Renewal Inspection Report

Bath Assisted Conception Clinic
0139

Date of Inspection: 16th January 2008
Date of Licence Committee: 24th April 2008

CENTRE DETAILS

Centre Name	Bath Assisted Conception Clinic
Centre Number	0139
Licence Number	LO139-11a
Centre Address	Forbes Fraser Royal United Hospital Combe Park Bath BA1 3NG
Telephone Number	01225 825560
Type of Inspection	Renewal Inspection
Person Responsible	Mr Nicholas Sharp
Nominal Licensee	Mr David Walker
Inspector(s)	Janet Kirkland HFEA (Lead inspector) Mr Tony Knox HFEA (Clinical inspector) Dr Vicki Lamb HFEA (Scientific inspector) Ellie Suthers HFEA (Observing)
Fee Paid – up-to-date	Paid
Licence expiry date	31st August 2008
NHS/Private/Both	NHS & Private

Index

About the Inspection:
This inspection visit was carried out on 16th January 2008 and lasted for 7 hours. The report covers the pre-inspection analysis, the visit and information received between October 2005 and December 2008.

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.

NB: Where there are very minor issues to be addressed these are noted in the "minor issues to be addressed" section for each topic, and this will facilitate the evaluation of 'no improvements required'. 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 Bath Assisted Conception Clinic is a well established centre first licensed by the HFEA in 1994.

There have been no additional conditions on the centre's licence since 2000 and the previous Licence Committee 5th October 2005 made no recommendations. The centre was granted an "inspection holiday" in 2006.

The centre is based in detached premises in the grounds of the Royal United Hospital (RUH) which is managed by the Bath NHS Trust. The clinic itself operates as part of the BMI Health Care Group.

Treatments are provided to patients who are both private and funded by the National Health Service (NHS). The Person Responsible informed the inspection team that NHS patient activity has increased since the last inspection in November 2005 and now represents 25% of the activity.

The Person Responsible informed the inspection team that the centre provide approximately 390 treatment cycles per year and are experiencing an increase in these numbers of approximately 9% per annum.

The team hope to relocate to new premises and will keep the authority informed regarding progress in this area.

The Person Responsible, Mr Nicholas Sharp has been in post since the clinics inception. He has completed the Person Responsible entry programme and this has been assessed as satisfactory.

The inspection team recommend the renewal of the centre's licence for a period of five years.

Activities of the Centre

Licensed treatment cycles	390	
Donor Insemination	18	
Unlicensed treatments	58 cycles of IUI	
Research	N/A	
Storage	N/A	

Summary for Licence Committee

The Bath Assisted Conception Clinic is a well established centre, first licensed by the HFEA in 1994.

There have been no additional conditions on the centre's licence since 2000 and the previous Licence Committee 19 December 2005 approved the continuation of the licence with no additional conditions. The centre was granted an "inspection holiday" in 2006.

The Person Responsible informed the inspection team that the centre are experiencing a increase in treatment numbers of approximately 9% per annum. Whilst they report that they have adequate resources they are hoping to recruit a further clinician and a trainee. They hope to relocate to new premises some time in the near future.

Patient feedback regarding the centre, team and treatments offered was in general complimentary. Patient information seen on inspection was considered by the inspection team to be clear and informative.

The inspection team considered that the centre was well organized and consideration had been taken for patient's privacy and dignity.

A well organised Quality System is in place and documents were seen to be dated and version controlled. All team members interviewed were aware of the system and how to access protocols, policies and procedures in addition to meetings from minutes.

Staff interviewed expressed a high level of job satisfaction and access to Continuing Professional Development. Training records seen on inspection were up to date and comprehensive.

The inspection team recommend the renewal of the centre's licence for a period of five years.

