refined and implemented.

			The PR should provide monthly updates regarding the audit plan and its revision and implementation to the Lead Inspector. This issue will also be reviewed regularly by the Lead Inspector through the on-going monitoring process.
Critical 4): The operational audit found problems with the timeliness and accuracy of treatment data submission to the HFEA (SLC T9e; General Direction 0005). The timeliness and accuracy of EDI data submission were highlighted as areas of non-compliance by the reports of the last renewal inspection in April 2010 and the incident inspection in June 2011. Issues were also observed suggesting further training and competence assessment are required for EDI data entry (SLC T12 and T15a). The SOP for use of the EDI system was also not in use and needed revision (SLC T33b) and a full audit of the processes for EDI	The PR should review procedures for submission of information to the HFEA register to ensure that the centre's systems, processes and staff competence allow timely and accurate reporting of treatment data to the HFEA register. A report of the review, any planned corrective actions and the timescale for implementation of those actions, should be provided to the HFEA by 25 July 2012. Any delay in implementing corrective actions should be reported to the HFEA. The PR should also ensure that training to perform EDI data entry is consistently provided to all relevant staff.	The PR can confirm that the updated SOP for submission of information to the HFEA register is in place. The QM reviews the HFEA online EDI compliance on a weekly basis and takes any corrective action required. The SOP includes competencies record and allows audit of staff awareness of required submission timescales (attached documentation). The KPI risk tool from HFEA clincal portal is included into EDI data entry SOP. The reported error rate has	25 July 2012: The PR provided in evidence of compliance the SOP for EDI data submission, a document defining the EDI reporting responsibilities at the centre and the guide to EDI data submission, which have all been recently revised. The EDI form error rate is regularly reviewed through the clinic portal EDI data reports and the centre's QMS. HFEA Registry staff reported that the centre's EDI form error rate is much improved and work on correcting historic EDI data errors is on-going. Indeed errors are present in 69 forms submitted since 1 January 2011. This error rate is much reduced from that seen on inspection, but is not 'minimal' as the PR states in her response. 17 August 2012: HFEA registry staff report that the centre current has errors in forms associated with 46 patients. The Lead Inspector considers that

data submission has not been performed for more than two years (SLC T36). The centre recognises some of these non-compliances and corrective actions are planned. These non-compliances are of concern given the timeliness and quality of data submission was an issue of non-compliance highlighted in the incident inspection report in June 2011 and at the last renewal inspection in 2010, and continues to be so (General Direction 0005; SLC T9e)	Competence should be assessed. Training and competence assessment should documented. The SOP for EDI data entry should be reviewed and released for use. These actions should be implemented by 25 July 2012.	reduced from 997 in June 2011 to minimal errors in May 2012, which are rectified through the weekly QM process.	corrective actions are on-going to correct this non-compliance, but notes that all errors need to be corrected. The PR should ensure that corrective actions continue and eradicate the remaining form errors. Thereafter EDI form errors should be cleared within the timescales specified in General Direction 0005. This issue will be subjected to on-going monitoring by the Lead Inspector.
Critical 5): A survey of the dewars in January 2010 stated that many needed replacement. This was highlighted by the renewal inspection in April 2010 and the centre was required to renovate the cryostorage facilities. The Executive was subsequently advised that all defective dewars had been replaced. On this inspection, one dewar, described in January 2010 as 'very old and	The PR should review the continued use of the dewar and should ensure that the storage of sperm samples within it is safe. If continued storage is found to be unsafe, actions should be taken to safely store the sperm samples. The dewar concerned should be removed from service until it has been repaired and revalidated.	The PR can confirm that the samples of the 4 patients will be moved to alternative tank on the w/c 16/07/2012 to ensure LM presence for oversight of the transfer. The dewar will then be disposed and the PR can confirm 2 new dewars have been ordered.	3 August 2012: In a telephone conversation on the 3 August 2012 the PR stated that the dewar tank had been reviewed by the new LM and had been deemed to be repairable. Review of liquid nitrogen usage data for the dewar in question, compared with six other dewars, indicated to the new LM that it was safe to use. This information has been provided by the LM who also stated that the repair required is a replacement of the dewar's neck core stopper and that this has been on order since 10 July 2012.

neck cork broken', was seen to be in use and to contained sperm from four patients. The inspection team suspect this is hazardous to staff and may pose a risk to the quality and safety of the sperm (SLCs T23 and T24).	These actions should be implemented by 25 July 2012. A summary report of the actions taken should be provided to the HFEA in the same timescale.		The inspector considers that this is a reasonable response and that no further corrective actions are needed. 9 August 2012: The LM advised that the replacement neck core has been delivered and fitted to the dewar in question. The dewar will now be monitored to ensure it is fit for service. No further action is required.
Critical 6): The laboratory undertakes diagnostic semen analyses and is not accredited by the CPA or an equivalent body. The laboratory also does not participate in the NEQAS for semen assessment (SLC T21). The lack of CPA accreditation for the semen assessment service was an issue highlighted at the last renewal inspection in April 2010 and at the incident inspection in June 2011.	The centre should seek to obtain semen analyses from an appropriately accredited laboratory by progressing, as quickly as is practicable, with the plan provided soon after the inspection to obtain CPA accreditation for the centre's semen analysis service. This should include entering the NEQAS scheme for semen analysis (CoP Guidance 23.23). The PR should provide monthly progress reports to HFEA regarding progress	The PR can confirm that the unit is currently working through the requirements for CPA accreditation with external expert support from Aneurin Bevan Health Board. The CPA accreditation action plan is attached. Monthly progress reports are being implemented to ensure compliance will be achieved. The laboratory participation	25 July 2012: The centre is progressing with its plan to gain CPA accreditation for the andrology service. The PR provided a suite of SOPs and supporting documents for the andrology service which have been revised, the action plan for obtaining CPA accreditation and a list of equipment and consumables which have been ordered to provision the service. Evidence was also provided of the secondment to the centre from 1 June 2012 of a senior andrologist (who has managed another andrology service to CPA accreditation) and that the service has registered with the NEQAS scheme for semen analysis and achieved good results in the first of the quarterly assessments.

	towards accreditation.	in the NEQAS scheme has been reinstated. Currently rated at amber level which is reduced from red. Indication to improve to green following latest validation (see email attached)	The Lead Inspector considers that corrective actions are on-going to correct this non-compliance and will be progressed by the PR as quickly as is feasible. The Lead Inspector considers the continued non-compliance to be low risk, as external quality assurance through NEQAS is now being performed and staff of appropriate competence and experience are present to support the service.

