Licence Renewal Inspection Report for Treatment and Storage Centres

IVF Hammersmith
0078

Date of Inspection: 13th June 2007
Date of Licence Committee: 10 October 2007

CENTRE DETAILS

Centre Address	Hammersmith Hospital, DuCane Rd, London W12 0HS
Telephone Number	0845 811 6644 / 0208 383 2385
Type of Inspection	Renewal
Person Responsible	Mr Stuart Lavery
Nominal Licensee	Mr Geoffrey Trew
Licence Number	L0078-11-b
Inspector(s)	Wil Lenton (Lead)
	Allison Cummings
	Grace Cunningham
Fee Paid - date	
Licence expiry date	31st December 2007

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About the Inspection:
This inspection visit was carried out on 13th June 2007 and lasted for 8 hours. The report covers the pre-inspection analysis, the visit and information received between July 2005 and May 2007.

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, 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

The centre is open 7 days a week, 07-00h to 17-00h weekdays and 08-00h to 10-00h at weekends. It has been licensed since July 1992 for treatment and storage and treats both NHS and private patients together with private patients from overseas. The centre does not presently provide any transport or satellite IVF services, but is looking to develop this service in the near future.

The centre has been ISO-9001 accredited since 19th July 2006 and has a robust quality management system (QMS) in place. Their accreditation is due for renewal in July 2009.
Their licence has been varied recently to include the requirements of the EU Tissues and Cells Directive (EUTD) with a low risk score of 5%.

Mr Lavery, the PR, stated that the last two years had seen a great deal of change, with established, senior personnel moving on and being replaced by new staff. The introduction of the ISO-9001 quality management system, had initially been a challenge, but once fully introduced had helped the unit to progress to a more stable phase and enabling a quality service being provided to patients.

Activities of the Centre (01/06/04 to 31/05/05)

Licensed treatment cycles	IVF 535 ICSI 366 FET 209
Donor Insemination	84
Unlicensed treatments	IUI, GIFT, ZIFT
Research	N/A
Storage	Yes

Summary for Licence Committee

The Hammersmith IVF unit has been licensed since 1992 and presently performs approximately 1200 licensed treatment cycles annually. The unit is very well organised and became ISO 9001 accredited in July 2006. It has recently successfully varied its licence in order to incorporate the requirements of the EUTD, with a low risk score of 5%.

A number of regulatory issues were identified during the course of the inspection and are summarised as follows:

- It is recommended that risk assessments be performed on;

i. the practice of patient notes being left insecurely on a trolley outside scan rooms on the ground-floor whilst scans are being performed.

ii. the new PGD suite when completed.

iii. the lack of distress alarms within the men's production rooms.

iv. the practice of transporting gametes/embryos between different floors within the unit.

- The unit should revise its laboratory witnessing protocol in order to address both, the contemporaneous witnessing when removing cryopreserved semen and all stages within the sperm preparation process in compliance with Chairs letter CH(04)02.

- The unit should ensure that it complies with the CoP when transferring embryo's in women < 40 years. (CoP 8.2) (CoP 7 G.8.5.1)

The inspection team recommend the continuation of the centre's licence

Risk Assessment

The risk assessment score as determined via the risk tool matrix was16%

Overall judgement of the effectiveness of the centre

No Improvements required	Some Improvement required	Significant Improvement required
	x	

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 or Code of Practice

Breach	Action required	Time scale
The transfer of 3 embryos in three women aged <40 years contrary to CoP 6 para 8.2	Adherence to the CoP	Immediately

Non-Compliance

Area for improvement	Action required	Time scale
Two areas of non-compliance were noted within the witnessing procedures; 1. Contemporaneous witnessing of the removal of cryopreserved semen samples was not occurring. 2. Not all stages of the sperm preparation process are directly witnessed.	The laboratory manager to revise the witnessing protocol.	Immediately

Recommendations	Time scale
The dissemination of HFEA Alerts should be monitored in order to ensure that they are reaching all staff groups.	Immediately
The centre may want to review its incident reporting to the HFEA	Immediately
HFEA patient questionnaires are to be made readily available to patients using the centre's services.	Immediately

It is recommended that risk assessments be performed on; i. the practice of patient notes being left insecurely on a trolley outside scan rooms on the ground-floor whilst scans are being performed. ii. the transportation of gametes/embryo's between floors within the unit.	Immediately
It is recommended that risk assessments be performed on ; i. the new PGD suite when completed. ii. the lack of distress alarms within the men's production rooms.	Within 3 months

Changes/ improvements since last inspection

Recommendation	Action taken
Careful consideration to be taken and reasons noted for the transfer of 3 embryos in women aged less than 40 years.	The reasons for the transfer of 3 embryos in women aged less than 40 years would be fully documented in the patient's notes.