Risk Assessment

The risk assessment performed after the inspection was 0%

Evaluations from the inspection

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

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
None identified		

Non-Compliance

Area for improvement	Action required	Time scale
None identified		

Recommendations	Time scale
Competencies to be documented for all team members (ref Code of Practice (S.6.2.2)	Within twelve months
Staff to ensure that security and confidentiality is maintained in all areas. For example ensure that doors are closed appropriately and patient identifying information is not left on view. (ref Code of Practice S.7.2.1)	Since the inspection the PR has advised that the reception desk has been re-positioned and folders removed from outside laboratory.
Oncology samples are stored with donor sperm samples. The centre have agreed to risk assess this practice taking into consideration that these samples have different levels of screening. (ref. Code of Practice S.6.3.8 (b))	Since the inspection the PR has undertaken a risk assessment.

The risk assessments seen on inspection required signatures	Since the inspection signed copies have been provided
Contingency arrangements with Bristol to be formalised and documented.	Ongoing
If laboratory equipment is found to be out of normal parameter range it is adjusted by the laboratory manager. This was discussed at inspection and the laboratory manager informed the scientific inspector that they will add to the protocol that equipment which is very out normal range must be removed from service. (ref. Code of Practice S.6.4.3)	Since inspection the PR has provided an updated protocol
The protocol for transportation of samples requires review and revision taking into account alert 21: Transport hazards of gametes/embryos nationally and internationally.	Since inspection the PR has provided the HFEA with an updated protocol.

Proposed licence variations by last L.C.

None

Changes/ improvements since last inspection

Recommendations	**Action Taken**
Not applicable	

Additional licence conditions and actions taken by centre since last inspection

Date	**Action taken**
	Not applicable

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:

1. Leadership and management
2. Organisation of the centre
3. Resource management
4. Risk management
5. Incident management
6. Contingency arrangements
7. Business planning
8. Clinical governance
9. Payment of treatment fees

Areas of firm compliance
The Person Responsible and Nominal Licensee are both clinicians at the centre. The inspection team were informed that the Person Responsible is present every morning and both he and the Nominal licensee can be contacted at any time. The Nurse Manager is a member of the Royal College of Nursing Fertility Nurse Group and is an external inspector with the Human Fertilisation and Embryology Authority (HFEA). She plays an active role in nurse training in the field of reproductive technology and recently led a workshop for nurse training in embryo transfers. The centre team has, on two occasions and with patient's consent offered to allow members of the HFEA to observe the activities of the centre. This opportunity was accepted and proved to be of particular value to the inspectors. The Lead Scientist is also the Quality Manager. All staff interviewed were aware of the reporting systems within the team and expressed a high level of job satisfaction. Each discipline meets regularly in addition to meetings for the entire staff. The counsellor attends clinic meetings when possible and reports that she feels that she is a valued member of the team. Meetings are minuted and staff unable to attend were able to describe and demonstrate to the inspection team how to access minutes. The centre team report that they have adequate staffing resources for the number of treatment cycles performed. It is however their intention to recruit an additional clinician and trainee to the team.

Risk assessments have been performed and examples were evidenced on inspection. These included assessments for clinical, nursing and laboratory practices:

Nursing:

- Oocyte collection
- Embryo transfer
- Blood taking
- Ovarian Hyperstimulation Syndrome

Clinical

- Consent forms

Laboratory

- All IVF procedures
- Labelling
- Loss of oocytes or embryos
- Using alcohol spray
- Dispensing liquid nitrogen

Risks are discussed at Senior Management Team Meetings.

Third party agreements were seen to be in place.

The team has reported incidents to the HFEA and these have been followed up and preventative/corrective action taken when required. Systems put in place have been described on incident reports and logged within the database system. This was seen by the Scientific inspector.

The inspection team was informed that in the unforeseen event of the centre team being unable to complete treatment cycles for patients a formal contingency arrangement is in place with a centre in Southampton and an informal arrangement with a centre in Bristol. The team will seek to define and document the arrangement with Bristol.