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
Major 1): Counselling referrals have almost doubled in the last year but counselling staff resources have not increased. There is also no cover if the counsellor takes leave so the counselling service is suspended. This situation is potentially non-compliant with SLC T12 and may prevent the centre from meeting the requirements of SLCs T60 and T61.	The PR should review the counselling provision and ensure that the counselling service can continue to be provided in the event of the absence of the centre's counsellor. This action should be completed by 25 July 2012 and the Lead Inspector informed of the actions taken.	The PR can confirm that improved access to the counselling service is now available. This has appropriately led to the observed increase in counselling referrals/patient requests. New service cover arrangements to support the appropriate delivery of this demand are in place as detailed below; The PR can confirm that an Honorary Employment Contract for a second independent counsellor	25 July 2012: The PR's response suggests that the increased counselling activity is a result of easier access to counselling and has not produced a counselling staff resource issue. This seems reasonable since the Counsellor works for approximately 150 days per year and the centre provides approximately 300 treatment cycles per year at present. The PR also provided evidence that the centre are in the process of issuing an honorary contract to another Counsellor to provide service cover when the Lead Counsellor is absent. Patient information sheets given to all patients were also provided by the PR as evidence that all patients are informed about the counselling service

		currently employed by London Womens Clinic has been established. This ensures that a counselling service is continuously available for patients even during leave periods (evidence attached). The PR can confirm that the patient information has been updated to indicate that a counselling service is available consistently (attached). All of the above actions meet the requirements of the service and HFEA recommendations.	The Lead Inspector considers that corrective actions are on-going to correct this non-compliance and will be progressed by the PR as quickly as possible. The PR should update the Lead Inspector when the second Counsellor has been appointed.
Major 2): The centre's processes have been validated but the validation report has not yet been provided to the centre by the external validation company (SLC T72). The validation programme has overrun the deadline for	The PR must ensure the completion of the process validation programme by the 25 July 2012. The PR must also ensure that appropriate resources are available to implement the corrective actions required by the	The draft independent report was provided to the HFEA inspectors in April 2012 (draft attached). The PR can confirm that a face to face meeting is scheduled for LM and Validair	25 July 2012: This response refers to the equipment validation report and is irrelevant to this non-compliance which concerns the lack of critical process validation. This issue will be further discussed with the centre. Further action is required.

completion (mid-February 2012) reported in the incident follow up inspection report in January 2012. The LM stated that the process validation report will now be completed by the end of May 2012. The centre remains non-compliant with SLC T72 until the process validation report is completed.	validation report to address non-conformities. These actions should be implemented by 25 July 2012 and the Lead Inspector informed of the actions taken.	w/c 16/7/2012 to confirm the final validation report and review progress against recommendations. Any further or outstanding actions arising will be addressed appropriately within the timescales. The final report and actions will be sent to the Lead Inspector by the 25/07/2012.	10 August 2012: Discussions with the new LM indicate that process validation by the external validation company will not be progressed. Instead the clinical processes have been validated by the PR; this document was provided at the inspection in April in draft and was of reasonable standard. It is now to be completed and finalised. The new LM also provided a validation document for the laboratory processes which is well-developed but will be completed with QI monitoring and practice audit data as it is performed. The LM advised that the clinical and laboratory process validation documents have now been combined into a single document which will be completed and finalised by 25 October 2012. Further actions are required to finalise the process validation documents. This should be achieved by 25 October 2012 and will be reviewed through the on-going monitoring process by the Lead Inspector.
Major 3): The equipment validation highlighted a significant number of non-	The PR should ensure that all equipment is validated and all non-conformities have been	The PR can confirm that there is a Dewar alarm system in place and fully	25 July 2012: The equipment validation report was provided in evidence by the PR. A contract with a supplier to provide

conformities: e.g. lack of servicing of the dewar alarm system; temperatures above limits in a reagent fridge and below limits in some incubator locations; some incubators not calibrated; absence of air quality monitoring data for air flow cabinets; absence of user SOPs; absence of electrical safety testing. Some non-conformities have been addressed but most have not (SLC T24).	addressed. These actions should be implemented by 25 July 2012 and the actions taken advised to the Lead Inspector.	operational. The Dewar alarm system checked weekly. The service contract is under review and action already implemented. One fridge repaired and one new fridge have been ordered by the LM. The QC temperature was corrected on 7/6/2012. The previous fridge target temperature was listed as 10c. This is now amended to for a target temperature of 5c. The tolerance range is 2c-8c. The PR can confirm that this is now compliant with the recommendations from the culture media companies [Origio and Vitrolife] The PR can confirm that air quality in laboratories and theatres is checked by Agar plate - audit report enclosed.	servicing and calibration of the mini-incubators was also provided. No other evidence of corrective actions in response to non-conformities seen on validation was supplied at this time. Regarding the PR's comments: • The dewar alarm system may be fully operational now but needs to be serviced to ensure it remains so. • The repair of one fridge and the ordering of a second is an advance, as is the revision of the QC target to 5 C, range 2 – 8 C and the confirmation with media manufacturers that these temperature limits are as they would recommend for media storage. • The testing of air quality in the critical work areas and background using agar plates on the 14 May 2012 was described in an air quality report provided on the 9 July 2012. The report contained no data however, so further information was requested. • The Lead Inspector notes that PAT has been performed on 19 June 2012 and that SOPs for users, with actions in the event of failure (presumably for equipment in the laboratory), are being written. The implementation of

		The PR can confirm that PAT testing undertaken on the19/6/2012 and is now complete. With regards to the Incubator calibration / absence of AQ monitoring data - SOPs for users/actions in failure are being written by the LM and will be in place by the action date. The Carecom service agreement is now in place. All bench top incubators are covered by warranty as confirmed by the LM.	corrective actions to address non-conformities already identified through validation remains essential. The Lead Inspector considers that further actions are still required. 10 August 2012: The new LM provided the equipment validation corrective action log and supporting information which indicated that: • The dewar alarm system was serviced on 1 August 2012 and was approved for use. • A new fridge has been delivered and is being validated before use. • Air quality testing data from the 14 May 2012 was provided which indicated that compliant air quality was present in the laboratory critical work areas and background. Further testing arrangements are discussed in Major 8). • In summary, 42 of 45 non-conformities identified by the validation have now been corrected. Two of those still outstanding will be corrected when the new monitoring and alarm system is introduced (see Major 7). The final one will be

			corrected by the issuing of a new TPA as part of corrective actions associated with 'Other 8'. The Lead Inspector considers that no further actions are required to address the particular non-conformities which led to this non-compliance being identified.
Major 4): Consumables which may influence the quality and safety of the gametes and embryos have not yet been validated to ensure their suitability (SLC T28).	The PR should ensure that all such consumables are validated to ensure their suitability. This should be completed by 25 July 2012 and provided to the Lead Inspector.	The PR can confirm that all consumables are CE marked (see email attached). MEA assurances are additionally reported in accordance to EUTCD. Central reporting system for all minor variances in use of equipment and near misses to be kept by QM.	25 July 2012: The procurement department have assured the centre that all consumables supplied by third parties are CE marked. The PR noted that all consumables used in oocyte and embryo culture are mouse embryo assay (MEA) tested. A non-conformities log and reporting form were provided in evidence of the reporting system. If used effectively these tools will support the use of appropriate equipment and consumables. CE marking and MEA testing contribute to validation but the centre needs to audit consumables available in the laboratory and clinical area for CE marking and MEA testing, to confirm this fact. The audit report should be sent to the Lead Inspector by 25 October 2012. Other evidence in support of the

			validation of consumables should also be documented. The evidence provided falls short of providing assurance that validation of consumables has been provided so further action is required. 10 August 2012: Discussions with the new LM indicate that process validation by the external validation company will not be progressed. Instead validation documents are being prepared by the PR and LM. These documents should also include validation data for all consumables which influence the quality and safety of the gametes and embryos.
Major 5): The oxygen monitoring system and dewar probes and alarm system have not been serviced since 2009; both systems are well beyond their normal service intervals (SLCs T24 and T26).	The PR must ensure the low oxygen monitor and the dewar probes and alarm system, are periodically serviced to check their function and support their future reliability. These actions should be implemented by 25 July 2012 and the actions taken advised to the Lead Inspector.	The PR can confirm that a service agreement is in place - service contractors and service visits are being scheduled before 25/07/2012 as part of the ongoing service agreement.	25 July 2012: The recently established service contract will facilitate maintenance and servicing of the dewar and low oxygen alarm systems. No evidence was however provided that a servicing visit has been performed or is scheduled. 10 August 2012: The LM provided evidence that the cryostore alarm systems were serviced on 1 August 2012. No further actions are required.

