Interim Inspection Report for a Treatment and Storage Centre

IVF Wales
0049

Date of Inspection: 25th March 2009
Date of Licence Committee: 10th June 2009

Centre Details

Person Responsible	Mrs Janet Evans
Nominal Licensee	Mr Ian Lane
Centre name	IVF Wales
Centre number	0049
Centre address	University Hospital of Wales, Heath Park, Cardiff, Wales, CF14 4XW 0292 076 4443
Type of inspection	Interim.
Inspector(s)	Andy Leonard (Inspector, HFEA) Wil Lenton (Inspector, HFEA) Robert Sawers (External Advisor)
Fee paid	N/A
Licence expiry date	L0049/13/b 30th September 2010
NHS/ Private/ Both	NHS Centre; NHS and private patients

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About the Inspection:

This interim inspection visit was carried out by two HFEA inspectors and an external advisor to the HFEA on 25th March 2009 and lasted for 7 hours. The report covers the pre-inspection analysis, the visit and information received between the last inspection on 25th March 2008 and this inspection.

The purpose of the inspection is to ensure that centres are providing a quality service for patients in compliance with the HF&E Act 1990, Code of Practice and to ensure that centres are working towards compliance with the EU Tissue and Cells Directive 2004/23/EC. Inspections are always carried out when a licence is due for renewal although other visits can be made in between.

The report summarises the findings of the interim inspection highlighting areas of good practice, as well as areas where further improvement is required to improve patient services and meet regulatory requirements. It is primarily written for the Licence Committee who make the decision about the centre's licence renewal application. The report is also available to patients and the public following the Licence Committee meeting.

At the visit the inspection team assesses the effectiveness of the centre through five topics. These are:
How well the centre is organised
The quality of the service for patients and donors
The premises and equipment
Information provided to patients and to the HFEA
The clinical and laboratory processes and competence of staff.

An evaluation is given at the end of each topic and for the overall effectiveness of the centre:
No Improvements Required – given to centres where there are no Code of Practice, legal requirements, recommendations or conditions that need to be imposed.
Some Improvements Required – given to centres that are generally satisfactory but with areas that need attention. Recommendations will usually be made to help Persons Responsible to improve the service.
Significant Improvements Required – given to centres that have considerable scope for improvement and have unacceptable outcomes in at least one area, causing concern sufficient to necessitate an immediate action plan or conditions put on the Licence.

The report includes a response form for the Person Responsible to complete following the inspection.

The HFEA welcomes comments from patients and donors, past and present, on the quality of the service received. A questionnaire for patients can be found on the HFEA website www.hfea.gov.uk.

Brief Description of the Centre and Person Responsible

IVF Wales is part of the Cardiff and Vale NHS Trust and has been licensed by the HFEA since 1992. Fertility treatment services include in vitro fertilisation (IVF), intracytoplasmic sperm injection (ICSI) and donor insemination (DI). Opening hours are typically from 08:00 – 16:30 Monday to Friday. Lab work is performed on the weekends as required. Open Evening sessions for pre-treatment information are held on a Wednesday evening between 6.00 pm and 8.00 pm. The Centre is ISO 9001:2000 accredited.

The Centre licence includes:

- **Storage of Eggs**
- **Storage of Embryos**
- **Intra Cytoplasmic Sperm Injection (ICSI)**
- **Procurement/Distribution of Gametes and Embryos**
- **Treatment with Donor Gametes and Donor Embryos**
- **Chemical Assisted Hatching**
- **Storage of Sperm**
- **In Vitro Fertilisation (IVF)**
- **Insemination**
- **Processing of Gametes and Embryos**
- **Mechanically Assisted hatching**
- **Laser Assisted Hatching**

The Centre also has small egg sharing, sperm donation and egg donation programmes. The Centre historically performs approximately 500 treatments per year. The Centre implemented an action plan to improve success rates in 2005. For example, the Centre reviewed its laboratory service in 2006 and moved to refurbished premises in September 2007. The Centre's outpatient activities have recently relocated to an area in the hospital's main outpatient's treatment area.

The PR has been a consultant in Obstetrics and Gynaecology at IVF Wales since 1992 and the PR since 2002. The PR works full-time at the Centre and has completed the PR Entry Programme appropriately.

Centre activities[1] for the time period 1st January 2008 to 31st December 2008

ACTIVITY	CYCLES
In vitro fertilisation (IVF)	241 cycles
Intracytoplasmic sperm injection (ICSI)	234 cycles
Frozen embryo transfer (FET)	4 cycles
Donor insemination (DI)	27 cycles
Egg donation or share provider	2 cycles
Egg recipients or share recipient	0 cycles
Gamete intrafallopian transfer (GIFT)	NO
Research	YES (R0161)
Storage gametes/embryos	YES

[1] This data is supplied to the HFEA by individual clinics who are responsible for its accuracy and verification. The data published by the HFEA is a snapshot of the state of the Register at a particular time. 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 Licence Committee

The inspection was an interim inspection of the treatment and storage licence held by IVF Wales, Centre 0049. The current licence L0049-13/b was granted on 1st October 2007 and will expire on 30th September 2010. The Centre is licensed for: in-vitro fertilisation (IVF); intracytoplasmic sperm injection (ICSI); insemination; treatment with donor gametes and embryos; processing of gametes and embryos; procurement and distribution of gametes and embryos, storage of eggs, embryos and sperm; mechanical, chemical and laser-assisted hatching.

It is a medium size centre providing approximately 500 treatment cycles per year. For the period 1st January 2005 to 31st December 2008, IVF/ICSI success rates at the Centre for women aged below 35 were significantly below the national average. Success rates in all other age groups for IVF/ICSI and for all age groups for frozen embryo transfer and donor insemination, were not significantly different from the national average.

Sufficient numbers of appropriately qualified and competent staff are employed at the Centre and there is an organisational structure in place which defines accountability, responsibility and reporting relationships. The Person Responsible is appropriately qualified to discharge her duties, as outlined in Section 17 of the HF&E Act (1990). She was familiar with all clinical, nursing, laboratory, administrative and managerial aspects of the service, and is well supported by staff and an established management team.

The Centre is ISO 9001:2000 accredited and operates an effective quality management system, though the Quality Manager role is divided between the departmental heads**.** The main treatment and laboratory premises were considered appropriate as were the Centre's clinical and laboratory practices and procedures, with the exception of those detailed below.

Improvements are needed in:

- The development of a documented contingency plan
- Payment of HFEA invoices
- Document control and review
- The maintenance of patient confidentiality and patient privacy in the outpatient facilities
- Validation and application of the air quality monitoring protocol
- Application of the Welfare of the Child Assessment protocol
- The clearance of long-standing errors in EDI data
- Sperm donor and egg provider screening
- Validation of key equipment and processes
- The accreditation of laboratories providing assay services

The inspection team note the positive advances made in other areas highlighted as issues in the last inspection report from March 2008. From the evidence seen on this inspection, and assuming that progress is made within the specified timescales in addressing the regulatory issues outlined in this report, the inspectorate are satisfied with the continuation of the Centre's licence.

