Renewal Inspection Report

Edinburgh Assisted Conception Unit
0201

Date of Inspection: 19th August 2008
Date of Licence Committee: TBA

Centre Details

Person Responsible	Dr K J Thong
Nominal Licensee	Ms Sandra Mair
Centre name	Edinburgh Assisted Conception Unit
Centre number	0201
Centre address	51 Little France Crescent Lothian Edinburgh EH164SA
Type of inspection	Renewal
Inspector(s)	Dr Andrew Leonard (lead) Dr Vicki Lamb Mrs Gill Walsh Miss Angela Sutherland (observing)
Fee paid	Yes
Licence expiry date	L0201/5/a; 28.02.09
NHS/ Private/ Both	NHS Clinic

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About the Inspection:

This inspection visit was carried out on 19th August 2008 and lasted for 8 hours.

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 licence renewal inspection highlighting areas of good practice, as well as areas where further improvement is required to improve patient services and meet regulatory requirements. It is primarily written for the 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 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.

Where recommendations are made the HFEA will provide details of what needs to be addressed but not how they should be carried out as this is the responsibility of the Person Responsible.

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

The Edinburgh Assisted Conception Unit has been licensed since 1992 and offers a range of fertility treatment services to NHS patients. The unit is located on the ground floor of the Edinburgh Royal Infirmary. The premises include a large waiting area, an overflow waiting area and a sub-waiting area for known donors.

The centre licence terminates on 28 February 2009 and includes:

- Storage of embryos
- Storage of sperm
- Intra Cytoplasmic Sperm Injection (ICSI)
- In Vitro Fertilisation (IVF)
- Processing of gametes and embryos
- Insemination
- Treatment with donor gametes and donor embryos
- Procurement and distribution of gametes and embryos.

Unlicenced activities:

- Ovulation induction with Gonadotrophins
- Sperm retrieval
- Tubal surgery
- Surrogacy

The centre is open Monday to Friday 08:00 – 16:00, Saturday 09:00 - 13:00 with occasional Sunday activity. Oocyte recovery takes place 4 (occasionally 5) days per week on weekdays and embryo transfers occur Monday to Saturday. Between 01.05.07 and 30.04.08 the unit provided 667 cycles of IVF/ICSI treatment to 530 patients and 61 cycles of donor insemination to 17 patients. These statistics are similar to those of the preceding year.

Centre 0201 intends to expand incubator space in 2009 to enable an increase in extended culture in MINC incubators and blastocyst transfers. Additional space has been identified and senior management approval obtained.

The Person Responsible, a Consultant gynaecologist and sub-specialist in Reproductive Medicine, has held the post of PR since 1998 and is full-time at the centre.

Centre activities[1] for the time period 1st June 2007 to 31st May 2008

In vitro fertilisation (IVF)	308 cycles
Intracytoplasmic sperm injection (ICSI)	236 cycles
Frozen embryo transfer (FET)	113 cycles
Donor insemination (DI)	57 cycles
Egg donation	8 cycles
Egg recipients	3 cycles
Gamete intrafallopian transfer (GIFT)	NO
Research	YES (R0181)
Storage gametes/embryos	YES

Summary for Licence Committee

The centre is a medium sized unit providing approximately 700 licensed treatment cycles per year. The centre has been proactive in the development and implementation of a quality management system, a detailed quality manual and the use of appropriate key performance indicators to monitor the quality of the centre's activities. The centre provides an appropriate quality of service and information and requires minor improvements only in issues related to its organisation, premises and laboratory and clinical procedures. Patients report satisfaction with the treatment that they receive. Improvements are needed in:

- Payment of HFEA invoices
- The organisational chart
- Incident reporting
- Third party agreements
- The safety and suitability of premises for staff and patients
- Donor screening
- Ensuring checks of the serviceability of the resuscitation trolley
- Validation of key processes

The inspection team recommend that progress in addressing the issue outlined should be made within the timescales specified. The Inspectorate are though satisfied with the key areas of service provided by the centre and recommend renewal of the centre's licence without additional conditions for 5 years.

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

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 Inspection Team 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;-

Breach	Action required	Time scale
In the year to July 2008 the centre took an average 31 days to pay invoices according to HFEA Finance Department. This is potentially a breach of Licence Condition A.13.3.	The Person Responsible should liaise with the Finance Department to review the arrangements for payment of invoices and ensure that there are no barriers to the prompt payment of invoices.	By 23rd October 2008 Progress to be monitored at the time of the next inspection.
Flooding events have been logged in the centre's incident log. They have not been reported to the HFEA as adverse incidents. This is potentially non compliant with Directions D.2007/3.	The PR should review the centre's adverse incident reporting procedures to ensure that they reflect the HFEA reporting requirements The flooding incidents should be reported retrospectively to the HFEA as soon as practicable and any future flooding incidents should be reported within with 12 working hours. The PR should ensure that premises and facilities are suitable for the activities for which the centre is licensed and provide a safe working environment for all staff in compliance with S.6.3.2. It is recommended that the PR seek guidance from local health and safety representatives on the measures that are required to ensure the safety and suitability of the premises following any flooding.	Flooding incidents to be reported retrospectively immediately. A copy of the guidance and any actions taken as a result should be provided to the HFEA by 19 November 2008.
Some long-standing equipment and critical laboratory processes have not been validated, which is a breach of standard licence condition A.11.11 and S.7.8.3	It is recommended that the centre identifies critical procedures and prepares a prioritised plan for the validation of all equipment and procedures which impact on gamete and embryo quality and safety	Progress to be monitored in the course of the next inspection.

Non-Compliance

Area for improvement	Action required	Time scale
The emergency resuscitation trolley had not been subject to daily checks in compliance with the centre's own procedures and with UK Resuscitation Council Guidelines[2]	The Nurse co-ordinator provided assurances at the time of the inspection that checking procedures would be implemented according to protocol. The PR should review whether there are any barriers to compliance with the documented procedures.	N/A
Egg donors have not been routinely screened for Neisseria Gonorrhoea or subject to karyotype analysis contrary to recommendations of professional body guidelines.	The PR should review the protocol for screening of prospective donors after consideration of the BFS guidelines, as recommended by Code of Practice, 7th Edition, G.4.9.1. The rationale for any non-compliance with guidelines should be documented. If screening procedures are changed, patient information should be updated to include all of the screening tests carried out. The PR should also ensure a system is in place which guarantees that all tests required by the screening protocol are performed on every donor.	Procedures to be reviewed immediately and any changes and/or corrective actions to be reported to the HFEA.