Major 6): At the last dewar service in 2009, it was noted that two probes were 'incorrectly calibrated'. No evidence was available of subsequent corrective actions (SLCs T24 and T26). A similar situation was observed regarding a filter on the down flow of an air flow cabinet which failed the last service but has not been replaced (SLCs T24 and T26).	The PR must ensure that corrective actions are taken in response to non-conformities which arise during equipment servicing. The issues with the dewar probes and air flow cabinet filter should be addressed. These actions should be implemented by 25 July 2012 and the actions taken advised to the Lead Inspector.	The PR can confirm that the filter is fitted - the delay to redressing this is was as a result of the incorrect equipment being delivered in first instance by the company. The Probe calibration issues are being addressed as part of the service contract - see major 5 above	25 July 2012: The Lead Inspector notes that the air flow cabinet filter has now been replaced and that the centre had been advised by the manufacturer that the unit would operate within its specified limits even though the filter had failed on servicing. The Lead Inspector accepts that the dewar probes will be dealt with when the dewars are serviced to satisfy recommendation Major 5). 10 August 2012: The LM provided evidence that the cryostore alarm systems were serviced on 1 August 2012 and that this included re-calibration of the two probes. No further actions are required
Major 7): The incubator carbon dioxide meters are not connected to a dial-out alarm system to summon assistance if carbon dioxide levels fall below defined limits, neither is the carbon dioxide manifold supplying the incubators so alarmed (SLC T24).	The PR should review the monitoring of critical parameters and associated alarm systems to ensure they are appropriate and will guarantee that critical parameters are maintained within acceptable limits at all times.	The PR can confirm that there is an alarm system in place with automatic dial through to UHB central switchboard in the event of any incubator failure. There is a 24/7 Embryologist on-call should the alarm be raised.	10 August 2012: Telephone and email communications with the LM have revealed that the incubator carbon dioxide levels are monitored by probes built into each incubator which are connected to a dial out alarm system. The alarm is activated if the carbon dioxide level falls below defined limits. The report was therefore inaccurate in

The temperature probe on the incubators is integral to each unit and connected to an automatic dial out system. The inspection team had some concerns whether the temperature probe had an independent power supply and would function and activate the alarm system if the electrical supply to the incubator failed (SLC T24).	The results of this review should be provided to the Lead Inspector by 25 July 2012 and any necessary actions should be implemented by 25 October 2012.	The LM is reviewing and benchmarking with other centres, any potential other alarming options available. The results of the review will be provided to the Lead Inspector as requested. Regular testing and assurance system is being implemented. The PR can confirm that the incubators are all connected to UPS (uninteruptable power supplies).	saying the carbon dioxide probes were not connected to the dial out alarm system. The LM has assured the inspection team that the carbon dioxide and temperature probes will trigger the alarm system if power to the incubators is cut. He also noted that the incubators are on a UPS. The LM has also advised that quotes have been obtained for the installation of a new integrated environmental monitoring and alarm system throughout the laboratory. The incubators will be connected to this system. The business case for this investment has been submitted and the LM has been advised that the CVUHB is supportive of the application. No further actions are required regarding this non-compliance.
Major 8): The centre has no documented air quality testing data for the critical work areas and laboratory background air since July 2010 and therefore cannot confirm that air quality in	The PR must ensure that a validated air quality testing programme is reinstituted and that the centre's activities, where required, are undertaken in air of the	As previously outlined in the reponse to Major 3 above - Agar plates used in May 2012 (please see report attached) As part of the final validation	25 July 2012: A map showing the locations of plate and particle count testing of air quality was provided and seems appropriate. The testing of air quality in the critical work areas and background using agar plates on the 14

these areas has been compliant with HFEA requirements since that time (SLC T20).	required quality. These actions should be implemented by 25 July 2012 and the actions taken advised to the Lead Inspector.	report discussion with Validair the LM will confirm that the electronic air quality tester works. The Lead Inspector will be updated accordingly. SOP for air quality tester in testicular biopsy theatre is being developed. SOP will be implemented for every procedure. A map confirming the location of the agar plates and the level of conformity will be forwarded by 25/07/2012.	May 2012 was described in an air quality report provided on the 9 July 2012. The report contained no data however so further information is required. No air particle counts were provided either. Evidence of a validated air quality testing programme being reinstituted has also not been provided. The SOP for air quality monitoring, its validation, and full tests of air quality by agar plate and particle counting were requested. 13 August 2012: Air quality test data from 14 May 2012 was provided and indicated compliant air quality in the laboratory critical work areas and background. A detailed SOP for air quality monitoring was provided which also contained validation of the testing processes. 17 August 2012: The LM informed the inspection team that settle plate and air particle counting performed in the last week has indicate the air quality is compliant with HFEA requirements. No further actions are required.

Other areas of practice that require 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
Other 1): Some clinical, embryology and administrative staff have not completed all modules required for their annual mandatory training (SLC T12 and T15).	The PR must ensure that all staff have the time and opportunity to complete all modules required by their annual mandatory training programme. This action should be implemented by 25 July 2012 and the Lead Inspector informed of the actions taken.	At the time of the HFEA inspection some staff groups contained staff on both long term sick leave and maternity leave. Staff who have subsequently returned to work during the intervening period will have completed mandatory training by 25/7/2012. The 1 remaining admin staff member who has not completed mandatory training remains on Long Term Sick leave and therefore is unable to attend. This will be address as part of standard return to work process. For those staff requiring additional tutor led sessions, arrangements have been made for C&V UHB further	25 July 2012: The PR provided a spreadsheet output from the training software showing that nearly all staff are now up to date with all aspects of the mandatory training programme. In the very few cases in which courses still have to be completed or attended, appropriate actions are being taken to arrange the courses. No further actions are necessary beyond ensuring the staff members complete these final few courses.