Additional licence conditions and actions taken by centre since last inspection

C	**N/A**
A	**Complied Y/N**

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 findings from inspection
Evidence is drawn from:

- Leadership and management
- Organisation of the centre
- Resource management
- Risk management
- Incident management
- Contingency arrangements
- Business planning
- Clinical governance
- Payment of treatment fees

Areas of firm compliance
Organisational charts supplied prior to the inspection adequately define working relationships and management structure. Documented staff induction programmes were seen both via the quality management system (QMS) and within individual staff training logs, which are held by heads of department. Staff interviewed on the day were happy with the structure of the induction process. The centre appears to have sufficient numbers of adequately qualified and trained staff to carry out the services provided. Evidence of continuing professional development (CPD) was seen within individual training logs, together with attendance at mandatory in-house training courses. The centre has been ISO-9001 accredited since July 2006 and has a well established quality management system in place. Most of the centres activities from minuted meetings, administrative, clinical and laboratory protocols, through to patient information are accessed via the system, and is available to centre staff through the internal IT system 'S'-drive, which was evidenced during the inspection. A document control system is in place whereby centre documents are regularly reviewed and updated. (A cd was received prior to the inspection which included all such centre protocols and information.) The centre is planning to develop a paperless system in the very near future. Regular minuted meetings take place within individual disciplines (administration, nursing, scientific and medical) generally on a monthly basis, together with multidisciplinary unit meetings. Heads of department meet for an ISO quality management meeting three times a year. Minutes of various meetings were seen on the day and accessed via the password-protected internal IT system 'S'-drive. Alerts are received by the PR who then passes them on to the quality manager who in turn disseminates to all heads of departments via the QMS. The issues are discussed at departmental level and at unit meetings and practice reviewed accordingly. During the visit it was noted that nursing staff were not aware of the recent alerts sent out by the Authority.

An incident log was reviewed on the day of the inspection. In discussion with the PR it was mentioned that the centre reported very few incidents to the Authority, which was acknowledged. The inspection team discussed incident reporting with the management team who said that they would review their practice, although it was noted that due to some staff being employed by different employers, NHS Trust and University, incidents were reported via different systems.

The centre has a contingency arrangement with 0035.

Areas for improvement

The dissemination of HFEA Alerts should be monitored in order to ensure that they are reaching all staff groups.

The centre may want to review its incident reporting to the HFEA

Executive recommendations for Licence Committee

None

Areas not covered on this inspection

None

Evaluation

Some improvements required.

2. Quality of service

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

Summary of findings from inspection:

- Live birth rates
- 'Welfare of the Child' arrangements
- Confidentiality (including safe storage of patients' records)
- Choice of treatments
- Privacy and dignity of patients
- Complaint handling
- Patient feedback and satisfaction
- Counselling facilities and services
- Donor selection
- Egg sharing and surrogacy
- Protection of children arrangements (for patients under 18yrs)

Live Birth Rates

From HFEA data March 2002 to April 2005.

i. Fresh IVF/ICSI success rates for women <35 and 35-37 are above the national average.
ii. Fresh IVF/ICSI success rates for women 38-42 and just below the national average.
iii. FET success rates for women <35 and 35-39 are above the national average.
iv. FET success rates for women 40-42 are just below the national average.
v. DI success rates for women <35 are just below the national average.
vi. DI success rates for women 35-42 are above the national average.

Areas of firm compliance

The HFEA licence and ISO Accreditation certificate were displayed on a wall within the ground-floor waiting area. There were also details of the complaints procedure and a patient suggestion box.

