Incident Inspection Report

Date of Inspection: 15 June 2011
Purpose of inspection: Incident inspection
Length of inspection: 6 hours
Inspectors: Andrew Leonard (centre inspector)
Paula Nolan (clinical governance lead)

Inspection details:
The report covers the pre-inspection analysis, the visit and information received from the centre between 19 April 2011 and 15 September 2011.

Date of Licence Committee: 29 September 2011

Purpose of the incident inspection report
The purpose of the incident inspection is to investigate incidents and further areas of concern that may impact on the quality and safety of the service provided by a centre and to assess whether the centre is complying with the Human Fertilisation and Embryology (HF&E) Act 1990 (as amended), the Human Fertilisation and Embryology (HF&E) Act 2008 and the HFEA Code of Practice. The report summarises the findings of the incident inspection. It is primarily written for the Authority's Licence Committee.

Centre details

Centre Name	IVF Wales
Centre Number	0049
Centre Address	University Hospital of Wales, Heath Park, Cardiff, Wales, CF14 4XW
Person Responsible	Dr Janet Evens (resigned as Person Responsible on 6 June 2011). Dr Arianna D'Angelo appointed on 24 June 2011.
Licence Holder	Dr Graham Shortland

Contents

Page

Report to Licence Committee

Brief background to incident inspection:

This inspection was undertaken following the reporting of two incidents by the centre in April and May 2011 and expanded to incorporate other concerns regarding the centre's overall performance.

The centre's head of embryology resigned and on her last working day (3 June 2011) wrote to the Chief Executive of the Trust expressing her concerns about the safe and efficient running of the centre. The Person Responsible (PR) was redeployed out of the centre. Furthermore, an andrologist and a senior embryologist were suspended from duty.

On 6 June 2011 the PR contacted the centre's inspector to explain she had resigned from the post with immediate effect, as she could no longer take legal responsibility for the service if she did not have access to the centre. Due to the accumulation of events at the centre the HFEA Executive held a management review on 6 June 2011.

The Executive contacted the Licence Holder explaining that it was unlawful (under Section 12 (1) of the HF&E Act 1990 (as amended)) for a HFEA licensed centre to undertake licensed activity without the supervision of a PR. The Executive required the Licence Holder to ensure that licensed activity was stopped at the centre with immediate effect, unless to do so would have a direct impact on the safety of a patient undergoing treatment. The centre complied with this recommendation.

Whilst gathering information prior to the incident inspection it was noted the centre's success rates[1] had significantly decreased. It was therefore decided to incorporate concerns regarding this and recent staffing issues as further areas to be explored as part of the incident inspection. In summary, the issues to be investigated were:

> **Incident A –** Whilst transferring stored sperm samples from dewars, being decommissioned, into a new dewar, some unlabelled straws were noted at the bottom of the tank with their visotube containers and label flags. The incident report indicated that the samples were disposed of without being witnessed. It was unclear from the incident report how many samples belonging to patients (some of whom may be oncology patients) and donors were allowed to perish.
>
> **Incident B –** During a donor sperm allocation procedure it was revealed that donor samples had been released for patient use before their six month quarantine period had expired and before the screening tests at the end of that period had been performed. The incident report also indicated that witnessing procedures prior to freezing of donor sperm had only been 'recently' established. Samples in quarantine

[1] Success rates show the number of treatments carried out by the clinic in a particular time frame and the number of pregnancies or live births that resulted.

were also said by the centre to be stored alongside samples released from quarantine.

Staffing issues – The head of embryology resigned and left the centre on 3 June 2011. The PR resigned from the position with immediate effect on 6 June 2011 on being redeployed to a clinical position within the same division but outside of IVF Wales. Further to this the andrologist involved in both incidents and a senior embryologist have been suspended indefinitely. At the time this report was drafted there is one Health Professional Council (HPC) registered embryologist (the head of embryology), two embryologists nearing HPC registration and one embryologist with three years experience. The lead nurse post within the centre has been filled by nurses 'acting up' since July 2010. The quality manager can only commit one day a week to the role as she is also responsible for the centre's administration and electronic data interchange (EDI) data entry.

Decrease in success rates - Outcome information was extracted from information submitted by the centre to the HFEA Registry and analysed using the HFEA risk tool. This analysis indicated that during the last 6 months of the period March 2010 – Feb 2011, the centre's success rates for in vitro fertilisation (IVF), intracytoplasmic sperm injection (ICSI) and frozen embryo transfer (FET) dropped considerably to levels significantly less than the national averages in most treatment/age groups, such that the centre's performance for most treatment/age groups breached the control limits on HFEA risk tool CUSUM[2] control charts. Prior to this decline, the centre's performance was in line with national averages. For example, the clinical pregnancy rates for IVF, ICSI and FET during September 2009 – August 2010 were all comparable with national averages and did not breach the limits on the control charts. Likewise the report of the renewal inspection in April 2010 stated: 'The centre historically performs approximately 500 treatments per year. Success rates for IVF, ICSI and donor insemination (DI) are comparable with national averages in patients aged <35 years, 35-37 years, 38-39 years, 40-42 years and >42 years, except for DI in the 38-39 year age group where the success rate is above the national average.'

An application was received by the Executive for a new PR. The new PR met the requirements and the application was approved by the Executive Licensing Panel on 24 June 2011[3]. The appointment of the new PR was not dealt with as part of the terms of reference of this inspection report.

Brief description of the centre and its licensing and incident history:

IVF Wales is part of the Cardiff and Vale University Health Board and has been licensed by the HFEA since 1992. Licensed activities at IVF Wales include the storage of eggs, sperm and embryos, in vitro fertilisation (IVF), intracytoplasmic sperm injection (ICSI), insemination, 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 small egg sharing, sperm donation and egg donation programmes.

[2] cumulative sum control chart – a sequential analysis technique used to detect changes in performance
[3] Executive Licensing Panel minutes for this item are attached in the licensing history bundle accompanying this report

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[4]. The Executive Licensing Panel (15 July 2010) determined that in accordance with guidance to award the full four-year licence it had to have no concerns. The Panel considered that this was clearly not the case. However in light of the progress made by the centre since the inspection the Panel agreed to the inspectorate's recommendation to renew the centre's licence for a period of two years with no additional conditions.

The PR at the time of the incidents had been a consultant in Obstetrics and Gynaecology at IVF Wales since 1992 and the PR since 2002.

A review of incidents reported by the centre since the previous renewal inspection indicated that no similar incidents had taken place regarding the storage of gametes or discrepancies in screening/releasing donor samples. Since the time of the previous renewal inspection the HFEA has also not received a patient complaint related to incidents of this type.

Outcomes*

Outcome information was extracted from information submitted by the centre to the HFEA Registry and analysed using the HFEA risk tool. This analysis indicated that:

- The clinical pregnancy rate (CPR) for IVF treatment using fresh embryos created using the patients' eggs in the below 38 age group, is below the national average (99.8% confidence limit). The centre's performance in this criteria breached the control limit on the risk tool CUSUM control chart in October 2010.
- The CPR for IVF treatment using fresh embryos created using the patients' eggs in the 38 and above age group, is comparable with the national average however the centre's performance in this criteria breached the control limit on the risk tool CUSUM control chart in December 2010.
- The CPR for ICSI treatment using fresh embryos created from the patient's eggs in patients aged less than 38 years, is below the national average (99.8% confidence limit). The centre's performance in this criteria breached the control limit on the risk tool CUSUM control chart in December 2010.
- The CPR for ICSI treatments, using fresh embryos created from the patient' eggs in patients aged 38 – 65, is below the national average (95% confidence limit). The centre's performance in this criteria breached the control limit on the risk tool CUSUM control chart in January 2011.
- The CPR for FET cycles using IVF or ICSI produced thawed embryos created from patient's eggs in patients aged less than 40 years, is below the national average (99.8% confidence limit). The centre's performance in this criteria breached the control limit on the risk tool CUSUM control chart in December 2010.
- The CPR for FET cycles using IVF or ICSI produced thawed embryos created from patient's eggs, in patients aged 40 years and over, is comparable with the national average and the centre's performance in this criteria does not breached the control limit on the risk

[4] See Appendix 1 at the back of this report for a table showing the areas of practice that required the attention of the PR, as identified by the renewal inspection on 14 & 15 April 2010.

tool CUSUM control chart.

Analysis of data from the HFEA register for the period September 2009 - August 2010 (i.e. for a year's activity offset 6 months earlier than the data period discussed above) showed the centre's success rates to be in line with national averages for all treatment/age groups investigated over that period.

*This outcome analysis was produced from HFEA registry data on 2 July 2011. 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

The Licence Committee is asked to note that at the time of the inspection there were a number of areas of practice that required improvement, including seven critical areas of non-compliance and four major areas of non-compliance. No “other” areas of non-compliance or poor practice were noted on inspection.

Since the inspection visit the PR has confirmed that the following recommendations have been fully implemented and has provided evidence to the Executive in support of this:

Critical areas of concern:

- **Declining success rates: it is recommended that the PR organise an external review of the centre’s clinical and laboratory activities including the interactions between teams within the centre.**
- **Staffing levels: the inspection team propose that the centre should limit the number of IVF and ICSI cycles, until all corrective actions described in the inspection report are complete and subject to a further inspection.**

Major areas of non compliance:

- Quality Management training and time allocation: the PR should ensure that the quality manager 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.
- Late submission of early outcome forms: the PR must ensure that early outcome forms are submitted within 8 weeks of the end of the treatment cycle.

The PR has given a commitment to fully implement the following recommendations and has provided actions plans to achieve this, and in some cases evidence to support their partially implementation:

Critical areas of concern:

- **Donor screening and laboratory testing: the contents of the 2 dewars used for donor samples should be audited against the storage log to ensure that all samples are stored in the correct dewar. The centre should suspend the donor recruitment programme until all corrective actions described in the inspection report are complete and subject to a further inspection.**
- **The disposal of some pre 2007 stored samples without identification and witnessing: the contents of the 2 dewars used for pre 2007 samples should be audited against the storage log to determine which patients’ samples have been allowed to perish.**
- **Quality Management System and Quality Monitoring: the PR should ensure an effective quality monitoring programme is established and maintained for all critical activities and processes within the centre.**
- **Quality Management System audit: the PR should ensure an effective procedural audit programme to verify that critical practices and processes at the centre adhere to the documented Standard Operating Procedures (SOPs) and that those SOPs comply with regulatory requirements.**

- **The validation of process and practice change: 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.**

Major areas of non compliance:

- Donor screening and laboratory testing: 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.
- Accreditation of the andrology laboratory: if the andrology service is to be continued, the PR must ensure that it obtains CPA accreditation at the earliest opportunity.

Recommendation to the Licence Committee

The PR has committed to take actions, or has already taken actions, to address all areas of non-compliance noted in this inspection report. The inspection team consider that the positive engagement by the centre with the inspection process has led to marked improvements in the centre's compliance with HFEA requirements. The inspection team therefore recommend the continuation of the centre's licence without conditions subject to the centre implementing all recommendations made in this report within the prescribed timescales. To ensure this has occurred effectively, the Executive recommend the Licence Committee direct the Executive to undertake a follow up inspection in six months time.