		training sessions. Communication sent (email attached) to all line managers to arrange required training for those non-compliant staff.	
Other 2): Some clinical, embryology and administrative staff have not been provided with an annual appraisal within the last year (CoP Guidance 2.3).	The PR must ensure that all staff have the time and opportunity to complete an annual appraisal. This action should be implemented by 25 July 2012 and the Lead Inspector informed of the actions taken.	All administation staff at time of inspection had undergone appraisal and records were available to the inspedtion team. The clinical team had also all undergone appraisal as is compulstory under C&V UHB policy. The locum consultant anaesthetist who had not yet been appraised is now scheduled for w/c 16/07/2012. The embryology staff appraisals will be completed by the locum Head of Embryology w/c 16/7/2012.	25 July 2012: The PR provided evidence that annual appraisals have now been provided to all relevant staff members. No further action is required to correct this non-compliance.
Other 3): The LM believes that all instruments and devices used in the centre's activities	The PR should arrange the audit of all instruments and devices to ensure they are	Audit planned for completion by 25/07/2012.	25 July 2012: The PR provided evidence that the procurement department have assured the centre that

are CE marked but agreed that this has not been recently audited so cannot be said with certainty (SLC T30).	CE marked. These actions should be implemented by 25 July 2012.	In addition procurement confirmation that all IVF consumable orders meeting required quality standard received. See major 4 above.	all consumables supplied to them are CE marked. The centre needs however to audit consumables available in the laboratory and clinical area for CE marking to confirm this fact, as the PR has stated they will do. The audit report should be sent to the Lead Inspector by 25 October 2012. 17 August 2012: An audit of all clinical and laboratory consumables used at egg collection, which could influence gamete quality and safety, was provided. The QM also provided an assurance that the audit of such consumables in all other activities would be completed by 25 October 2012. Actions have been taken to correct this non-compliance but further actions need to be implemented and will be reviewed through the on-going monitoring process.
Other 4): The performance of the QMS has not been reviewed in the last year (CoP Guidance 23.13).	The PR must ensure the QMS is reviewed at least annually. The PR should provide the inspection team with minutes	QMS meeting arranged for 11/07/2012. Minutes will be provided to the inspection team as requested.	25 July 2012: The PR provided the agenda and minutes of a QMS review performed on 12 July 2012, as well as a SOP for management review meetings. These documents provide good evidence of QMS review.

	of the next review of the QMS, which should be undertaken by 25 July 2012.		No further actions are required to correct this non-compliance.
Other 5): SOPs are being reviewed but this programme is progressing slowly and a number have not been reviewed in the last year (55 of 101 listed SOPs and other documents), including the SOPs for witnessing, traceability, ICSI, emergency alarms and air quality monitoring (CoP Guidance 31.6). A significant proportion of other QMS contents, such as the patient information documents, have also not been reviewed in the last year (CoP Guidance 31.6). The significant number of SOPs and patient information documents which are out of date, suggests that document control processes at the centre are dysfunctional (SLC T34).	The PR should ensure that the SOP revision programme is progressed and completed by 25 October 2012. The PR should also ensure that patient information documents are all reviewed by 25 October 2012, and annually thereafter. The PR must ensure that document control is effective. This action should be implemented by 25 July 2012 and the Lead Inspector informed of the actions taken.	The LM is developing an action plan for full SOP review by 25/10/2012. The unit currently has a manual document management system in place. This will be improved as part of the CPA accreditation process which requires use of QPulse which can be used for all QM aspects of SOP renewal for all areas of service ensuring appropriate 'flag' system utilised for SOP review. Patient information documents have been reviewed.	25 July 2012: The PR has provided evidence that patient information has been reviewed. The Lead Inspector also welcomes the plan to use document management software to control SOPs and other documents and the development of an action plan to ensure full SOP review by 25 October 2012. Evidence provided in support of the PRs responses and subsequent communications with the LM have evidenced on-going SOP review. It is clear that actions to correct this non-compliance are being implemented. The issue will be subjected to on-going monitoring to insure the recommendation is fully implemented within the expected timescale, i.e. by 25 October 2012.

Other 6): The centre has not documented procedures for the operation of all items of equipment (SLC T27), albeit equipment operating manuals are available for most of items. The actions to take in the event of equipment failure are not documented for all items of equipment (SLC T27).	The PR should ensure that appropriate SOPs for equipment operation are prepared and that they include the actions to take in the event of equipment failure. This action should be implemented by 25 October 2012 and the Lead Inspector informed of the actions taken.	The PR can confirm that this non compliance is being addressed as part of the overall review of SOPs as outlined above. See Other 5 above	25 July 2012: The PR has provided evidence that patient information has been reviewed and that SOPs for the operation of laboratory gas systems, air flow cabinets, incubators and refrigerators have been documented (including instructions re. responding to malfunction). The Lead Inspector welcomes the plan to use document management software to control SOPs and other documents and the development of an action plan to ensure full SOP review by 25 October 2012. Other evidence provided indicates SOP review is on-going. It is clear that actions to correct this non-compliance have been implemented and are on-going. The issue will be subjected to on-going monitoring to insure the recommendation is fully implemented within the expected timescale, i.e. by 25 October 2012.
Other 7): The centre does not consistently document non-conformities (e.g. in QI monitoring for ICSI), their investigation, the recommended corrective actions and their	The PR should ensure the documentation of all non-conformities, their investigation, the recommended corrective actions, the implementation	The PR can confirm that a Non-conformity/variance page has been added to the dashboard to ensure monitoring, investigation and any required corrective	25 July 2012: A non-conformities log and reporting form were provided in evidence of a system having been developed to log non-conformities and corrective actions. Evidence was also present in the annual QMS review

implementation and subsequent impact (T36: CoP Guidance 23.27). Thus non-conformities can be seen in QI monitoring data but no evidence of their investigation and the implementation of corrective actions is available.	of those actions and their subsequent impact. This action should be implemented by 25 July 2012 and the Lead Inspector informed of the actions taken.	actions (documentation attached).	minutes of the adoption of the non-conformities log by all disciplines at the centre. No further actions are required to implement the recommendation beyond the QM ensuring that all non-conformities throughout the centre are reported and followed up through this system.
Other 8): The content of the TPAs reviewed was non-compliant with SLCs T114a, T114d, T114e, T114f, T116 and T117.	The PR should ensure that the plan, discussed on inspection, to review all TPAs against CoP requirements, to revise them accordingly and to re-issue them, is progressed. The QM said this will be annually assessed in future for a subset of the TPAs. This action should be implemented by 25 October 2012 and advised to the Lead Inspector.	The PR has escalated to the legal department for agreed TP SH w/c 09/07/2012 (email correspondance attached)	25 July 2012: The response from the PR included the template TPA. It was reviewed by the Lead Inspector and was considered to be now compliant with SLCs T114a, T114d, T114e, T114f, T116 and T117. The final sign off of the template by the legal department is on 10 August 2012 and the centre will begin thereafter to re-issue third party agreements to its suppliers. Actions to correct this non-compliance are on-going. The issue will be subjected to on-going monitoring to insure the recommendation is fully implemented within the expected timescale, i.e. by 25 October 2012.

Other 9): The centre has not obtained specific assurances or evidence from third party commercial donor sperm banks that the compensation paid to the donors is compliant with General Direction 0001 (SLC T69).	The PR should contact the third party commercial donor sperm banks and obtain assurance and evidence that compensation provided to sperm donors is compliant with General Direction 0001. The steps taken to obtain this assurance should be documented. This action should be implemented by 25 July 2012 and the Lead Inspector informed of the actions taken.	The PR can confirm that this action has been completed. Information obtained from donor sperm banks regarding payments made to donors. Information from donor banks attached	25 July 2012: The PR supplied in evidence assurances from two donor sperm providers that their compensation arrangements are in line with General Direction 0001 v3. A further donor sperm provider's assurance was not considered to be good evidence but the centre have on 9 August 2012 advised the inspector that they have not used this company since May 2011 and will not do so in the future. No further actions are required.
Other 10): The SOP for import and export of gametes and embryos is also used for transferring samples between centres in the UK, but this use is not clearly stated within the SOP (SLC T33b). The SOP also states that recalled material should be placed back into its original storage location. Such material should be placed into quarantine until investigation of	The PR should review the transportation SOP against CoP requirements and should provide a copy of the revised SOP to the Lead Inspector. This action should be implemented by 25 October 2012.	The PR can confirm that this non compliance is being addressed as part of the overall review of SOPs as outlined above. See Other 5 above	25 July 2012: This SOP will be revised as part of the wider SOP review process needed to satisfy the recommendation associated with 'Other 5'. Actions to correct this non-compliance are on-going. The issue will be subjected to on-going monitoring to insure the recommendation is fully implemented within the expected timescale, i.e. by 25 October 2012. 17 August 2012: A corrected SOP was provided to the Lead Inspector.

