# Renewal Inspection Report

# Epsom and St Helier University Hospital Assisted Conception Unit
# 0259

## Date of Inspection: 15 January 2009
## Date of Licence Committee: 26 March 2009

## Centre Details

| | |
|---|---|
| Person Responsible | Dr Elizabeth Sherriff |
| Nominal Licensee | Currently no NL |
| Centre name | Epsom and St Helier Assisted Conception Unit |
| Centre number | 0259 |
| Centre address | Wrythe Lane<br>Carshalton<br>Surrey<br>SM5 1AA |
| Type of inspection | Renewal |
| Inspector(s) | Miss Angela Sutherland<br>Miss Allison Cummings<br>Dr Lynne Nice (External Inspector) |
| Fee paid | Yes |
| Licence expiry date | 30 June 2009 |
| NHS/ Private/ Both | NHS and self funded |

## Index

**About the Inspection:**

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

The report summarises the findings of the 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 Assisted Conception Unit (ACU) at Epsom and St Helier University Hospital provides IUI treatment only and has been licensed since 05 July 2007.

Dr Elizabeth Sherriff has been Person Responsible (PR) since then and has completed her HFEA Person Responsible Entry Programme (PREP). She has been registered with the General Medical Council since1989 and has been a member of the Royal College of

Obstetricians and Gynaecologists since 1997. There is currently no Nominal Licensee (NL) at this centre however at inspection it was discussed that an application for the NHS Trust Chief Executive to take on this role will be submitted to the HFEA imminently.
The centre provides transport services for The Bridge (0070) and ACU Kings College (0109) centres, performing approximately 130 cycles of transport IVF per year.

**Activities of the Centre for the time period from 7 July 2007 – 31 December 2007**

| | |
|---|---|
| Intra uterine insemination (IUI) | 11 |

**Summary for Licence Committee**

Epsom and St Helier ACU is a small IUI centre that appeared to be generally well run at the time of inspection. It comprises a small cohesive team and patient feedback is consistently positive.

A number of areas for improvement were identified in the course of the inspection relating to the following:

- Third party agreements
- Patient feedback
- Training for Quality Manager
- Laboratory facilities
- Air quality
- Management of equipment and materials
- Staff training and competencies
- Laboratory practice
- Traceability
- Validation

Subject to a commitment to address the recommendations of the current report the inspection team would recommend that continuation of the centre's licence for a period of one year.

**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 |
|---|---|---|
| The centre do not have a documented third party agreement with Hunter Scientific, suppliers of their centrifuge. | The PR should obtain and maintain third party agreements with suppliers of all external products that have the potential to influence the quality and safety of gametes processed and/or procured at the centre in compliance with standard licence condition A.5.1. | To be monitored in the course of the next inspection |
| Sperm processing currently takes place in a flow hood cabinet in the same room that inseminations are performed. There has been no previous testing of air quality, within the hood or in the surrounding room. The room opens directly onto a corridor that is at times busy with pedestrian traffic. Temperature is controlled with an air conditioning unit vented to the exterior of the building. | The failure to monitor air quality is a breach of standard licence condition A.10.19. The PR should arrange for the testing of air quality in the area where sperm is being processed, document a plan for the ongoing maintenance and monitoring of air quality and act upon the results of testing in order to ensure that sperm is being processed in an environment compliant with the requirement of standard licence condition A.10.19. | Immediate |
| At inspection several items were observed to have passed the manufacturers recommended expiry date and other items were stored in such a way that their expiry date and batch number could not be identified. For example sperm tubes from different batches are stored loose in a drawer out of their original boxes. | This is a breach of CoP S.6.4.1.The PR should ensure that all equipment and materials (including disposables, reagents, calibration and control materials) shall meet the requirements of the relevant EU Directives, 93/42/EC Medical Devices and 98/79/EC In vitro Diagnostic Medical Devices guidelines. This should include storing materials in such a way that staff can be assured of compliance with CoP S.6.4.1 before use.<br><br>The Centre should establish documented procedures for the management of equipment and | Immediate |