Details of incident inspection findings

Summary of incidents & Consequences

Incident A

A decision was made by the former head of embryology to transfer stored sperm samples from donors and patients from two liquid nitrogen storage dewars which were to be decommissioned due to their age, into one new dewar. These samples were from pre-2007 sperm donors and pre-1998 patients (including oncology patients).

The old dewars were emptied of samples on 30 and 31 March 2011, with all samples being transferred to one new dewar. The old dewars were then emptied of liquid nitrogen and the contents in the bottom of the dewars were examined for any remaining samples. A number of labelled coloured flags used to identify samples, visotubes and loose cryostraws were found. The andrologist tasked with decanting the old dewars did not keep a record of any identifiable samples nor was the discard of the samples witnessed by a second member of staff.

The head of embryology reported to the PR that a whole set of straws and flags were found on the bottom of one dewar. At a later check by the head of embryology, the andrologist informed her that he had discarded a whole set of unidentifiable straws of donor and patient samples. The andrologist had discarded these samples without the presence of a witness and without informing the head of embryology about the exact inventory of the straws.

The former head of embryology asked the andrologist to give exact details on all straws/flags that were found and those that were discarded. They are as follows:

- Four loose flags were found for donor samples that were due out of storage (1988-1997). These were recorded and allowed to perish.
- A mixture of unlabeled straws from patients and donor sperm (number unknown – intact and broken) were allowed to perish.
- Three visotubes with flags and straws were found for donors that were not yet due out of storage having been stored in 2002. The storage records were amended accordingly. These samples had been marked as ‘missing in the tank’ after previous audits of the tank’s contents. These straws were not labelled individually and totaled 39 straws from two different donors, stored on three different dates.
- One visotube with an identification flag and straws was found for a patient who subsequently could not be found in the storage records (1988). These samples were retained pending further attempts to find out more information.

The inspection team considered that this incident report indicated non-compliance with:

Standard Licence Conditions (SLC) T71 - centres must have witnessing protocols in place to double check the identification of samples and the patients or donors to whom they relate at all critical points of the clinical and laboratory process. These checks must be completed and recorded at the time the relevant clinical or laboratory process/procedure takes place. A record must be kept in each patient’s/donor’s medical records. These records must include the name, status and signature of the person performing the activity and the name, status and

signature of the person who witnesses the procedure.

SLC T99 - The centre must establish, implement and comply with documented procedures to ensure that:

a. all gametes and embryos are traceable from procurement of gametes to patient treatment or disposal and vice versa.

Incident B

During a donor sperm allocation procedure it was revealed that donor samples had been released before the six month period of quarantine was complete. The andrologist had failed to check that follow up viral screens had been undertaken or were negative. In six treatments the samples used did not have the appropriate screening in place (the screening results are now available and are negative). Three other donor samples have been released prior to completion of the quarantine period and without urine testing for Chlamydia or genital swab testing for gonorrhea having been completed and the results reviewed.

The centre's incident report also indicated that witnessing procedures prior to freezing of donor sperm were not in place and that samples in quarantine are stored with samples released from quarantine.

As part of the immediate action taken in light of this incident, the previous head of embryology had embargoed the donor dewars (one quarantine dewar and one post screening dewar) and temporarily suspended new donor treatments. If patients currently in treatment require donor gametes, samples are ordered from a European sperm bank and are stored in a separate monitored and alarmed dewar from those discussed above, in which samples produced by donors recruited at centre 0049 are stored.

The inspection team considered before the inspection that this incident report indicated non-compliance with:

SLCT52 – Prior to the use and/or storage of donor gametes and/or embryos created with donor gametes the centre must comply with the selection criteria for donors and the requirements for laboratory tests and storage set out below;

- c. the centre must devise a system of storage which clearly separates: quarantined/unscreened gametes and embryos,
- e. sperm donors must be negative for chlamydia on a urine sample tested by the nucleic acid amplification technique (NAT)

SLC T53 – The centre must ensure that the laboratory tests required by licence condition T52 meet the following requirements, namely:

- c. donor sperm must be quarantined for a minimum of 180 days, after which repeat testing is required

Incident type:	Both incidents: Laboratory processes – witnessing failure, non-adherence to the screening, storage and use of donor sperm protocols.
Specialty/Location:	Both incidents: Cryostorage room
Effect on patients/donors:	**Incident A** – potential emotional/psychological distress regarding the discard of samples for oncology patients, patients and donors that could have been used in treatment or for sibling use. **Incident B** - potential risk of infection to patients; potential risk of contamination of donor samples held within the screened dewar.
Severity level:	Unable to ascertain until audits of the contents of the two old decommissioned dewars (incident A) and the post quarantine donor dewar contents (incident B) are complete.

Scope and Level of Investigation

The incident reports were reviewed

Site visit including:

- Interviews with the acting head of embryology, former PR, accredited consultant and Licence Holder
- A review of documentation on site including donor files and the card based donor database

Standard Operating Procedures were reviewed

Previous Inspection reports and Licence Committee minutes were reviewed

A Root Cause Analysis was undertaken

Notable Practice

The centre submitted written reports of both the incidents to the HFEA within the required twenty – four hour time period.

The centre complied immediately with the HFEA Executive's requirement that in the absence of a PR, activity at the centre should cease unless to do so would carry a risk to patient safety. Subsequently, the centre have liaised effectively with the HFEA Executive regarding the use of stored samples to treat patients who would have been at increased risk if there treatment had been suspended.

It was decided by the Licence Holder that an independent assessment of the centre's activities was necessary. This had been communicated to staff effectively and they are in agreement with the need for an external review of the centre's activities.

The centre management team have met regularly to discuss the incidents and provided the inspection team with a documented response plan. This plan included a limit on activity so that it matches the reduced staffing resources available, as well as an embargo on the use of gametes from donors recruited at the centre.

The centre staff during the inspection and subsequently have engaged effectively with the inspection team and provided all information requested.

Inspection findings

Incident A

The acting head of embryology explained that some of the material allowed to perish from the old dewars was nothing more than shattered fragments of cryostraws and that it was impossible to identify them. The storage system at the time (pre-2007) these samples were placed in storage consisted of an open system: sperm was stored in unlabelled glass straws (albeit with colour coded plugs for identification) which were placed in an open storage canister with a colour coded flag for identification. This system was compliant with Code of Practice (CoP) requirements at the time[5]. Since 2007 the centre has moved to a closed storage system consisting of cryovials (labelled with the sample providers name(s), date of birth, hospital number and the date of storage) stored within plastic visitubes from which they cannot escape, which are then held in the open canisters within the dewars. This ensures that individual samples are labelled in a manner compliant with current guidance. This incident is thus restricted to samples stored pre-2007 which were held in two old dewars recently decanted into one new dewar. The remainder of samples stored at the centre post-2007 are unaffected. Indeed many of these samples have also been recently moved into new dewars and the acting head of embryology stated that no stored material was found in the bottom of the original dewars used to store these post-2007 samples.

The inspection team was not able to speak to the andrologist who is currently suspended from duty. The team's discussions with the acting head of embryology and the previous PR and a review of the incident report, indicate that the disposal of the pre-2007 samples found in the bottom of the two old dewars was not witnessed, non-compliant with SLC T71 and CoP Guidance 18.4 and with the centre's andrology witnessing SOP. It is noted that this would have been difficult for straw fragments, since they did not have identifiers on them and the single colour coded plug in a fragment would not have allowed identification. The inspection team considers however that a count of the straws and fragments disposed of, carried out by two persons, should have been performed and documented if compliant witnessing could not be performed. The inspection team also note that some samples were identifiable and their disposal should have been witnessed appropriately.

There is also significant concern regarding the traceability of the gametes stored in these two dewars, non-compliant with SLC T99a, since it is unclear whose gametes have been allowed to perish.

Incident B

The former PR explained that in this case of a donor whose samples had been inappropriately released from quarantine, the andrologist had assumed that the donor had attended for a

[5] Prior to 2007 guidance stated that the sources of gametes and embryos were expected to be accurately recorded and labelled in a way that is not susceptible to unauthorised or undetectable alteration (Code of Practice 6th edition, 9.9). Since 2007 the guidance issued for the identification and labelling of samples has expanded and requires centres to ensure that samples should be labelled with at least the patient's or donor's full name and a unique identifier (Code of Practice 8th edition, Guidance Note 18.20 & 18.21).

post-quarantine screening test appointment he had arranged, when the donor had in fact missed the screening appointment. The donor was later screened and found to be clear of disease. This premature release from quarantine was contrary to SLC T53c as well as to the centre's donor recruitment, screening and use standard operating procedure (SOP). This SOP states that a check of the results of screening tests performed after 180 days quarantine should be made prior to release of donor material. There would appear to have been a lack of rigour regarding adherence to this SOP within the laboratory.

The acting head of embryology was asked to explain how donor samples are released for use and who manages this process. The head of embryology explained that this service was run primarily by the andrologist with very little input from the embryologists. The donor coordinator would contact the andrologist to enquire what samples could be released for patient use. An embryologist would then liaise with the andrologist to retrieve the samples and prepare them for patient use. The acting head of embryology explained that the embryologist would not check to ensure that all the appropriate screening results had been completed and reviewed when collecting the donor sample they were told to use by the andrologist. The embryologists assumed that the andrologist completed this check as part of the process prior to releasing samples. The centre's donor recruitment, screening and use SOP states that such a check should be made prior to release of donor material. Review of the donor records held within a card based database indicated that the only documentation of such a check was a tick on each released donor record, with no date or signature, and inconsistently located given most donors had several cards in their records.

The incident form supplied by the previous head of embryology stated that donor samples were not witnessed when they were transferred from the quarantined dewar into the post screening dewar, nor was there any documented witnessing of the samples' release for patient use. The former PR explained that the andrologist had advised her that witnessing of donor samples was performed and recorded on sheets in a binder but not in patient/donor records. This included witnessing of the donor identity against the records, of the cryovials and sperm pot against the records prior to processing, and at the initial placement in storage, but not at the movement of samples from the quarantine dewar into the 'donors in use' dewar. This was later confirmed by the acting head of embryology who had retrieved the binder containing the witnessing sheets from the laboratory, and also that the removal from storage for use in treatment was witnessed and recorded in the record of the patient undergoing treatment. Thus it is clear that some required witness checks were not performed, while others were performed but were inappropriately documented, non-compliant with SLC T71 and with the centre's witnessing SOP.

The inspection team reviewed a subset of donor notes cross referenced with the card based donor database. This revealed that the time difference between the collection of the last sample and the last screening test data for one donor's samples was less than 180 days. This was bought to the attention of the head of embryology who said she would investigate the case and find whether further screening tests had been performed but had not been placed in the donor notes. If such records are not present, this will represent a second donor whose samples have been inappropriately released from quarantine, non-compliant with SLC T53c.