Recommendations

None

[2] Cardiopulmonary Resuscitation Standards For Clinical Practice And Training, A Joint Statement from The Royal College of Anaesthetists, The Royal College of Physicians of London,The Intensive Care Society, The Resuscitation Council (UK), revised June 2008

Changes/ improvements since last inspection

Recommendations	Action Taken
Information about the complaints procedure should be clearly displayed at all times in the waiting area.	Complaints procedure now clearly displayed
The organisational chart should be updated to reflect that there are two separate teams of doctors and nurses involved in licensed treatments (IVF and DI / ICI respectively).	The organisational chart has now included the Andrology service.
Communication between the two nursing teams should be improved.	New staff who were unaware of the meaning of the acronym “ICI” have been updated. Staff are aware of the terminology IUI.
Recommend harmonization of ACU and RML polices regarding storage of viral positive samples.	There has been harmonization of policy between RML and ACU, regarding storage of samples which show evidence of a previous infection with Hepatitis B, but are no longer infectious

Additional licence conditions and actions taken by centre since last inspection

None

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 was formed 6 years ago in new premises, by the amalgamation of three services: IVF/embryology in the assisted conception unit (ACU) and donor insemination and andrology in the Reproductive Medicine Laboratory (RML). Together the ACU and RML form the Edinburgh Fertility and Reproductive Endocrine Centre (EFREC). The management structure of the RML and ACU have been reviewed to ensure close working between the two. The centre quality manual contains an organisational chart with clear lines of responsibility and communication which mostly concur with those observed on inspection. The Person Responsible (PR) is in overall control of licensed activity but devolves authority to experienced departmental leads in embryology and the RML. Medical/clinical matters are dealt with by the PR. The PR is accredited with the General Medical Council (GMC) as a Consultant Obstetrician & Gynaecologist and sub-specialist in reproductive medicine and has completed the PR Entry Programme. The centre Management team have responsibility for resource management in their areas and these are integrated to provide centre-wide resource management at regular management group meetings, the minutes of which were observed on inspection. Adverse clinical outcomes are reported to the local Health Board and the HFEA if appropriate. Hospitalised cases of ovarian hyperstimulation syndrome (OHSS) are reviewed to assess whether treatment was appropriate and for other learning points. The centre was advised that such cases should now also be reported to the HFEA as adverse incidents. The PR is the incident reporting officer. An appropriate incidents log was provided which detailed investigation and actions to minimise the risk of recurrence. Incidents are discussed at the weekly all staff meeting if appropriate. Discussions with centre staff indicate an open

and positive 'learning' attitude regarding incident reporting and investigation. All staff interviewed had read the incident reporting protocol.

The centre's complaints procedure was clearly displayed in the patient waiting room, a requirement of the last inspection. The centre has a nominated Complaints Officer. Complaints are all logged, even if made verbally, as is their review and any follow up actions. Complaints are also discussed at the weekly all staff meeting if necessary. There have been two complaints in the last year, as seen in the complaints log, both being received after the centre had submitted its pre-inspection questionnaire.

The centre is compliant in risk management, using the DATIX risk management system. Area and procedural risk assessments have been performed in the laboratories and clinical areas. Other risk assessments are undertaken as required and have recently included witnessing; storage of Hepatitis B core positive samples; UPS installation; various COSSH assessments

The centre has a formalised contingency plan with the fertility unit at Ninewells Hospital, HFEA centre 0004, for emergency service provision in the event of significant failure(s) in the centre. A part-time consultant works at the centre alongside the full-time PR, also a consultant. The former covers clinical issues in the absence of the PR while the Embryology Consultant covers HFEA related issues.

Integrated control of the centre is achieved through quarterly management group meetings, the minutes of which were observed on inspection and are available to all staff. Regular departmental team meetings are also held, generally monthly. Weekly all staff unit meetings are held at which centre activity levels are discussed to ensure activity levels are safe given the resources available. Activity has declined in the last year and the PR explained that the centre had been short of 2 embryologists at times in the last year, hence the decreased activity, indicating activity is regulated according to the resources available. Minutes are taken at all meetings and are available to all staff. For example, the minutes of the all staff meeting are emailed to all staff. Minutes from meetings were provided to the inspectorate. They were considered to be well presented and detailed, providing clear descriptions of subjects discussed and actions required.

HFEA Alerts are disseminated from the PR to management by email then discussed by the PR with the managers of relevant departments. Response plans are developed if necessary. The PR and managers cascade HFEA Alerts and response plans to staff at departmental meetings and/or the weekly all staff meetings. The PR and Consultant Embryologist both described the last HFEA Alert issued (Alert 25).

Areas for improvement

This centre had on the 15th August 2008 no invoices outstanding but in the last year has taken on average 31 days to pay invoices according to HFEA Finance Department. This is greater than the 28 day payment period required by Licence Condition A.13.3. The PR understands the requirements of this licence condition but pointed out that as for other NHS centres, HFEA invoices have to be transferred to the Finance Department for payment and he has no control over their efficiency.

In the organisational chart, the Clinical Nurse Manager is responsible for nursing matters and the Assistant Service Manager for administration, these managers reporting with the PR to

the Clinical Director of Women's Services. In the centre, the nursing staff providing licensed treatment are actually managed by a Charge Nurse and the ACU Nursing Coordinator, who communicate with the PR regarding nursing issues in the centre. This communication and line of responsibility should be included in the organisational chart to ensure its accuracy and compliance with Standard Licence Condition A.10.1.