Evaluations from the inspection

Topic	No Improvements required	Some Improvement required	Significant Improvement required
1. Organisation		X	
2. Quality of the service		X	
3. Premises and Equipment		X	
4. Information		X	
5. Laboratory and clinical processes		X	

Breaches of the Act, Standard Licence Conditions or Code of Practice:
The table below sets out matters which the Inspectorate considers may constitute breaches of the Act, Standard Licence Conditions and/or the Code of Practice, and their recommended improvement actions and timescales. The weight to be attached to any breach of the Act, Standard Licence Conditions or Code of Practice is a matter for the Licence Committee;-

Breaches

Breach	Action required	Time scale
The Centre has a contingency plan, but it has yet to be documented, contrary to Licence Condition A.10.23	The contingency plan should be documented as rapidly as possible.	1st July 2009
At the time of the present inspection, the Centre had 2 invoices outstanding and in the previous year had taken an average of 60 days to pay HFEA invoices. The Centre is thus in breach of Licence Condition A.13.3.	The PR should investigate the invoice payment mechanism and ensure removal of all barriers to the payment of invoices within 28 days.	To be assessed at the next inspection
Most documents inspected were within their review dates and had appropriate document control features. Some documents were however not controlled appropriately with regard to review periods, version control and document control footers, contrary to Code of Practice, 7th edition, Standard S.5.2.5 and S.5.2.6.	The PR should ensure that all centre documents are reviewed annually, as required by Code of Practice, 7th edition, Standard S.5.2.5, and have document control headers or footers containing the required information, as required by Code of Practice, 7th edition, Standard S.5.2.6.	To be assessed at the next inspection
The suitability of the new outpatient facility as regards the confidentiality of patient records, and patient confidentiality and privacy, as required by Code of Practice, Standard S.7.2.1 and Licence Condition A.10.31, and Code of Practice, Standard S.6.3.4, is questionable.	The PR should ensure a formal documented risk assessment is performed on the new outpatient facility. Appropriate risk control measures should be applied to limit identified risks. The PR should be especially	1st June 2009

	mindful during this process of the legal requirements of the HFE Act (1990) with amendments, Section 33 (5), regarding the prevention of inadvertent disclosure of confidential patient information.	
The air quality monitoring protocol has yet to be validated, as required by Code of Practice, Standards, S.6.3.6. Furthermore the air quality monitoring protocol has not been accurately applied since December 2008 was the last month on which data was available due to malfunction of the air particle counter.	The air quality monitoring protocol should be validated to provide documented evidence in support of the chosen method(s) and time intervals of air quality monitoring. Deviations from the protocol should be risk assessed, and appropriate actions taken to control risks which are indicated.	1st June 2009
The Centre has a Welfare of the Child (WoC) assessment protocol which is not always adhered to, as indicated by a HFEA Operational Audit in December 2008, and contrary to HFE Act (1990) with amendments, Section 13(5).	The PR must ensure that the WoC procedure is always applied, so that WoC assessment and consent for disclosure is present in all cases. This will ensure compliance with the HFE Act (1990) with amendments, Section 13(5), and prevent the possibility of breaching Section 33 of the same Act.	1st June 2009
The Centre has a considerable number of long standing errors in data entered to the HFEA via the electronic data interface (EDI), contrary to the Code of Practice, 7th Edition, Standards, S.6.5.1 (b) and the HFEA policy on the collection, confirmation and publication of Registry data, which was attached to Direction 2008/6.	It is essential that all EDI errors are corrected and that weekly clearance of errors occurs, compliant with Direction 2008/6. The PR must ensure that resources are in place to correct all errors and maintain weekly error clearance.	1st August 2009
The records of two egg providers and two sperm donors indicated that screening was not compliant with Licence Condition A.7.2 or the Code of Practice, 7th Edition, Guidance G.4.9.1.	The PR should investigate how these providers/donors were used in treatment even though screening tests were inadequate given Licence Condition 7.2 and the BFS	1st June 2009

	screening guidelines active at the time of donation. Donation protocols should be reviewed after consideration of Licence Conditions and the revised joint UK guidelines for the medical and laboratory screening of sperm, egg and embryo donors (Human Fertility 11, 201 - 210), introduced in December 2008. If the donor screening procedure is changed, patient information should be updated to include all of the screening tests carried out. The rationale for any remaining non-compliance with this professional body guidance and thus with G.4.9.1 should be documented.	
The Head of Laboratory provided a process validation report for the Centre's activities, but noted that the validation was only 30 - 50% complete and equipment validation was lacking. This situation constitutes a breach of standard licence condition A.11.11.	The PR should ensure the validation of key processes and equipment used by the Centre is completed as soon as feasible.	To be assessed at the next inspection
Analysis of semen samples is carried out in a separate andrology laboratory which is not CPA accredited, contrary to Code of Practice, 7th edition, Standard S.7.8.2,	The PR should review the requirement for clinical pathology accreditation (CPA) of the andrology laboratory. If the laboratory requires CPA accreditation, then the PR should demonstrate progress towards obtaining it at the next inspection. If the laboratory is considered not to require CPA accreditation, the reasons why should be communicated to the Licence Committee in appendix C of this report.	1st June 2009

Non-Compliances

Area for improvement	Action required	Time scale
A recent near miss regarding loss of power to a computer which is part of the alarm system was not reported to the HFEA when, in the consideration of the inspectorate, it would have provided useful learning if it had. This is contrary to Code of Practice, 7th Edition, G.14.1.1.	The Centre is considered by the inspectorate to be a compliant reporter and investigator of incidents. It is recommended that the Centre applies the same approach to near misses.	1st July 2009
The witnessing and gamete/embryo freezing protocols require updating to include that the location of the gametes and embryos in the storage dewar is cross-checked against patient and storage records by the operator and the witness, to ensure witnessing is compliant with all requirements of Code of Practice, Guidance, G.13.	To modify the witnessing and gamete/embryo freezing protocols as appropriate	1st July 2009
The Centre must review and update its witnessing and donation of oocytes to research protocols, as the research project (R0161) at the Centre, which has been inactive for some time, became active again in April 2009. The protocol will need to include witnessing of details on the oocyte container against patient records when removed for transfer to research, to ensure compliance with Code of Practice, Guidance, G.13.	To review and update the witnessing and donation of oocytes to research protocols, as appropriate	1st July 2009

Recommendations

The departmental heads are the designated quality managers in their respective areas. The inspection in March 2008 found that this places extra work pressure on them and the appointment of a full-time Quality Manager was being considered by the Centre's management. The present inspection found that this appointment has not been made. The inspectorate supports the planned appointment of a full-time Quality Manager to facilitate the continued development of the quality management system.

The inspectorate found it difficult to find the Centre as the signage within the hospital for the Centre was unclear and infrequent. It is recommended that the PR engage with Trust management and ensure signage is provided to enable patients to find the Centre easily.

Changes/ improvements since last inspection in March 2008

Outpatient activities have been moved from a dedicated secure corridor adjacent to the clinical and laboratory areas on the first floor, to a dedicated, but less secure, spur corridor in the main hospital outpatient department on the ground floor. This move occurred because the previous secure corridor interrupted staff and patient movements between labour ward and the maternity unit.