At the time of the renewal inspection in April 2010, the donor coordinator was in the process of developing an electronic database that would incorporate screening test results and

whether further screening tests were required, as well as donor use and outcomes. This database could easily have been used to control the release of quarantined and screened samples. The former PR and acting head of embryology explained that this work had not been progressed due to pressure of work within the centre.

Although there is a protocol for the screening and storage and use of donor sperm[6] it was not adhered to on several occasions, regarding witnessing checks, screening tests, separation of quarantined from non-quarantined samples and the release of samples from quarantine.

Staffing levels

The acting head of embryology explained that activity within the centre increased significantly from January 2011 to March 2011. In the opinion of the inspection team this has placed stress on the centre's ability to maintain compliance with EDI data entry, quality indicator (QI) monitoring and procedural audit, non-compliant with SLC T12. The inspection team also note that the increase in activity occurred simultaneously with longstanding staffing pressures, for example:

- The lead nurse role vacated approximately one year ago has yet to be permanently filled. One reason for this, in the opinion of the former PR, is that the Trust wish to appoint at a remuneration point less than that required to attract suitably qualified and experienced applicants. The role has been filled instead by experienced nursing staff at the centre 'acting up', including the donor coordinator. One effect of this has been that the donor database has not been developed.

- The appointment of a dedicated quality manager (QM), as recommended by the report of the renewal inspection in April 2010, was only achieved in April 2011. Previously, the quality management system (QMS) was managed by a committee: each head of discipline was responsible for the QMS appropriate to their discipline. Most heads of discipline felt this impeded their ability to focus on their area of expertise, hence the recommendation that a dedicated QM be appointed. The QM appointed in April 2011 is the centre's established head of administration. This unfortunately means that she can spend only a maximum of one day per week in the QM role given her other duties, which also include data input into the HFEA EDI system. The QM has also not yet undergone any quality management training. This situation is non-compliant with SLC T12. Thus quality management activities at the centre, for example quality indicator (QI) monitoring and review and the audit of critical processes for their adherence to SOPs and regulatory compliance, have been restricted in the last year, non-compliant with SLC T35 and T36.

- The former PR and acting head of embryology stated that the andrologist had complained about his workload. Embryologists were supposed to provide cover and assistance to the andrologist, but sometimes this did not happen because the embryologists preferred to work in the embryology laboratory on what they saw as their core work – embryology. This may have led to: work stress on the andrologist; the development of andrological practices which did not comply with the centre's SOPs;

[6] Clinical, Embryology and Andrology protocol for witnessing in assisted conception cycles (version 2) (reviewed March 2010).

and difficulty in witnessing andrological processes in a compliant manner. It would also have undermined team work in the laboratory and effective interaction between the andrology and embryology functions.

The departure of the former head of embryology on 3 June 2011 and suspension of a senior embryologist and the andrologist on 6 June 2011 has reduced the staffing available in the embryology laboratory. Permanent embryology staff now comprise one HPC-registered, ACE-certified embryologist (the acting head of embryology), two ACE-certified embryologists within one year of HPC registration and one embryologist with three years experience who has not yet completed the ACE certificate. A locum embryologist (ACE-certified and within one year of HPC registration) was also working at the centre on a 2 week contract due to finish in the week after the inspection.

The inspection team were advised that given the staffing issues noted above, the management team decided on the day before the inspection to limit workload when activity is re-commenced after a new PR is appointed. This new work plan would aim to:

- Reduce the caseload to an average of six egg collections per week and two frozen embryo transfers per week.
- Control activity by allowing only the head of administration to book patients onto the treatment pathway.
- Suspend the provision of IUI as a service.
- Limit leave to allow only one person in each discipline to be absent at any one time.
- Limit the diagnostic semen analysis service to two afternoons per week only.
- Cancel all sperm storage appointments and activities.
- Suspend the donor recruitment service at the centre and rely for a time on donor sperm sourced from European donor banks.

In the opinion of the inspection team, the recent departure of the former PR and suspension of a senior embryologist and the andrologist, as well as the staffing issues identified above, restrict the staffing resources available to undertake treatment activities safely, in a manner compliant with SLC T12. They also reduce the centre's ability to correct the regulatory non-compliances noted in this report. It is important that treatment activity at the centre is restricted to allow safe operation and the implementation of corrective actions given the reduced staffing resources available.

Success rates at the centre:
The centre's success rate data for treatments in 1 March 2009 – 28 February 2010 were discussed with staff, these being derived using the HFEA risk tool from data submitted to the HFEA registry by the centre. The staff expressed surprise at the scale of the reduction in CPR for IVF, ICSI and FET since September 2010 in the figures presented (see Outcomes, page 5 of this report). The accredited consultant provided data to support a 19% CPR in all treatments for January – March 2011, but accepted this was a reduction on the CPR in previous months.

The QM on the day of inspection had approximately one hundred and fifty early outcome forms from 2010 and 2011 which had yet to be submitted through the HFEA electronic data interface (EDI). Thus these treatment outcomes were not included in the initial HFEA risk tool analysis provided to the centre, which could have partially explained the difference in CPR

between the risk tool and the centre's data analyses. There was however little improvement in the success rates when these early outcome forms were submitted to the HFEA Register - the analysis provided in the 'Outcomes' section on page 5 was prepared on 2 July 2011 after the early outcome forms had been submitted. The submission of early outcome forms more than 8 weeks after the treatment cycle ends is non-compliant with General Direction 0005. Moreover this suggests that staffing resources to facilitate compliant data submission through the EDI system are not in place.

The accredited consultant and acting head of embryology explained that centre staff had noted a decline in success rates at a meeting in March 2011. Causes were debated by the management team and it was concluded that it was possibly due to a change in the stimulation drugs prescribed to patients. The centre is now using different medication and has started to see an increase in the quality of eggs produced and subsequent embryo development.

The inspection team note that the decline in success rates started around September 2010 in most treatment/age groups, albeit control limits in the HFEA risk tool control charts were not breached until December 2010. The fact the centre did not notice this decline until March 2011 suggests the centre's QI monitoring system was not functioning, contrary to SLC T35.

Other relevant issues and contributory factors identified on inspection

1) Non-adherence to Standard Operating Procedures (SOPs) and non-compliant working practices.
A significant factor in these incidents is non-adherence to SOPs and an acceptance of practices, notably in witnessing, non-compliant with HFEA CoP and SLC requirements. Several other examples were noted on inspection:

- The acting head of embryology reported that a patient had recently been subjected to a PESA[7] procedure to obtain sperm for treatment, because the witnessing records for the provider's samples collected by a previous PESA procedure were missing, non-compliant with SLC T71. This incident was subsequently reported to the HFEA and has been investigated by the centre. Contributory factors discussed on inspection with the acting head of embryology included lack of knowledge of, and non-adherence to, the centre's SOP regarding PESA procedures and witnessing (SLC T12 and T15a). The acting head of embryology also related that corrective actions have already been taken including the review of the PESA SOP and associated witnessing record sheets and the training of staff regarding PESA procedures and the revised SOP.

- The acting head of embryology noted that many sperm donors had been tested for chlamydia using an antibody reactive blood test. This is non-compliant with SLC T52e

7 Percutaneous Epididymal Sperm Aspiration - This procedure may be performed under GA or local anaesthetic with sedation. A fine needle is passed into the epididymis to extract fluid. This is then checked in the laboratory by the embryologist for sperm.

and the centre's own donor screening protocol, which both require sperm donors be negative for chlamydia in a urine sample tested by the nucleic acid amplification technique (NAT).

- The acting head of embryology stated that the transfer of post-2007 samples from old to new dewars had been carried out 'en masse', i.e. canisters containing visitubes with multiple samples inside had been transferred in entirety. The transfer of each individual sample was not witnessed, rather the transfer of each canister of samples was carried out and witnessed by two persons. This practice is not compliant with SLC T71 and CoP Guidance 18.4. The inspection team accept however that to individually witness the transfer of each sample from approximately 20 dewars into their new storage locations would take considerable staffing resources and have carried an increased risk to the safety of the stored samples. In addition, the centre will be auditing the contents of the new dewars against the storage logs and patient records by the end of 2011, to comply with CoP Guidance 17.16 and ensure sample traceability.

2) Failure of the Quality Management System (QMS)

Another contributory factor to these incidents and the recent poor success rate was the failure of the QMS to detect non-compliant procedures, non-adherence to procedures and the decline in success rates, through effective audit and Quality Indicator (QI) monitoring activities. Such activities are required by SLC T35 and T36. This failure resulted from a lack of development of the QMS due to:

- The devolved mode of QMS management used in the past.
- The failure until April 2011 to appoint a dedicated QM to oversee the QMS.
- The failure to provide the appointed QM with the time and training to complete the role effectively.
- The failure to consider the QMS as an integral and essential part of the centre's functioning - as well as important to its regulatory compliance.
- The failure to provide adequate staffing resources to support the QMS effective functioning.

Findings on inspection which support these assertions are discussed elsewhere in the report and also include:

- It was stated by the former PR that the former head of embryology changed the collection of QI data relating to laboratory performance in a manner which prevented the PR having an overall view of the centre's performance. Indeed the former PR stated that she was provided with no QI data from the laboratory from approximately August 2010 until the resignation of the former head of embryology on 3 June 2011.

- Monthly QI monitoring data for the laboratory for January 2010 – December 2010, was provided by the acting head of embryology to the inspection team *but had only been recently collated*. The 2010 QI data included IVF fertilisation rates, IVF abnormal fertilisation rates, ICSI fertilisation rates (total and by each embryologist), ICSI degeneration rates (total and by each embryologist), ICSI abnormal fertilisation rates, ICSI mature egg rate, and the pregnancy rate per embryo transfer (annualised for each embryologist and each doctor). Review of this data suggested, surprisingly, that there

was little decline in these laboratory QIs in the latter part of 2010.

- It was noted that the performance of some embryologists in the 2010 QI data was outside the lower control limit on the QI monitoring charts for periods of more than one month. This should have been investigated at the time but was not. The acting head of embryology advised the inspection team that no formal system was in place to initiate corrective actions (as required by SLC T36) when the performance of an embryologist breached control limits on the QI monitoring charts. She also noted that the laboratory staff would have little time carry out formal corrective actions given their workload.

- The acting head of embryology stated that the QI control charts for 2011 were not available, non-compliant with SLCs T32 and T35, as they were not being maintained due to lack of time resulting from the increased activity level at the centre. The accredited consultant concurred with this saying that little quality management activity had been undertaken since December 2010 due to the high work load, non-compliant with SLC T32.

3) Management
The drive to increase the number of treatment cycles provided by the centre in the first three months of 2011 was at the detriment to the centre's compliance with its regulatory obligations. The staff had a "feeling" that success rates had decreased but without hard data that would have been available via effective QI monitoring, as required by SLC T35, they did not have adequate data to detect the decline in specific areas or to robustly interrogate the reasons for this decline.

