# Interim Inspection Report

**Date of Inspection:** 10 February 2010
**Length of inspection:** 5 hours
**Inspectors:** Gill Walsh & Ellie Suthers

**Inspection details:**
The report covers the pre-inspection analysis, the visit and information received between January 2008 and January 2010.

**Date of Executive Licensing Panel:** 21 April 2010

**Purpose of the Inspection report**
The purpose of the inspection is to assess whether centres are complying with the HF&E Act 1990 (as amended), the HF&E Act 2008 and the Code of Practice to ensure that centres are providing a quality service for patients. The report summarises the findings of the licence interim inspection highlighting areas of good practice, as well as areas where further improvement is required to improve patient services and meet regulatory requirements. It is primarily written for the Authority's Licence Committee/ Executive Licensing Panel which make the decision about the continuation of the centre's licence.

## Centre details

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| **Centre Name** | Reproductive Medicine Clinic, Bristol |
| **Centre Number** | 0276 |
| **Licence Number** | E0276/2/d |
| **Centre Address** | Reproductive Medicine Clinic<br>Level 6, St Michael's Hospital<br>Southwell Street, Bristol BS2 8EG |
| **Telephone Number** | 0117 928 5805 |
| **Person Responsible** | Dr David Cahill |
| **Licence Holder** | Dr Jacqueline Cornish |
| **Licence expiry date** | 30/06/2011 |
| **Additional conditions applied to this licence** | None |

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# Report to Licence Committee / Executive Licensing Panel

## Recommendation to the Executive Licensing Panel:

In considering overall compliance, the Inspectors considers that they have sufficient information drawn from documentation submitted by the centre prior to inspection and from observations and interviews conducted during the inspection visit to conclude that::

- the Person Responsible (PR) has discharged his duties effectively under Section 17 of the HF&E Act 1990 (as amended)
- centre staff acting under the supervision of the PR are suitably qualified for their designated roles and are currently of sufficient number for safe clinical and laboratory practice
- the premises and equipment inspected are suitable for the treatment procedures for which the centre is licensed
- the centre largely demonstrates appropriate practices in respect to laboratory, clinical and administrative procedures to minimise risk and optimise outcomes for patients and offspring
- prospective and current patients appear to be treated fairly and all licensed activities are conducted in a non-discriminatory way
- the centre respects the privacy, confidentiality, dignity and well being of prospective patients and their partners.
- proper account is taken of the welfare of any child born as a result of licensed treatment or of any child who may be affected by that birth

The inspectorate considers that, overall there is sufficient information available to recommend the continuation of the centre's licence without additional conditions.

The inspectorate also recommends that the Executive Licensing Panel requires that the Person Responsible complies with following recommendations within the prescribed timeframes set out in the inspection report:

- the welfare of the child standard operating procedure (SOP) should be audited against current regulation
- staff competence in their assigned tasks should be documented
- quality objectives and indicators for all key procedures and processes should be formulated and agreed
- key procedures and processes should be audited.

# Details of Inspection findings

## Brief description of the centre and its licensing history:

The centre is a small unit located within St. Michael's Hospital which is part of University Hospitals Bristol, NHS Foundation Trust. The centre provides outpatient investigation and diagnosis of sub-fertility and intrauterine insemination (IUI) treatment to NHS funded couples from the South Bristol and Weston Super Mare area. The centre shares facilities with general and oncology gynaecology services.

The centre does not have facilities for the analysis or preparation of semen for use in treatment on site. This service is provided by nearby licensed centre 0295 Bristol Centre for Reproductive Medicine, where the male partner will attend for sample production. Following preparation for insemination, the sample is transported by the male partner to St. Michael's. Any documentation and consumable equipment required for the procedure accompanies the sample.

The PR is Dr David Cahill who is Reader in Reproductive Medicine at Bristol University and is an honorary Consultant in Obstetrics and Gynaecology at St. Michael's Hospital.

The centre was last inspected in January 2008 following which a Licence Committee granted the renewal of the centre's licence for a period of three years without additional conditions.