Staffing levels have increased, registered doctors by 0.75 whole time equivalents (WTE), nursing staff by 2.5 WTE, healthcare assistants by 0.2 WTE, pre-registration scientists by 1 WTE and support staff by 2 WTE.

Additional licence conditions and actions taken by Centre since last inspection

No additional Licence Conditions. Improvements in service related to regulatory issues raised at the last inspection in March 2008 are discussed within the body of the text in this report.

Report of inspection findings

1. Organisation

Desired Outcome: The Centre is well-organised and managed and complies with the requirements of the HFE Act.

Summary of the findings from the inspection of the following areas of practice:

- Leadership and management
- Organisation of the centre
- Resource management
- Clinical governance
- Risk management
- Incident management
- Alert management
- Complaints management
- Contingency arrangements
- Establishment of third party agreements
- Meetings / dissemination of information
- Payment of licence/treatment fees

Areas of firm compliance
The Centre has a defined organisational structure and clear paths of responsibility. The PR is in ultimate control of the Centre as well as of clinical matters. Scientific matters are delegated to the Head of Embryology, nursing matters to the Ward Manager (a Lead Fertility Nurse) and administrative matters to the Centre's Administrator. A unit manager has recently been appointed to facilitate service improvement plans. Integrated control of the Centre is achieved through weekly heads of department meetings, the minutes of which were observed on inspection and are available to all staff. Centre activity levels are discussed at these meetings to ensure activity levels are safe given the resources available. The Centre's management team have responsibility for resource management in their areas and resource issues are also discussed at the heads meeting to provide integrated resource management. A fortnightly strategy group meeting and a monthly all staff meeting are also held. Minutes are taken and are available to all staff on the Centre's server. The PR interacts with the local NHS management structure to access funding/resources. An action plan was prepared in response to the number of breaches seen on the last HFEA inspection and this was updated and provided by the PR to the HFEA when required. The PR has had some success in accessing funding to raise staff levels at the Centre in the last year. An action plan for developing the service at IVF Wales in 2009 and minutes of a heads of department meeting, a strategy group meeting and a management review meeting were reviewed by the inspectorate. These documents provided clear evidence of business planning, risk management, resource management and effective consideration and investigation of patient complaints. The Centre is considered a compliant reporter of serious adverse events, the PR being the designated incident reporting officer. Recent adverse incidents at the Centre have been reported, investigated and corrective actions taken in a compliant manner. Discussions with

the staff indicate an open attitude regarding incident reporting and a no-blame culture. The Centre utilises the University Hospital of Wales Trust Clinical Governance Policy.

The Women's and Children's Health Directorate Associate Clinical Director is the designated Complaints Officer for the Centre. A detailed procedure is in place for processing complaints which complies with the Hospital Trust Complaints Policy and HFEA requirements. At the inspection in March 2008, the inspectorate were concerned that complaints may be made which constituted serious adverse events or reactions, but were not immediately reported to the PR for referral as incidents on to the HFEA. Subsequent to that inspection, the PR briefed the Complaint's Officer regarding the HFEA definition of an adverse event so that complaints which constitute adverse events are immediately notified to the PR. To ensure effective feedback to the Centre regarding all complaints, the Complaints Officer has been allocated a permanent slot on the agenda of the monthly all staff meeting, at which an analysis of complaints will be presented to centre staff. This was considered by the inspectorate to be a compliant method of ensuring that patient complaints are effectively discussed with centre staff to facilitate their resolution.

The Centre has developed third party agreements with all suppliers of goods and services which may influence the quality and safety of gametes and embryos

Areas for improvement

At the last inspection, it was noted a contingency plan had been informally agreed with London Women's Clinic, Swansea, verbally sanctioned by the Health Commission of Wales, for the transfer of services. It was required that this agreement must be documented (Licence Condition A.10.23). The PR has corresponded with the second clinic and has been asked to develop a third party agreement for the contingency arrangement. This is still in preparation, thus the Centre is still not compliant with Licence Condition A.10.23. The inspectorate recommends that the contingency plan is documented as rapidly as possible.

At the last inspection in March 2008 it was noted that the Centre took on average 65 days to pay HFEA invoices. The Centre's Administrator explained that invoices had to be referred to the Trust Finance Department for payment, which sometimes meant that payment was delayed without the Centre having control over it. This situation is not uncommon in NHS hospital hosted licensed centres. The Centre's Administrator has advised the Finance Department of the importance of quick payment of HFEA invoices. At the present inspection, the Centre had 2 invoices outstanding and in the previous year had taken an average of 60 days to pay HFEA invoices. The Centre is thus in breach of Licence Condition A.13.3. The PR should investigate the invoice payment mechanism and ensure removal of all barriers to the payment of invoices within 28 days.

While risk management is applied in the treatment and laboratory areas through risk assessment, the new location for outpatient activities have not been formally risk assessed as a facility in which HFEA regulated activities occur. This is discussed further in Section 3, with recommendations.

Areas for consideration

A recent near miss regarding loss of power to a computer which is part of the alarm system was not reported to the HFEA when, in the consideration of the inspectorate, it would have provided useful learning if it had been. This is contrary to Code of Practice, 7th Edition,

G.14.1.1. The Centre is considered by the inspectorate to be a compliant reporter and investigator of incidents and is recommended to apply the same approach to near misses.
Executive recommendations for Licence Committee
The Inspectorate recommend that the Licence Committee require the PR to: 1) Develop and document a contingency plan as rapidly as possible to ensure compliance with Licence Condition A.10.23 2) Investigate the Centre's invoice payment mechanisms and ensure removal of all barriers to the payment of invoices within 28 days, to ensure compliance with Licence Condition A.13.3.
Evaluation
Two improvements required
Areas not covered on this inspection
Alert Management

2. Quality of service

Desired Outcome: Patients receive a good standard of service, appropriate treatment and are treated with courtesy and respect.

Summary of the findings from the inspection of the following areas of practice:

- Quality management system
- Quality policy
- Quality manual
- Quality objectives and plans
- Quality management review/evaluation
- Feedback
- Document control
- Live birth rates

Live birth rates[1]
Outcome data calculated from pre-Validation and pre-Quality Assured HFEA Register data for the period 1st January 2005 – 31st December 2008, indicate that IVF/ICSI success rates for women aged below 35 were significantly below the national average. Success rates in all other age groups for IVF/ICSI and for all age groups for frozen embryo transfer and donor insemination, were not significantly different from the national average. On inspection, Centre staff asserted that their clinical pregnancy rates for 2008 were greater than HFEA figures (albeit calculated from pre-validation and pre-quality assured data), suggest. This discrepancy was thought to result from inaccuracies in the Centre's data submission to HFEA via the Electronic Data Interface (EDI), as discussed in Section 4 of this report. Subsequent improvements in data entry after the inspection have brought the clinical pregnancy rates calculated from HFEA data into line with those calculated by the centre.
Areas of firm compliance
The Centre has a quality management system accredited to ISO9001:2000 standards which passed inspection in December 2008. The departmental heads are the designated quality managers in their respective areas. Regular minuted quality management meetings are held between the four departmental heads, with the PR as chair. A detailed quality manual as well as all the Centre's protocols and procedures, are available to all staff within the quality management system area on the Centre's server. An audit schedule for 2008 was provided to the inspectorate which included multiple audits of the Centre's activities and the procedures through which they are implemented. The schedule stated the month in which each audit occurred and the person responsible for performing it. An audit schedule for 2009 is in preparation. Part of the audit schedule includes continual monitoring of an appropriate range of clinical and laboratory quality indicators, e.g. clinical pregnancy rates after IVF, ICSI, frozen embryo transfer, IUI etc, the prevalence of ovarian hyperstimulation syndrome (OHSS) and poor responders, protocol adherence, witnessing adherence and the percentage of embryos growing to the 8 cell and blastocysts stages.