4) Communication
The protocol for the screening and storage and use of donor sperm for treatment – from enquiry to baby, clearly defines the lines of responsibility for the different disciplines involved in this process. During discussions with the former PR and the acting head of embryology, it became apparent that this protocol was not adhered to and various members of staff assumed that someone else had checked the screening results or witnessed the samples being removed from the dewar.

The nurse responsible for donor coordination was in the process of developing an electronic donor database but due to the pressure of work this project was not completed. The andrologist had a separate paper-based system that was difficult to use and was incomplete. Neither system in its current state is compatible for sharing information between departments.

5) Working Conditions
The inspection team were not able to speak to the andrologist involved with both incidents as this member of staff has been suspended. However the incident reports drafted by the previous head of embryology state that this member of staff worked in isolation and had a very high workload.

Other issues of compliance noted on inspection
1) The acting head of embryology and former PR both alluded in discussions with the inspection team to changes in the centre's practices and procedures in the previous year.

Little validation evidence was considered or documented when these changes were made, contrary to SLCs T24 and T72. Some validation data for newly introduced equipment was provided to the inspection team.

2) It was noted by the inspection team that the andrology laboratory has made no progress with attaining accreditation from the CPA (Clinical Pathology Accreditation (UK)), despite this being a corrective action recommended by the report of the renewal inspection in April 2011 due to the lack of accreditation being non-compliant with SLC T21.

Document Review

The clinical, embryological and andrology SOP for witnessing in assisted conception cycles does not specifically mention witnessing the disposal of embryos/gametes. However the andrology laboratory witnessing protocol states that two appropriate people, one of whom should be an embryologist/andrologist, must witness the disposal of all gametes/embryos.

The protocol for the screening, storage and use of donor sperm for treatment – from enquiry to baby[8] states that:

- A chlamydia urine test should be carried out and the donor is expected to carry out a self swab of the penile orifice for gonorrhoea testing. At the renewal inspection in April 2010, the issue of self swabbing was raised as a concern as swabbing by a nurse would be more likely to provide a definitive test result. The PR's response in the inspection report stated that she has written to a urologist to ask him to see and examine the donors and take swabs. This has either not been acted upon or the protocol has not been amended to say that the donors should be seen by the urologist.
- When the screening test results are returned they should be reviewed and filed in the donor's notes, and a checklist and database update completed. According to the protocol this action is the nurses' responsibility.
- Donor specimens are to be quarantined for six months before the first sample can be used (laboratory responsibility). The donor is to be screened every three months, and the results reviewed and recorded on a database and communicated to the Andrology Laboratory if abnormal. Abnormal results are to be acted upon (nurses' responsibility).
- At the end of the quarantine period, stored material is to be transferred from the quarantine tank to the 'in use' tank (in the Andrology Laboratory) following receipt of satisfactory repeat screening test results (laboratory responsibility).

The donor database used by the andrologist consists of two small card filing boxes. Each donor has a card, or several cards, which contain information regarding when sperm samples were produced and stored, when bloods were taken for screening and when the results were made available, along with information regarding the usage of samples in treatment and the treatment outcomes. The information was difficult to decipher and incomplete in relation to screening test results. The acting head of embryology explained that test results may be on the Trust's electronic pathology system but not transcribed onto the donor's card. The acting head of embryology expressed concern with the quality of the data on the card system and also with her ability to use the card system in the future when using donor gametes in

[8]Protocol for the screening and storage and use of donor sperm for treatment – from enquiry to baby (version 2) reviewed March 2010

treatment.

Discussion

The non-compliances noted during this inspection point to a failure of leadership and management resulting in a poorly performing centre. This can be further illustrated by the dysfunctional relationships within the management team leading to poorly supervised staff working outside of their remit. This has been compounded by insufficient monitoring of work flows such that senior staff were not alerted to the decrease in success rates at an early point in time.

These issues could persist at the centre because of a failure of the QMS to provide robust audit of processes and procedures. This failure also allowed changes to practice and procedures without documented validation, which may have undermined success rates.

Failure of the QI monitoring and review components of the QMS contributed to the centre not detecting the decline in success rates at an early opportunity.

Failure of the QMS audit and QI monitoring functions probably occurred because of a lack of staffing resources to manage and support QMS activities.

Staffing resources were not available to support the QMS because activity at the centre had been increased to a level at which the staff could not undertake activities to do so. Excessive activity may also have led to the andrologist using alternative non-compliant practices which were different from those documented in SOPs and may also have a role in the decline in success rates at the centre.

Corrective actions to remedy these failures and non-compliance are discussed below and should be implemented as rapidly as possible to ensure compliant and safe activity at the centre. The Executive will actively monitor the centre's progress in resolving the areas of non-compliance to ensure that they are completed within the specified timeframes.

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 require are given as well as the timescales in which these improvements should be carried out.

Critical areas of non compliance and concern

A critical are of non compliance is an area of practice which poses a significant direct 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
Declining success rates and non-compliance with SLCs T12, T21, T24, T32, T35, T36, T52, T53c, T71, T72, T99a and General Direction 0005	The degree of non-compliance with SLCs and General Direction 0005 and the decline in success rates at the centre, caused the inspection team to have concerns about the centre's current operational systems. It is recommended that the PR organise an external review of the centre's clinical and laboratory activities and the interactions between the teams within the centre, including but not limited to donor recruitment, screening	• External reviewers identified as a PR and a Senior Embryologist from another HFEA Licensed centre[9]. • Due to pre existing leave commitments the review may not be completed by 25 of August but I will ensure the report will be forwarded to the	The inspection team considers the centre have taken appropriate steps to implement this recommendation and will be monitoring the outcome closely. The slight delay in implementation is to be expected given the holiday arrangements of the external reviewers.

[9] Individuals' names have been redacted by the HFEA Executive

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
	and release and the quality management system. This external review should be carried out by appropriately qualified and experienced persons. The PR should provide the Executive with an action plan, by 5 August 2011, to implement this external review. The review should be completed by 25 August 2011. A summary of the findings of this review should be provided to the HFEA Executive as soon as possible thereafter and the final report by 30 September 2011.	inspector by 30 September. • Review dates arranged and confirmed for 30-31/08/2011 (agreed by the HFEA Head of Research and Clinical Governance)	30 September 2011: The review was carried out on 14 September 2011. Due to the delay in completing it, the report is still in preparation but will be provided by the PR as soon as it is ready.
Staffing levels **T12: Personnel in the centre must be available in sufficient number and be qualified and competent for the tasks they perform.**	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	• Activity reduced to: 6 OPU /pw 2 FET/pw 2 IUI/pw[10] • During the 3 weeks in August when part of the staff is on annual leave, activity will be reduced to: 6 OPU/pw 1 FET/pw	The inspection team considers the centre have taken appropriate steps to implement this recommendation. The PR should ensure that activity only increases to a level at which the staffing resources available can safely provide the treatment

[10] These activities refer to egg collection (OPU), frozen embryo transfer (FET) and intrauterine insemination (IUI).

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
	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 services and simultaneously maintain regulatory compliance. **In the absence of agreement from the centre to implement this activity limit, the Executive will consider the centre's operations to be non-compliant with SLC T12 and potentially unsafe given the other areas of non-compliance noted in this report. The matter will be reported to the Licence Committee with a recommendation**	No IUIs • The QM had locked the excel datasheet of starters in a way that it is not possible to add extra rows • The daily nurse coordinator will daily book patients in, filling the appropriate slots available (we are currently booking November) • Two designated senior nurses are the only responsible for moving patients to make sure that we comply to the numbers recommended by the HFEA. • Obviously, due to the nature of our patients we cannot guarantee that the 6 OPUs will occur in that designed week but overall **no more than 24 OPUs will be performed**	services and simultaneously maintain regulatory compliance. 30 September 2011: The centre is still operating under activity restrictions imposed after the incident. The impact of various staffing restrictions on activity at the centre has been risk assessed in detail. This risk assessment has been provided to the inspection team who consider it will enhance the centre's ability to manage future activity safely given the staffing resources available.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
	that the centre's licence is suspended.	**in a month**. When there are less than 6 OPUs planned, it was felt that it was safe to authorised FET when needed to replace the cancelled OPUs.	
Incident A: **The disposal of some pre-2007 stored samples without identification and witnessing** **SLC T71** **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 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.	• 2 new staff members (embryology practitioners) have been in post since the 1st August 2011 to support the team in carrying out the audits for incidents A and B. • Individual patients affected will be contacted (attempts will be made to contact the GP or recorded delivery will be arranged in case they do not answer to the contact numbers that we have in the notes); they will be sent an appointment to see the PR together with head of the lab where the	The PR has provided an action plan and the inspection team considers the centre is taking appropriate steps to implement this recommendation. The outcome will be closely monitored. The slight delay in implementation is to be expected given the need to recruit and induct staff to assist such audits. These staff are now recruited and the audits will progress. The proposed actions when it is found that a patient's samples have been discarded have been

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
		news will be given. Counselling support will be offered. • Where appropriate cases will be discussed on an individual basis with senior managers if further action is required. • The audit is planned to start 1st October and results will be available before the end of the calendar year.	reviewed by the inspection team and are considered reasonable and proportionate. 30 September 2011: This action is still on-going.
Incident B: **Donor screening and laboratory testing** **SLC T52** **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.	• 2 new staff members (embryology practitioners) have been in post since the 1st August 2011 to support the team in carrying out the audits for incidents A and B. • The audit is planned to start 1st October and results will be available before the end of the Year.	The donor recruitment programme at the centre has been suspended. The results of the donor record audit were reviewed and indicated that the centre has partially complied with the recommendation. The donor records remain however to be audited against the card based system storing donor details.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
	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 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.	• Results of the audit of the donor records and action plan is attached • The risk of cross contamination will be clarified after the viral load test of the individual straws will be carried out.	Advice has been provided to the centre regarding the audit report and the method of audit. Information has been requested to ensure the recommendation is implemented. The centre plans to audit the donor samples in storage against the records starting 1 October 2011, which will completely satisfy the recommended actions. The slight delay in implementation of this recommendation is to be expected given the need to recruit and induct staff to assist the audit. Update – 10/09/2011 – the PR has provide a revised audit report that is currently under review. 30 September 2011: The audit report has been

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
			reviewed by the inspection team and was considered detailed and thorough, and included audit of the clinical records as well as the card based system. It indicates that 12 donated sperm samples were used in 76 treatments, though they were inappropriately quarantined. Corrective actions have been taken to prevent recurrence and the revised procedures have been risk assessed and have been determined to be safe. Follow up actions, including viral testing of the 12 donor sperm samples, are being implemented and patients will be contacted if there any risks to their safety are identified.
QMS; QI monitoring SLCs T35 and T32	The PR should ensure an effective QI monitoring programme is established and maintained for all critical activities and	• A dashboard is being developed (attached), this will allow the QM to	The dashboard document provided was considered by the inspection team to be