| | | |
|---|---|---|
| | materials that include traceability of any materials that come in contact with gametes or embryos in compliance with CoP S.6.4.3 (d) | |
| At inspection a service/repair log was provided by the Quality Manager (QM) that documented items of equipment that had not been serviced within the timeframes specified by the manufacturer or supplier. | This is a breach of CoP S.6.4.2(c). The PR should assess which items of equipment have not been serviced as recommended by the manufacturer and take steps to ensure that servicing takes place and results are acted upon. | To be monitored in the course of the next inspection |
| The inspectorate noted that there was no documented procedure for the management of equipment and materials. | This is a breach of CoP S.6.4.3/4. The PR should arrange for the development of a documented procedure for the management of equipment and materials. | To be monitored in the course of the next inspection |
| While it is reported by the QM that all staff are subject to regular assessment of their competence and take part in continuous education and professional development but in most cases, this is not documented. This includes nurse IUI, scanning and sperm preparation training. | This is a breach of CoP A.10.11. It is recommended that the PR take steps to ensure that the competence of each person to perform designated activities is evaluated at intervals specified in the Quality Management System. Re-training should be undertaken when required and competence reviews and assessments documented and regularly updated<br><br>The PR should ensure that any training programme ensures and documents that each individual: has demonstrated confidence in the performance of their designed tasks in compliance with the requirements of A.10.11. | To begin immediately and be monitored in the course of the next inspection |
| The centre has not participated in inter-centre or inter-laboratory comparisons. | The centre should participate in inter-centre comparisons such as those organised by professional bodies and inter-laboratory comparisons (e.g. external Quality assessment schemes) and by other external bodies. The results of | To be monitored in the course of the next inspection |

| | | |
|---|---|---|
| | these comparisons should be evaluated and documented and relevant findings be used to improve the service in compliance with the requirements of CoP S.9.2.6 and S.4.2.9 (e). | |
| The centre was found to have no traceability procedures. Materials and consumables are not traced and in some instances were stored in such a way that they could not be matched with their batch numbers and/or expiry dates. For example sperm tubes from different batches are stored loose in a drawer out of their original boxes. | The Centre should establish documented procedures for the management of equipment and materials that include traceability of any materials that come in contact with gametes or embryos in compliance with CoP S.6.4.3 (d) | To begin immediately and be monitored in the course of the next inspection |
| The centre was found to have no documented procedures for validation of key equipment and processes and no validation has taken place to date. | This is a breach of CoP S.7.8.3. The PR should ensure that procedures are validated in accordance with professional guidelines, based on previously published studies or retrospective evaluation of the centre's own data. | To be monitored in the course of the next inspection |

**Non-Compliance**

| Area for improvement | Action required | Time scale |
|---|---|---|
| While verbal accounts of witnessing by staff during inspection suggest that procedures are compliant with CoP S.7.8.15 this is not reflected in the documentation which is designed in such a way that there is no obvious space for staff to record the date and time of each witnessing step. | This is a breach of CoP G.13.1.1(c) The PR should arrange for the review of the witnessing documentation in consideration of the HFEA guidance.. | Immediate |

**Recommendations**

| Area for improvement | Action required | Time scale |
|---|---|---|
| No recommendations | | |

**Additional licence conditions and actions taken by centre since last inspection**

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|---|
| This centre has not been previously inspected. |

**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

**Leadership and Management**

The PR has completed the HFEA PR Entry programme (PREP) and is considered appropriately qualified and experienced for the role (CoP S.4.1.5; S.4.1.4). The PR, nursing staff, quality manager and counsellor were present for the inspection and provided all written and verbal information that was requested (CoP S.4.1.3). An organisational chart was supplied at inspection that indicates the lines of responsibility.