The Quality Management System is reviewed annually and minutes of the last review on the 10th December 2008 were observed. Items discussed include audit results and action points, patient complaints, clinic performance, staffing changes, the quality management system, quality objectives, improvement plans, staff training and 'any other business'.

The Centre carries out a continuous patient satisfaction survey, the results of which are reviewed monthly. Patient complaints are a standing item on the all staff meeting agenda. Patient comments can also be noted down in a 'comments' book in the patients waiting room, which is checked daily by the Ward Manager. The Centre sends out a regular newsletter to keep patients abreast of changes in the centre. The Centre also hosts a weekly introductory evening for new patients at which the IVF process is discussed and prospective patients can experience the Centre's environment. Feedback from staff is also a standing item on the all staff meeting agenda.

Areas for improvement

Most documents inspected were within their review dates and had appropriate document control features. Some documents were however not controlled. For example, the '3 embryo replacement protocol' was dated 5/3/08 in its document control footer, while the document control header detailed a review date of 31st December 2009, suggesting the period between reviews to be greater than 1 year, contrary to Code of Practice, 7th edition, Standard S.5.2.5. The previous version of the protocol provided at the last inspection in March 2008 was also reviewed for comparison. It was also dated 5/3/08 and the document control header detailed a review date of 31st December 2008. The document did not appear to have been modified from that provided at this inspection and the version numbers in the document control headers were the same (i.e. 122006/CLIN 1(2)), suggesting version control was absent on this document. Likewise, the 'witnessing protocol clinical' was dated 22/02/08 in its document control footer and had no review date displayed. It was compared with the version present for the inspection in March 2008 and appeared to be identical. This document was provided to the inspectorate on 3rd March 2009 for the present inspection and was therefore out of date, having not been subjected to annual review, and incorrectly formatted in not having a review date detailed on the document. The PR should ensure that all centre documents are reviewed annually, as required by Code of Practice, 7th edition, Standard S.5.2.5, and have document control headers or footers containing the required information, as required by Code of Practice, 7th edition, Standard S.5.2.6.

Areas of consideration

The departmental heads are the designated quality managers in their respective areas. The inspection in March 2008 found that this places extra work pressure on them and the appointment of a full-time Quality Manager was being considered by the Centre's management. The present inspection found that this appointment has not been made. The inspectorate supports the planned appointment of a full time quality manager to facilitate the continued development of the quality management system.

Executive recommendations for Licence Committee

The Inspectorate recommend that the Licence Committee require the PR to ensure that all centre documents are reviewed annually, as required by Code of Practice, 7th edition, Standard S.5.2.5, and have document control headers or footers containing the required information, as required by Code of Practice, 7th edition, Standard S.5.2.6.

Areas not covered on this inspection
Quality Policy
Evaluation
One improvement is required.

3. Premises and Equipment

Desired outcome: The premises and equipment are safe, secure and suitable for their purpose.

Summary of the findings from the inspection of the following areas of practice:

- Premises
- Clinical facilities
- Counselling facilities
- Laboratory facilities
- Air quality
- Management of equipment and materials
- Storage facilities for gametes and embryos
- Staff facilities
- Storage of records

Areas of firm compliance
In August 2007, Centre 0049 re-located to refurbished premises within the same hospital building as part of a phased re-development plan of Women's and Children's Health services at University Hospital of Wales. The premises comprised two perpendicular first floor corridors, one for treatment, administration and laboratory work and a secure outpatient corridor, for patient waiting, consultation, ultrasound scanning and notes storage. The treatment/laboratory corridor is a permanent location for these activities, but the outpatient corridor was an interim location. Subsequently, it was found that the secure outpatient corridor interrupted hospital staff and patient movement between the labour ward and the maternity unit. The hospital Trust therefore relocated the Centre's outpatient activities to a dedicated spur corridor in the main hospital outpatient department on the ground floor of the hospital. This move was accomplished in June 2008; the premises were not inspected at this time. The original plan for the phased re-development of Women's and Children's Health Service was that the Centre's outpatient activities would relocate to their final permanent location on the upper ground floor of the hospital in mid-2010. The PR advised the inspectorate during inspection that she has been informed that this is being reconsidered and the final location of the Centre's outpatient clinic is yet to be decided. The Centre's management have prepared an analysis of potential final locations for the outpatient facilities, detailing the advantages and disadvantages of each location and the Centre's management's preferred option. This analysis has been presented to the Trust management and it is to be hoped that the preferred option is acceptable to the Trust. On this inspection, it was considered that the treatment, administration and laboratory premises provided an appropriate environment for patients and licensed activities, being secure and well equipped. Cleaning services are provided by a designated person from the hospital cleaning staff and these premises appeared clean and tidy on the day of inspection; no patient complaints had been received related to the cleanliness of the Centre. The Centre has procedures for ensuring the effective servicing and maintenance of equipment. A sample of clinical and laboratory equipment showed evidence of annual maintenance within the last year. Laboratory incubators are connected to an uninterruptible power supply. Evidence of equipment monitoring (in the form of paper logs) was seen on a sample of laboratory equipment and these logs were annotated to outline the tolerances for

the critical parameters being measured, and included a description of the necessary corrective action should a non conformity be identified. The Centre plans to fit digital dataloggers to the incubators in the near future to store temperature and CO_2 level data.

An emergency resuscitation trolley was positioned in the corridor adjacent to the treatment and recovery area. A log of weekly checks of the trolley's contents was present; according to the Ward Manager, the frequency of checks is in line with local Trust policy.

Monitoring of air quality by the assessment of particle counts is carried out twice a month, each time in the 'at rest' and 'operational' modes, according to the air quality monitoring protocol. Records of air quality monitoring data were reviewed in the course of the inspection and showed that air quality has been consistently compliant with HFEA requirements.

At the last inspection, it was noted that the PR should ensure that logs were kept for the relevant time periods of environmental monitoring and of equipment and products likely to influence embryo or gamete quality and safety, as per licence conditions A.3.2 and A.10.30. The Centre has established and implemented procedures to ensure the keeping of all relevant information relating to environmental parameters and products and equipment to ensure traceability. Logs were observed on this inspection which support compliance with conditions A.3.2 and A.10.30.