the recall has been completed and it has been confirmed that the material is safe and compliant with requirements (SLC T109).			No further actions are required.
Other 11): The final dewar storage location for emergency oncology sperm freezes is sometimes witnessed retrospectively. This is non-compliant with SLC T71 which requires all witnessing to be performed at the time of the process. The LM noted however that guidance on the HFEA website allows retrospective witnessing of gamete storage, contrary to SLC T71 (see: http://www.hfea.gov.uk/docs/witnessing-protocols.pdf).	The PR should ensure that all witnessing is performed at the time of the process whenever possible. When it cannot be, the PR should risk assess practice and ensure it is as safe as possible. This action should be implemented by 25 July 2012.	The PR can confirm that this action has been rectified since the 06/06/2011 with the implementation of a revised crystorage process.	25 July 2012: The PR provided in evidence the revised 'Andrology Sperm Freezing Procedure'. This was seen to have been revised in many ways including manually witnessing samples at the time they are placed into cryostorage. No further actions are necessary to correct this non-compliance
Other 12): The tubes and dishes used during egg collection are not marked with patient identifiers (SLC T101).	The PR should either ensure that the plastic ware is all appropriately labelled during egg collection, or should ensure the practice is risk assessed and that the laboratory SOP for egg collection states that only one	The PR can confirm that a risk assessment has been undertaken which identified that whilst normally only 1 collection is undertaken at any one time. However to provide additional assurance a procedure has been put in	25 July 2012: The PR's response and the evidence provided by the PR (an email to IVF Wales staff dated 22 June 2012 and a revised egg collect protocol) indicate that the PR has taken appropriate corrective actions to correct this non-compliance. Egg collection tubes are now labelled prior to egg

	person's gametes should be in the critical work area at a time and that the air flow cabinet must be emptied of all plastic ware and cleaned between each egg collection. Corrective actions should be implemented and advised to the HFEA by 25 July 2012.	place to label all egg collection tubes and relevant plastic ware to be using the Research Instruments [RII witnessing labels with immediate effect. Staff informed (email attached) and egg collection SOP updated to reflect change in practice.	collection and are included in the witnessing step when the patient is identified against their records. No further actions are necessary to correct this non-compliance
Other 13): The centre has two SOPs for witnessing, which may be confusing to new staff. Neither discusses appropriate witnessing checks during sperm preparation (SLC T33b) or has been reviewed in the last year (CoP Guidance 31.6).	The PR should ensure that the witnessing SOPs are reviewed and revised to be compliant with CoP requirements associated with witnessing checks. The validity of the reasons for using two SOPs should be reviewed and the SOPs should be amalgamated if necessary. These actions should be implemented by 25 July 2012.	The PR can confirm that at present all activities are still both manually and electronically witnessed. Action plan in place to assess current process and recommend changes as follows; LM will create a Risk Assessment folder for manual vs.electronic witnessing. Embryologists to compile the manual and electronic witnessing for the past 50 IVF/ICSI cases.	25 July 2012: The PRs response indicates that one SOP relates to electronic witnessing and one to manual witnessing and that currently electronic and manual witnessing are used. This is a reasonable situation and will not confuse any new staff, and is compliant with CoP requirements. The Lead Inspector understands that the electronic system is undergoing extensive testing in service against the manual system as part of its validation. This is an example of compliant practice. The inspector notes that the non-compliance also included that neither SOP discussed appropriate witnessing checks during sperm preparation (SLC T33b) or had been reviewed in the last

		LM will review this evidence and assess witnessing competence. Provided all is OK, the e-witnessing system should be validated, and can be used thereafter for all acceptable e-witnessing steps. An electronic file has been produced to record any e-witnessing errors. (S-drive - 2012 – IVF Witness Configurations – E-witnessing Non-Conformities)	year. Further actions are necessary to address these outstanding issues. 9 August 2012: The LM provided documents which include manual and electronic witnessing checks during sperm preparation. No further actions are necessary to correct this non-compliance.
Other 14): The SOP for the use of embryos in training does not state that roles involved in the clinical and training uses of embryo should be clearly separated to prevent any actual or perceived conflict of interest (SLC T33b); appropriate working practices to achieve this have not been implemented (SLC T95).	The PR should ensure that the SOP is revised to include the practices used to prevent any actual or perceived conflict of interest between the use of embryos in treatment and training. This action should be implemented by 25 July 2012.	The LM is scheduled to review this in July 2012	25 July 2012: The SOP for the use of embryos in training was provided by the PR in evidence of compliance. It states that roles involved in the clinical and training uses of embryo must be clearly separated but does not state how this is to be achieved. The SOP should be revised to include this information. Some actions have been taken to address this non-compliance but further actions are still required.

			8 August 2012: The LM provided a revised SOP which was compliant in including more detail about the separation of clinical and training roles. No further actions are required.
Other 15): The centre's laboratory and clinical premises and critical equipment within, appeared to be clean, but the centre does not document the cleaning and decontamination of the premises and critical equipment (SLC T26).	The PR should ensure that records of the cleaning, disinfection and sanitation of the premises and all critical equipment are documented. This action should be implemented by 25 July 2012.	The PR can confirm that the cleaning folder with relevant documented audits undertaken monthly were available at the time of the inspection but were not requested. Cleaning audit provided at time of inspection.	25 July 2012: Records of the cleaning of the premises and equipment were requested on inspection but were not provided, hence this non-compliance. Monthly audits of cleaning may be carried out but these do not constitute the appropriate records of the cleaning of the premises and equipment required by SLC T26. Evidence has however been provided by the PR that work sheets are maintained by the facilities personnel which record the daily cleaning of the centre's rooms and satisfy one part of the recommendation. Subsequent email communications with the LM on 7 and 8 August 2012 have provided evidence that equipment cleaning was being logged at the time of inspection but these records were not presented to the inspection team. The LM has developed a system to ensure

			equipment cleaning will be documented in future and has updated and provided the SOP for equipment cleaning which records this revised process. Actions to correct this non-compliance have been implemented and no further actions are necessary.
Other 16): The centre has not performed a PAT programme since 2010 (SLC T26).	The PR must ensure that PAT is performed on the centre's equipment at an appropriate frequency. A programme should be completed by 25 July 2012. The Lead Inspector should be advised when the action is completed.	The PR can confirm that this has been completed. See Major 3 above.	25 July 2012: The PR and the LM have both provided assurances that a PAT programme was performed on 19 June 2012. No further actions are necessary.
Other 17): Some counselling notes are stored in the home of the counsellor. Discussions with the counsellor indicate that the storage arrangements are probably appropriate however the PR has not assessed the confidentiality of the storage arrangements (SLC T43).	The PR should assess the confidentiality of the notes storage arrangements at the counsellor's home. This action should be implemented by 25 July 2012 and the Lead Inspector informed of the actions taken. .	The PR can confirm that the Counsellor has been made aware of requirement for all patient details to be kept on licensed premises. ML informed 26/6/2012 PR will review with Counsellor that all notes are now stored appropriately on	25 July 2012: The HFEA do not require that all notes are kept on licensed premises. The requirement is that all notes are kept securely and access to them is controlled by the PR to licensed staff and any other persons whom patients have specifically consented to being provided access. The PR is responsible for the confidentiality of patient identifying information. This complex situation is reflected in the