**Organisation of the centre**

The PR confirmed that all members of staff are appropriately qualified and experienced for their roles. This was supported by an onsite review of staff curriculum vitae and training logs supplied at inspection. (CoP S.4.1.7)

**Incident/complaints management**

The Quality Manager supplied a log of incidents to the inspectorate (related to both IUI and IVF services). These appeared to have been appropriately managed and all had been reported to the HFEA within Code of Practice specified timeframes. (CoP A.4 and S.9.4.2).

Similarly a log of past (nil current) complaints was supplied that appeared to reflect appropriate complaints management compliant with CoP S.9.2.2. There have been no patient complaints reported directly to the HFEA to date.

**Meetings/dissemination of information**

A comprehensive record of weekly meetings was provided to the inspectorate. This suggested discussion of a wide range of topics. Weekly meetings appeared to be well

attended by all staff members.

**Payment of licence/treatment fees**

The centre is reported by the HFEA finance department to be taking on average 27 days to pay fees. This demonstrates compliance with standard licence condition A.16.3.

Areas for improvement

**Third party agreements**

The centre do not have a documented third party agreement with the supplier of their centrifuge.

The PR should obtain and maintain third party agreements with suppliers of all external products that have the potential to influence the quality and safety of gametes processed and/or procured at the centre incompliance with CoP A.5.1.

Areas for consideration

Nil

Executive recommendations for Licence Committee

The Licence Committee is asked to endorse the executive recommendations with regard to;

- Third party agreements

Evaluation

Some improvement required.

Areas not covered on this inspection

Risk management

**2. Quality of service**

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

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

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

| Live birth rates[1] |
| --- |
| In the time period between on 05 July 2007 and 31 December 2007 the centre report carrying out 11 licensed treatments resulting in one clinical pregnancy. |
| Areas of firm compliance |
| **Quality management system**<br><br>The Quality Manager (QM) has been in post since July 2008 and has no previous quality management experience. It was noted at inspection that a comprehensive quality management system is being developed that includes;<br><br>• A quality manual that appeared to comply with the requirements of CoP S.5.2.3/4.<br><br>• Quality objectives and plans including the intention to review and evaluate it's effectiveness at the end of 2009. (CoP S.4.2.4)<br><br>• Standard operating procedures relevant to key activities and processes (CoP S.5.2.2 (a))<br><br>**Document control**<br><br>The QM demonstrated an effective document control system and all documents examined at inspection were found to have been controlled in compliance with CoP S.5.2.5. |
| Areas for improvement |
| Nil |
| Areas for consideration |
| **Feedback**<br><br>It was found at inspection that a patient questionnaire is in use at the centre. However the QM discussed that it was not in constant circulation and response rates had been too low to provide useful analysis. It is noted that analysis is further hindered by low numbers of IUI patients.<br><br>The PR should consider why response rates are low for the patient feedback questionnaire and make changes where possible to ensure compliance with CoP S.4.2.9 (a) and S.9.1.2.<br><br>**Training for quality manager**<br><br>The PR may wish to consider providing quality management training for the QM to ensure she is able to maintain the development of the quality management system beyond it's early development and fulfil the requirements of CoP S.4.2.7 |
| Executive recommendations for Licence Committee |
| The Licence Committee is requested to consider the executive recommendations made with regard to; |

- Feedback
- Training of the Quality Manager

| Evaluation |
| --- |
| No improvement required. |

| Areas not covered on this inspection |
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| Nil |

### 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 |
| --- |
| **Premises**<br><br>The centre is small in size and is situated within the Trusts gynaecology outpatient department. Clinical facilities appear to be suitable for the activities for which the centre is licensed (CoP S.6.3.2), and the centre appeared clean and well organised with a cleaning rota that was seen on inspection.<br><br>Scanning currently takes place in two gynaecology consultation rooms that appeared fit for the intended purpose. While an over-flow waiting area is shared with the wider department a small waiting area exclusive to the Assisted Conception Unit is used predominantly and was found to be private and comfortable, in compliance with CoP S.6.3.4.<br><br>At inspection the PR reported that working within the gynaecology department has not caused any difficulty to date and the area as a whole is to be redecorated in the near future.<br><br>**Staff facilities**<br><br>The centre provides a lockable cupboard for staff property, a shared kitchen/tea room and shared office space all of which appeared adequate for the intended purpose (CoP S.6.3.9). |

**Storage of records**

Clinical records are stored in locked cabinets within the main nursing office, which is further protected by a keypad lock. At times they are held in another administrative office where they are locked if unattended.