The embryology and andrology cryopreservation dewar storage areas contain 2 and 14 dewars respectively, and are accessible to licensed personnel only. Both storage areas are fitted with low oxygen level alarms which will be linked to a 'traffic light' warning system displayed outside the laboratories in April 2009; currently, the alarms sound in the corridor but there is no visual indication of oxygen level. Personnel low oxygen monitors are also worn by staff while working in the cryostore. Liquid nitrogen levels in dewars are monitored and a log of the monitoring is maintained. At the last inspection, it was noted that some dewars were not fitted with functioning low level nitrogen alarms. On this inspection it was observed that all dewars were alarmed appropriately. The low oxygen and low nitrogen level alarms input to a computer which monitors and records their output and notifies the hospital switchboard in the event of a non-conformity. Recently, power to the computer was lost which meant that the switchboard would not have been notified in the event of an alarm. The Centre has responded to this near miss by preparing a business case, presented to the Trust management, for an autodialer system to be fitted in the laboratory which will automatically call the Centre's on-call staff in the event of an emergency.

Several other issues were noted in the cryostores at the last inspection: The andrology laboratory door was kept unlocked at all times for safety reasons; The embryology dewar store venting system did not function; Staff were unclear regarding the procedure for responding to the low oxygen monitor alarm and the procedure was not displayed on the cryostore doors. On this inspection it was observed that all these issues had been addressed.

Staff facilities are available on the Centre's treatment and laboratory corridor and were considered to be appropriate.

The Centre's main patient records storage area is currently in the old outpatient facility. This room is secure and remains under the control of the PR, however an annex room to one consulting room in the new outpatient facility, currently a staff tea room, will soon become the Centre's main patient records store.

Areas for improvement

The Centre's new outpatient facility was inspected for the first time on this inspection. It is situated in the University Hospital of Wales main outpatient department. This consists of a long, wide corridor with paired outpatient clinics down each side. Paired clinics share a common reception area, though the receptionist for each clinic has a separate desk area. Paired clinics have facilities which are mirror images of eachother. The outpatient clinic for IVF Wales consists of the reception area with adjacent patient waiting area, from which a corridor provides access to 3 consulting rooms, 2 ultrasound scanning rooms, a nurses' office, a toilet, and a blood/injection training room, before exiting back to the main outpatient department corridor. All patient consultations and scanning prior to egg collection are held in the outpatient facility. Counselling is also provided in the consulting rooms. An annex to the blood room provides lockable secure storage for 'active' patient records, which was considered suitable by the inspectorate.

The inspectorate noted several regulatory issues concerning the new outpatient facilities.

1) The reception area is shared with another clinic. This is a hazard to patient confidentiality as patient names and details may be discussed in the hearing of unlicensed staff and patients attending the outpatient clinic with which IVF Wales is paired. Similarly, patient paperwork may be observed by unlicensed staff and patients. The PR said the reception desk is constantly staffed during working hours and that records for the day's patients are stored in plastic bins on the reception desk. It is questionable whether these arrangements are sufficient. For example, on the day of inspection it was noted that the receptionist had had to leave the reception area unattended for approximately 5 minutes. This was brought to the attention of the PR and the Centre's intention to fit a locked filing cabinet for patient records in the reception area was discussed with the inspectorate.

2) The reception and waiting area are visible to passing staff and patients in the main outpatient's corridor. Centre staff described how hospital staff attending the Centre as patients had been observed by passing unlicensed acquaintances and/or colleagues and engaged in conversation as to their presence at the centre. Staff patients are now offered the option of waiting in a more private area, however, this private area is not spacious enough to fit patients who are not hospital staff, who might easily be observed by neighbours and friends attending the outpatient department for other reasons. Indeed, a patient complaint has been received regarding the lack of privacy in the waiting area. The inspectorate believes that the current situation does not maintain patient privacy to an appropriate extent. The PR informed the inspectorate that a screen is due to arrive soon which will prevent observation of the Centre's patients from the main outpatient department corridor. Patient feedback has suggested that some patients feel this innovation may draw attention to them, while others are happy with the proposal.

3) The corridor leading from the reception area to the clinical rooms, then to the main outpatient department corridor, exits to that corridor through unlocked double doors. This provides unrestricted access to the clinical rooms and any patient records which might be in them.

The current suitability of the new outpatient premises as regards the confidentiality of patient records, patient confidentiality and patient privacy, as required by Code of Practice, Standard S.7.2.1 and Licence Condition A.10.31, and Code of Practice, Standard S.6.3.4, is open to question. The facilities were an existing outpatient area and had been risk assessed as such

by the local Trust. The premises were reviewed by some of the Centre's management team when they were allocated to the centre, and improvements were requested from the Trust to ensure patient confidentiality was protected. Given the issues raised in this Section, it is recommended that the PR ensures a formal documented risk assessment is performed on the new outpatient facility as an area in which patients subject to HFEA Code of Practice requirements are treated. Appropriate risk control measures should be applied to prevent the occurrence of any identified hazards. The PR should be especially mindful during this process of the legal requirements of the HFE Act (1990) with amendments, Section 33 (5), regarding the prevention of inadvertent disclosure of confidential patient information.

The air quality monitoring protocol discusses the important effects of airborne volatile organic compounds (VOCs) on embryo development, but does not discuss their measurement. If VOCs are considered important, they should be measured. This confusion arises partly because the protocol has yet to be validated, as required by Code of Practice, Standards, S.6.3.6. The Head of Laboratory informed the inspectorate that the validation of laboratory processes and equipment is on-going, but has been delayed by the late release of validation tools from the Association of Clinical Embryologists. It is recommended that the air quality monitoring protocol is validated to provide documented evidence in support of the chosen method(s) and time intervals of air quality monitoring. Furthermore the air quality monitoring protocol should be accurately applied. The protocol describes the assessment of particle counts twice a month, each time in the 'at rest' and 'operational' modes. Thus four sets of data should be available per month. Inspection of the monitoring log showed there to be one set of data for November 2008 and two for December 2008. December 2008 was the last month on which data was available due to malfunction of the air particle counter. The Head of Laboratory described how the aftercare service provided by the supplier had been poor but said the counter will soon return to service. It is recommended that the Head of Laboratory risk assess these deviations from the Centre's air quality monitoring protocol and, if the counter is not repaired soon, determines how long monitoring can be suspended before an alternative counter is sourced and air quality monitoring resumed at the frequency designated in the Centre's protocol.

Areas for consideration

The inspectorate found it difficult to find the Centre as the signage within the hospital for the Centre was unclear and infrequent. It is recommended that the PR engage with Trust management and ensure signage is provided to enable patients to find the Centre easily.