		licenced premises by 25/07/2012.	recommendation. The PR has chosen to require the Counsellor on 26 June 2012 to store all counselling records on licensed premises, which will achieve appropriate security for the records and will be under the control of the PR. 9 August 2012: The Lead Inspector was assured that this plan has now been implemented and that counselling records are securely stored within the licensed premises. No further actions are required regarding this non-compliance.
Other 18): The inspection team found in an area open to patients, a computer containing patient identifying information which was unsupervised by staff and could be operated by the inspection team. The inspection team considered that this may allow unlicensed persons to access patient identifying information (SLCs T43 and T44).	The PR should ensure that access to the centre's computers is appropriately controlled (SLCs T43 and T44). This action should be implemented by 25 July 2012 and the Lead Inspector informed of the actions taken.	The PR can confirm that following inspection all PCs updated with appropriate screen saver ensuring PC only accessible by licenced staff.	25 July 2012: Evidence was provided by the PR that all staff have been advised how to protect computers to which they are logged on through activating a screensaver after 5 minutes inactivity. Confirmation has been sought from the centre that these actions will also lock the computer and that the implementation of these actions has been audited. 9 August 2012: An audit of

			implementation of the corrective action was provided. The QM confirmed that the computers are locked by the corrective action. No further actions are necessary.
Other 19): The counselling room in the centre's temporary outpatients' clinic does not have telephone or computer connections. This means that the counsellor has to call clients from a telephone at the nurses' station which has limited confidentiality given the flow of patients and staff in this area (SLC T43).	The PR should ensure a secure and confidential telephone is provided for the counsellor. This action should be completed by 25 July 2012.	It should be noted that the current accomodation is temporary only - however the PR can confirm a secure/restricted telephone has been made available within the Unit for the counsellors use.	25 July 2012: The PR's response indicates that this recommendation was implemented. The Lead Inspector notes that the centre has now relocated the outpatients' clinic back to its permanent location. The site and the plans for its renovation were reviewed on inspection and suggested that the facilities will be suitable for the centre's outpatient activities. No further actions are required.
Other 20): The centre displays a board of 'thank you' cards from patients who have had a child after treatment at the centre. These cards are in a public area, contain the patients' names and are not sealed shut, which allows persons not subject to a HFEA licence to identify persons who	The PR should ensure that actions are taken to protect the confidentiality of the patient identifying information inside the cards. This action should be implemented by 25 July 2012 and the Lead Inspector informed of the actions taken.	The PR can confirm that all thank you cards have been removed and a notice put in place of the appreciated cards indicating that the Unit do receive a high volume but due to confidentiality we have been requested to remove these.	25 July 2012: The PR's response indicates that actions have been taken to correct this issue which may have led to a breach of patient confidentiality. No further actions are required.

have had licensed treatment and have not consented to disclosure of their identifying information (SLC T43).			
Other 21): The outpatients' clinic has some out of date wall furnishings: an academic poster reporting treatments at the centre and success rates from 2007, some of the treatments being no longer provided; and an ISO 9001 (2000) accreditation certificate which is no longer valid (HF&E Act 1990 (as amended), Section 13 (6)).	The PR should ensure that all information displayed within the centre premises is up to date and should not potentially mislead patients. This action should be implemented by 25 July 2012 and the Lead Inspector informed of the actions taken.	The PR can confirm that the poster has been removed. ISO certificate removed at time of inspection.	25 July 2012: 25 July 2012: The PR's response indicates that actions have been taken to correct this non-compliance. No further actions are required.
Other 22): The written information provided to IVF and ICSI patients was audited against CoP requirements and was found to not include discussion regarding: • The recording and protection of personal data and confidentiality by Section 33 of the HF&E Act 1990 (as amended) (SLC T58d). • A person's right to vary the conditions of their consent	The PR should ensure the information provided to patients is reviewed against CoP requirements. It should be updated so that the information provided is compliant with those requirements. This action should be implemented by 25 July 2012 and the Lead Inspector informed of the actions taken.	The information brochure is currently being reviewed as outlined and will be completed by 25/07/2012.	25 July 2012: The information brochure was provided in evidence and had been in part revised to cover some, but not all, of the information content issues. Those which still need to be addressed have been advised to the PR who will revise the information brochure further. 9 August 2012: A revised information brochure has provided and was now considered compliant with the recommendation and CoP requirements.

and the procedure by which this can be achieved (SLC T58e; Interpretation of Mandatory Requirements 5B). • A person's right to vary or withdraw an existing consent and the procedure by which this can be achieved (SLC T58e; Interpretation of Mandatory Requirements 5B). • Multiple pregnancies: the increased risk of complications which are serious and life threatening to the future mother and baby and lead to miscarriage, still birth and perinatal infant death (CoP Guidance 7.7 a,b). • Gamete and embryo storage: the possible deterioration or loss of viability resulting from storage (CoP guidance 17.12a); the statutory storage periods and the regulations for extending the statutory storage period (CoP guidance 17.12b); in the			No further actions are required.

event of a withdrawal of embryo storage consent by one gamete provider, the provision of a 'cooling off' period of one year or until the statutory storage period expires, whichever is shorter, and the actions taken by the centre to inform the other gamete provider and facilitate resolution of the conflict (CoP 17.12b). • Written information about ICSI does not discuss the risk that damage caused by the ICSI procedure may reduce the number of eggs/embryos available for treatment (CoP Guidance 21.1a). These requirements are not satisfied by the written information however, given the audit was performed after inspection, it could not be determined whether they are satisfied through verbal communications between centre staff and the patients.			

Other 23): Recruitment of oocyte donors is currently suspended but the information provided to donors and recipients was reviewed. The written information was last reviewed in 2005 and was non-compliant with multiple CoP requirements. In the opinion of the inspection team, the information does not satisfy the requirement of the HF&E Act 1990 (as amended), Section 13 (6) that patients receive 'such relevant information as is proper' before consenting to treatment. These requirements are not satisfied by the written information however, given the audit was performed after inspection, it could not be determined whether they are satisfied through verbal communications between	The PR should ensure the information provided to oocyte donors and recipients is reviewed against CoP requirements. It should be updated so that the information provided is compliant. This action should be completed by 25 October 2012 and the HFEA should be provided with copies of the revised information.	The PR can confirm that updated patient information has been forwarded to inspector for review on the 09/06/2012. Revised donor/recipient information and pathway attached.	25 July 2012: The recruitment of oocyte donors remains voluntarily suspended at present. The PR provided in evidence of compliance the egg donor and egg recipient information and care pathway documents. The information documents were reviewed and were found to be considerably improved. No further actions are required to comply with this recommendation.

centre staff and the patients.			
Other 24): Information provided to egg share providers and recipients was audited against CoP requirements even though the egg share programme was said to be currently suspended. Written information provided to egg share providers was found to not include discussion regarding: • The scope and limitations of the genetic testing that will be done and the implications for the donor and their family (CoP Guidance 11.30c); • What information about the donor must be collected by the centre and held on the HFEA Register (CoP Guidance 11.30h); • The importance of supplying up-to-date contact information so that the donor can be informed if and when disclosure of identifiable information will be made	The PR should ensure the information provided to egg share providers and recipients is reviewed against CoP requirements. It should be updated so that the information is compliant. Recruitment of oocyte sharers is currently suspended and should remain so until the information is updated. This action should be implemented by 25 July 2012 and the HFEA should be provided with copies of the revised information.	The PR can confirm that the egg share provider service has been suspended for the last year and will continue to be suspended indefinitely.	25 July 2012: The Lead Inspector notes the PR's statement. If this aspect of the service is to be resumed at any time in the future, the PR should revise the information provided to patients and should forward it to the Lead Inspector for approval before the egg share service re-commences. No further action is required at this time.