Discussions with centre staff revealed an on-going problem with flooding from the sewage/drainage system escaping out of toilets and the bed pan washer in the centre. There was a small puddle in a corridor on day of inspection from a leak through the ceiling. The Nurse Coordinator after the inspection confirmed that 'from 1/7/06 to 30/6/08 we have had 36 reported leaks, of those 4 were reported as incidents because they were serious'. By serious it is meant that the flooding involved contamination of the centre such that activity was disrupted. Centre staff related on inspection that the hospital infection control unit are now called at every occurrence, and they initiate the rapid arrival of plumbers and a clean up squad. They also related however that bacteriological testing has not, to their knowledge, been performed to assess whether clean up procedures have on any occasion been successful. The PR and Charge Nurse have 'emailed repeatedly' about the sewage leak issue to hospital management and been advised that nothing can be done as it would require extensive building work to the drains under the centre in the building foundations. The serious flooding events have been logged in the centre's incident log, but have not been reported to the HFEA as adverse incidents. This indicates short comings in the centre's incident reporting procedures.

The PR stated that most third party agreements are in place and are subjected to annual review. A file of third party agreements was evidenced. The PR noted that one third party agreement outstanding was that sent to the hospital's procurement department. A third party agreement with a laboratory supplier had also not been returned by the supplier after review in March 2008 and this supplier is no longer used. Centre Management should continue to make progress in the establishment of documented agreements with third parties when an activity takes place which influences the quality and safety of gametes and embryos in compliance with the requirements of Code of Practice, Standards S.4.2.10.

Areas for consideration

None

Executive recommendations for Licence Committee

The Person Responsible should liaise with the Finance Department to review the arrangements for payment of invoices and ensure that there are no barriers to the prompt payment of invoices with progress to be monitored at the time of the next inspection.

The PR should review the description of a HFEA reportable adverse incident in the Code of Practice, Standards S.3.1.1, and review the centre's adverse incident reporting procedure to ensure it incorporates this description and that such events are reported appropriately to the HFEA, to comply with Code of Practice, Standard S.9.4.2 (c). The flooding incidents should be reported retrospectively to the HFEA as soon as practicable and any future flooding incidents should be reported within with 12 working hours in compliance with Directions D.2007/3. This documented procedure should then be appropriately released and all staff advised about it.

The PR should ensure that premises and facilities are suitable for the activities for which the centre is licensed and provide a safe working environment for all staff in compliance with S.6.3.2. It is recommended that the PR seek guidance from local health and safety representatives on the measures that are required to ensure the safety and suitability of the premises following flooding of the premises. A copy for guidance and any actions taken as a result should be provided to the HFEA by 19 November 2008.
Evaluation
Some improvements required
Areas not covered on this inspection
All areas covered

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]
In the last year (June 2007 – May 2008), the centre reported 544 IVF/ICSI cycles (308 IVF, 236 ICSI), 113 frozen embryo transfers (FETs) and 57 donor insemination (DI) cycles. This is a slight decrease on the activity in 2006 (560 IVF/ICSI cycles, 127 FETs and 85 DI cycles). The live birth rate for all IVF/ICSI treatment cycles in the calendar years 2004 - 2006 was 26%, which was significantly greater than the national average for all centres during this time. The centre is in the top 10% of centres when ranked on live birth rate in 2004 – 2006. Considering data recorded in 2006, when age stratified (<35 years; 35-37 years; 38-39 years; 40-42 years and >42 years), IVF/ICSI, frozen embryo transfer and donor insemination live birth rates in all age groups tended to be in line with national averages.
Areas of firm compliance
The centre is ISO 9001:2000 certified and has a well developed quality management system. The Quality Manager is also the ACU Nursing Coordinator; she splits her time 33% on Quality Management, 17% on nurse training and 50% on her nursing role. The Consultant Embryologist and Senior Andrologist provide support to the Quality Manager regarding laboratory issues. A designated Document Control Secretary also works with the Quality Manager. A quality policy signed by the PR which defines the centre's quality objectives and commitment to its patients was displayed in the patient waiting area. The centre has a well developed quality manual which is available on the centre server. Further copies of SOPs can be printed but are marked as for review only and/or not for use as a procedure. The Document Control Secretary maintains an index of all documents with their document control details. When documents approach their review date, the Secretary organises for review by the author. Reviews are performed and released to the quality manual by designated individuals. New/revised SOPs are notified to staff at monthly departmental meetings and/or weekly all staff meetings. Documents have appropriate document control footers and staff are required to confirm in writing that they have read the master document. Quality management review and evaluation reviewed in the course of the inspection was appropriate. Annual Quality Management Reviews are performed and detailed minutes were

provided of the last annual meeting in May 2008. Quality objectives and an analysis of multiple key performance indicators (KPIs; defined in the quality manual) were discussed at this meeting, and recent performance analysed by month and by year compared with historic data. Embryologist performance is also reviewed individually and corrective actions taken if performance falls below defined levels. Other items discussed include results of internal audits, customer feedback with preventative actions, review of service and performance, review of the quality management system, review of the achievement of quality objectives and the setting of new objectives, regulatory changes and future resources and training needs.

The centre has an active programme of audit and contract an external auditor who is on the licence to perform audits twice a year. In the last year 14 audits were reported in areas considered by the quality management committee to be essential for providing a compliant service, including document and data control, customer complaints, maintenance and calibration, HFEA consent forms and clinical waste. These audits are in addition to routine monthly, quarterly and annual audit of clinical/embryology data according to standard operating procedure. Audit results were seen to have been discussed in the quality management review minutes for May 2008.

The PR is the accredited consultant and clinical standard operating procedures (SOPs) are reviewed annually by the PR. The PR gave an example of modification of clinical practice which indicated appropriate review of practice against recent advances in best practice, and of controlled release of the reviewed procedure. The Consultant Embryologist is responsible for review of procedures in the embryology laboratory, as is the Nursing Coordinator regarding clinical nursing procedures, and the Senior Andrologist regarding RML procedures.

Feedback from patients is obtained through patient questionnaire surveys carried out annually in December. These questionnaires have a range of questions however a free text comment section has been included in response to a recommendation from an ISO inspection. The questions are derived from the HFEA patient questionnaire with some additional questions added which were developed by a multidisciplinary team at the centre. The centre also provide HFEA feedback forms for some months prior to the HFEA inspection which tends to fall in August. Patient satisfaction surveys are reviewed at the quality management meetings. Staff feedback is encouraged at the all staff and departmental meetings.