Areas for improvement

**Laboratory facilities/Air Quality**

Sperm processing currently takes place in a treatment room in a flow hood. There has been no previous testing of air quality, within the hood or in the surrounding room. The room is also used for IUI and opens directly onto a corridor that is at times busy with pedestrian traffic.

The failure to monitor air quality is a breach of standard licence condition A.10.19. The processing of gametes while exposed to the environment should take place in an environment of at least Grade C air quality with a background environment of at least Grade D air quality. It must be demonstrated and documented that the chosen environment achieves the quality

**Management of equipment and materials**

At inspection several items were found that had passed the manufacturers recommended expiry date and other items were stored out of their packaging in such a way that their expiry date and batch number could not be traced.

This is a breach of CoP S.6.4.1 and S.6.4.3 (d). The PR should ensure that all equipment and materials (including disposables, reagents, calibration and control materials) meet the requirements of the relevant EU Directives, and 93/42/EC Medical Devices and 98/79/EC In vitro Diagnostic Medical Devices guidelines. This should include storing them in such a way that staff can be assured of compliance with CoP S.6.4.1 and S.6.4.3 (d) before use.

The Centre should establish documented procedures for the management of equipment and materials that include traceability of any materials that come in contact with gametes or embryos in compliance with CoP S.6.4.3 (d)

At inspection a service/repair log was provided by the QM that contained several items of equipment that had not been serviced within the timeframes specified by the manufacturer or supplier.

This is a breach of CoP S.6.4.2 (a) and (c). The PR should assess which materials and items of equipment have not been serviced or maintained as recommended by the manufacturer and make steps to ensure that servicing takes place and results are acted upon.

The inspectorate found that there is no documented procedure for the management of equipment and materials.

This is a breach of CoP S.6.4.3/4. The PR should arrange for the development of a documented procedure for the management of equipment and materials.

Areas for consideration

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|---|
| Nil |
| Executive recommendations for Licence Committee |
| The Licence Committee is requested to consider the executive recommendations made with regard to;<br><br>• Laboratory facilities/air quality<br>• Management of equipment and materials |
| Evaluation |
| Significant improvement required. |
| Areas not covered on this inspection |
| Nil |

**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

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| Areas of firm compliance |
| **Information for service users**<br><br>Two patients were interviewed on the day of inspection. Both reported that they felt well informed and were happy with the level of written and verbal information provided to them. One noted that the centre were particularly efficient with responding to telephone queries.<br><br>Patient information sheets were provided to the inspectorate all of which appeared compliant with S.7.4.1 of the HFEA Code of Practice.<br><br>**Consent/Welfare of the child**<br><br>Two sets of patient records were audited at inspection and appropriate consent to treatment forms found in both (CoP D2006/05). It is notable that the centre has chosen to consent patients for disclosure of information and carry out Welfare of the Child assessments although they are not mandatory requirements for patients undergoing basic partner treatment services (IUI). |
| Areas for improvement |
| Nil |
| Areas for consideration |

| |
|---|
| Nil |
| Executive recommendations for Licence Committee |
| No recommendations |
| Evaluation |
| No improvement required |
| Areas not covered on this inspection |
| Access to health records |

**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**

| | |
|---|---|
| GMC registered doctors | 1.3 |
| NMC registered nurses | 2.6 |
| Non NMC registered clinical staff | |
| HPC registered scientists | |
| Scientists working towards registration | |
| Support staff (receptionists, record managers, quality and risk managers etc) | 1.9 |
| Counsellors | Ad hoc |

| |
|---|
| Summary of laboratory audit |
| N/A |
| Summary of spot check of stored material |
| N/A |

Areas of firm compliance

**Screening of donors/Counselling**

It is notable that the centre is routinely screening patients for HIV, Hep B and Hep C and offering independent counselling although they are not mandatory requirements for patients undergoing basic partner treatment services (IUI).