(CoP Guidance 11.30k); • The procedure for donors to withdraw consent for the use of their gametes, or embryos created with their gametes (CoP Guidance 11.30n); • The fact that if the donor is an egg donor who is not a patient, she is free to withdraw from the donation process after preparation for egg recovery has begun without incurring a financial or other penalty (CoP Guidance 11.30o); • That anyone born as a result of their donation will have when they are 16 years old access to each specific item of the non-identifying information provided by the donor stated by CoP Guidance 11.35 a-m. Written information provided to egg share recipients does not state: • That when any donor-conceived child is 16 years old, they will have access to			

each item of non-identifying information about the donor specified by CoP Guidance 20.11 a – m. These requirements are not satisfied by the written information however, given the audit was performed after inspection, it could not be determined whether they are satisfied through verbal communications between centre staff and the patients.			
Other 25): Written information provided to couples using donated gametes who are not married or in a civil partnership, does not contain information about the mechanism by which they can withdraw their consent to be the legal second parent or their consent for their partner to be the legal second parent (SLC T61). These requirements are not satisfied by the written	The PR should ensure the information about legal parenthood provided to couples using donated gametes, contains appropriate information about the mechanism by which they can withdraw their consent to be the legal second parent or their consent for their partner to be the legal second parent. This action should be implemented by 25 July 2012 and the Lead Inspector	The PR can confirm that the updated patient information has been forwarded to inspector for review on the 09/06/2012. Revised donor/recipient information and pathway attached.	25 July 2012: The issue was not addressed. Further information has been requested from the centre. 13 August 2012: The QM provided the information sheets given to users of donated sperm and eggs. It was seen to contain the required information concerning legal parenthood and the withdrawal of parenthood consents. No further action is required.

information however, given the audit was performed after inspection, it could not be determined whether they are satisfied through verbal communications between centre staff and the patients.	informed of the actions taken.		
Other 26): In seven (39%) of the 18 consent to disclosure forms audited, the register did not reflect the fact that the patient or partner had provided a consent to disclosure in their medical records. Thus the centre's data submission to the HFEA had been inaccurate (SLC T9e). These discrepancies mean that the consent expressly given by patient and partners is frustrated and the pool of data available to researchers is reduced.	This situation carries no risk that identifying information is disclosed to researchers without patient consent. It means however that the expressed consent to disclosure provided by some patients will not be acted upon as the HFEA register records that no consent for disclosure was provided. The PR should therefore review the mechanisms by which the consent to disclosure of identifying information to researchers is submitted through the EDI system to ensure that it is accurately submitted in the future. This action should be implemented by 25 July 2012	The PR can confirm that an email to nursing/medical staff to ensure compliance was sent on 22/06/2012. This was followed up with a formal team meeting with minutes which took place on 28/06/2012 to discuss further with staff. Audit included on audit plan for 3/12 review.(see audit plan)	25 July 2012: The PRs response and other evidence provided indicate that appropriate actions have been taken to correct this non-compliance. No further actions are required beyond the continued quarterly audit of consent for disclosure to researchers recorded in the patient notes against the consenting decisions communicated to the HFEA via EDI.

	and the Lead Inspector informed of the actions taken.		
Other 27): In the 2011/2012 financial year, the centre took an average of 71 days to pay HFEA invoices issued. The PR should note that the terms of payment of HFEA invoices are that payment should be received within 28 days, and that the PR is obliged, under Licence Condition T9d, to do this. The HFEA Finance Department also reported however that there has been a significant recent improvement and 'of late the centre is paying invoices within 28 days', hence this non-compliance being listed in 'other' rather than 'major'. Delayed payment of HFEA invoices was an issue at the last renewal inspection in April 2010.	The PR should take appropriate actions to meet the 28 day payment terms for HFEA invoices.	According to the Risk tool published in the HFEA web page the average number of days for paying invoices over the last six months is 30.5 days. It should be noted that the NHS Wales statutory payment requirment is not 28 days. The 30.5 days for payment is within the time required for NHS Wales. Please see copy of risk tool in attachment	25 July 2012: The PR's response regarding the improved payment in the last 6 months confirms what this non-compliance states; i.e. that 'In the 2011/2012 financial year, the centre took an average of 71 days to pay HFEA invoices' but that 'there has been a significant recent improvement …. hence this non-compliance being listed in other rather than major'. The PR should note that the 'NHS Wales statutory payment requirement' is irrelevant to the centre's HFEA Licence Conditions which she is required to ensure are adhered to. No further actions are necessary however the PR should continue to ensure payment of HFEA invoices within the HFEA Finance Department's 28 day payment terms, as required by SLC T9d.

Additional information from the Person Responsible

As PR I accept the draft recommendations within this report and I have provided evidence of remedial action or confirmation of previous action as appropriate to address them. Notwisthstanding this, I am personally and professionally very upset by aspects of the report. It raises non compliances, and despite regular contact and interim reports by the HFEA over the last year, the overall recommendation is in excess of the verbal feedback the unit received following the April 2012 inspection.

I commenced my role as PR in IVF Wales in June 2011, and during that time I have sucessfully dealt with major and critical incidents which were the results of many years of previous superficial practice at a laboratory and managerial level. I feel that this report does not acknowledge the progress that has been made during my time as PR.

During my year as PR I have fully investigated the incidents, I have fullfilled the required recommendations, and have actioned them according to the clinical governance and the HFEA standards. During this time, and specifically as a result of the improved governance and compliance processes I have put in place, incidents from previous years have been identified (as expected) and directly as a consequence of the historical leadership of the service.

As PR, whilst not responsible for the original incidents I am appropriately and diligently dealing with these historic issues. I believe that no recognition has been made of the fact that for the first time in years, the unit is fully compliant with the EDI, and our Risk tool shows a green level of compliance in nearly all the areas monitored by the HFEA. I have started implementing the required process for the CPA accreditation for andrology to ensure safety and quality in assessing the semen analysis. I have established an effective process of performance management by implementing the dashboard which gives a clear picture of the overall centre performance. I have implemented regular team meetings to keep the entire team informed about the latest audits and KPIs in the unit. I have arranged for the validation of all the equipment and clinical procedure to be carried out. I have kept activity at a safe level fully complying to the HFEA license condition.

I feel that in the last year together with the valuable help and support of my team I have achieved more than has ever been achieved in the past, and certaintly I have made every effort to ensure that IVF Wales is a safe and appropriate place for patients to undergo their treatment.