Areas for improvement

None

Areas for consideration

It was noted during inspection that documents relating to RML activities appeared to be separately controlled, formatted and organised from documents used in the ACU, though the former were provided as part of the centre's quality manual. The PR should ensure that all documents related to licensed activities are held within a single quality manual which is effectively controlled by the Quality Manager.

The PR discussed that donor insemination activity at the centre has decreased considerably in recent years (2004, 263 cycles; 2006, 85 cycles; 2007, 57 cycles), this being related to the decline in sperm donor supply. The centre would like to increase the provision of DI however this will require the initiation of a sperm donor programme as the centre has attempted to enter a third party agreement with a donor sperm supplying centre but this has not been

returned. They therefore no longer use this donor sperm source. The centre have submitted several business cases for such a programme, however, so far these have not been successful. We are hopeful that this will change at some point in the future. The Centre will continue to try and purchase donor sperm from appropriately accredited/licensed Centres under third party agreement.

The current waiting list at the centre for IVF treatment for NHS patients was described by centre staff as being between 2 and 3 years. The PR would like to provide more treatment to reduce the waiting list but this is impossible given the current level of funding. Again, the centre have submitted several business cases for such a programme, however, so far these have not been successful.

Executive recommendations for Licence Committee
None
Areas not covered on this inspection
All areas covered
Evaluation
No improvements 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
The inspectorate considered that the premises were appropriate for the centre's activities, except for the sewage overflow issue raised in Section 1 of this report. On entry from the main hospital to the centre through lockable doors (open during service hours), there is a reception and waiting area, with access to toilets and a children's play area. The centre licence, quality policy and complaint's procedure were on display, as well as a range of patient information leaflets related to fertility treatment, counselling and contact details for patient support groups. A secure notes store is accessed from the waiting area. This store is staffed by a dedicated notes storage officer who locks the store when it is left unoccupied. Most of the centre's facilities are accessed through a door adjacent to the reception desk leading to two corridors. The left corridor provides access to 2 consultation rooms, a research ultrasound scanning room also used for phlebotomy and injection training, a nurses station/clinical reception desk, 3 scanning rooms (one also used for intracervical inseminations), 4 examination rooms, 5 toilets (with emergency call buttons), a consulting/counselling room, a drugs store room and a rubbish store room. This corridor terminates in a secure fire door. The right corridor provides access to two production rooms, the RML office, a staff coffee room, a nurses office, 2 utility rooms, a 6 bed recovery area with adjacent nurses station and 2 theatres with a scrub room between them and the embryology laboratory behind. It then leads into a perpendicular corridor providing access to 2 staff changing rooms, a medical gas storage room, an endocrinology laboratory, an andrology laboratory, an andrology dewar cryostore, an embryology dewar cryostore, a wash room, a research office, a cold store, a research laboratory and the embryology laboratory. Clinical areas were clean and appeared comfortable and appropriately equipped. The 6 curtained bays in the recovery area were fitted with heart rate/blood pressure monitoring as well as oxygen and suction lines and emergency call buttons. A nurses' station adjacent to the recovery room is permanently staffed while patients are present in recovery. The 2 treatment rooms were effectively equipped as operating theatres. The scanning and consulting rooms were also comfortable and clean, and the scanners were within service periods. Curtains are used to ensure privacy during scanning and chaperones are present at

all examinations and scanning sessions.

A counselling room is available within the centre. This room is private, quiet and comfortably furnished. The room was considered by the inspectorate to be fit for purpose.

The two production rooms were comfortable, appropriately equipped and were considered fit for purpose by the inspectorate. The ACU Nursing Coordinator considered the area outside the production rooms to be sometimes noisy; a refurbishment of the rooms to mitigate this is planned.

The laboratory premises were considered compliant. They are regularly cleaned and a sign off sheet for this was observed by the inspectorate. Laboratory equipment showed evidence of annual servicing and a procedure is in place for equipment servicing and maintenance. Laboratory incubators and other key equipment are connected to a power supply which is backed up by the hospital's emergency generator and by a recently fitted uninterruptible power supply with 10 outlets in the embryology laboratory for essential equipment. Daily monitoring of temperatures of hot blocks, fridges and heated stages is recorded in a log book which was reviewed in the course of the inspection. Weekly checks are also performed with a calibrated temperature probe. Incubator temperatures and carbon dioxide concentrations are monitored daily with a fitted calibrated probe.

To facilitate an increase in blastocyst culture as part of the centre's plans to implement more single embryo transfers, the centre plans to refurbish the embryology laboratory to incorporate a currently under-utilised adjacent room.

Air quality in the laboratory is compliant with the requirements of the Code of Practice, 7th edition, being grade A in the flow hoods and Grade C in the andrology and embryology laboratories. An SOP is in place for air quality monitoring which was seen on inspection. It describes that air quality is monitored on a half yearly basis as part of the servicing contract, as required by the local Health Board. In addition, weekly settle plate tests used to assess air quality in the embryology and andrology laboratories, and the air flow hoods. Originally settle plates were used daily but variability was limited and weekly tests were considered to provide an effective assessment of bacteriological airborne contamination. The centre has recently purchased an airborne particle counter which is being validated, after which it will be used weekly to test air quality.

The embryology and andrology cryostores are next to each other and access to them is restricted by digital locks. All dewars are locked and fitted with low level nitrogen alarms linked to an auto dial out system. During the week the RML biomedical scientists are on call to respond to alarms. The embryologists provide on call cover at the weekends. Low oxygen alarms are present in both cryostores. The procedure for responding to the alarms was reviewed during the inspection,. A back-up dewar for storage of sperm and embryos is available in cases of an emergency. The storage facilities for embryos and gametes were considered compliant with the requirements of the HFEA Code of Practice.

Cleaning in the centre is provided by the same hospital cleaning staff, all listed on the licence. The rubbish store was tidy and was reported to be emptied daily. The centre appeared clean and tidy on the day of inspection, except for the leak already discussed in Section 1.