The counsellor was interviewed on the day of inspection and reported that she practices from home when her services are required. She reported that she is a current member of British Association for Counselling and Psychotherapy (BACP) and the British Infertility Counselling Association (BICA). The counsellor also reported attendance at patient information sessions approximately every four-six months.

Areas for improvement

**Staff training and competence**

While it is reported by the Quality Manger that all staff have their competence to perform designated tasks assessed and take part in continuous education and professional development, in most cases, this was not documented. This includes nurse IUI, scanning and sperm preparation. It was also noted at inspection that some staff had not attended mandatory training within timeframes specified by the Trust.

Failure to provide required training and to document training is a breach of standard licence condition A.10.11.IThe PR should ensure that personnel are provided with initial/basic training, updated training as required and that any training programme ensures and documents that each individual has demonstrated confidence in the performance of their designed tasks in compliance with the requirements of A.10.11.

**Laboratory practice**

All sperm preparation at the centre is performed by nursing staff who have received training from an andrologist at another centre.

The centre has not participated in inter-centre or inter-laboratory comparisons. When interviewed staff performing sperm preparation did not appear to be aware of NEQAS or the requirement for comparisons.

This is a breach of CoP S.9.2.6. The PR and QM should review the current quality management system and consider adding inter-laboratory comparisons as part of a programme of ongoing improvement and evaluation.

**Traceability**

The centre was found to have no documented traceability or coding procedures. Materials and consumables are not traced and in some instances were stored in such a way that they could not be matched with their batch numbers and/or expiry dates. For example sperm tubes from different batches are stored lose in a drawer out of their original boxes.

The Centre should establish documented procedures for the management of equipment and materials that include traceability of any materials that come in contact with gametes or embryos in compliance with CoP S.6.4.3 (d)

**Validation**

The centre was found to have no documented procedures for validation of key equipment and processes and no validation has taken place to date.

This is a breach of CoP S.7.8.3. The PR should ensure that procedures are validated in accordance with professional guidelines, based on previously published studies or retrospective evaluation of the centre's own data. A plan for validation should be drawn up which takes into account professional body guidelines on validation and the particular needs of the unit. Validation of those processes considered to be most likely to impact on the quality of the service should be prioritised.

Areas for consideration

**Witnessing**

While verbal accounts of witnessing given by staff during inspection suggest that procedures are compliant with CoP S.7.8.15 this is not reflected in the centre's documentation. Witnessing forms are designed in such a way that there is no obvious space for staff to document the date and time each step is carried out. An audit of two sets of patient's records found in both cases that witnessing had not been documented in accordance with guidance.

This is a breach of CoP G.13.1.1(c) The PR should arrange for the review of the witnessing documentation in consideration of the HFEA guidance.

Executive recommendations for Licence Committee

The Licence Committee is requested to consider the executive recommendations made with regard to;

- Staff training and documentation of the assessment of confidence to perform designated tasks
- Laboratory practice
- Traceability
- Validation
- Witnessing

Evaluation

Significant improvement required

Areas not covered on this inspection

Nil

**Report compiled by:**

Name: Angela Sutherland…….

Designation: Inspector…….