The Person Responsible informed the inspection team that the centre provides approximately 390 treatment cycles per year and is experiencing an increase in these numbers of approximately 9% per annum.

The team hopes to relocate to new premises and will keep the Authority informed regarding progress in this area.

The centre complies with the Royal United NHS Trust policy in relation to Clinical Governance.

The Nominal Licensee Mr David Walker is on the board of the hospitals governance group and notifies the centre of any relevant issues.

The clinical governance group conducts an audit of all departments in the hospital and each

department is given a score and recommendations if necessary. There are no issues with payment of treatment fees.
Areas for improvement
The risk assessments seen on inspection required signatures.
Areas for consideration
Contingency arrangements with Bristol will be defined and documented.
Executive recommendations for Licence Committee
None
Areas not covered on this inspection
None

Evaluation
No improvement 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:

1. Quality Management System
2. Quality Policy
3. Quality Manual
4. Quality objectives and plans
5. Quality Management review/evaluation
6. Monitoring and resolution of complaints
7. Staff suggestions
8. Document control
9. Live Birth Rates

Live Birth Rates
Pre-validation and pre-quality assured analysis of HFEA held register data for the time period from 31 March 2003 -1st April 2006 show that the centres outcomes for all treatments provided were in line with national average success rates.

Areas of firm compliance
The Lead Scientist is the Quality Manager and the inspection team considered that a good Quality Management System was in place: • The Quality Manual was reported as being near completion. • Protocols and procedure folders were seen to be available in clinical areas. • Staff interviewed were able to describe the systems in place for reviewing and updating documents. • Procedures and protocols submitted for the inspection were seen to be version controlled with author and date of issue. The Person Responsible and the Nurse Manager are the complaints officers, their names and details of how to make a complaint were clearly on view in the waiting area. The complaints folder was seen on inspection. Seven complaints have been received at the centre since 2006. All have been resolved. The document management system is Q Pulse Data base system. This was demonstrated for the inspection team.
Areas for improvement
None
Areas for consideration
None
Executive recommendations for Licence Committee
None
Areas not covered on this inspection
None

Evaluation
No improvement required

3. Premises and Equipment

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

Summary of findings from inspection:

1. General Suitable premises
2. Clinical facilities

3. Counselling facilities
4. Laboratory facilities
5. Air quality
6. Storage facilities for gametes and embryos
7. Staff facilities
8. Management of equipment and materials
9. Control of records
10. Risk assessments

Areas of firm compliance
The centre is situated within the grounds of the Royal United Hospital in Bath. The premises have not changed since the last inspection and consist of two consulting rooms, counselling room, one scanning room, laboratory, cryostore, theatre, recovery area, men's room and patient's waiting room in addition to several store rooms, offices and toilets. The clinical areas were considered to take into account patients privacy and dignity. A emergency trolley was seen to be in place and the inspection team were informed that this was checked daily. In the event of a patient emergency the hospital resuscitation team would be called and it is estimated that they could be at the centre within three minutes. This had been tried and tested and proved to be effective. The counselling room was seen on inspection. The counsellor will visit patients in their own home if required. The scientific inspector considered that the laboratory whilst small, was well lit and appeared to be well organised. Equipment seen on inspection were: • Three incubators - one for equilibration of dishes and two for culture. • Two rigs for Intracytoplasmic sperm injection (ICSI). • One flow hood • Temperature monitor on fridge • Air purifier • Security grills on outside windows A weekly temperature log was seen to be in place for critical equipment. Settle plates are placed weekly and particle counts are performed six monthly. Evidence was seen of: • Servicing of air handling and incubators performed within the previous twelve months. • Satisfactory air quality results (particle and colony growth). • Risk assessments • Weekly checking of the cryostore low level oxygen monitor • Weekly checking and topping up of levels within the dewars.

A low level oxygen monitor was seen to be in place in the cryostore.