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
	processes within the centre. To initiate this action, 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 HFEA Executive should be provided with a monthly update on progress and the action should be completed by 30 September 2011.	monitor the QIs at glance and alert the PR of any problem • A lead clinician and a senior embryologist have been allocated to develop the QIs according to the HFEA guidance. • A monthly update will be provided • Up to date QIs attached at the bottom of validation document for your information	incomplete in providing QIs for all critical processes at the centre. It provides QIs which were generally targeted at the service provision and top level functioning of the centre, rather than at the level of the critical processes. The dashboard is though said to be in development and senior staff should consider including further QIs to cover all critical processes. For example the process validation document provided by the centre to the inspection team includes laboratory QIs not found in the dashboard, such as monthly monitoring of:; IVF fertilisation rate; the post ICSI fertilisation rate, abnormal fertilisation rate and degeneration rate; oocyte immaturity; post freeze survival rates. These QIs provide a useful overview of

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
			the laboratory function which the inspection team considers important given the scope of this inspection and suggest should be included in the dashboard. These laboratory QIs have been updated to June 2011 indicating that QI monitoring in the laboratory is now occurring. The on-going design and implementation of the QI programme will be monitored by the inspection team. 30 September 2011: An updated version of the dashboard was provided by the centre which includes more QIs related to laboratory function. The dashboard also contains monthly data for the centre's performance indicating it is being completed.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
			The implementation of the QI monitoring programme will be regularly reviewed by the inspection team.
QMS; audit **SLC T36 and T32**	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. 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 programme by 5 August 2011.	• SOPs are currently under revision and update • An update audit plan is attached • The subspecialist trainee (AGS) had been allocated the task of Audit coordinator and he will work jointly with QM to provide monthly audits at the WCM • At the monthly WCM audits will be presented and appropriate actions will be discussed accordingly.	The inspection team notes that the audit plan provided details of audit by Key Performance Indicator (KPI) monitoring and/or retrospective review of patient records. The recommendation requires the centre 'to verify that critical practices and processes at the centre adhere to the documented SOPs and that those SOPs comply with regulatory requirements.' This will need review of the actual practices carried out against the protocols, and of the protocols against the regulatory requirements. The PR should revise the audit plan to include these practice audits.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
			Some recommendations have also been made to the PR regarding further items to be included in the audit plan, e.g the multiple birth minimisation strategy, processes involved in maintaining confidential, information provision. The on-going design and implementation of the audit programme will be monitored by the inspection team. Update - 10/09/2011 – the PR has provided a copy of the revised audit plan and this is currently under review. 30 September 2011: The revised audit programme states that practice audits against the documented procedures will be completed and also includes audits in

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
			further areas identified by the inspection team. The implementation of the audit programme will be monitored by the inspection team.
The validation of process and practice changes SLC T24 and T72	Change in processes and practices at the centre should be validated before implementation. This validation must be documented. 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.	• Updated validation document attached • However, according to the new Head of embryology who recently saw this document for the first time, the lab processes have not been described completely and this needs major work. • The new validation document will be produced by the 30th September and it will incorporate also the possible changes suggested by the external reviewers.	The existing validation document was reviewed and it was noted that some evidence for validation was not referred to specifically enough e.g. 'research papers' was stated without further references. The major work planned by the new Head of Embryology should address this issue. The inspection team considers that the completion date for the revised validation documentation for the centre's processes of 30 September 2011 is reasonable. The review of the centre's process validation documentation will continue

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
			to be monitored by the inspection team. 30 September 2011: The lead embryologist has liaised with the centre's inspector regarding process validation. The centre plans a full revalidation of their processes using the templates produced by the Association of Clinical Embryologists. This will take considerably more time than a revision of the existing validations, however the centre wish to progress in this manner to ensure their processes are as effective as possible. The centre's inspector considers that a revised deadline of 15 January 2012 would be appropriate for the completion of this task. This longer deadline is considered reasonable given the work

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
			required and safe given the existing process validation already in place

Major area of non compliance and concern

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
Incident B: **Donor screening and laboratory testing** **SLC T52** **SLC T53c**	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. Any non-compliances should be corrected, and should also be reviewed to determine whether the non-compliance may have implications for the safety of users of donor gametes.	• Revised donor SOPs attached	The inspection team have reviewed the SOPs and have provided the PR with recommendations for their improvement which should be implemented. The revised SOPs should be submitted to the Executive for review. The PR should also note that any non-compliances in past practices should be reviewed to determine the implications for the safety of users of donor gametes. The Executive should be updated

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
	This action should be completed by 5 August 2011		monthly on progress. Update - 10/09/2011 – the PR has sent in the revised SOPs and they are currently under review. 30 September 2011: The donor audit indicated that inappropriate testing for chlamydia has been performed on all donor sperm used at the centre - a complement fixation based blood test rather than a nucleic acid amplification test of urine. The risks of this have been determined and risk control measures have been implemented. Corrective actions have also been taken to prevent recurrence and the revised procedures have been risk assessed and determined to be safe. The inspection team will liaise with the centre if

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
			any further follow up actions are deemed necessary. SOPs for donor screening have been reviewed and amended as suggested by the inspection team.
QMS; QM training and time allocation **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. This action should be completed by 31 August 2011.	• QM will attend the earliest available training course on the 05-06/12/2011 (already booked and paid) • Copy of QM appraisal is attached • QM will spend 2 full days in the O&G Directorate office to focus on QMS without distractions and 3 full days on site (C1 IVF Wales) to provide support and perform her duties according to her job plan.	The inspection team considers the centre have provided evidence that appropriate steps have been taken to implement this recommendation. The inspection team will continue to monitor the development of the QMS and thus, indirectly the training and time in the role allocated to the QM.
The accreditation of the andrology laboratory	It was noted by the inspection team that the andrology laboratory has made no progress	• Decision NOT to apply for CPA accreditation for	The inspection team is disappointed that the

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
SLC T21	with attaining accreditation from the CPA, despite this being a corrective action recommended by the report of the renewal inspection in April 2011. 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.	andrology in IVF Wales was taken • Negotiations are ongoing with the Pathology department to move the service to them within the LHB • If no agreement reached andrology potential to move to an accredited service within a different LHB – that service is visiting site 5th Sept. to discuss activity and potential model of working. • A monthly update on this very issue will be provided	andrology service will not be seeking CPA accreditation but note that the centre is taking action to move the service to bring it under the responsibility of the Pathology Department at the current hospital site, which is CPA accredited, or to move the andrology department to an accredited service within a different hospital. The centre should note that until the andrology service is CPA accredited, it is contrary to SLC T21 for the centre to use the andrology service to provide diagnostic tests to patients undergoing HFEA licensed treatments. The PR should therefore continue to provide monthly updates on this matter to the HFEA and should ensure the centre are using a CPA

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
			accredited andrology service to satisfy their patients' diagnostic andrology needs.
The late submission of early outcome forms via the EDI system General Direction 0005	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.	• New EDI SOP generated and circulated (attached) • Nurse (LG) allocated to task in order to clear backlog and to keep up to date • 100% of clinical backlog cleared (29/07/2011); Newly appointed embryology practitioners will clear lab backlog • Newly appointed admin officer (CB) being trained to validate EDI data entry weekly • Weekly report and monthly audit to be generated by CB for the attention of the PR • Any error will be investigated, rectified and discussed with the team to avoid this from	The inspection team considers the centre have taken appropriate steps to implement this recommendation and will be monitoring the centre's EDI data entry closely to ensure successful implementation.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
		happening again • EDI audit to be presented to the team and the Whole clinic meeting (WCM) monthly (as included in the audit plan) • Email to the HFEA to install EDI access in more PCs	

Other areas of practice that require improvement

Other areas of practice that require 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
None noted at time of inspection.			

Additional information from the Person Responsible
1) Page 15: Interview for the appointment of full time nurse manager planned on Friday 5th August 2011; 2 embryology practitioners appointed and in place since 1st August 2011. 2) Page 18: The former head of the lab changed the way the lab data were collected in the database, preventing the former PR from having a clear picture of the lab performance, however, the clinical database was never changed and data were inserted always on time. There was no time between Jan-March 2011 to generate any QI because of the high workload; however it would have been very easy for the former PR to check the current pregnancy rate simply checking the clinical database. The accredited Consultant (ADA) and the Lead Clinician (GJ) have raised the issue of the dropping PR with the former PR several times. Also the QIs were produced on time until Dec 2010 but the drop in the PR was not that high. The trend was there and the PR reached the lowest level in the first 3 months of 2011. I am now attaching our latest clinical QIs for information (end of validation document). 3) Since I started my PR role within IVF Wales (June 2011) lots of changes happened in the Unit. Firstly a new organizational chart was created where in addition to the designation each member of the team was given a task and was made accountable to me. In this way I feel that I am valuing the individual qualities of my team and engaging them more actively in the running of the Unit. Allocating tasks was an important step and it helped me to provide this completed action plan on time. Without the help of each member of the team this would not have been possible. This reflects the high level of commitment from all the staff in the Unit and a strong team spirit. To me this is something new in Ivf Wales! Moreover, the clinical pregnancy rate has incresed drammatically and it is still increasing, showing that the level of activity agreed between the HFEA and the PR is adeguate to the tasks that we have to undertake at the moment.This has been possible thanks to the deep commitment of the UHB Managerial Team who have supported me in undertaking the recommended level of activity. Seeing positive pregnancy test boost everyone morale!

I felt my Unit needed some help and this was provided very quickly by the Managers in arranging for an external review to be carried out by a PR from another licensed centre who had attended the unit on the 30th August 2011. I felt that his input was essential for my role as PR and for my Unit.

I believe that I have shown that we are a strong and qualified team, that we can provide a good and safe service to our patients and that we can comply to the HFEA and the clinical governance regulations. Whilist there are still investigations pending at the level of the some of the lab/andrology and the former PR, I would like to draw the HFEA attention to the fact that such changes were never achieved before by my predecessor and this should be taken into account should the return of the former PR be considered following the investigation outcome. Currently there is a very positive and constructive team atmosphere with no personality conflicts which makes the work more pleasant and staff feel in general more motivated to perform their task efficiently, reflecting on better patient care.

It is important to highlight that the very stressful experiences we have all lived in IVFWales over the past few months, as a result of the two major incidents reported to the HFEA and to the suspension/deployment of three members of staff, have also been very important learning experiences. These experiences have shown how paramount it is to be 100% compliant with the HFEA regulations, keeping up to date quality indicators and protocols and undertaking regular competency assessments and audits, just to name a few of the many compliance activities that a licensed centre should undertake routinely. Having an adequate staffing level in order to ensure that compliance activities can be undertaken efficiently has also been shown to be of paramount importance. We have all learned that non-conpliance with HFEA regulations can potentially result in catastrophic events, compromising patient safety, and having huge negative effects on staff, the Unit and the Health Board, including finantial loss.

For the future I hope to be able to lead my team and my Unit at the highest standard to be able to provide our patients top class

care and new treatments in a safe and pleasant enviroment complying 100% to the HFEA regulations.

Appendix 1: Areas of practice that required the attention of the Person Responsible as detailed in the report of the renewal inspection on 14 & 15 April 2010

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 direct risk of causing harm to a patient, donor or to an embryo. A critical area of non-compliance requires immediate action to be taken by the Person Responsible.