The Centre has a programme of transferring patient records to digital media. They have used a company who have provided this service to other licensed centres as well as the genito-urinary medicine clinic at University Hospital Wales. The PR obtained a letter of recommendation from the latter clinic and has informed the company of the confidentiality requirements of Section 33 of the HFE Act. The company employees involved are a named team, with a defined manager for Centre liaison, who have all signed confidentiality agreements referring to Section 33 of the Act and returned them to the centre. The company also have a third party agreement with the Centre. Patient records are removed from the Centre in batches in sealed boxes by a van with an identified driver, and driven directly to the digitizing company. Disposal of the notes on confirmation of the accuracy of digitization is by a bleach, shred then pulp process, destroying them effectively. The Centre has taken all steps possible to maintain patient confidentiality given the requirement to digitize the patient records. The notes have however passed out of their control to an off-site company under the

protection of a third party agreement. This solution has been applied by other centres in an identical situation, but internal legal advice at HFEA is that the use of third party agreements to govern these arrangements is inappropriate given the statutory definition of a third party agreement contained in section 2A(1) of the HFE Act (1990) with amendments.
Executive recommendations for Licence Committee
The Inspectorate recommend that the Licence Committee require the PR to ensure that: 1) The outpatient facility is formally risk assessed as an area in which patients subject to HFEA Code of Practice requirements are treated, and that appropriate risk control measures are applied to prevent the occurrence of any identified hazards. 2) The air quality monitoring protocol is validated to provide documented evidence in support of the chosen method(s) and time intervals of air quality monitoring. 3) The air quality monitoring protocol is correctly applied and that the deviations from that protocol are risk assessed, to determine how long the Centre can delay before obtaining a second counter with which to resume testing at the frequency designated in the protocol.
Areas not covered on this inspection
Counselling records
Evaluation
Two areas of improvement are required

4. Information

Desired outcome: Information is relevant, clear and up to date for patients and the HFEA

Summary of the findings from the inspection of the following areas of practice:

- Information for service users
- Consent
- Welfare of the child
- Access to health records
- Provision of information to the HFEA register

Areas of firm compliance
Patient information was not reviewed at this inspection as there were no significant issues noted at the last inspection. Patient consents were not reviewed at this inspection, as there were no significant issues noted at the last inspection. Furthermore, a recent operational audit inspection in December 2008, found no errors in HFEA consents in 16 patient records reviewed. Patient identity is checked by passport or driving licence verification when the patients are issued with an IVF Wales photographic identity card. Patients thereafter use this to identify themselves during treatment. The release of records to patients is covered by appropriate procedures on written application by the patients to the PR. While in use the patient records follow a defined pathway and measures have been taken to ensure they are secure, albeit further control measures may be required in the outpatient area, as discussed in Section 3. Brief notes of counselling consultations are stored within the main patient notes. A document retention procedure is in place which defines 10, 30, and 50 year storage periods, as required by the Code of Practice, 7th edition. The Centre's server is operated by the Hospital IT Department and is secure and accessible to licensed staff only. The Centre is currently operating the ACUBASE data management system in tandem with a paper-based records system. The PR considers electronic data management will enhance performance within the centre. For effective implementation of the ACUBASE system, the PR outlined at the last inspection that the local Trust would need to fund at least 5 computer terminals within the centre. These have yet to arrive. Given the importance of this project it is hoped that the computers will be made available. There are robust systems in place for recording and reviewing the expiry of consents to storage. A spreadsheet reviewed in the course of the inspection demonstrated that written consent was in place for all cryopreserved material in store.
Areas for improvement
The Centre has an established Welfare of the Child (WoC) assessment protocol which requires consent for disclosure to their General Practitioner to be obtained from all patients. If staff have concerns after WoC assessment using the HFEA form, the case can be discussed with colleagues, information sought from the couple's General Practitioner and/or the case referred to the Centre's Social Issues Group Meeting. The couple are offered counselling

regarding any social issues raised, and the counsellor can also undertake social welfare assessment of the patients. It was noted at the operational audit inspection in December 2008 that evidence of WoC assessment was missing from 6 of the 16 patient records reviewed, while consent to disclosure was missing from 4 of 16 records. The PR must ensure that the WoC procedure is always applied, so that WoC assessment and consent for disclosure is present in all cases. This will ensure compliance with the HFE Act (1990) with amendments, Section 13(5), and prevent the possibility of breaching Section 33 of the same Act.

The Centre has a considerable number of errors in data entered to the HFEA via the electronic data interface (EDI), and these errors prevent patient data entry onto the HFEA Register. This has produced a significant differential in clinical pregnancy rate for 2008 between the Centre's data and that held on the HFEA Registry and also the statistic, confirmed by the Centre as incorrect, that they have only performed 4 frozen embryo transfers in 2008. The accuracy of data entry on the EDI system must be improved, as should the frequency of clearing of errors, to ensure compliance with Code of Practice, 7th Edition, Standards, S.6.5.1 (b) and the HFEA policy on the collection, confirmation and publication of Registry data, which was attached to Direction 2008/6. It is essential that all EDI errors are corrected and that weekly clearance of errors occurs, compliant with Direction 2008/6. Subsequent to the inspection, there has been an improvement in the submission of early outcomes, so that clinical pregnancy rates for 2008 in HFEA and Centre data are now comparable. A significant number of EDI errors remain however; an action plan is in preparation to facilitate their clearance and more effective EDI data entry in the future.

Areas for consideration

None

Executive recommendations for Licence Committee

The Inspectorate recommend that the Licence Committee require the PR to ensure that:
1) The WoC procedure is applied correctly such that WoC assessments and consents to disclosure are completed for all patients treated.
2) Resources are available to allow all EDI errors to be corrected as soon as possible and to facilitate weekly clearance of EDI errors, compliant with Direction 2008/6.

Areas not covered on this inspection

Patient information content

Evaluation

Two areas for improvement are noted

5. Clinical, laboratory and counselling practice

Desired outcome: Clinical, counselling and laboratory practices are suitable and are provided by competent staff.

Summary of findings from inspection:

- Staff training and competency
- Clinical practice
  - Screening of donors
  - Three embryo transfer
- Laboratory practice
  - Procurement, distribution and receipt of gametes and embryos
  - Traceability and coding
  - Selection and validation of laboratory procedures
  - Coding/ identification of samples
  - Witnessing
- Counselling practice
  - Counselling audit
- Storage of gametes and embryos

Full time equivalent staff

Registered doctors	3.6
Registered nurses	6.0
Non NMC registered nurses/health care assistants	1.28
Registered scientists	3
Scientists working towards registration	4
Laboratory support staff	1
Counsellors	1
Support staff (receptionists, record managers, quality and risk managers, etc).	7

Summary of laboratory audit
A spreadsheet documenting the laboratory's audit of cryopreserved material was provided at the previous inspection, dated January 2008. No discrepancies were observed and it is not yet 2 years since that audit was performed.
Summary of spot check of stored material
No spot check of stored material was carried out on this interim inspection as there was no indication that non-consented storage was an issue and the electronic bring-forward system was demonstrated effectively to the scientific inspector.
Areas of firm compliance
New staff and those returning from career breaks follow specified induction programmes tailored to their roles, to integrate them into the centre. A protocol for induction of staff in the laboratory and induction records for a nurse, were provided to the inspectorate and were considered appropriate. Staff interviewed verified the induction process occurred and they considered it was effective. Staff induction was raised as a concern in the last inspection report, however evidence observed on this inspection suggests those concerns have been

appropriately addressed. The Centre operates to the Hospital Trust recruitment procedures which include professional registration and Criminal Record Bureau checks.