## Activities of the Centre:

| Type of treatment | Number of treatment cycles for the period Jan – Dec 2008 |
|---|---|
| Partner Insemination | 75 |

| Other licensable activities | ✓ or Not applicable (N/A) |
|---|---|
| Storage of eggs | N/A |
| Storage of sperm | N/A |
| Storage of embryos | N/A |
| Research | N/A |

*These data were extracted from the HFEA register for the period January – December 2008. The data in the Register may be subject to change as errors are notified to us by clinics, or picked up through our quality management systems.

## 1. Focus of inspections for 2010-12

| Witnessing |
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| Evidence of how the centre demonstrates compliance with the requirement to double check the identification of samples and the patients or donors to whom they relate at all critical points of the clinical and laboratory process. GN 18.<br><br>Staff asked were able to describe a comprehensive and thorough process for the receipt of prepared semen samples for use in treatment, demonstrating positive confirmation of sample and partner identity by two staff members in the presence of the partner. Staff were also able to describe comprehensive double witnessing of each stage of the transfer of the sample to insemination catheter to insemination, again in the presence of the patient and partner.<br><br>The centre has appropriate witnessing steps required embedded into their SOPs for the relevant processes. (T33(b))<br><br>Witnessing documentation retained with the health care records indicates that when conducted, witnessing is contemporaneous and denotes the name, status and signature of the persons performing and witnessing the activity. (T71) |
| What the centre does well.<br><br>The centre demonstrates good communication with the Bristol Centre for Reproductive Medicinecentre 0295 in all related matters and demonstrated thorough witnessing processes from the receipt of the prepared sample to insemination. |
| What they could do better.<br><br>The documentation retained in the health care records does not record the signature of the second person witnessing the process on all occasions. It is suggested that the centre should consider that an additional section be added to the witnessing form in ensure the second signature is captured.<br><br>Staff were able to describe appropriate witnessing training and competency assessment with 'refresher' assessments being conducted by the PR at regular intervals in accordance with licence condition T12 and guidance 2:1. The centre should ensure that these assessments are appropriately documented. (Guidance 2:11(b)). Competency assessments were however seen for a comprehensive number of other clinical procedures. |

| Legal Parenthood |
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| Evidence of how the centre demonstrates compliance with the requirements in relation to legal parenthood GN 5<br><br>N/A This centre does not provide treatment with donor gametes. |
| What the centre does well. |
| What they could do better. |

| Information about the cost of treatment |
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| Evidence of how the centre demonstrates that it has introduced personalised costed treatment plans for all patients<br><br>N/A This centre does not provide self funded treatment. |
| What the centre does well. |
| What they could do better. |

| Patient consent to the disclosure of information, held on the HFEA Register, for use in Research |
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| Evidence of how the centre demonstrates that it provides information to patients about the use of information, held on the HFEA Register, for use in research. GN 5<br><br>N/A This centre provides partner IUI treatment only. |
| What the centre does well. |
| What they could do better. |

| Consent issues in relation to the storage of embryos (including cooling off period) |
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| Evidence of how the centre demonstrates compliance with the requirements relating to the withdrawal of consent to storage of embryos intended for use in treatment. Guidance Note 5 (H)<br><br>N/A This centre does not store embryos. |
| What the centre does well. |
| What they could do better. |

## 2. Changes / improvements since the last inspection 16 January 2008

| Area for improvement | Action required | Action taken as evidenced during this inspection |
|---|---|---|
| It was recommended that the centre risk assess its key procedures and processes. | The centre should evaluate its risk assessment process to ensure all key processes have been assessed. | Evidence of risk assessments in key areas were seen on inspection. |
| Development and maintenance of the quality management system. | The centre should ensure there are sufficient resources available to ensure the required development and maintenance of the quality management system. | .<br>The Quality Manager was able to demonstrate significant development of the quality management system.<br><br>The quality management 'group' meet bi – monthly during which the quality management system is reviewed. Any non-conformities identified are reviewed along with any changes required to SOPs, risk assessments or other quality issues to ensure continuous improvement and systematic improvement in accordance with Schedule 3A 10) 2006/86/EC, appendix 2 F |