In the event of the alarm system in the cryostore being activated an alarm triggers in the main office during working hours. Out of hours a dial out system rings a specific mobile phone, carried by a member of the centre team.

A kitchen and locker facilities were seen for the staff.

In the event of a power failure the pre- inspection questionnaire states that the centre are part of a hospital wide back up system. Monthly generator checks are undertaken by the Trusts Estates department.

With regards to patient safety the pre-inspection questionnaire states that :

All staff are trained to a level appropriate to their position to deal with medical and security risks.

- There is a standard clinical emergency cover for cardiac arrest.
- Fire alarms are tested routinely by the Royal United Hospital (RUH) Estates department.
- All electrical equipment is tested regularly by the RUH Estates department.
- All equipment is serviced regularly.
- RUH security staff are on site to deal with violent or aggressive patients.

Patient's records were seen to be stored in locked filing cabinets in a separate storage room which is locked when not in use. The centre answer phone is also in this area to ensure that patients who choose to leave messages are not overheard. The messages are checked at regular intervals.

The Nurse Manager informed the inspection team that records were also held in a secure facility off site and was able to describe the system for retrieving files whilst maintaining patient confidentiality.

Areas for improvement

It was considered by the inspection team that as sign posting to the centre was unclear it could be difficult to locate.

The clinical areas seen by the inspection team were considered to be fit for purpose, however, the team are hoping to relocate in the near future. All centre team members interviewed commented that improvements could be made to the premises.

The centre has a dedicated dewar storage room. This room contains a low level oxygen alarm. It was however considered by the scientific inspector that the storage room was lacking in space and had not been fully adapted from its previous function. This will be addressed with the relocation to new premises.

If laboratory equipment is found to be out of normal parameter range it is adjusted by the laboratory manager. This was discussed at inspection and the laboratory manager informed

the scientific inspector that they will add to the protocol that equipment which is considered to be seriously out of normal range must be removed from service. (ref. Code of Practice S.6.4.3)

It was noted during the inspection that the door to the andrology laboratory was not closed properly. The Nurse Manager indicated that this was only the case during the working day and when staff were located within the room. As this entry point is just outside the male producing room staff should ensure that they have closed the door properly.

It was noted that a filing tray outside of the laboratory contained a form with identifying patient information. The Nurse Manager agreed that an alternative location for the tray would be sought to avoid a potential Breach of Confidentiality.

Areas for consideration

The cryostore was considered by the scientific inspector to be lacking in space and had not been fully adapted from its previous function.

Oncology samples are stored with donor sperm samples. The centre have agreed to risk assess this practice taking into consideration that these samples have different levels of screening. (ref. Code of Practice S.6.3.8 (b))

Executive recommendations for Licence Committee

None

Areas not covered on this inspection

None

Evaluation

Some improvement needed

4. Information

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

Summary of findings from inspection:

1. General Information
2. Meetings and communication
3. HFEA Alerts
4. Welfare of child
5. Confidentiality and access to health records
6. Traceability and coding
7. Coding/ identification of samples
8. Information for service users/consents
9. Donor information
10. Donor registration
11. Surrogacy
12. Procurement and distribution of receipt of gametes and embryos
13. Home procurement report documentation
14. Packaging &distribution
15. Labelling of packages containing procured gametes
16. Transportation, labelling of shipping container and recall
17. Receipt of gametes

Areas of firm compliance
Patient information submitted for the inspection was seen to be of a high quality, clear and concise. Fifteen patient questionnaires were returned to the HFEA. All of the questionnaires reflected a high level of satisfaction. Comments include: "The staff are second to none" "We always felt cared for and treated as individuals" The following were seen within the centre's waiting area: • A suggestion box • An information board containing posters for many support groups • A complaints notice • HFEA licence • Quality policy Regular team meetings are held within the centre. An example of the minutes was seen on inspection. They include who was present at the meetings, apologies and actions. HFEA alerts are received by the Person Responsible and disseminated appropriately. Every member of the team is required to sign the alert to state that they have read it. Staff interviewed reported that the Welfare of the Child was considered when offering treatment. Patients are required to complete a Welfare of the Child questionnaire and any

issues highlighted are discussed at team meetings. The counsellor also informed the inspection team that she may be involved in assessments, and, with the patients consent present a report to team meetings. The team also have access to an ethics committee. They reported that they have not presented any cases to the committee in the previous twelve months.