At the last inspection it was noted that some staff had not been provided with some aspects of mandatory annual safety training. At this inspection, evidence was provided to show that all staff had been provided with annual mandatory training in fire safety, health and safety and infection control, and all staff except clinicians had had manual handling training. The Centre does not treat patients under 18 years of age so child protection training and arrangements are not in place. Clinical and nursing staff are trained annually in basic life support; some complete advanced life support training. Continual professional development (CPD) was reviewed for the PR, a nurse and a laboratory worker and was seen to be appropriate, consisting of a mix of in-house training, professional body CPD activities and conference attendance. Junior staff are encouraged to undertake certified training courses (e.g. Association of Clinical Embryologist, ultrasound scanning qualifications) and membership of professional bodies. Staff training was raised as a concern in the last inspection report, however evidence observed on this inspection suggests those concerns have been appropriately addressed.

The Centre has competency assessment programmes for laboratory, nursing and clinical staff. The inspectorate considered the laboratory programme to be appropriate, providing assessment of a broad range of key competencies by an appropriate senior staff member. Competency assessment of nursing staff uses the key skills framework and has been recently applied to band 5 and 6 nursing staff, and is the process of being applied to band 7 staff. A competency assessment programme for clinical staff was also seen by the clinical inspector and has considered to be suitable and appropriate. Annual appraisal is performed for all staff which includes review of competency assessments, and discussion of training needs. The outcome of annual appraisal is documented for each staff member, though the process by which this occurs is currently under review.

Patient treatments are guided by documented clinical selection criteria. The Centre makes consideration of patient privacy and dignity, with the exception of the issue described in Section 3. Ultrasound rooms are locked during scanning and have curtains. The recovery area has appropriate screening between bays.

The 3 embryo transfer (ET) rate at the Centre has declined in the last 5 years from 57%/18% (FET/IVF-ICSI rates in 2003) to 5.4%/4.8% in 2007. These declines show compliance with the aim of the HFEA to limit 3ETs and the guidance that 3ETs are only performed in patients aged >40 years. Indeed the Centre performed no 3ETs in women under 40 years in 2008.

The Centre has established a policy for minimising multiple births, a protocol for selection of patients for elective single embryo transfer and a log of non-compliances with that policy. These were provided to the HFEA when requested. These actions indicate compliance with Direction 2008/5.

The Centre has an established procedure for responding to ovarian hyperstimulation syndrome and patient information on this subject is detailed, providing contact details for out of hours access, and was considered appropriate. Patients with OHSS are admitted to an adjacent 6 bed emergency gynaecology ward by the Centre's clinical staff.

The Centre is equipped to enable processing and storage under appropriate conditions to

protect gametes and embryos, as well as the Centre's staff. For example, air flow cabinets are used in the laboratory to provide a sterile Grade A air environment for processing, background air in the laboratory and treatment rooms is also purified to be compliant, and embryos and gametes are stored either in incubators or liquid nitrogen dewars, with appropriate monitors and alarms.

At the last inspection it was noted that the Centre had yet to develop protocols for the transfer of frozen samples between clinics or for the maintenance and validation of vapour shipper dewars, and thus did not comply with the requirements of Alert 21 (transport hazards of gametes/embryos). The inspectorate was provided on this inspection with a detailed gamete and embryo transportation protocol and with validation for the dry shipper. This documentation was reviewed and considered compliant with the requirements of Alert 21.

At the last inspection it was noted that traceability logs needed to be maintained and stored for the appropriate time intervals, for products and equipment which could affect the quality and safety of gametes and embryos. On this inspection it was seen that the Centre has implemented procedures to ensure the keeping of all relevant information relating to products and equipment which may influence gamete and embryo quality and safety. Logs were observed which support compliance with Licence Conditions A.3.2 and A.10.30.

At the last inspection, witnessing practices were considered broadly compliant with HFEA guidelines, though several minor issues were raised. It was noted that two sperm preparations were spun together in a centrifuge and not witnessed when removed from the machine; this issue has been addressed through the purchase of a second centrifuge which was observed on inspection. The Centre also only processes one sperm sample in the flow cabinet at any one time. It was also noted previously that at some stages the operator and witness did not both check patient details on the sample containers and compare them with patient records. On this inspection it was seen that the witnessing protocol now specifies the operator and witness should both check patient details on the sample containers and compare them with patient records.

Evidence of participation in inter-laboratory comparison of sperm analysis through the National External Quality Assessment Service was provided in the course of the inspection. The Centre is also considering partaking in the NEQAS embryo morphology assessment programme when it begins.

The Head of Embryology provided evidence that critical laboratory and Centre performance indicators had been audited recently and the inspectorate were provided with a monthly analysis for the last year.

The compliance of embryo and gamete storage premises was discussed in Section 3. The Centre has comprehensive paper and electronic logs of samples in store and operates an appropriate bring-forward system, which indicated that no samples were in storage past their consented storage period.

Counselling at the Centre was considered compliant at the last inspection and was not investigated on this inspection. The Lead Counsellor has provided a counselling service to the Centre for 18 years and is a qualified social worker, as well as having a diploma in fertility counselling and membership of the British Infertility Counselling Association and the British Fertility Society. A counselling report was provided for 2008 which indicated that 92 face-to-

face sessions were held (*versus* 480 treatment cycles performed) as well as an un-stated number of telephone consultations. Most counselling was said to be provided at the start of treatment or after a failed treatment. The Counsellor related in the report how she feels very much part of the staff team and attends patient open evenings and staff meetings. She also attends the Social/Ethics group where concerns about ethical and WoC issues are discussed.

Areas for improvement

At the last inspection, it was noted that an egg provider had not been screened for *Neisseria gonorrhoea,* contrary to BFS Guidelines and Code of Practice, 7th Edition, G.4.9.1. On this inspection, the records of two egg providers were reviewed. It was noted that for one provider, no records were available to evidence they had been screened for syphilis and chlamydia, contrary to Licence Condition A.7.2, or for *N. gonorrhoea,* as required by BFS guidelines at the time of donation, and thus by Code of Practice, 7th Edition, Guidance G.4.9.1. There was no evidence to show that the other provider had been screened for syphilis or CMV, contrary to Licence Condition A.7.2, or for *N. gonorrhoea* or cystic fibrosis, as required by BFS guidelines at the time of donation, and thus by Code of Practice, 7th Edition, Guidance G.4.9.1. Records for 3 sperm donors were also reviewed and 2 records were found to be missing evidence of chlamydia screening, contrary to Licence Condition A.7.2. The PR should investigate how these sperm donors and egg providers were used in treatment even though screening tests were inadequate given Licence Conditions and the BFS screening guidelines active at the time of donation. Donation protocols should be reviewed after consideration of Licence Conditions and the revised joint UK guidelines for the medical and laboratory screening of sperm, egg and embryo donors (Human Fertility 11, 201 - 210), introduced in December 2008. If the screening procedure is changed, patient information should be updated to include all of the screening tests carried out. The rationale for any remaining non-compliance with this professional body guidance and thus with G.4.9.1 should be documented.