## 3. Areas of concern

The analysis of the centre's self assessment questionnaire and the information the centre has submitted to the HFEA e.g. staff changes and the treatment cycles carried out at the centre, have identified that the following areas needed to be looked at during the inspection visit to this centre.

| Area of concern | Inspection findings | Assessment of whether the action taken meets requirement or whether any further action is required |
|---|---|---|
| Welfare of the child SOP (T33(b)) | The SOP requires updating to reflect the HFEA 8th Code of Practice. | Further action required:<br><br>The centre's SOP requires audit against compliance with regulatory requirement. |
| Welfare of the child assessment process – demonstration of staff competence (T15 (a/d). | Staff asked were aware of the requirement for a welfare of the child assessment in all licensed treatment cases but described that the PR routinely conducts this and so were unfamiliar with the actual process. | Further action required:<br><br>The PR should ensure that staff are familiar with the welfare of the child assessment process and ensure they are adequately informed of the broader ethical, legal and regulatory context of their work. Staff should be able to provide documented evidence of their competence to carry out a welfare of the child assessment if required. |
| Availability of a documented induction training procedure and participation in clinical profession development (CPD). (T15) | A comprehensive induction programme and induction pack was seen on inspection for clinical staff. The pack also contained a programme of competence assessment for medical devices in addition to clinical procedures.<br><br>Evidence of recent, relevant clinical professional development was described by clinical staff asked and was seen documented in personal development files. | No further action required. |

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| Assessment and documentation of competence. | Overall staff were able to describe a comprehensive assessment of clinical competence at regular intervals by the PR. The majority of these assessments were comprehensively documented and were considered to be of a very good standard. | Further action required:<br><br>The centre should ensure all key elements of their practice are assessed and documented. |
| Development of quality objectives and indicators for all key process and procedures. (T35) | The centre has not formulated and agreed quality objectives or indicators for all key activities of the centre. | Further action required.<br><br>The centre should establish key quality objectives /indicators for all licensed and unlicensed activities carried out in the course of providing treatment. |
| Audit of key procedures and processes (T36 & Schedule 3A (10) 2006/86/EC, appendix 1 F). | The centre currently has recently audited patient satisfaction and clinical outcomes in terms of pregnancy rates. The majority of key processes have not been audited nor is there a schedule for audit in place. | Further action required:<br><br>The centre should ensure that an audit of the activities authorised by this licence and other activities carried out in the course of providing treatment services that do not require a licence against compliance with the approved protocols, the regulatory requirements and quality indicators is undertaken. These audits must be performed in an independent way, at least every two years. Findings and corrective actions must be documented. |
| Section 2. Staff<br><br>SAQ – staffing. The centre indicated that they were not fully staffed. This had been an area of concern at the last inspection also. | Following a management review staffing levels have been increased within certain areas of the centre, notably in the laboratory and reception areas. The appointment of a Health Care Assistant was imminent at the time of inspection. The Trust has agreed in principle to an additional nurse being seconded from the gynaecology | Pending appointments discussed – no further action required at this time.<br><br>The PR should monitor the decision 'in principle' to train a additional nurse on secondment to ensure that appropriate |