Date: 22 January 2009……

**Appendix A: Centre staff interviewed**

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| Person Responsible<br>Quality Manager<br>Counsellor<br>Nursing staff |

**Appendix B: Licence history for previous 3 years**

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| **Licence committee meeting 17 April 2007**<br><br>The Committee decided to issue a 2 year licence, based on the strength of the application. |

**Appendix C: Response of Person Responsible to the inspection report**

Centre
Number…0259……

Name of PR…Dr Elizabeth Sherriff ……

Date of Inspection…15th January, 2009……

Date of Response…6th March, 2009……

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

Signed……

Name…Dr Elizabeth Sherriff……

Date…6th March, 2009……

1. Correction of factual inaccuracies

Please let us know of any factual corrections that you believe need to be made. We will make alterations to the report where there are factual inaccuracies.

| |
|---|
| 1.Brief description of Centre and P.R.<br>Approximately 130 transport IVF cycles are carried out per year within the unit, not 30.<br>I have been a member of the RCOG since 1989.<br>GMC Reg Drs. – The department has a full time research fellow. Therefore this should read 1:3 not 0:3 |

**The above factual inaccuracies have been amended within the body of the report.**

2. Please use the space below to document any comments or additional information that you would like to be considered by a Licence Committee.

2. Laboratory facilities/air quality.
Regarding air quality the centre accepts that the air quality has not been formally measured and this will be addressed. However, significant changes to previous practice, prior to requirement for a licence, have been made. This includes refurbishment of the IUI/Scan room, purchase of a biosafety cabinet and servicing of the air conditioning unit. We appreciate that air quality recommendations are a standard. In the interim, whilst we address this standard I would ask that the committee consider that the facilities are used only for fresh sperm preparation and not for handling oocytyes or embryos.

Management of Equipment and Material
The items found, which had passed their manufacturers recommended expiry dates, were sachets of water which in fact are not used either for IUI preparation or patient care. I accept however that nonetheless they should not have been present, and they have been removed.

Traceability
The centre does have documented traceability and coding procedures (protocol PR33 and PR29 form C). I acknowledge this does not however include batch numbers of the sperm preparation tubes.

The Service/Repair Log submitted to the inspection panel included items no longer used by the unit. It was for this reason that these items were not serviced.

Regarding documented procedures for the management of equipment and materials.
I would refer you to our protocol PR05 which is called Servicing/Maintaining Equipment which I feel covers COP S.6.4.3/4.

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

Section 3.

1. Organistion. Third Party Agreements.
The Third part agreement for the centrifuge with Hunter Scientific was in place but the unit was missing the copy at the time of the HFEA inspection. The centre now holds a copy. Action – completed.

2. Quality of Service. Feedback
In order to improve response rates of the patient feedback questionnaires, we have decided to include them in the IUI Patient Information packs. Action – immediate.

Training for Quality Manager
The PR is supportive of formal QM training and will seek trust support for this. Action – six

months.

3. Premises and Equipment
Air Quality.
Trust Infection Control Team to maintain and document air quality.
Plan - monitor monthly for three months. If air quality satisfactory as per standard licence condition A.10.19 then annually. If air quality not satisfactory then action to be taken. Action – immediate.

Management of Equipment and Materials
All materials not required for IUI have been removed from the IUI/scan room. A system has been introduced in order that those materials (essentially sperm preparation tubes) not included in the centres documented traceability and coding procedures (protocol PR33 and PR29 form C) are now included in compliance with COP S.6.4.3 (d). Action – completed.

Equipment no longer used by the unit has been removed from the service/repair log, all items on the log now only contain equipment in current use – all of which have up to date service records as per COP S.6.4.2 (a) and (c). Action – completed.

Clinical laboratory and counselling practise.
Staff training and competence. Competency manuals are being introduced since the inspection in order to formalise the previous informal practise, as per A.10.11. A protocol for training will be introduced. Action – 3 months.

Laboratory Practise
Ref Breach COP S9.2.6.
The centre is committed to addressing this breach. We hope to be able to utilise our close relationships with both Kings College Hospital Assisted Conception Unit, and The Bridge Fertility Centre in order to do this. Action – 4 months.

Traceability. Please see earlier comment.

Validation.
A validation protocol for key equipment is being written. Action – immediate.

Check list forms are already in circulation and being completed (ref FS 14 and FS 16 )
Action – completed.