Patient records were observed to be securely stored on the ground floor of the premises. A tracking system is used to locate any notes which are removed.

Staff interviewed on the day were aware of confidentiality, privacy and dignity issues concerning patient care.

A documented complaints procedure was in place which staff were aware of as evidenced during interviews. The complaints log was observed and found to be in order, with no outstanding issues.

An audit of the counselling service was provided by the senior counsellor, which showed that during the period from 01/01/06 to 31/12/06 there had been a total of 1026 counselling sessions, involving 288 clients. Approximately a quarter were NHS clients and three quarters private, with 56% being self referrals and 44% team referrals.

Patients interviewed on the day of the inspection were generally pleased with their treatment and quoted aspects such as, 'friendly environment', 'reassuring, competent staff' and 'privacy respected' as some of the key positive points.

Prior to the inspection it was noted that the Authority had not received any patient questionnaires from the centre's patients. This was discussed with the PR who stated that the unit had its own questionnaire as part of the QMS and that they had not distributed the HFEA questionnaire as it may have led to confusion. This was to be rectified in the future, with both questionnaires being made available.

Areas for improvement

HFEA patient questionnaires are to be made readily available to patients using the centre's services.

Patient notes are currently being left insecurely on a trolley outside scan rooms on the ground-floor whilst scans are being performed.

Executive recommendations for Licence Committee

Risk assessment be performed on the practice of patient notes being left insecurely on a trolley outside scan rooms on the ground-floor whilst scans are being performed.

Areas not covered on this inspection

None

Evaluation

Some improvements required.

3. Premises and Equipment

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

Summary of findings from inspection:

- Suitable premises
- Storage facilities for embryos and gametes
- Safe equipment, servicing and maintenance
- Prevention of incidents/ accidents

Areas of firm compliance

The centre is situated within the Wolfson family clinic and is split over two floors.

Ground floor: As you enter the clinic there is a reception area, leading into a large waiting room which is broken up into smaller, discrete seating areas. The patient record storage area, dedicated egg-collection theatre with an adjacent laboratory, together with 3 scan rooms, 2 men's production rooms, 2 phlebotomy rooms, main recovery area for 6 patients, plus an overflow recovery area for a further 2 patients are situated on this level. The remainder of the ground floor comprises of a staff common room, a nurses office incorporating an EDI terminal, a counselling office, a clinic preparation room and the senior nurses office.

First floor: There is a smaller waiting area, a changing room for patients awaiting ET, 3 offices and a meeting room. The main embryology laboratory is situated on this floor together with an adjacent embryo transfer room and a post-ET patient recovery area. An ICSI laboratory, newly developed PGD suite and an embryology office complete the floor. An alarm monitoring system for critical laboratory equipment is located on the corridor outside the laboratory.
All laboratory/clinical rooms were secured via either swipe-card or keypad entry.

The cryostorage area is located within a separately licensed area within Hammersmith hospital (centre 0080). Only 0078 centre staff have access to this secure area. All storage vessels were alarmed and secure, with a low O_2 monitor in operation. Liquid nitrogen levels are checked weekly and recorded on a monitoring sheet.

A folder containing details of equipment service/maintenance was observed and seen to be up-to-date.

A risk assessment log was seen during the visit, showing that all areas of the clinic have been risk assessed and found fit for purpose.

Areas for improvement

It is recommended that a risk assessment be performed on both;

1. the new PGD suite when completed.
2. the lack of distress alarms within the men's production rooms.

Executive recommendations for Licence Committee

Risk assessments be performed on;

1. the new PGD suite when completed.
2. the lack of distress alarms within the men's production rooms.

Areas not covered on this inspection

None.

Evaluation

Some improvements required.