Staff are provided with facilities in a changing room/toilet suite with lockers and a common

room. The staff facilities were compliant with Code of Practice, 7th edition, requirements.

Records of patients undergoing treatment are kept in the nurses office, then returned for storage in the centre records store which is fitted with a key-pad locked door. Records storage in this room was well organised by a dedicated records storage officer, who is well acquainted with the confidentiality requirements of the HFEA Code of Practice. When records are in use in the clinic, tracking slips are used to prevent them being mislaid and they are stored in locked cupboards if the room is left unattended. Patient records are stored within the centre records store if patients have undergone treatment in the previous ten years. Inactive records are transported for storage by the records storage officer to an off-site specialist data repository, in sealed boxes labelled with a code rather than patient identifying information, as well as date of storage and date for disposal. Staff at the repository have also been made aware of the confidentiality requirements of the HFEA Code of Practice.

Counselling records are stored locked in the counselling room and a summary is inserted in the patient record.

The premises are inspected for health and safety purposes and each room has been risk assessed in the last year.

Areas for improvement

An emergency resuscitation trolley was present in the utility room adjacent to the recover area. The centre's own protocols require that, resuscitation equipment be checked every day when licensed treatments are provided. It was noted that daily checks had not always been performed. This was confirmed by the ACU Nursing Coordinator who assured the inspectorate that she would ensure checks are performed on a daily basis in future according to the centre's procedures and in line with Resuscitation Council UK guidelines.

Areas for consideration

One patient record contained a counselling summary which contained details which the clinical inspector considered were too extensive to be freely available to all medical staff in the patient record. The PR and counsellor were asked to consider this opinion and consider Code of Practice, G.7.4.2 which requires that counselling records remain confidential.

Executive recommendations for Licence Committee

The PR should ensure that the resuscitation trolley checks are performed in compliance with the centre's documented procedures and/or whether there are any barriers to compliance with the procedures.

Areas not covered on this inspection

All areas covered

Evaluation

One improvement is 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
After referral, couples are sent information sheets regarding treatments at the centre then have an initial consultation with an infertility specialist in the Infertility Clinic, to ensure that investigations are complete and, if they are, to discuss treatment options and develop a treatment plan. The patients are then placed on the centre's waiting list. Patients are supplied with HFEA consent forms to read through at the review consultation. For couples needing general advice, counselling is available from nursing staff or an independent counsellor for which there is no charge. Counselling is discussed in the patient information. With the patient's consent, the patients' general practitioners are contacted informing them of the proposed treatment and requesting any relevant information. The patients are seen by a member of the nursing staff a few weeks before their treatment to discuss the proposed treatment plan and for the couple to ask any further questions. Baseline observations and blood tests are performed. Relevant consent forms are then signed and checked by a member of nursing staff in the presence of the couple. If the couple are unsure of the treatment plan or their clinical circumstances have changed, they may arrange a further clinician consultation. The centre has a procedure to ensure that all necessary information is provided to patients and that they have an opportunity to ask questions, prior to consent forms being signed. This involves a detailed checklist which is kept in patient records, on which it is indicated that specified information has been supplied verbally and/or in writing. The ACU Nurse Coordinator considered that patients are well informed about treatment and have plenty of time for consideration before consenting. This was confirmed by a patient interviewed on the day of inspection and no patient complaints have been received on this matter. Review of 10 patient records indicated that all HFEA consent forms had been completed appropriately The centre has a Welfare of the Child procedure in place which ensures that the assessment is completed and reviewed and that consent for disclosure is taken. Staff with concerns report them to the ACU Nursing Coordinator and/or the PR and they can be raised in the weekly multidisciplinary meeting by doctors, counsellors and nursing staff. The PR can take any concerns into consideration and, if necessary, access specialist services through the local health board. The centre also has access to an ethics committee. Review of 10 patient records indicated Welfare of the Child (WoC) assessment had been appropriately completed. Access to patient records is controlled and a specified person is responsible for managing patient records. Patients can obtain a copy of their patient records by written application to the centre, signed by both patients. One member of the administration team has responsibility

for photocopying the notes and sending them to the patients. Patient records are subjected to a HFEA compliant records control policy which describes the appropriate 10, 30 and 50 year document retention periods.

The HFEA registry reported no concerns or issues with the centre's returns and the last HFEA operational audit visit in December 2007 found a data error rate of 1% and a late reporting rate of 1%. The centre have recently recruited a dedicated data entry worker input data on the HFEA electronic data interface (EDI) system, which will lessen workload on nursing staff who enter data at present.

Areas for improvement
None
Areas for consideration
General patient information was provided to the inspectorate and it was consider well written and presented. It was compliant with some of the requirements of the Code of Practice, as described in Guidance (G.5. Providing proper information). Some information was not however provided, for example, waiting times (G.5.3.1.b), information about withdrawal of consent, how to do so and the consequences of so doing (G.5.2.1 b-d), options in the event of death (G.5.2.1 f,g), the risks of gamete collection (G.5.3.1g) and the uncertainty regarding the association between ovarian cancer and ovarian induction (G.5.3.1 i). It is possible that this and other required information are supplied to patients verbally or in other written information. It was also noted however that the general patient information included incorrect information regarding parental responsibility derived from the Children Act (1989), which has been superseded by the Adoption and Children Act (2002).
Executive recommendations for Licence Committee
That the PR review all written and verbal information provided to patients to ensure it complies with all requirements of the Code of Practice, as described in Guidance (G.5. Providing proper information).
Areas not covered on this inspection
All areas covered
Evaluation
No improvements required.