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| | department, a date for this appointment is to be determined.<br><br>Centre managers and staff asked stated they feel there is currently sufficient staff to manage day to day operations.<br><br>On inspection it would appear that any historical issues regarding the staffing of the laboratory have now been resolved. Staff in the laboratory state that they have no problems booking or taking leave with notice and are able to attend planned training when scheduled. All CPD and scheduled training was seen to be up to date for laboratory staff.<br><br>The current nursing staffing position is that day to day operations are accommodated but as the team is very small, changes to this should there be unexpected sick leave or other absences (including CPD) means that cover for the two part time nurses can be very difficult to arrange.<br><br>It also came to light on inspection that the fertility centre traditionally fell outside of the normal gynaecology and women's health directorate. As a result, the specialist fertility nurses have not had consistent professional line management for some years, the result being that their current job descriptions do not fully reflect their roles and they have not had any formal clinical professional development (CPD) planning or appraisal of their performance for several years. Staff stated that it is hoped that this has now been resolved as a new senior nurse has been appointed to whom the fertility nurses will report professionally and will be responsible to their appraisal | staff are in place to accommodate the current and anticipated workload, especially during training for the scope of practice of the nurses to extend to ultrasonography commences.<br><br>.<br>T12 T13 15 |

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| | and job review.<br><br>As part of the management review it was proposed by the centre that the nurses role should be expanded following training, to include ultrasonography. This would provide greater flexibility in availability of the service to patients. | |

# Areas of practice that require the attention of the Person Responsible

The section sets out matters which the Inspection Team considers may constitute areas of non compliance. These have been classified into critical, major and others. Each area of non-compliance is referenced to the relevant sections of the Acts, Regulations, Standard Licence Conditions, Directions or the Code of Practice, and the recommended improvement actions require are given as well as the timescales in which these improvements should be carried out.

### Critical area of non compliance

A critical are of non compliance is an area of practice which poses a significant direct risk of causing harm to a patient, donor or to an embryo. A critical area of non compliance requires immediate action to be taken by the Person Responsible

| Area of practice | Reference | Action required | Timescale for action | PR Response | Executive Review |
|---|---|---|---|---|---|
| None identified at the time of inspection. | | | | | |

## Major area of non compliance

A major are of non compliance is a non critical are of non compliance:

- which poses an indirect risk to the safety of a patient, donor or to an embryo through the procurement, use, storage or distribution of gametes and embryos, which do not comply with the centre's licence;
- which indicates a major shortcoming from the statutory requirements;
- which indicates a failure of the Person Responsible to carry out his/her legal duties
- a combination of several "other" areas of non compliance, none of which on their own may be major but which together may represent a major area of non compliance.

| Area of practice | Reference | Action required | Timescale for action | PR Response | Executive Review |
|---|---|---|---|---|---|
| Welfare of the child standard operating procedure and process. | T33(b) | The welfare of the child SOP should be audited against compliance with approved protocols and regulatory requirements to ensure compliance. | April 2010 | Welfare of the child SOP is undergoing review to ensure compliance with the 8th Code of Practice and will be presented at the next monthly centre meeting for ratification. | |
| Training and competence to conduct welfare of the child assessments | T15 (a) and (d) | PR should ensure that staff are trained in the welfare of the child assessment process and can demonstrate appropriate understanding of the process and | June 2010 | Once the amendments to the Welfare of the Child SOP have been approved and circulated, arrangement will be | |

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| | | competence in assessment when required. | | made for this to be the subject of the next scheduled training session. | |
| Documentation of competence | T12 & T15 (a) | The centre should review its competence assessments to ensure all key elements of its practice are assessed and documented and that all staff are able to demonstrate competence in the performance of their designated tasks. | August 2010 | A review of competency assessments outstanding is underway, the result of which will be acted upon. | |
| Development of quality objectives and indicators for all key procedures and processes. | T35 | Required standards of quality and safety, in the form of quality indicators for all activities authorised by this licence and other activities carried out in the course of providing treatment services that do not require a licence, must be established. | August 2010 | This will be discussed at our next centre meeting to determine the parameters of the request and what we want to work towards. | |
| Audit of key procedures and processes. | T36 | The centre should agree a schedule of audit of activities authorised by this licence and other activities carried out in the course of providing treatment services that do not require a licence. The | Ongoing – to be monitored. | We will revise our list of planned audits and commence this process. | |

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| | | audit should be against compliance with the approved protocols, the regulatory requirements and quality indicators. These audits must be performed in an independent way, at least every two years. Findings and corrective actions must be documented. | | | |