4. Information

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

Summary of findings from inspection:

- Information management
- Information to patients and donors
- Information to the HFEA registry and updates
- Consent
- Protocols
- Record keeping

Outcome of audit of records
Ten sets of mixed notes were reviewed on the day of the inspection. It was found that four sets contained only page 1 of the WT and MT forms. The lab' manager explained that this was normal centre policy to avoid patient confusion over embryo freezing/storage. Pages 2 and 3 were only completed on the day of ET after consultation with the patients, if there were suitable embryo's to freeze. One set of DI notes did not contain either the 'Consent to Disclose' or 'Welfare of the Child' forms. Following the inspection the nurse manager informed the Executive that after an investigation these forms were located and replaced in the correct file. The last operational audit had been carried out at the centre between 17th and 21st May 2004. The audit team concluded that the centre was reporting the majority of cycles accurately and on time, but that there was a delay in reporting some DI cycles, due to the high proportion of overseas patients, who become lost to the system. It was noted by the PR that there had been some initial problems with the EDI reporting system, which did lead to a backlog of information being sent to the Authority, but that this had now been resolved satisfactorily.
Areas of firm compliance
HFEA registry and finance departments reported no outstanding problems associated with the centre prior to the inspection. Information regarding patient support groups and ongoing research was on display within the patient waiting areas. All patient information reviewed was clear and accurate. All such information is held within the QMS, together with administrative, clinical and laboratory protocols. This documentation is regularly reviewed and updated to reflect changing professional guidelines, patient feedback and/or HFEA alerts. All centre staff have access to this information via the secure IT network. Only named individuals can authorise the updating of patient information and/or centre protocols in keeping with the QMS document control policy. The integration of the QMS into the daily functioning of the centre's activities has contributed significantly to information being readily available to either staff and/or patients via pc

terminals. It is the intention of the centre to move to a ‘paperless’ system in the future and enquiries into how this can be achieved are already under way.

Patients interviewed on the day stated that information concerning all aspects of the treatment pathway was readily available from the centre and that staff were usually available to answer queries.

Areas for improvement

None.

Executive recommendations for Licence Committee

None.

Areas not covered on this inspection

None

Evaluation

No improvements required.

5. Laboratory and Clinical Practice

Desired outcome: Staff are competent and recruited in sufficient numbers to ensure safe clinical and laboratory practice.

Summary of findings from inspection:

- Assessment of patients and donors
- Safe handling systems
- Procedures in practice
- Laboratory processes and practice
- Clinical practice
- PGD/ PGS
- Recruitment and retention of staff
- Staff competence, qualifications, training and CPD

Full time equivalent staff

GMC registered doctors	8
NMC registered nurses	10
HPC registered scientists	1
Scientists working towards registration	5 (2 have ACE certificates; 2 are within ACE process) 1 part-time (presently on maternity leave)
Support staff (receptionists, record managers, quality and risk managers etc)	12 (3 part-time)

Summary of laboratory audit
The latest frozen samples audit was undertaken in December 2006 with no discrepancies found. It is intended to undertake a rolling audit in the future, whereby two cryostorage tanks are audited per month.
Summary of spot check of stored material
One embryo was tracked from notes to tank and another from tank to notes with no discrepancies found. A similar process was performed for stored sperm samples again with no discrepancies found.
Areas of firm compliance
The laboratory operates 7 days a week, with a full staff team present Monday to Friday and 1-2 staff at the weekend, dependent on workload. At weekends other staff (clinical) assist with witnessing procedures. The training logs for all staff were made available and seen to be up-to-date. The laboratory manager had completed his ACE five year CPD cycle (2000 to 2005) and started a fresh cycle in 2006 which is mainly electronic learning. Laboratory meetings take place monthly and were seen to have been minuted since June 2006. HFEA alerts are discussed at embryology team meetings, with staff signing to indicate their viewing. The laboratory manager will review procedure(s) dependent on alerts received and amend accordingly if required. Departmental heads can review/amend documentation, which is then forwarded to the quality manager for authorisation and inclusion within the

QMS.

Key performance indicators are routinely monitored (daily, weekly, monthly) within the laboratory and if any negative trends are observed an investigation is carried out, the outcome from which is fed back into practice via the QMS. Media batches and equipment used in each cycle are recorded on individual laboratory treatment sheets and kept in the patient notes ensuring traceability. All equipment and most consumables are CE marked.

Incubator parameters (temperature and % CO_2) and cryostorage tank temperatures are monitored electronically.

All gamete/embryo handling takes place within class II laminar airflow workstations, giving grade C air. Additional portable HEPA filters are utilised in the embryology laboratory and a protocol for regular air-quality monitoring is presently being devised.