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	4.5 WTE
Registered nurses	8.3
Non NMC registered nurses/health care assistants	1.8
Registered scientists	4 in Embryology 6 in Andrology/RML
Scientists working towards registration	2 in Embryology
Laboratory support staff	0
Counsellors	1 contracted 0.3 WTE. One counsellor has zero contract and does extra sessions as required
Support staff (receptionists, record managers, quality and risk managers, etc).	3.8 WTE + 1 locum cover 0.7 WTE

Summary of laboratory audit
The centre provided audits of stored sperm and embryos from November 2007 and July 2007, respectively, as well as appropriate procedures for those audits. The procedures and audit were considered compliant by the inspectorate. When audited, the expected number of embryos was present. The audit recorded 12 minor incidents of computer records not being accurate relatively to laboratory notes and/or patient records. Inaccuracies were all corrected. It also detailed one incorrect labelling of an embryo storage tube which could not be corrected but was logged for future reference. There were no apparent errors in patient records and consents. The sperm audit reviews samples, patient records and the computer database for 10% of samples per month for 10 months (January – October) in every second year. The database detailing their storage has recently been reconfigured. The audit reported that the centre has

sperm samples from 730 patients in cryostorage. It noted 8 recurrent errors, 28 data entry errors in the new database, 7 audit errors, 13 errors related to erroneous assumptions made in data entry in the old database, 2 loose straws, 1 straw and 1 visitube labelling error and 1 error related to samples being in an incorrect location. All errors were corrected except the 8 recurrent errors and the 1 straw labelling error. The audit also investigated patient records and reported 5 cases in which the number of samples remaining was unclear, 2 cases of the consented storage period being unclear, 5 cases of consent discrepancies which would affect use but not storage, and one case of sperm usage without consent being verified even though appropriate consent was stored elsewhere in centre records. All errors in patient records associated with stored sperm were either corrected or have been followed up with the patients concerned. The sperm audit indicated that the new database and storage procedures will further reduce the error rate.

Summary of spot check of stored material

No spot check of stored material was carried out as a compliant laboratory audit was provided which had been performed in the last year

Areas of firm compliance

The centre has an established induction programme in which all new staff and those returning to work after career breaks, undertake a hospital and Trust wide induction course of 3 days duration covering all aspects of mandatory training, including manual handling, health and safety and fire training. Induction training in the centre involves six months of active mentoring and assessment of competencies to complete required procedures. Logs of induction for staff in several different roles training were reviewed in the course of the inspection.

Update training is provided at regular intervals. For all professional groups within the unit there is a documented orientation, training and induction programme to provide training and assess competence in all relevant procedures. For CPD, different professional groups have different requirements, but all are required to undertake CPD as part of their professional development and this is supported by the Trust. All staff interviewed considered that on-going training and continual professional development (CPD) needs were well supported by the centre.

The centre has an established system of competency assessment for staff. Embryology and medical staff competency is monitored by comparison of KPIs between staff. There are defined KPI limits outside of which investigation of competency is undertaken and re-training initiated if needed. Adherence to SOPs is also audited in the laboratory and in clinical practice as part of competency assessment.

A member of medical staff is contactable 24 hours a day, 7 days a week, via the centre number or an emergency number, both provided in patient information. A patient interviewed on the day of inspection described having had no problem with contacting centre staff for advice.

The centre has an oocyte donor programme but uses donor sperm from a third party supplier. All oocyte donors and recipients are referred to the counsellor for counselling. The centre has a procedure in place to ensure that the 10 families limit is not breached, unlikely though this is for oocyte donors. The third party supplier ensures the 10 family limit is not breached by the sperm donors. All donors and recipients are referred to the counsellor for donor counselling.

The centre has not performed a 3 embryo transfer for some years and have already established a protocol for selection of patients for single embryo transfer. To assist with the implementation of single embryo transfer policy, the centre is planning to introduce more blastocyst culture and day 5/6 embryo transfers. The centre considers that this is clinically required however note that patients may well be resistant to the change.

Patients attending the centre for the first time are asked to bring a photograph and a passport or driving licence as proof of identity. These are photocopied and kept in patient records to facilitate later identification of patients.

The centre has exported one sperm sample in the last year. This export was processed appropriately. The centre has a transportation procedure which was reviewed by the scientific inspector and found to be compliant.

The centre only uses CE marked or sperm motility tested consumables and has established traceability procedures. For traceability purposes, batch records are maintained for plasticware and culture media. The incubator used for oocyte/embryo culture for each patient is logged.

The Consultant Embryologist has risk assessed the manual witnessing procedure used within the centre. The centre clinical and embryology staff are all trained in witnessing procedures as part of the initial induction training programme and witnessing has been audited in the last year and competency assessed. The Scientific Inspector considered the witnessing procedures at the centre to be compliant with the requirements of the HFEA Code of Practice, 7th edition.

The centre has a contracted Fertility Counsellor who is a member of the British Association of Counselling and Psychotherapy, who provides approximately 2 days per week. A non-contracted Counsellor provides cover and occasional sessions as demand requires. The Lead Counsellor has the regular supervision required to maintain chartered status. Counselling information is provided to patients from first attendance at the unit and throughout their treatment and patients seldom wait more than 2 weeks for a counselling appointment. A detailed counselling audit was submitted prior to the inspection which showed that a total of 257 sessions were provided in January – June, 2008. Counselling sessions divide approximately 50%: 30%: 20% between supportive, implications and therapeutic sessions, respectively. Most are provided to IVF/ICSI patients however donor counselling is also performed.

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. Separate dewars are used for quarantined and non-quarantined samples.

Areas for improvement

In the pre-inspection questionnaire, it was reported that all oocyte/embryo donors have screening for cystic fibrosis, CMV, Hepatitis B, Hepatitis C, HIV, syphilis serology and Chlamydia screening. Inspection of patient records for 3 oocyte donors indicated that these tests were performed. The inspectorate draw the PR's attention to British Fertility Society

Guidance[3] for screening oocyte donors, which recommend that screening is also carried out for Neisseria Gonorrhoea and karyotype in all donors. Neisseria Gonorrhoea and karyotype screening had not been performed in 3 and 2 of the oocyte donor records inspected, respectively.

The centre informed the inspectorate that all new processes and equipment introduced within the laboratory have been validated. Some long-standing equipment and critical laboratory processes have however not been validated, which is a breach of standard licence condition A.11.11 and Code of Practice, 7th edition, Standards S.7.8.3. The PR is aware of the need for validation but is waiting for the publication of professional body guidelines, which have recently been released.