## Other areas of practice that requires improvement

Areas of practice that requires improvement is any area of practice, which cannot be classified as either a critical or major area of non compliance, but which indicates a departure from good practice.

| Area of practice | Reference | Action required | Timescale for action | PR Response | Executive Review |
|---|---|---|---|---|---|
| The | Guidance Note 18 | It is suggested that the | 31 March | This has been done. | |

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| documentation retained in the health care records does not record the signature of the second person witnessing the process on all occasions. | | centre should consider that an additional section be added to the witnessing form in ensure the second signature is captured. | 2010 | | |

## Additional Information from the Person Responsible

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| PR response send in letter form which is appended to this report and transcribed into the PR response column. |

# HFEA Executive Licensing Panel Meeting

**21 April 2010**

21 Bloomsbury Street London WC1B 3HF

## Minutes – Item 2

**Reproductive Medicine Clinic, Bristol (0276) Interim Report**

| Members of the Panel: | |
|---|---|
| Peter Thompson, Director of Strategy & Information (Chair)<br>Mark Bennett, Director of Finance & Facilities<br>Juliet Tizzard, Acting Director of Strategy & Information | Committee Administrator:<br>Joanne McAlpine |

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 ( 27 pages)
- no papers were tabled for this item

The Committee also had before it:

- HFEA Protocol for the Conduct of Licence Committee Meetings of the Authority's Executive Licensing Panel
- 8th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- Direction 0008 (where relevant), and any other relevant Directions issued by the Authority;
- Decision Trees for Granting and Renewing Licences and Considering Requests to Vary a Licence
- Guidance for members of Authority and Committees on the handling of conflicts of interest approved by the Authority on 21 January 2009
- Indicative applications guidance on the time period for which licences should be granted approved by the Authority on 21 October 2009
- Indicative sanctions guidance approved by the Authority on 18 March 2009
- Licence application and any relevant documentation

1. The Panel considered the papers which included an interim inspection report, a letter from the Person Responsible in response to the report and previous Licence Committee minutes.

2. The Panel noted that the inspection took place on 10 February 2010 and lasted five hours.

3. The Panel noted that the centre is a small unit located in St Michael's Hospital which is part of University Hospitals Bristol, NHS Foundation Trust.

4. The Panel noted that the centre provides outpatient investigation and diagnosis of sub-fertility and intrauterine insemination (IUI) treatment to NHS funded couples from the South Bristol and Weston Super Mare area.

5. The Panel noted that the centre shares facilities with general and oncology gynaecology services. It does not have facilities for the analysis or preparation of semen for use in treatment on site; this service is provided by licensed centre 0295 Bristol Centre for Reproductive Medicine, where the male partner will attend for sample production. Following preparation for insemination, the sample is transported by the male partner to St. Michael's.

6. The PR is Dr David Cahill who is Reader in Reproductive Medicine at Bristol University and is an honorary Consultant in Obstetrics and Gynaecology at St. Michael's Hospital.

7. The Panel noted that the centre was last inspected in January 2008 for a renewal inspection, following which the Licence Committee granted a three year licence without any additional conditions.

8. The Panel noted that the centre had carried out 75 partner insemination January – December 2008.

9. The Panel noted the inspectorate's recommendation for the continuation of the licence without any additional conditions. However, the Panel also noted and endorsed the inspectorate's recommendations regarding the following outstanding areas:
    - the welfare of the child standard operating procedure should be audited against current regulation
    - staff competency in their assigned tasks should be documented
    - quality objectives and indicators for all key procedures and processes should be formulated and agreed
    - and key procedures and processes should be audited.

10. The Panel noted the PR's response to the outstanding areas on pages 13 – 16 of the inspection report and was satisfied with his comments and his willingness to address these areas listed above in a positive manner. The Panel would, however, like the Executive to monitor progress.

The Panel's Decision

11. The Panel agreed to continue the centre's licence with no additional conditions.

Signed.....Date.....

Peter Thompson (Chair)