Areas for improvement

A breach of the Code of Practice was identified during review of the 3-ET log which indicated that 3 women < 40 had been given 3 embryos at ET. This was discussed with the PR who indicated that each case was very carefully considered well in advance of the transfer and all relevant details recorded in the patients' notes.

Two areas of non-compliance were noted within the witnessing procedures;

1. Contemporaneous witnessing of the removal of cryopreserved semen samples was not occurring.
2. Not all stages of the sperm preparation process are directly witnessed.

It was agreed that the laboratory manager would review these procedures to ensure compliance.

With the egg-collection theatre and embryology lab' being on separate floors, it was noted that eggs, sperm and embryos are transported between the floors at different stages within laboratory procedures. Although no incidents have been reported in the past, it may be good practice to risk assess the movement of all such materials between the different floors, in order to minimise the risk of any potential problems occurring.

Executive recommendations for Licence Committee

The centre should be reminded of its requirement to comply with the CoP when replacing embryos in patients < 40 years old.

The witnessing procedures within the laboratory should be revised to take into account the two areas where non-compliance was found.

Areas not covered on this inspection

None

Evaluation

Some improvements required

Report compiled by:

Name…….Wil Lenton…….

Designation…… Inspector……..

Date……12/07/07……

Appendix A: Centre Staff interviewed

Mr Stuart Lavery (PR)

7 other centre staff

3 sets of patients

Appendix B: Licence history for previous 3 years

- **Licence Committee 26th April 2007**
  Variation of licence to include the requirements of the EUTD

- **Licence Committee 30th November 2005**
  Centre reminded of Code of Practice guidance on three embryo transfers in women aged less than 40 years

- **Interim Inspection 26th July 2005**

Appendix C:

RESPONSE OF PERSON RESPONSIBLE TO THE INSPECTION REPORT

Centre Number……

Name of PR……..

Date of Inspection……..

Date of Response……

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

I have read the inspection report and agree to meet the requirements of the report.

Signed……

Name…….

Date……

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).

We also welcome comments about the inspection on the inspection feedback form, a copy of which should have been handed out at the inspection. If you require a copy of the feedback form, please let us know.

Please return Appendix C of the report to:
Regulation Department
Human Fertilisation & Embryology Authority
21 Bloomsbury Street
London
WC1B 3HF

Licence Committee Meeting

10 October 2007
21 Bloomsbury Street London WC1B 3HF

MINUTES Item 1

The Hammersmith Hospital (0078)
Licence Renewal

Members of the Committee:	In Attendance:
Anna Carragher, Lay Member – Chair	Alan Doran, Interim Chief Executive
Richard Harries, Lay Member	Trish Davies, Director of Regulation / Deputy Chief Executive
Maybeth Jamieson, Consultant Embryologist, Glasgow Royal Infirmary	David Gomez, Legal Advisor
	Stephanie Sullivan, Head of Inspection
William Ledger, Professor of Obstetrics and Gynaecology, University of Sheffield	Barbara Lewis, Business Support Team Leader
	Claudia Lally, Committee Secretary
	Providing Legal Advice: Graham Miles, Morgan Cole Solicitors

Conflicts of Interest: members of the Committee declared that they had no conflicts of interest in relation to this item. However, Professor Ledger asked it to be noted that he is acquainted with the Person Responsible and Nominal Licensee for this centre.

The following papers were considered by the Committee:

- papers for Licence Committee (39 pages)
- no papers were tabled.

1. The papers for this item were presented by Wil Lenton, HFEA Inspector. Mr Lenton informed the Committee that the renewal inspection visit took place on 13 June 2007. The centre has been licensed since 1992 and carries out 1,200 cycles per year, for a mixture of NHS and privately funded patients. The centre has a risk score of 16%, which is in the low range.

2. Mr Lenton summarised the findings of the inspection visit. He drew the Committee's attention to the finding that the centre reported very few incidents to the Authority (as reported at page 12 of the inspection report). Mr Lenton informed the Committee that since the inspection the centre is now reporting

incidents in line with HFEA guidelines. This was noted by the Committee who agreed to remind the centre of the importance of adhering to the incident reporting procedure.