It is devasting for both myself and the team, given the significant progress that has been made, that after this dedicated hard work the unit risks losing the license. I do not believe it is because I failed to discharge my duties, rather had I not been so diligent and rigorous in trying to address

issues then many of the issues we are currently correcting would not have been highlighted. I think it is important to distinguish between those issues that occurred prior to the new team in June 2011, and the management of any issues that have arisen since.

I feel it is important that the HFEA recognises that whilst the inspection held in 2010 by the HFEA highlighted 1 critical and 23 major areas of non compliance, an unconditional licence for 2 years was granted. Within a year several major incidents regarding andrology had been reported, and subsequent interim inspections have highlighted more historical issues. I feel that the underlying serious non compliances that caused these incidents should have been picked at the HFEA inspection in 2010, and in this current report many of the critical and major issues relate to these. This unit has previously undergone several HFEA inspections and none of these problems were highlighted at the time.

I believe that the good progress that the current unit team in conjunction with the HFEA has made in addressing these shortfalls should continue, as there is clearly a shared responsibility on both parties to recognise and address some of these historic issues that occured.

I would also like to note that, in October 2011 the WHSSC (Specialist Commissioners) decided to transfer the Unit's management to ABMU Health Board to form a South Wales IVF Service. This transfer was planned for the 1st April 2012, however was subsequently postponed to the 1st October 2012. The effect of this decision both in terms of the original transfer and subsequent delay should not be underestimated. Key members of the IVF team have left because of the uncertainty and the way the whole process was being managed with very little communication. As a result in the last year I have lost many valuable and skilled colleagues which has meant I have had to reduce the activity of the unit to such a level to maintain quality and safety for the patients. The uncertainty and disruption caused by the transfer decision makes recruitment and retention of staff (a key underlying criticism within the report) extremely difficult until the transfer is completed.

It is testament to the dedication and support of the IVF clinical and managerial team that the progress we have made has been accomplished despite such uncertainty.

In conclusion, I fully understand that as PR I am responsible for the Unit, and I have personally worked extremely hard to ensure that the unit is continually improving and addressing the issues that are as a result of years of mismanagement prior to my assuming the role as PR. I love my job and I have done and will continue to do it to the best of my abilities. I would ask that the HFEA constructively support me in continuing to lead the progress that is being made at IVF Wales.

HFEA Licence Committee Meeting

30 August 2012

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

Minutes – Item 4

Centre 0049 – IVF Wales – Renewal Inspection Report

Members of the Committee: David Archard (lay) Chair Sue Price (professional) Debbie Barber (professional) Jane Dibblin (lay) Anna Carragher (lay) Mair Crouch (lay) – VC	Committee Secretary: Lauren Crawford Legal Adviser: Sarah Ellson, Field Fisher Waterhouse

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

The Committee had before it:

- HFEA Protocol for the Conduct of Meetings of Executive Licensing Committee
- 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 Committee noted that the centre had applied to renew their Licence and that an inspection of the centre had taken place in April 2012.

2. The Committee noted that the centre provides intrauterine insemination (IUI), in vitro fertilisation (IVF) and Intracytoplasmic Sperm Injection (ICSI) treatments to NHS and self-funded patients across South Wales.

3. The Committee noted that annually the centre performs approximately 340 IVF and ISCI treatments and 110 frozen embryo transfers.

4. The Committee noted that, at the time of the inspection report, the centre's reported treatment cycle figures for 1 January 2011 – 31 December 2011 were in line with the national average with the exception of

    - The clinical pregnancy rate for IVF in patients aged below 38 years is significantly below the national average

    - The clinical pregnancy rate for ICSI in patients aged below 38 years is significantly below the national average.

5. The Committee noted that, at the time of the inspection, there were a number of areas of practice that required improvement and led to recommendations for corrective actions being made, comprising six critical and eight major areas of non-compliance, and twenty-four 'other' areas of non-compliance or poor practice. The Committee also carefully noted the compliance history of the centre and its recent licensing history. It noted that Licence Committee has expressly requested that this renewal application be considered by Licence Committee and not the Executive Licensing Panel.

6. The Committee noted that, since the inspection on 16 April 2012, the Person Responsible (PR) has provided evidence that the recommendations for one critical and five major areas of non-compliance and 20 'other' areas for improvement have been fully implemented.

7. The Committee noted that the PR has provided evidence that corrective actions have been implemented in part and are on-going given a commitment to fully implement the remaining recommendations within the time frames stated in the report.

8. The Committee noted that the Welsh Health Specialised Services have decided to transfer the unit's management to Abertawe Bor Morgannnwg University Health Board to form a South Wales IVF Service. The transfer was planned for 1 April 2012 but has been postponed until 1 October 2012.

9. The Committee noted the Inspectorate's recommendation to renew the centre's licence for a two year period with the additional condition that 'For the remainder of the licence, and calculated over a six-month period, the centre

must limit the number of IVF and ICSI cycles provided to an average of twenty-four cycles per calendar month in total, and of frozen embryo transfers to an average of eight per calendar month in total'.

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

The Committee's Decision

11. The Committee referred 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.

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

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

14. The Committee noted that the PR has been in post since June 2011 and is a consultant in Obstetrics and Gynaecology. She has completed the PR Entry Programme and has the required academic qualifications and more than 2 years practical experience.

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

16. The Committee noted that the application involves the use of embryos for training purposes and agreed that this was necessary for training embryologists at the centre.

17. The Committee referred to 'Guidance on periods for which new or renewed licences can be granted'. The Committee took into account matters set out in paragraph 4.3 and noted paragraph 4.4 of the guidance which states [The Executive Licensing Committee] 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.

18. The Committee decided to grant the application and to renew the centre's licence, for a period of 2 years with one additional condition.

19. The length of the licence was based on the ongoing and recent history of non-compliance which has been reported since the current PR has been at the centre, but taking into consideration the efforts made to address the areas of

non-compliance. The Committee considered the length of the licence to be proportionate, having recognised the recruitment needs of the centre.

20. The additional condition to be imposed is that 'For the term of the licence, and calculated over a six-month period, the centre must limit the number of IVF and ICSI cycles provided to an average of twenty-four cycles per calendar month in total, and of frozen embryo transfers to an average of eight per calendar month in total'. The condition was considered necessary and proportionate given the ongoing issues to be addressed by the centre, the current resources and the need to safeguard patients. The Committee noted that the condition, worded in this way, had previously been accepted by the centre.

21. The Committee noted and agreed with the Inspectors' recommendation that condition should remain on the licence until such time as the centre has provided evidence which shows that all non-compliances have been addressed. It is then open to the PR to apply to have the licence varied to remove the additional condition. If such an application is made the Committee directed that the matter should come back to the Licence Committee.

22. The Committee endorsed the outstanding Inspectors' recommendations and the timetable for compliance. Whilst it recognised that the Executive considered that compliance with the outstanding recommendations would be ensured by the Lead Inspector through the ongoing monitoring system the Committee wishes to strongly encourage the Executive to undertake an Interim Inspection within six months of the new licence to enable inspectors to be able to verify compliance with the recommendations and to assess how the centre is operating under a new management structure.

23. The Committee further requested that the Interim inspection report containing updated success rates and progress report on the areas of non-compliance be seen by the Licence Committee rather than the Executive Licensing Panel.

Signed Date 07/09/2012

David Archard (Chair)