The pre-inspection questionnaire states that all Bath Assisted Conception centre staff are aware of the requirements of the HFE Act regarding patient confidentiality. Confidentiality is also covered on the Standard Operating Procedures (SOP) manuals for each discipline. In addition it is specified in job descriptions.

Any data collected to which third parties have access is anonymous. Identification details of donors and patients are not disclosed to each other.

Requests for access to health records are dealt with by the senior administrator.

Royal United Hospital (RUH) policies are followed on data protection and freedom of information

Patient's records were seen to be stored in locked filing cabinets in a separate storage room which is locked when not in use. The centre answer phone is also in this area to ensure that patients who choose to leave messages are not overheard. The messages are checked at regular intervals.

Counselling records were seen to be stored in a locked cabinet within the counselling room. The inspection team were informed that the counsellors are the only members of the centre team with access to these notes.

All computers are password protected for each individual staff member to be able to access patient records.

The batch record keeping and traceability systems were discussed, and evidence seen by the Scientific inspector of the system was considered to be acceptable. The IDEAS data base has batch records of all medium and consumables.

The procedure for witnessing and identification of gametes and embryos was provided for the inspection.

The inspection team was informed that the nursing staff discuss consents with patients and that the laboratory assistant records whether they have been completed.

Egg donation is performed at the centre.

The team does not recruit sperm donors.

Treatments involving surrogacy arrangements are performed at the centre.

In exceptional circumstances patients may produce a sample at home to bring to the centre. They complete a sample form and sign to confirm their identity.

Areas for improvement
Patient feedback to the HFEA was generally complimentary. It was noted however that one comment from a patient was that they had not received adequate information. The protocol for transportation of samples requires review and revision taking into account alert 21: Transport hazards of gametes/embryos nationally and internationally. It was noted that a filing tray outside of the laboratory contained a form with identifying patient information. The Nurse Manager agreed that an alternative location for the tray would be sought to avoid a potential Breach of Confidentiality. (ref Code on Practice S.7.2.1)
Areas for consideration
None
Executive recommendations for Licence Committee
None
Areas not covered on this inspection
None

Evaluation
Some improvement 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:

1. Laboratory processes
2. Selection and Validation of laboratory procedures
3. Laboratory's documented procedures
4. Storage of gametes and embryos
5. Counselling
6. Witnessing

Full time equivalent staff

GMC registered doctors	2
NMC registered nurses	5
HPC registered scientists	1
Scientists working towards registration	1 applied for certificate of competence and awaiting interview 1 working towards registration
Support staff (receptionists, record managers, quality and risk managers etc)	4
Counsellors	2

Summary of laboratory audit / Audit of records
The results of an audit of stored material performed in September 2007 was provided for the inspection team. No discrepancies were noted. Nine patient files were reviewed by the inspection team. These were found to be in good order. In one file the Welfare of the Child questionnaire could not be located
Summary of spot check of stored material
A spot check of two samples performed on inspection indicated a discrepancy. Computer records required updating for one of the samples.
Areas of firm compliance
Critical equipment has been validated. The pre-inspection questionnaire states that staff registrations are checked in January each year. Records are maintained by the Clinical Nurse Manager. All staff interviewed expressed satisfaction with opportunities for Continuing Professional Development. This included representatives from the nursing, clinical, scientific and administrative teams.

General induction was reported by a member of the team as being good. The Nurse Manager described the process which included:

A three to four day Trust induction.