Areas for consideration
One case of usage of a sperm sample without consent being verified was noted in the sperm audit. Appropriate consent was stored elsewhere in centre records and this was, according to the PR, verified by clinicians at the time of use. This usage was however in contravention of the centre's procedures in that it occurred without the consent being verified by laboratory staff when the sample was taken out of storage for use. The Lead Andrologist recognised this indicated a flaw in procedure which could have led to a contravention of the HFE Act (1990). Consequently, adherence to procedures has been tightened to prevent recurrence. The inspectorate notes that this should have been reported to HFEA as a 'near miss'. The PR should ensure that procedures to prevent a breach of patient consent are rigorously adhered to. The PR should also note this reinforces the importance of reviewing the adverse incident reporting protocol, as required in Section 1. To achieve an increase in blastocyst transfer, the centre plan a refurbishment of the embryology laboratory and an adjacent room, to increase the space for incubators. It is hoped that this refurbishment is implemented to enable the centre to implement the elective single embryo transfer policy it has introduced to comply with professional body guidelines.
Executive recommendations for Licence Committee
The PR should review the protocol for screening of prospective donors after consideration of the BFS guidelines, as recommended by Code of Practice, 7th Edition, G.4.9.1. The rationale for any non-compliance with guidelines should be documented. If screening procedures are changed, patient information should be updated to include all of the screening tests carried out. The PR should also ensure a system is in place which guarantees that all tests required by the screening protocol are performed on every donor. It is recommended that the centre identifies critical procedures and prepares a prioritised plan for the validation of all equipment and procedures which impact on gamete and embryo quality and safety
Areas not covered on this inspection
All areas covered
Evaluation
Some improvements required.

[3] Recommendations for Good Practice on the Screening of Egg and Embryo Donors, (British Fertility Society,) 2000, Human Fertility (2000) 3, 162-165

Report compiled by:

Name Dr Andrew Leonard

Designation Scientific Inspector, HFEA

Date 10th September 2008

Appendix A: Centre staff interviewed

PR, Senior Embryologist, Charge Nurse, Nursing Coordinator for ACU/Quality Manager, Counsellor, Junior Nurse, Junior Embryologist, Quality Manager

Appendix B: Licence history for previous 3 years

Status	Licence	Type	Active From	Expires
Active	L0201/5/a	Treatment with Storage	05/07/2007	28/02/2009
Replaced by New Version	L0201/4/b	Treatment with Storage	01/05/2006	28/02/2009
Replaced by New Version	L0201/4/a	Treatment with Storage	01/03/2006	28/02/2009
Replaced by New Version	L0201/3/a	Treatment with Storage	03/10/2005	28/02/2006
Replaced by New Version	L0201/2/a	Treatment with Storage	01/03/2003	28/02/2006

L0201/5/a
No Conditions or Recommendations on Licence

Centre had an inspection holiday in April 2007 – March 2008

Licence Committee Meeting, 14 February 2007
Edinburgh Assisted Conception Unit (0201)
Interim Inspection

1. The papers for this item were presented by Elliot Lawrence, HFEA Inspector. Mr Lawrence informed the Committee that this centre is organised unusually with a separation of the provision of IVF and of treatment with donor gametes. This unusual division of services has a number of implications for the way in which the centre is run and in particular for the communication of information to centre staff, notwithstanding this point, however, the systems in place do seem able to overcome these potential difficulties.

2. The Committee noted Dr Lawrence's comments and also accepted the centre's reasons for not wanting to reorganise the centre along more conventional lines.

3. The Committee noted that the inspection report records the fact that the centre did not have its complaints procedure clearly displayed in the patient's waiting room, and that this is a breach of the Code of Practice part 13.4.

4. Dr Lawrence informed the Committee that the names of all the Trust's doctors and

gynaecologists are recorded on the centre's licence. The Committee noted that this was highly unusual, and they agreed that it was concerning that this might result in a high volume of information about patient's treatment being passed to individuals who would, in more usual circumstances, require specific consent from the patients concerned in order to access the information. The Committee also expressed its concern that the large list of Doctors and Gynaecologists named on the centre's licence but who are not involved on a daily basis with the treatment of individuals might not be being kept up to date with regulatory requirements in the way that would normally be expected. The Committee asked the Executive to investigate these concerns and to report back to the Committee with their findings.

5. The Committee agreed that the centre's licence should continue with no additional conditions.

Licence Committee Meeting, 26 April 2007
Edinburgh Assisted Conception Unit (0201)
Licence Variation pursuant to the Human Fertilisation and Embryology Act 1990, as amended by the Human Fertilisation and Embryology (Quality and Safety) Regulations 2007

1. The papers for this item were presented by Grace Cunningham, HFEA Inspector. Ms Cunningham drew the Committee's attention to the centre's risk rating with regard to compliance with the EUTCD, which was 6%, in the low range.

2. Ms Cunningham drew the Committee's attention to the particular areas of non-compliance, which were:

- Third party agreements
- Continuous improvement of the Quality Management System (including internal and external audits)
- Air quality
- Records control policy
- Procurement Report.

3. The Committee noted that the centre is working towards full compliance with the requirements of the EUTCD and that progress will be assessed at the next inspection visit to the centre.

4. The Committee agreed to vary the centre's licence pursuant to the Human Fertilisation and Embryology Act 1990, as amended by the Human Fertilisation and Embryology (Quality and Safety) Regulations 2007.