3. Mr Lenton's presentation referred to the fact that the centre had developed its own patient questionnaire as part of its Quality Management System and had been asking patients to complete this rather than the HFEA questionnaire. At the time of the inspection the Person Responsible agreed to a request by the inspection team to make both questionnaires available to patients. This was noted by the Committee.

4. Mr Lenton discussed the fact that patient notes were seen on the trolley outside the scan rooms, with the potential risk that these notes could be seen by other patients. The Committee noted that the inspection team had requested that a risk assessment be carried out on this practice and that the Person Responsible considers adopting a different practice such as taking the notes into the scan rooms.

5. The Committee considered the suggestion in the report that the Person Responsible considers installing a distress alarm inside the male production room. The Committee noted that such alarms are mandatory in the NHS for any room where patients spend time on their own. The Committee took into account that oncology patients also used this service and could suffer ill-health while in the room, causing them to require urgent assistance. The Committee therefore endorsed the recommendation by the inspection team that installing an alarm should be considered by the centre.

6. Mr Lenton drew the Committee's attention to the fact that the centre has carried out 3 embryo transfers to women under forty on three occasions over the previous two years. To put his figure in context, the Committee asked Mr Lenton how many cycles the centre carried out in that time, and heard that it was about 1,800 to 2,000 cycles. Mr Lenton informed the Committee that a log was kept at the centre detailing the reasons for the transfers. The inspection team had seen this log and noted that the transfers were carried out to patients who had previously experienced multiple failed embryo transfers. The Committee agreed that it appeared to them that the three embryo transfers had all taken place on the basis of a consideration of the specific clinical situation of each of the patients concerned. The Committee called to mind the guidance given in the 7th edition of the Code of Practice:

> G.8.5.1: Where the woman is aged under 40 at the time of transfer the centre should not transfer more than two eggs or two embryos in any treatment cycle, regardless of the procedure used.

7. The Committee noted that the 3 embryo transfers constituted a breach of the Code of Practice.

8. The Legal Adviser advised the Committee that breach of the Code is not, of itself, a ground for regulatory action. However, a breach of the Code may be relied upon in assessing whether suitable practices are being carried out. Clinical judgment should be taken into account, but, ultimately, it was for a Licence Committee to determine whether a practice is suitable. In order to make such an determination a Licence Committee needed to be able to evaluate the reasons given in each case for transferring more than 3 embryos.

9. The Committee noted that in addition to the transfers to women under 40 the centre had a high rate of three embryo transfers for women over forty. The Committee agreed that the centre should be asked to audit the outcome of all 3 embryo transfers over the past five years and to submit the results to the Executive. Members of the Committee recognised that this breach had been identified in recent inspections of a number of centres and requested that the issue to taken to the Authority's Regulation Committee for general consideration

10. Mr Lenton drew the Committee's attention to the fact that the inspection identified that contemporaneous witnessing of the removal of cryopreserved semen samples was not taking place at the centre. The Committee noted that this was a breach of witnessing Directions D 2004/4. Mr Lenton informed the Committee that it was his understanding that the centre had changed its practice following the inspection visit, and the Committee asked the Executive to ensure that this is the case.

11. The Committee noted that the requirement that all stages of the sperm preparation process are directly witnessed has been changed and the updated version of the Code of Practice will make it clear that under certain circumstances it will not be necessary to witness every step of the process.

12. The Committee discussed the point raised at page 17 of the inspection report, that asking patients to complete consent documents relating to the storage of embryos takes place at the point of embryo transfer. The Committee expressed a number of concerns about this practice, noting that it carries the risk that the patients will be so focused on the transfer itself that they will not be able to give the consent process the careful reflection that is required for informed consent. The most serious risk is that the male patient will not be able to attend the embryo transfer, or that the female patient is hospitalised and the transfer is therefore cancelled. This would result in a situation in which embryos required storage but could not be legally stored due to the absence of the necessary signed consent forms.

13. The Committee considered the statutory conditions for granting a licence and agreed that these were all satisfied. They decided to grant a five year licence to the centre with no additional conditions.

Signed…… … Date……..
Anna Carragher (Chair)