Area of practice/reference	Action required with timescale	PR Response (16/06/2010)	Executive Review
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 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.	I am assured by the clinical director that this is being actioned- if not I will resign as PR	16 June 2010: The PR provided a document detailing the options available to address the regulatory issues in the cryostore raised by this inspection report. These options need to be reviewed, costed and agreed by Health Board management. 30 June 2010: Evidence was provided in emails from the PR that an action plan for addressing the cryostore regulatory issues has been prepared and that the Health Board management have agreed to support and finance the plan. The inspectorate considers the plan, if

The suitability of the cryostore for licensed activity is thus questionable (Licence Condition T17)	These actions should be immediately initiated and completed as quickly as possible.		fully implemented, should bring the centre to compliance regarding this issue.

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 or to an embryo through the procurement, use, storage or distribution of gametes and embryos, which do not comply with the centre's licence;
- 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/reference	Action required with timescale	PR Response	Executive Review
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. Third party agreements are in place with some but not all suppliers, non-compliant with Licence Condition T111.	The PR should ensure that third party agreements, 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	Non responders are being chased up. Done 3rd party agreement with courier service and surgical short stay. Bristol contingency plan is currently with them waiting for signature - I have sent a reminder today	21 June 2010: The proposed third party agreement with the contingency centre was provided. The PR has also stated that agreements are in place with the third party courier company and the day surgery unit. The inspectorate consider the PR has acted appropriately but needs to continue efforts to ensure appropriate third party agreements are developed with all providers of critical goods and services, to comply with T111.

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 third party agreements already in place, non-compliant with Licence Condition T116.	Third party agreements 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	Additional clauses have been inserted into recent agreements and will need to be inserted into old agreements	The inspectorate considers the actions taken comply with those required. New agreements have been amended to comply with T116, while older agreements will be assessed for compliance and amended accordingly, by April 2011, according to the centre's post-inspection action plan
There have been staffing resource issues at the centre, which have in general initiated positive action plans. These include the proposed appointment of a QM, an embryologist and nursing staff, and staff training (e.g. in conscious sedation; life support training; ultrasound scanning). The nominated medical practitioner has not had time however to have an effective handover, or to cover the clinical governance aspects of the role and to obtain appropriate training to do so. Some staff have also not undergone basic and advanced life support training in the last year. These issues are potentially non-compliant with Licence Conditions T12 and T15a.	It is recommended that the PR ensures that all actions plans regarding staffing issues are progressed to completion, to ensure compliance with Licence Conditions T12 and T15a. It is recommended that the PR regularly reviews staff numbers and training and centre resources, to ensure they are adequate to support the proposed activity, as required by HF&E Act (1990) as amended, 17 (1) and Licence Conditions T12 and T15a. This is especially important in times of increasing activity, as are likely at the centre in the coming year.	The management of the directorate is aware that there will be no change in staff / activity ratios. Also that the nominated medical practitioner has concerns over her SPA sessions to support this activity - this will need to be covered at her next appraisal with her line manager - the clinical director. Life support training is being cascaded form one trained senior nurse. More nurses to start scan training	15 June 2010: The PR advised the inspectorate of significant staffing changes due to the resignation of several staff members, two of whom are members of the centre management team. It was confirmed by email (on 30 June 2010) that these posts have been advertised. The PR provided a document reviewing the staffing resources needed to support various levels of activity, dependent on future development plans. This has been provided to Health Board management and the PR has advised them that the proposed activity level must be appropriate for these documented staffing ratios. The document will be regularly reviewed The centre's post-inspection action plan includes the progressing to completion, by 1 October 2010, of the actions

	It is also recommended that the nominated medical practitioner be provided with effective induction and training for the role, as well as adequate time to perform it, to comply with Licence Conditions T12 and T15a. These actions should be completed by 1 October 2010.		already initiated and discussed in 'Area of Practice'. In discussions with the nominated medical practitioner, she confirmed that she had been provided with induction and training for the role. The inspectorate consider the centre is complying with the required actions, though some remain to be completed
The DVD video provided to patients regarding ART treatment at the centre was produced before the regulatory changes which occurred in October 2009. Thus it discusses an initial statutory storage period for embryos of five years, rather than the current 10 year initial period. It also refers to evening patient information sessions at the centre, which have not occurred for more than a year due to financial constraints. These inaccuracies may be confusing to patients.	The PR should review the information provided to patients in the DVD video and ensure that where there are inaccuracies, that these are clarified to the patient in written document which can be provided with the DVD video. These actions should be completed by 1 October 2010.	We will write a memo to go with the DVD to bring it up to date	The centre's post-inspection action plan, provided on the 16 June 2010, details that the DVD will be reviewed for accuracy. A leaflet will then be prepared and provided with each DVD to correct inaccurate information. This action will be completed by 1 October 2010 and will satisfy the requirements detailed in the inspection report

The 'procedure for confidentiality' and/or SOP for 'maintenance of patient case note folders', do not include all requirements of Licence Condition T44, including documenting 'arrangements for establishing and maintaining procedures to identify and resolve data discrepancies. '	The PR should review the 'procedure for confidentiality' and/or SOP for 'maintenance of patient case note folders' and ensure that mechanisms are described within either or both procedures, for identifying and solving all data discrepancies, to comply with Licence Condition T44. This action should be completed by 1 September 2010	We will look at the protocol and amend	The required action is detailed in the centre's post-inspection action plan, provided on the 16 June 2010, for completion by September 2010 and will satisfy this requirement if completed.
The QIs developed for patient confidentiality focus on the collection of consents for disclosure. The inspectorate consider that other QIs need to be developed to provide the PR with on-going measures of the centre's compliance with all aspects of the CoP confidentiality requirements, to attain compliance with Licence Condition T35	The PR should investigate including other QIs for patient confidentiality to ensure compliance with Licence Condition T35. This action should be completed by 1 September 2010	We will look at other possible QIs	The centre's post-inspection action plan, provided on the 16 June 2010, states that new QIs are to be discussed between senior staff. When decided upon, the new QIs will be included in the audit programme. These actions should be completed by September 2010 and will satisfy this requirement when completed.
Some of the forms of documentation by which identity is 'verified', as listed in the patient care pathway document, are possibly unreliable, for example a works ID badge, bank card or recent utility bill. This contradicts the centre's	The PR should limit the forms of documentation used to verify patient identity, to those which are most likely to be reliable and include photographic information, such as a passport or driving licence. This will	We will amend the process and protocol to use just photo ID	The centre's post-inspection action plan, provided on the 16 June 2010, states that the patient care pathway document will be updated to allow only photographic forms of identification to be used. This action should be completed by August 2010 and will

protocol for confidentiality ('all couple are asked for photo ID at the first visit') and is non-compliant with CoP Guidance 5.10 and 5.11.	ensure compliance with CoP Guidance 5.10 and 5.11 and should be completed by 1 August 2010.		satisfy this requirement when completed.
The centre reported a MPR of 28% in 2009. It is likely that this will lead to a MBR above the 24% target set by Direction 0003 for 2008/09. The inspectorate recognises however the significant improvement in MPR relative to 2008 and the recent review of the MBMS at the centre which may allow them to comply with the 20% MBR target for 2009/10.	It is recommended that the PR monitors the centre's MBMS and how it is applied, to ensure that the 20% MBR target is achieved. Patient information should be reviewed to ensure any reference to a target MBR is accurate (e.g. 20% in 2010/11). These actions should be on-going.	We will continue to encourage patient couples to have eSET	The centre's post-inspection action plan, provided on the 16 June 2010, states that the proposed provision of a second IVF cycle on the NHS should make it easier to convince patients regarding SET. It also states that the MBMS will be regularly audited. This action is on-going and will satisfy this inspection report requirement.
There is no documented procedure for generating a patient's laboratory worksheet. Given this document is used in recording all laboratory processing, as well as in witnessing, its preparation should be according to a documented procedure to ensure consistency and accuracy (Licence Condition T33b)	The PR should ensure a procedure for establishing a patient's laboratory worksheet is prepared to comply with Licence Condition T33b. This action should be completed by 1 August 2010.	SOP written	The centre's post-inspection action plan, provided on the 16 June 2010, states that the SOP for work sheet completion has already been prepared. There remain no outstanding regulatory issues regarding this matter

The documented SOP for gamete and embryo distribution does not include procedures for recall, including responsibilities and actions to be taken, or for dealing with returned samples, contrary to HF&E Act (1990) as amended, Schedule 3A (11) and Licence Condition T122.	The PR should review the gamete and embryo distribution protocol and modify it to include procedures for recall, including responsibilities and actions to be taken, and for dealing with returned samples, to comply with Licence Condition T122. This action to be completed by the 1 September 2010	SOP being amended	The centre's post-inspection action plan, provided on the 16 June 2010, states that the SOP for distribution will be modified as required by the LM. This action should be completed by 1 September 2010 to satisfy this requirement.
The centre has sent a third party agreement to the courier company who transport samples, which includes a specification of the required transport conditions. It has not yet been returned so the centre is non-compliant with HF&E Act (1990) as amended, Sch 3A (11) and Licence Condition T111	The PR should ensure that a third party agreement, compliant with HFEA requirements, is established between the centre and the courier company, to comply with Licence Condition T111. This action should be completed by 1 September 2010.	Done	21 June 2010: The third party agreement with the courier company was stated by the PR, in an email, to have been established. This was confirmed by email on 6 July 2010. There remain no outstanding regulatory issues regarding this matter
The SAQ stated that QIs for laboratory processes had not been developed, contrary to licence condition T35. This was in part confirmed on inspection (e.g. for cryostorage and traceability), though a number of performance indicators in the laboratory are monitored and regularly reviewed, for example the fertilisation rate, ICSI survival rate, and the percentage of embryos growing to the eight cell and	The PR and Laboratory Manager should assess the performance indicators currently monitored, and review which other QIs are required to provide adequate information to the management team regarding the quality, safety and effectiveness of the laboratory processes, to ensure compliance with Licence Condition T35. This action should be completed by 1 September 2010	We willl discuss extra QIs at the next whole clinic meeting	The centre's post-inspection action plan, provided on the 16 June 2010, states that laboratory QIs will be reviewed to ensure all critical processes have QIs. This action should be completed by 1 September 2010 to satisfy this requirement.

blastocyst stages.			
Some procurement and processing procedures have not been audited against the approved procedures, the regulatory requirements and QIs in the last two years, for example cryostorage and transportation procedures, non-compliant with Licence Condition T36.	The PR should ensure procurement and processing procedures are reviewed against the regulatory requirement and QIs, to comply with Licence Condition T36. This action should be completed by 1 September 2010	We will include in audit programme	The centre's post-inspection action plan, provided on the 16 June 2010, states that procurement and processing procedures will be audited against QIs and the regulatory requirements by September 2010. This action must be completed by 1 September 2010 to satisfy this requirement.
The Laboratory Manager notified the Executive prior to the inspection that the centre had imported sperm under General Directions 0006 but due to confusion over the status of the supplying centre, had failed to notify the HFEA within five days of the import, as required by General Directions 0006.	The PR should review procedures and ensure that the HFEA is notified of any transfer under General Directions 0006 within five days. This action should be completed by 1 September 2010	We will review protocol and ensure all are aware	The centre's post-inspection action plan, provided on the 16 June 2010, states that the transportation SOP will be updated appropriately by September 2010. This action should be completed by 1 September 2010 to satisfy this requirement.