Appendix C:

RESPONSE OF PERSON RESPONSIBLE TO INSPECTION REPORT

Centre Number 0201

Name of PR Mr Joo Thong

Date of Inspection 19th August 2008

Date of Response 26th October 2008

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

PRs response to Draft Renewal Inspection Report

I wish to respond to your Inspection Report.
NOTE INSPECTOR'S RESPONSES ARE IN CAPITALS UNDERNEATH EACH COMMENT

1. Page 2. Our nominal licensee is Ms Sandra Mair.
CHANGED IN TEXT

2. Page 5. Last paragraph. This should read, The Person Responsible, a Consultant Gynaecologist and Sub Specialist in Reproductive Medicine. I no longer practice as an Obstetrician.
CHANGED IN TEXT

3. Page 8. Regarding payment to the HFEA, I shall liaise with our finance department to reduce the number of days to pay the invoices from the HFEA finance department.
THANK YOU FOR ACTIVITIES TO PREVENT BREACHES IN THIS AREA

4. Page 9. I wish to confirm that egg donors will be screened for Neisseria Gonorrhoea and karyotype as from the last inspection. We have virtually no egg donors for the past 12 months and gonococcal infection is rare among women attending our clinic. For example, I have not seen a case of gonococcal infection in our Fertility or IVF clinic for over 17 years! In over 17 years of egg donation treatment, I wish to confirm that none of the donors had gonoccocal pelvic infection after donation.
THANK YOU FOR ACTIVITIES TO PREVENT NON-COMPLIANCES IN THIS AREA

5. Page 12. I shall review our organisational chart so that the line of responsibility is clear. As you are aware, there is only so much information you can put on the flow chart.
IF YOU CAN INVESTIGATE UPDATING THE CHART IT WILL BE APPRECIATED

6. Page 13. Paragraph 3. I wish to confirm that we are not using the supplier which did not return our third party agreement.
NOW STATED IN TEXT THAT SUPPLIER IS NO LONGER USED

7. In the last paragraph on page 13, I wish to confirm that we have reported the flooding incidents retrospectively to the HFEA. I wish to confirm that work is in progress to change all the carpets in the sub waiting area and the carpets for clinic rooms 1, 2, 3 and 4 were deep cleaned following the inspection.
THANK YOU FOR ACTIVITIES TO PREVENT BREACHES IN THIS AREA. I NOTE THAT DEEP CLEANING WAS PERFORMED AND HOPE THAT IF SUCH A LEAK HAPPENS AGAIN THAT THE CLEANING IS VALIDATED THROUGH APPROPRIATE ENGAGEMENT WITH THE INFECTION CONTROL SERVICE

8. Page 15. Last paragraph. I wish to confirm that our annual quality management meeting is held yearly and that this will not be held every 2 – 3 months as stated in the first sentence on page 16.

REPORT HAS BEEN MODIFIED TO STATE: Annual Quality Management Reviews are performed and detailed minutes were provided of the last annual meeting in May 2008. I AM HAPPY WITH THE SITUATION GIVEN THE OBVIOUS DEPTH OF YOUR ANNUAL REVIEW. I REMEMBER HOWEVER THAT MEETINGS WHICH REVIEW QUALITY OBJECTIVES ARE MORE FREQUENT, E.G. TO REVIEW LABORATORY DATA AND OUTCOMES, SO THAT IF A PROBLEM ARISES IN THE SERVICE IT IS RAPIDLY DETECTED FROM ITS EFFECTS ON KEY PERFORMANCE INDICATORS

9. Page 16. Regarding single quality manual, work is in progress to ensure that all documents relating to licensed material will be held in a single quality manual.

THANKS FOR YOUR ASSURANCE OF THIS. CAN YOU PLEASE LET ME KNOW WHEN IT IS COMPLETED

10. Page 20. Under areas for consideration, the Inspector suggested that there were too much details in the counselling summary. In this particular case, the donor's General Practitioner raised concerns regarding whether the egg donor should be donating eggs for treatment because of her psychiatric history. With the patient's permission, we sought the advice of her Consultant Psychiatrist and therefore, under the circumstances, it was appropriate that all members of staff understand concerns raised by her General Practitioner and are aware of the views of her Consultant Psychiatrist who felt that the she can donate.

THANK YOU FOR YOUR CLARIFICATION ON THIS ISSUE. IT WILL BE PROVIDED TO LIICENCE COMMITTEE FOR THEIR CONSIDERATION

11. I wish to confirm that the resuscitation trolley will be checked during working days of the week from Monday to Friday.

THANK YOU FOR ACTIVITIES TO PREVENT BREACHES IN THIS AREA

12. Page 22. Thank you for bringing this to our attention in the areas for consideration.

THANK YOU FOR ACTIVITIES TO PREVENT NON-COMPLIANCES IN THIS AREA

13. Page 24. Last paragraph. Donors and recipients are referred to a counsellor and not a Psychologist

TEXT HAS BEEN AMENDED.

14. Page 25. Paragraph 3. This should read "the Centre has exported one sperm sample" and this should replace the wording in the draft report.

TEXT HAS BEEN AMENDED – sorry for the error

15. Page 26. Under areas for consideration, in line 3, "use of a sample without consent being verified" was inaccurate. We suggest that it should read "the sample was not used without consent being verified. The error was that the consent was verified only once (by clinical staff at the time of treatment) and not twice (by laboratory staff at transfer to treatment storage tanks and by clinical staff at the time of treatment)." I wish to confirm that the current protocol is now revised and that the laboratory staff and the clinical staff would check the consents prior to examination.

THANK YOU FOR MODIFYING THE PROTOCOL TO PREVENT BREACHES/NON-COMPLIANCES IN THIS AREA. I WILL AMEND THE TEXT TO MORE ACCURATELY REFLECT THE NEAR-MISS TO READ

One case of usage of a sperm sample without consent being verified was noted in the sperm audit. Appropriate consent was stored elsewhere in centre records and this was, according to the PR, verified by clinicians at the time of use. This usage was however in contravention of the centre's procedures in that it occurred without the consent being verified by laboratory staff when the sample was taken out of storage for use. The Lead Andrologist recognised this indicated a flaw in procedure which could have led to a contravention of the HFE Act (1990). Consequently, adherence to procedures has been tightened to prevent recurrence. The inspectorate notes that this should have been reported to HFEA as a 'near miss'. The PR should ensure that procedures to prevent a breach of patient consent are rigorously adhered to. The PR should also note this reinforces the importance of reviewing the adverse incident reporting protocol, as required in Section 1.

On behalf of our staff, we found your inspection very helpful. I am pleased to hear that the Inspectorate are recommending renewal of the Centre's Licence without additional conditions for 5 years.

Please do not hesitate to contact me if you require further clarification.

With kind regards.

Yours sincerely

Dr K J THONG
Person Responsible

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).

See above