At the last inspection it was noted that validation of processes and equipment had not been performed. At this inspection, the Head of Laboratory provided a process validation report for the Centre's activities, but noted that the validation was only 30 - 50% complete and that the project had been delayed by the late release of the Association of Clinical Embryologists validation package. The validation report was reviewed and considered to provide appropriate validation for some of the key processes, though equipment validation was lacking. This situation constitutes a breach of standard licence condition A.11.11, however it is recognised by the inspectorate that progress has been made and that the late release of the ACE validation tools will have delayed the programme.

At the last inspection, it was noted that analysis of semen samples is carried out in a separate andrology laboratory. Code of Practice, 7th edition, Standard S.7.8.2, states that if the Centre has laboratories or contracts third party laboratories or practitioners to undertake the diagnosis and investigation of patients, patient partners or donors, or their gametes, embryos or any material removed from them, these laboratories shall obtain suitable accreditation. It is noted at S.7.8.2 that the pathology disciplines involved in diagnosis and investigation include andrology. The PR should review the requirement for clinical pathology accreditation (CPA) of the andrology laboratory. If it is concluded that the laboratory should obtain CPA then the PR should be able to demonstrate significant progress towards obtaining accreditation at the time of the next inspection. If it is concluded that the laboratory should not obtain CPA accreditation, the reasons why should be communicated to the Licence Committee in

appendix C of this report.

Areas for consideration

The witnessing and gamete/embryo freezing protocols require updating to include that the location of the gametes and embryos in the storage dewar is cross-checked against patient and storage records by the operator and the witness, to ensure witnessing is compliant with all requirements of Code of Practice, Guidance, G.13.

The Centre must review and update its laboratory protocol for donation of oocytes to research as the research project (R0161) at the centre, which has been inactive for some time, became active again in April 2009. The protocol will need to include witnessing of details on the oocyte container against patient records to ensure compliance with Code of Practice, Guidance, G.13.

Executive recommendations for Licence Committee

The Inspectorate recommend that the Licence Committee require the PR to ensure that:
1) An investigation is carried out as to how donors were used in treatment even though screening tests were inadequate given Licence Condition 7.2 and the BFS screening guidelines active at the time of donation.
2) Donation protocols are modified to ensure Licence Condition 7.2 is not breached again.
3) The protocols for donor screening are reviewed after consideration of Licence Conditions and the revised joint UK guidelines for the medical and laboratory screening of sperm, egg and embryo donors (Human Fertility 11, 201 - 210), introduced in December 2008.
4) If the screening procedure is changed, patient information is updated to include all of the screening tests carried out.
5) To document the rationale for any remaining non-compliance with joint UK guidelines for the medical and laboratory screening of sperm, egg and embryo donors (Human Fertility 11, 201 - 210).
6) The completion of the validation of key equipment and processes to comply with Licence Condition 11.11
7) The requirement for clinical pathology accreditation (CPA) of the andrology laboratory, as suggested by Code of Practice, 7th edition, Standard S.7.8.2, is reviewed. If it is concluded that CPA accreditation is required, significant progress to this goal should be available at the next inspection. If it is concluded CPA accreditation is not required, the reasons why should be communicated to the Licence Committee in appendix C of this report.

Areas not covered on this inspection

All areas covered

Evaluation

Improvements required in four areas.

Report compiled by:

Name Dr Andrew Leonard

Designation Scientific Inspector, HFEA

Date 6th May 2009

Appendix A: Centre staff interviewed

PR
Nursing staff (1)
Scientific staff (2)
Administrative staff (2)

Appendix B: Licence history for previous 3 years

Licence	Status	Type	Active From	Expiry Date
L0049/13/b	Active	Treatment with Storage	01/10/2007	30/09/2010
L0049/12/a	Replaced by New Version	Treatment with Storage	05/07/2007	30/09/2007
L0049/11/a	Replaced by New Version	Treatment with Storage	01/03/2006	30/09/2007
L0049/10/a	Replaced by New Version	Treatment with Storage	01/10/2004	30/09/2007
L0049/9/a	Replaced by New Version	Treatment with Storage	01/10/2001	30/09/2004

L0049/13/a
No Conditions or Recommendations on Licence

Appendix C:

RESPONSE OF PERSON RESPONSIBLE TO INSPECTION REPORT

Centre Number 0049

Name of PR Janet Evans

Date of Inspection 25th March 2009

Date of Response 14th May 2009 (by email, TRIM 2009/000003041)

Please state any comments regarding the inspection and actions you have taken or are planning to take following the inspection with time scales

Re inspection report comments
The centre has met to consider the report – action plan in place – issues easily dealt with in house – actioned with named persons, actions requiring trust involvement will need meeting with management next week – will get action plan to you as soon as we have cut and pasted the concerns from your format

- The process validation report was only half completed as the information had only come from ACE at the beginning of the year and the inspection was only 8 weeks later- as it is a dynamic document it will always be undergoing change it is now complete for current practice
- The andrology lab is not a separate entity but part of the embryology laboratory and managed as part of the team- with the same line management, SOPs and quality control, with staff from embryology often working in andrology. It has already been inspected by yourselves as part of the centre on previous inspections, as well as being inspected by ISO as part of the centre. Furthermore we have taken advice from our pathology labs and WAG (Welsh Assembly Government), that they are satisfied that these inspections are sufficient
- It is likely that a risk assessment of the out patient area was undertaken by our directorate management prior to our move. Unfortunately we were not informed about it, and it is unlikely to be comprehensive or have been done with a knowledge of the HFE Act. We will therefore be repeating the process with the benefit of experience of working in the unit and hearing patient concerns
- GC and chlamydial swabs for egg donors - it emerged that the nurses had been working from an old paper protocol – these have been destroyed and screening is now in place in line with the latest protocol which has been printed for them for reference
- A contingency plan has been written but will need agreement by the new chief executive and LWC
- Discussions re quality manager have been ongoing for a year- a job description has been written and a business case developed- your comments will serve to revive the issue- thank you
- Signage is a continuing issue for patients and our temporary manager has agreed to pull a few strings- thank you
- Re WOC , disclosure, an audit of the new patient care pathway will be undertaken

2. Correction of factual inaccuracies

Please let us know of any factual corrections that you believe need to be made (NB we will make any alterations to the report where there are factual inaccuracies. Any other comments about the inspection report will be appended to the report).

- The issue around competency assessment confused us- Debbie had showed Rob Sawyer the nurse's competency and he had complemented her on it. The medical staff competency 2008 was available with steph in a file upstairs (unfortunately we met down stairs) and I showed you the new format that we are now completing for 2009- so for both doctors and nurses it was complete. *(The situation regarding competency assessment has been clarified with the PR and Ward Manager and the comment in the report which led to this reported inaccuracy has been removed – report author).*
- Pg 17 the new patient evening is on a weekly basis *(corrected in text – report author)*