The centrifuges, air flow cabinets and ICSI microscopes used for gamete and embryo processing are not logged in patient records, to allow for full traceability, non-compliant with Licence Condition T22.	The Laboratory Manager stated that plans are in place to log the centrifuges, air flow cabinets and ICSI microscopes used for gamete and embryo processing. These plans should be implemented to comply with Licence Condition T22. This action should be completed by 1 September 2010	Equipment to be included on patient lab record	The centre's post-inspection action plan, provided on the 16 June 2010, states that the laboratory work sheet will be modified to allow the recording of equipment for traceability purposes. This modification will be completed by September 2010. This action should be completed by 1 September 2010 to satisfy this requirement.
PESA and TESA procedures, which constitute procurement i.e. a licensed activity, are performed in a day surgery unit within the same hospital. These premises are not listed as licensed premises, thus procurement there would be in breach of HF&E Act (1990) as amended, Section 12 (1) and Licence Condition T1.	It is recommended that the PR develop a third party agreement with the day surgery unit, to allow licensed procurement there and comply with Licence Condition T1. This action should be completed by 1 July 2010. Procurement activities should not occur in the day surgery unit until this third party agreement has been developed.	Done and signed	21 June 2010: The PR stated in an email that a third party agreement has been established with the day surgery unit. The third party agreement was provided to the inspectorate on 6 July 2010. There remain no outstanding regulatory issues regarding this matter
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.	We are working towards this	The centre's post-inspection action plan, provided on the 16 June 2010, states that the centre will attempt to obtain CPA accreditation for the diagnostic andrology service. Several options are available. The recruitment of a QM and the purchase of an effective document management database will facilitate the process. Accreditation should be completed by 1

			January 2011 to satisfy this requirement
The centrifuges used in sperm preparation have not been validated, contrary to Licence Condition T24.	The PR should ensure that the centrifuges are validated, to comply with Licence Condition T24. This action should be completed by 1 September 2010	The head of embryology is looking at this, but it would be cheaper to buy a new one	The centre's post-inspection action plan, provided on the 16 June 2010, states that the centrifuges will be validated by the LM by September 2010. This action should be completed by 1 September 2010 to satisfy this requirement.
The Centre has a considerable number of errors in HFEA registry data entered to via the electronic data interface (EDI), a situation also noted at the inspection in March 2009 and non-compliant with General Directions 0005; paragraph 4. It was also noted that IT issues at the centre have prevented upgrading of the EDI system	The PR should ensure adequate staff and other resources are available to provide accurate data to the HFEA Registry and to clear errors in the historic data set in a manner compliant with General Directions 0005; paragraph 4. This action should be completed by 1 September 2010	The staff have put in a big effort and cleared the majority there are still interface problems at the EDI2 installation however	1st June 2010: Staff at the centre have worked closely with the HFEA and the upgraded EDI2 system is now operational. The centre staff have also corrected numerous registry data errors. Virtually all errors in Registry data from 01/01/2005 to date have been cleared. There remain no outstanding regulatory issues regarding this matter
The centre does not have QIs in place relevant to the submission of data to the HFEA, non-compliant with Licence Condition T35.	The PR should ensure that appropriate QIs and objectives are established for data entry to the HFEA, to comply with Licence Condition T35. This action should be completed by 1 September 2010	Done	The centre's post-inspection action plan, provided on the 16 June 2010, states that QIs for EDI data entry have been established. The rapid clearance of EDI errors suggests the centre have control of EDI data entry issues. There remain no outstanding regulatory

			issues regarding this matter.
The procedures relevant to EDI data entry have not been reviewed against regulatory requirements in the last two years, non-compliant with Licence Condition T36.	The PR should ensure that procedures relevant to EDI data entry are reviewed against the regulatory requirements to comply with Licence Condition T36. This action should be completed by 1 September 2010	We have included this on the audit programme	The centre's post-inspection action plan, provided on the 16 June 2010, states that EDI data entry procedures have been added to the audit schedule. The audit of those procedures needs to be completed by 1 September 2010 to satisfy this requirement.
The 'maintenance of patient case note folders' procedure does not describe how patient records are tracked while moving around the centre (Licence Condition T44a and T44c) or specify the responsibility of the holder for the confidentiality of the record (Licence Condition T47). This procedure also requires record retention 'for at least a 10 year period after expiry, clinical use or disposal', contrary to Licence Condition T48.	The PR should review the 'maintenance of patient case note folders' procedure and ensure it states appropriate 10, 30 or 50 year retention periods, as required by Licence Condition T48. It should also contain processes to ensure the security and traceability of patient records, as required by Licence Conditions T44a, T44c and T47. This should be completed by 1 September 2010.	We will review this	The centre's post-inspection action plan, provided on the 16 June 2010, states that an SOP will be developed for tracking notes in the centre, which will also discuss the records retention requirements. These procedures need to be completed by 1 September 2010 to satisfy this requirement.

Other areas of practice that requires improvement

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

Area of practice/reference	Action required with timescale	PR Response	Executive Review
The centre's egg donor and sperm donor SOPs are compliant with Licence Condition T52g, but not with CoP Guidance 11.15 which requires screening to be in accordance with professional body guidelines. These require all sperm and egg donors should be: 1) screened for HTLV-1 and HTLV-2; 2) physically examined; 3) assessed for prion disease risk; 4) tested for blood group and rhesus factor. These assessments are currently not stated in procedures or performed. The inspectorate also has concerns regarding the use of self swabbing for testing for gonorrhoea; swabbing by a nurse would be more likely to provide a definitive test results.	The PR should ensure that the centre's practices for donor screening are fully and reliably compliant with Licence Condition T52 and CoP Guidance 11.15. This will require review of the procedures for dealing with egg and sperm donors. All patient information provided to sperm donors, egg share recipients and providers, egg donors, and parties to surrogacy arrangements will also need review to ensure compliance with CoP Guidance 4.2 h This assessment and review should be completed by 1 August 2010.	I have written to virology to inform them that we will be commencing HTLV screeing on donors. the reason for not doing so previously, was that their advice was that the prevalence in the locality was so low - they have never had a positive. I have written to our urologist to ask him to see and examine all the donors and take swabs	The centre's post-inspection action plan, provided on the 16 June 2010, concurs with the actions indicated in the PRs response and states that the screening protocol will be updated The PR should note that these responses have not met the requirements regarding: 1) prion disease risk; 2) testing for blood group and rhesus factor. The PR should ensure actions are taken to address these screening issues. These actions need to be completed by 1 August 2010 to satisfy this requirement.

Information provided to patients regarding egg sharing stated that a cancellation cost would be charged to the egg provider in the event of them withdrawing their consent to the sharing arrangement during ovarian stimulation. Such a charge is contrary to CoP Guidance 12.10.	12.10 states that 'If either the egg provider or recipient in an egg sharing arrangement withdraws their consent after preparation has begun, the centre should bear any financial loss it sustains'. The PR should review the centre's practice and patient information in this area to comply with CoP Guidance 12.10. The should be completed by 1 August 2010	Actioned and protocol being revised	The centre's post-inspection action plan, provided on the 16 June 2010, indicates that the centre will bear the financial loss in this situation and that the protocol and patient information will be revised. These actions need to be completed by 1 August 2010 to satisfy this requirement.
It was recommended in the last inspection report that a dedicated QM be appointed. This is now a regulatory requirement (CoP Guidance 23.3a and 23.4) and its importance is indicated by the assistance a QM will provide with other non-compliance noted in this report.	The PR should progress with the appointment of a dedicated QM to ensure compliance with CoP Guidance 23.3a and 23.4. This should be completed by 1 October 2010	Management still identifying funding	Health Board management said on inspection that a dedicated part-time QM would be appointed, finance having been recently approved. This would appear to not concur with the PRs response. It is suggested that the centre act on this recommendation by 1 October 2010.
Complainants at the centre must address formal written complaints to the Health Board Chief Executive, who is an unlicensed person. There is a risk that the consent for disclosure implied by the letter may not be freely given, as there is no option to make a formal complaint to a licensed person.	The PR should appoint a nominated complaints officer from the centre staff, to receive formal written complaints, to comply with CoP Guidance 28.4. Practices and procedures should be modified to reflect this change. These recommendations should be	We have a nominated an in-house complaints officer who is on the licence, and anonymises the complaints before they leave her office. Some complainants write directly to the chief exec however	The centre's post-inspection action plan, provided on the 16 June 2010, concurs with the PRs response. It states that there is a nominated complaints officer on the centre's licence. Thus there are no outstanding regulatory issues regarding this matter. The inspectorate note that the complaints procedure and patient

To prevent this, the centre should have a nominated complaints officer, as is required by CoP Guidance 28.4 Written complaints can then be directed to this person and an anonymised version forwarded to the Chief Executive.	completed by the 1 August 2010.		information will need updating to include that complaints can be made to the nominated person
The 'procedure for confidentiality' states that 'notes are released to the complaints manager in the event of a complaint'. As the centre does not have a nominated complaints officer, and all formal complaints must be sent by patients to the Health Board Chief Executive, it is likely that the complaints manager is a Health Board employee and is unlicensed. In addition, as formal written complaints must be sent to the Chief Executive, they can not be considered as freely providing informed consent for disclosure. These procedures may potentially lead to the disclosure of patient identifying information to an unlicensed person, without effective consent, in contravention of HF&E Act (1990) as amended, S33	It is recommended that the PR appoints a complaints officer within the centre and then puts in place a system by which complaints can be anonymised and sent to the Health Board Complaints manager. In the event that an investigation by non-centre staff is performed, it is recommended that such staff are briefed regarding the confidentiality issues related to the HF&E Act (1990) as amended, provided an appropriate induction to the centre's activities, and placed on the licence. This action should be completed by 1 September 2010	See above	The centre's post-inspection action plan, provided on the 16 June 2010, concurs with the PRs response. It states that there is now a nominated complaints officer on the centre's licence. Thus there are no outstanding regulatory issues regarding this matter.