A personalised induction including :

- Protocols and procedures
- Introduction to the HFE Act & Code of Practice
- Confidentiality

All staff undertake mandatory training following the RUH Trust requirements. There is a budget for training and education. Individual staff training needs are identified and personal development plans are implemented. All staff are encouraged to attend relevant meetings and conferences.

The centres training matrix folder was reviewed by the clinical inspector. It contained the names of each member of staff and the training that they had attended. The training included the following:

- Health and Safety Risk
- Manual Handling
- Fire
- General Health and Safety
- COSHH
- Risk Assessment
- Incident Reporting
- Patient Handling
- Infection Control
- Waste Management
- Diversity and Equality
- Key Skills Framework (KSF)
- Basic Life Support
- Intermediate Life Support
- Information Management

In addition staff have attended training events/conferences relevant to their discipline.

Evidence was seen that all staff had attended the mandatory training courses. Training records for each member of staff were also included in the folder and had been updated by the staff appropriately for each course they had attended.

A nurse's portfolio seen on inspection was considered to be of an especially high standard.

There are two counsellors associated with the clinic. Both are fully qualified and registered with The British Association of Counselling and Psychology (BACP), one is also registered with The British Infertility Counselling Association (BICA). They receive regular supervision and some funding towards their Continuing Professional Development (CPD).

Counselling is offered free to all patients and they can be seen at the centre or, in exceptional circumstances in their home. The counsellor interviewed attends the Wednesday meetings whenever possible at which "special cases" are discussed.

The counsellors work appears to comprise of two aspects:

Report provision:
The counsellor is requested to see some patients to provide a report. This she states is factual and unbiased. These reports may be presented to the Wednesday meetings for discussion. It was noted that patients are always made aware of the fact that the sessions conducted are for the purpose of creating a report, and the patients are always provided with a copy of the completed report for their comment prior to presenting this information to the rest of the team.

Independent Counselling:
Counselling is provided to those patients who seek it which is separate from the report producing sessions. Notes made from these sessions are private and are not shared with the rest of the team.

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The counsellor attends the three monthly clinic meeting whenever possible. She stated that in the event that she is not able to attend, she is aware of where the minutes are located and would be able to catch up on what was discussed if required.

Areas for improvement

In addition to other nursing duties some nurses within the team perform :

- Intrauterine inseminations
- Embryo transfers
- Ultrasound scans.

Whilst they could describe their training and mentorship in detail there was no recorded documentation of competencies or sign off. (ref Code of Practice (S.6.2.2)

Evidence of competencies to be documented for all team members.(ref Code of Practice (S.6.2.2)

The protocol for witnessing was provided for the inspection team:

It was noted by the scientific inspector that in some witness sheets the space for entering the time was missing. The team will ensure that this is added and completed.

Areas for consideration

It was noted that operative procedures are carried out under heavy sedation. The initial dose is administered by the clinician after which the nursing staff administer the top up as required and as directed by procedures. The Nurse Manager stated that they conform to the local Trust policy on sedation and that in the case of an emergency an anaesthetist would be called and could be on the unit within three minutes. The Nurse Manager was able to

describe an incident, which was not considered to be serious, when this procedure had been activated.

It was discussed that a sign off system be devised for each nurse administering sedation to attest to their competence in this area. (ref. Code of Practice G.1.3.1.(b).

It was discussed that the team had previously on occasions pre-witnessed dishes if there was only one embryologist on duty – for example at a weekend. It was reported that this was rarely done and had not been practised within the previous twelve months. The inspection team stated that this practise was no longer acceptable. (ref. Code of Practice G.13.2.1.)

The validation of processes is in progress.

Executive recommendations for Licence Committee
None

Areas not covered on this inspection
None

Evaluation
Some improvement required

Report compiled by:

Name……Janet Kirkland…….

Designation……HFEA inspector……..