Witnessing
Comments regarding the layout of the IUI witnessing forms made by the inspection team have been noted and the layout of the forms is to be altered in order to make clear space for staff to document the date and time each step is carried out in order to comply with COP G 13.1.1.(c). Action – immediate.

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

Please return Appendix C of the report electronically to your inspector or in hard copy to:
Regulation Department
Human Fertilisation & Embryology Authority
21 Bloomsbury Street
London
WC1B 3HF

# HFEA Licence Committee Meeting

## 26 March 2009

21 Bloomsbury Street London WC1B 3HF

### Minutes – item 3

**Epsom and St Helier University Hospital (0259), Licence Renewal**

| Members of the Committee: | |
|---|---|
| Clare Lewis-Jones, Lay Member – Chair<br>Ruth Fasht, Lay Member<br>Sue Price, Consultant in Clinical Genetics, Oxford Regional Genetics Service<br>Roger Neuberg, Consultant Obstetrician and Gynaecologist, Leicester Royal Infirmary | Committee Secretary:<br>Claudia Lally<br><br>Legal Adviser:<br>Graham Miles, Morgan Cole<br><br>HFEA Members Observing:<br>Jane Dibblin<br>Lillian Neville<br>Debbie Barber |

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

The following papers were considered by the Committee:

- papers for Licence Committee (34 pages)
- one tabled paper: fax addressed to Angela Sutherland, dated 17 March 2009 (2 pages).

The Committee also had before it:

- HFEA Protocol for the Conduct of Licence Committee Meetings and Hearings
- 7th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- HFEA (Licence Committees and Appeals) Regulations 1991 (SI 1991/1889)
- Decision Trees for Granting and Renewing Licences and Considering Requests to Vary a Licence; and
- Guidance for members of Authority and Committees on the handling of conflicts of interest approved by the Authority on 21st January 2009.

1. The Committee noted that this centre is part of the Epsom and St Helier University Hospital and was first licensed on 5 July 2007. The centre provided 11 IUI treatments from July 2007 to January 2008.

2. The Committee noted that the first licence renewal inspection of the centre took place on 16 December 2008 and found that some improvements were required in the following areas:

- the establishment of third party agreements
- increasing the use of patient feedback questionnaires
- training for Quality Manager
- laboratory facilities
- monitoring air quality
- the management of equipment and materials
- staff training and competencies
- inter-laboratory comparisons
- traceability of consumables; and
- the validation of key equipment and processes.

3. The Committee noted the findings of the report and the statement by the Person Responsible setting out all the work being done in addressing the identified areas for improvement. In addition, the Committee noted the tabled fax to Angela Sutherland which included a letter certifying that the air quality in the processing area and in the flow cabinet had been monitored and found to be Grade D and Grade B respectively. The Committee noted that these measurements met the requirements of the Code of Practice.

4. In relation to the requirement that consumables at use in the laboratory should be traceable, the Committee made it clear that this includes the requirement to document batch numbers on sperm preparation tubes.

5. On the basis of the response by the Person Responsible the Committee agreed that they were satisfied as to the suitability of the centre premises and as to the use of suitable practices at the centre. The Committee also noted that there were no issues regarding the character, qualifications or experience of the Person Responsible or her ability to perform her duties under Section 17 of the 1990 Act and agreed that it was satisfied that the Person Responsible is suitable.

6. The Committee further agreed that it was satisfied that it had sufficient and satisfactory information on which to make a determination and that the relevant fee had been paid. On the basis of the number of areas for

improvement identified in the report, the Committee decided to grant a licence for a period of 1 year, in accordance with the recommendations of the Executive.

7. The Committee noted that counselling of patients takes place at the Counsellor's own home and agreed to remind the Person Responsible that she should satisfy herself that this arrangement is consistent with the provisions in the Code of Practice at: G.1.4.2 and S.6.3.5.

8. The Committee agreed that they expected the areas for improvement identified at the inspection to be addressed in the timescales stated in the report.

Signed…… … Date……..
Clare Lewis-Jones (Chair)