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 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.	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. These actions should be completed by 1 August 2010.	SOP to be revised	The centre's post-inspection action plan, provided on the 16 June 2010, indicates that the centre will update the procedure for training, as required, and will develop appropriate QIs to monitor the effect use of embryos in training. These actions need to be completed by 1 August 2010 to satisfy this requirement.
The centre's 'ovarian hyperstimulation protocol' does not include the requirement to report OHSS which requires a hospital admission, to the HFEA as an incident (CoP guidance 27.1).	It is recommended that the PR amends the 'ovarian hyperstimulation protocol' to include the reporting to HFEA of all incidents of OHSS requiring hospitalisation, to comply with CoP guidance 27.1. This action should be completed by 1 August 2010	SOP to be revised	The centre's post-inspection action plan, provided on the 16 June 2010, indicates that the OHSS protocol will be updated, as required, by August 2010. These actions need to be completed by 1 August 2010 to satisfy this requirement

An audit of counselling QIs is planned in 2010 but was not listed on the centre's audit schedule for 2010, with appropriate quality objectives, non-compliant with Licence Condition T35.	The PR should ensure the audit schedule for 2010 includes the counselling audit, to ensure compliance with Licence Condition T35. This action should be completed by 1 September 2010	We will include on the audit programme	The centre's post-inspection action plan, provided on the 16 June 2010, states that new QIs, including for counselling, are to be discussed between senior staff. The new QIs will be included in the audit programme. These actions should be completed by 1 September 2010 to satisfy this requirement.
Some documents in the quality manual have not recently been reviewed (CoP Guidance 31.6), while others do not have appropriate document control features (CoP Guidance 31.4). One document could not be found in the quality manual index.	The PR should ensure that all documents in the quality manual are reviewed at least annually (CoP Guidance 31.6) and that all have a common pattern of document control features which include: (i) a unique identifier (for instance, the edition, or current revision date or revision number); (ii) page numbers and total number of pages (for example 'page 3 of 10'); (iii) authority for their issue; (iv) author identification (CoP Guidance 31.4).	I am advised that if we obtain a CD writer (NHS PCs do not have these) then the SOPs can be stored as PDF and amended in an organised way	The centre's post-inspection action plan, provided on the 16 June 2010, indicates that this issue will be assisted when the QM is appointed. The centre also plans regular protocol review sessions at the centre management meeting. Finally the purchase of a CD writer is described. The inspectorate considers the appointment of a QM will significantly enhance the centre's success in dealing with this issue.
In the year to 6 March 2010, the centre took an average of 43 days to pay the 12 HFEA invoices issued. This is a significant improvement compared to the situation in March 2009. The PR should note however	The PR should take appropriate actions to attempt to meet the 28 day payment deadline for HFEA invoices, as required by Licence Condition T9d.	I will let finance know	The inspectorate were informed on 1 July 2010 that one reason for delays in paying invoices is that they are sometimes sent to the wrong address in the hospital (that of the research licence). HFEA Finance has been advised of this. The PR has discussed this issue with the Health Board

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 ensure fees are paid within the written specified timescale.			Finance Director. The inspectorate is satisfied with the centre's progress in this area.

HFEA Licence Committee Meeting

20th October 2011

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

Minutes – Item 1

Centre 0049 (IVF Wales) – Incident Inspection Report

Members of the Committee: David Archard (lay) – Chair Anna Carragher (lay) Mair Crouch (lay)	Committee Secretary: Terence Dourado 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 following papers were considered by the Committee:

- Incident Inspection Report
- Latest clinical quality indicators (for information – as mentioned on page 37 of the report)
- E-mail to Licence Committee Secretary with a copy of the external review report and the comments to the review by the Person Responsible.

Licence History

- Executive Licensing Panel (ELP) minutes – variation to change the Person Responsible (PR), 04/06/11
- ELP minutes – variation to change the Licence Holder (LH), 20/10/10
- Executive Licensing Panel minutes – renewal inspection report, 15/07/10
- ELP minutes – variation to change LH, 24/02/10
- Licence Committee (LC) minutes – breach of licence conditions, 03/12/09
- LC minutes – interim inspection report, 10/06/09
- LC minutes – incident report, 28/01/08

The Committee also had before it

- HFEA Protocol for the Conduct of Licence Committee Meetings and Hearings
- 8th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- Decision trees for granting and renewing licences and considering requests to vary a licence (including the PGD decision tree); and
- Guidance for members of Authority and Committees on the handling of conflicts of interest approved by the Authority on 21 January 2009.
- Guidance on periods for which new or renewed licences should be granted
- Standing Orders and Instrument of Delegation
- Indicative Sanctions Guidance
- HFEA Directions 0000 – 0012
- Guide to Licensing
- Compliance and Enforcement Policy
- Policy on Publication of Authority and Committee Papers
- HFEA Pre-Implantation Diagnostic Testing ("PGD") Explanatory Note For Licence Committee

Background

1. The Committee noted that it had received an incident inspection report for centre 0049. The Committee noted that it was also in receipt of an External Review of the Centre and an email from the Executive to the Licence Committee Secretary regarding the External Review. The Committee noted that the full 109 pages of the item before it today had been sent to the PR of the Centre and could therefore be considered by the Committee in its entirety.

2. The Committee noted that the Centre has been licensed since 1992 and most recently, on 15 July 2010, the Centre's licence was renewed for a further period of two years.

Consideration

3. The Committee noted that an inspection took place following the reporting, in April and May 2011, of two incidents by the Centre. The two incidents related to (i) the disposal of some sperm samples which had not been witnessed, and (ii) the release of donor samples for patient use before the expiration of the quarantine period and before screening tests had been performed. During preparation for an incident inspection the Inspectorate also noted that the Centre's success rates had significantly decreased and that staffing levels were a serious

concern. The Executive incorporated these additional matters to the inspection which took place on 15 June 2011.

4. The Committee noted that at the time of the inspection a number of areas of practice required improvement including seven critical areas of non-compliance and four major areas of non-compliance. No “other” areas of non-compliance or poor practice were noted on inspection. The Inspectorate notes that the PR has since confirmed that some of the recommendations made had been fully implemented by the Centre and that evidence had been provided to the Executive to support this.

5. The Committee noted the Executive’s report which recommended the continuation of the Centre’s licence without condition and the report of the External Review dated 12 September 2011. The Executive had recommended that the PR organise an External Review of the Centre’s clinical and laboratory activities and the interactions between the teams within the centre. The External Review report suggested two potential ways forward and included a statement that ‘it is likely that there are more adverse events to be ‘discovered’ in the future as a result of historically-based witnessing of PESA/TESA sperm storage. This also holds true for embryos that are currently stored’.

6. The Committee carefully considered the PR’s comments on the External Review and the Executive Summary for Licence Committee which set out progress made against the Executive’s recommendations, however the Committee had ongoing concerns about the suitability of practices by the Centre.

Legal Advice

7. The Legal Adviser reminded the Licence Committee of the provisions of the HFE Act 1990 (as amended) (“the Act”), which only permit variation of a licence under section 18A(3) (where that variation has not been requested) in circumstances where the Committee had the power to revoke a Licence under section 18(2) of the Act.

8. The Committee was also referred to the Indicative Sanctions Guidance document which set out the key legislative provisions, the purpose of sanctions and non exhaustive factors which might be relevant to any decision to impose a sanction. The Committee was reminded that any sanction must be fair, reasonable and in the public interest

9. The Legal Adviser reminded that Committee that in the absence of grounds to revoke the Licence it could not propose to vary the Licence

to impose conditions. The Committee could endorse recommendations made by the Executive and/or could make its own recommendations.

10. The Legal Adviser indicated that any conditions imposed by the Licence Committee should be specific, measurable, achievable, realistic and time spanned and that it should give reasons for its decision.

Decision

11. The Committee decided, having carefully considered all of the evidence available to it, that it was satisfied that the PR was failing to discharge her duties under section 17 of the Act. Specifically the Committee concluded that the entirety of the evidence demonstrated a failure to ensure that suitable practices (required under section 17(1)(d) of the Act) were being used in the course of the activities. The Committee was mindful that the PR is relatively new to the post and had to a certain extent inherited historical challenges. The Committee was encouraged that the inspection team reported positive engagement by the Centre but considered that the very serious ongoing concerns were such that suitable practices were not yet fully in place.

12. Given its conclusion as to the PR's discharge of duties the Committee noted that under section 18 (2)(b) it had the power to revoke the Centre's licence. However, having regard to the HFEA Indicative Sanctions Guidance For Licence Committees it considered that neither revocation or suspension were necessary at this stage and lesser regulatory action would be more in line with the principles of fairness and proportionality.

13. The Committee agreed to vary the Centre's licence to impose the following condition:

    1. The Centre must 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.

14. This condition is to remain on the licence until varied or removed by the Licence Committee.

15. The Committee considered that this condition was necessary to allow the Centre to function efficiently and effectively given the staffing resources available and noting the significant other areas of non-compliance which the Authority requires to be addressed. The

Committee noted that there were new members of staff being trained and inducted and considered that the Centre needed a period of consolidation and time to implement the outstanding recommendations.

16. The Committee was mindful that there were economic pressures on the Centre but felt that this restriction on activity was necessary until all the corrective actions in the inspection report have been completed and satisfactory completion had been evidenced at a further inspection. The Committee noted that the Centre has already, in accordance with a recommendation made in the Inspection Report, been restricting its activity to these levels

17. The Committee considered the condition was reasonable and was required to ensure that the licensed activities undertaken at the Centre could be done safely to protect those using or affected by the services offered at the Centre and to maintain confidence in the conduct of licensed activities there

18. In concluding that a condition was a proportionate sanction and that a more severe sanction was not required the Committee noted that it thought the non-compliance was capable of being remedied in the timescales proposed, a realistic condition could be formulated and there was evidence that the current PR had insight and was likely to comply with the condition.

19. In addition to the Condition the Committee recommends:

- That the PR widens the scope of the outstanding audit requirement to ensure that it includes:
    a. The audit required by the Executive in relation to Incident A (of pre 2007 samples against the storage logs) and appropriate follow up actions
    b. An audit of the PESA/TESE sperm and all embryos stored at the Centre

    And that such Audit should be completed and a report provided to the Executive by 31 December 2011.
- That the donor recruitment plan at the Centre remains suspended until such time as the Executive can provide assurances to a Licence Committee that it is safe to be resumed;
- That the PR ensures that an effective quality monitoring programme is established and maintained for all critical activities and processes within the Centre.

- That the PR ensures that an effective procedural audit programme be put in place to verify that critical practices and processes, at the Centre, adhere to the documented Standard Operating Procedures (SOPs), and that those SOPs comply with regulatory requirements.
- That the PR reviews 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.
- That if the andrology service is to be continued the PR ensures that it obtains CPA accreditation at the earliest opportunity
- That the PR submit an action plan for the implementation of a 'buddying' system with another larger, well-performing IVF centre, (the precise arrangements to be agreed between the Executive and the Centre) to the Executive by 31st January 2012

20. The Committee further recommends that the Executive undertakes a follow up inspection at the Centre to take place no later than 31 January 2012, to ensure the recommendations listed above have been met and to provide information to enable the Licence Committee to consider whether the condition should be varied or revoked.

21. In reaching what it was satisfied was a proportionate and appropriate decision in this case the Committee recognised that the Centre has engaged positively with the inspection process which in turn has led to marked improvements to the Centre's compliance with HFEA requirements. The Committee noted that they had endorsed the outstanding recommendations made by the Executive to support the Centre to achieve compliance, so that it might return, in due course to unrestricted licensed activities.

Signed: Date: 25/10/2011

David Archard (Chair)