Date……February 15th 2008……

Appendix A: Centre Staff interviewed

Mr Nicholas Sharpe

Five centre staff

Appendix B: Licence history for previous 3 years

2008

Renewal Inspection 16th January

2006

Centre was granted an inspection holiday

2005

Licence Committee 19th December

Interim inspection. The Licence Committee agreed to the continuation of the licence with no conditions or recommendations.

2005

Interim inspection 5th October

2005

Licence Committee 12th January

Interim inspection report: The Licence Committee agreed to the continuation of the licence with no conditions or recommendations.

Appendix C:

RESPONSE OF PERSON RESPONSIBLE TO THE INSPECTION REPORT

Centre Number……

Name of PR…….

Date of Inspection……..

Date of Response……

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

Signed……

Name…….

Date……

1. 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).

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

Since the inspection the PR has advised the Executive of the following: • Hospital signage is under review. • The door to the andrology department has been adjusted to close properly. • The filing tray outside the laboratory containing patient identifying information was removed immediately. • A risk assessment has been performed regarding the storage of donor and oncology samples in the same dewar. • Documentation of witness sheet altered to include space for recording time. • Lab manual updated to state witness must always be present for handling/preparation/mixing of gametes/embryos.

The PR has requested that the following statement be added to Appendix C:

"We acknowledge that the statistics used to compile our recent report show a reduced pregnancy rate in the age band 38-39. However more recent data (see HFEA Website) now indicates that our pregnancy rates in this age group are comparable to the national average".

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

24 April 2008
21 Bloomsbury Street London WC1B 3HF

MINUTES Item 3

Bath Assisted Conception Unit (0139)
Licence Renewal

Members of the Committee:
Clare Brown, Lay Member – Chair
Ruth Fasht, Lay Member
Sue Price, Consultant in Clinical Genetics, Oxford Regional Genetics Service
Roger Neuberg, Consultant Obstetrician and Gynaecologist, Leicester Royal Infirmary
Chris Barratt, Head of the Reproductive and Developmental Biology research group, University of Dundee

In Attendance:
Debra Bloor, Head of Inspection
Claudia Lally, Committee Secretary

Providing Legal Advice:
Graham Miles, Morgan Cole Solicitors

Observing
Lisa Jardine, HFEA Chair

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

The following papers were considered by the Committee:

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

1. The papers for this item were presented by Debra Bloor, HFEA Inspector. Dr Bloor informed the Committee that about 400 treatment cycles took place at the centre last year, which is a 9% increase on the previous year's figures. The centre has been licensed since 1994 and is part of the BMI Health Care group, providing both NHS funded and self funded treatments. Dr Bloor reported that the centre management hope that the centre will be relocating to new premises in the near future.

2, Dr Bloor reported that a number recommendations were made at the renewal inspection, for example that competencies are documented for all team members and that security and confidentially is maintained in all areas. Dr Bloor summarised the recommendations listed at pages 7 and 8 of the report and drew the Committee's attention to the requirement that the protocols for transportation of samples be reviewed in light of HFEA alert 21, which describes potential hazards when transporting gametes and embryos.

3. Dr Bloor described the response to the inspection report by the Person Responsible (included at page 24 of the report). She recommended that the centre's licence be renewed for a period of five years.

The Committee's Decision

4. The Committee noted that the Person Responsible had requested that a statement be included in the report which states that recent data shows that the pregnancy rate for the age band 38-39 are comparable to the national average. The Committee asked that this claim be checked by the Executive and be allowed to remain in the report if it is correct.

5. The Committee noted that the Person Responsible's response does not contain mention of the requirement to review transportation of samples in the light of the recent HFEA alert.

6. The Committee agreed that they were satisfied as to the suitability of the Person Responsible, the centre premises and the use of suitable practices at the centre. The Committee noted that a signed application had been received from the centre and the renewal fee had been paid.

7. The Committee agreed to renew the centre's licence for a period of five years with no additional conditions.

Signed…… … Date……..
Clare Brown (Chair)