# Interim Inspection Report

# The Bridge Centre
# 0070

## Date of Inspection: 17 February 2009
## Date of Licence Committee: 10 June 2009

**Centre Details**

| | |
|---|---|
| Person Responsible | Professor Alan Handyside |
| Nominal Licensee | Mr Paul Williams |
| Centre name | The Bridge Centre |
| Centre number | 0070 |
| Centre address | One St Thomas Street, London Bridge London, SE1 9RY |
| Type of inspection | Interim |
| Inspector(s) | Dr Vicki Lamb |
| | Mr Wil Lenton |
| | Miss Angela Sutherland |
| | Mrs Carmel Dodson-Brown |
| Fee paid | N/A |
| Licence expiry date | 30 September 2010 |
| NHS/ Private/ Both | Private |

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**About the Inspection:**

This inspection visit was carried out on 17 February 2009 and lasted for 7.5 hours.

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

The report summarises the findings of the licence renewal inspection highlighting areas of good practice, as well as areas where further improvement is required to improve patient services and meet regulatory requirements. It is primarily written for the Licence Committee who make the decision about the centre's licence renewal application. The report is also available to patients and the public following the Licence Committee meeting.

At the visit the inspection team assesses the effectiveness of the centre through five topics. These are:
How well the centre is organised
The quality of the service for patients and donors
The premises and equipment
Information provided to patients and to the HFEA
The clinical and laboratory processes and competence of staff.

An evaluation is given at the end of each topic and for the overall effectiveness of the centre:
No Improvements Required – given to centres where there are no Code of Practice, legal requirements or conditions that need to be imposed.
Some Improvements Required – given to centres that are generally satisfactory but with areas that need attention. Recommendations will usually be made to help Persons Responsible to improve the service.
Significant Improvements Required – given to centres that have considerable scope for improvement and have unacceptable outcomes in at least one area, causing concern sufficient to necessitate an immediate action plan or conditions put on the Licence.

Where recommendations are made the HFEA will provide details of <u>what</u> needs to be addressed but not <u>how</u> 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 <u>www.hfea.gov.uk</u> .

**Brief Description of the Centre and Person Responsible**

The Bridge centre is a privately run unit which offers a wide range of assisted reproduction treatments. The centre has been licensed since 1992, is well established and carried out approximately 1860 cycles of licensed treatments between December 2007 and November 2008.

The centre successfully attained ISO accreditation in November 2007.

An extensive network of satellite and transport centres feed into the Bridge centre, enabling some patients to undergo part of their treatment at a centre local to them.

The PR is a scientist with considerable experience in assisted conception. He has completed the PR entry programme.

**Activities of the Centre[1] for the time period from 1 December 2007 – 30 November 2008**

| | |
|---|---|
| In vitro fertilisation (IVF) | 720 |
| Intracytoplasmic sperm injection (ICSI) | 858 |
| Frozen embryo transfer (FET) | 288 |
| Research | No |
| Storage gametes/embryos | Yes |

**Summary for Licence Committee**

Improvements are required in areas of organisation, premises and equipment, information and laboratory and clinical processes and are summarised below:

- Some relevant incidents had not been reported to the HFEA
- A third party agreement was still outstanding for one of the transport/satellite centres
- Average payment times exceed the 28 day limit
- A functional low oxygen monitor should be in place in the IVF laboratory
- Air quality testing had not been performed at the frequency stated in the SOP
- One consent form had been incorrectly completed meaning there was no effective consent for treatment
- HFEA form submission errors had not been cleared within two months
- Approximately 130 storage consent forms had expired or were missing
- No ongoing laboratory staff competencies have been performed
- Embryos that had been biopsied had been replaced with embryos that had not been

[1] This data is supplied to the HFEA by individual clinics who are responsible for its accuracy and for verifying it. The data published by the HFEA is a snapshot of the state of the Register at a particular time. The data in the Register may be subject to change as errors are notified to us by clinics, or picked up through our quality management systems.

biopsied
- PGS screening includes chromosome 15 but this is not included on the centre's licence
- Validation of some equipment has not been done
- Reimbursement of sperm donors did not appear to comply with directions D.2006/1
- A record of all communications with complainants may not be accurately maintained
- One set of records had two witnessing signatures missing
- Welfare of the child forms are not being fully completed
- Three patients who had PGS had had three embryos transferred

The inspection team is concerned that the cumulative effect of a number of significant issues may be putting at risk the effective and safe operation of the centre.

The PR was invited to attend the HFEA offices and to provide a detailed improvement plan to address the issues set out in this report, detailing the precise measures and steps to be taken to address all breaches and areas of non-compliance. The plan submitted by the PR is included in appendix C along with an update on progress dated 8 May 2009.

The licence committee is asked to consider what, if any, regulatory sanctions are warranted in consideration of the breaches and areas of non compliance documented in this report.

**Evaluations from the inspection**

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

**Breaches of the Act, Standard Licence Conditions or Code of Practice:**
The table below sets out matters which the Inspection Team considers may constitute breaches of the Act, Standard Licence Conditions and/or the Code of Practice, and their recommended improvement actions and timescales. The weight to be attached to any breach of the Act, Standard Licence Conditions or Code of Practice is a matter for the Licence Committee;-

| Breach | Action required | Time scale |
|---|---|---|
| Some relevant incidents had not been reported to the HFEA and some incidents had been reported significantly in excess of the required HFEA reporting timeframes. The procedure for non-conformances and incident reports was provided to the inspection team. This procedure included staff who were responsible for dealing with incidents but did not refer to reporting incidents to the HFEA. This appears to be a breach of S.9.4.2. | The PR should ensure that all staff are aware of their roles and responsibilities for reporting incidents and that procedures meet the requirements of S.9.4.2 | By 1 June 2009 |
| A third party agreement was still outstanding for one of the transport/satellite centres. This is a breach of standard licence condition A.5.1. | The PR should ensure that third party agreements are in place and up to date to ensure compliance with A.5.1. | By 1 June 2009 |
| The average payment time for treatment fees is 39 days. The HFEA payment terms are 28 days and payment outside these terms is a breach of standard licence condition A.13.3 which states that in consideration of the grant of the licence (or its variation to designate the individual named in this licence as Person Responsible), the Person Responsible agrees that s/he will pay to the Authority any additional fee, as defined in section 16(6) of the Act, | The PR should take steps to ensure that in future fees are paid within 28 days in compliance with A.13.3 | By the next inspection |

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| within 28 days of the date of the notice of such additional fee. | | |
| The low oxygen monitor in the IVF laboratory was not functional. As cryovessels are stored in this area a functional low oxygen monitor should be in place to ensure compliance with S.6.3.2. | A functional low oxygen monitor should be in place in the IVF laboratory to ensure compliance with S.6.3.2. | By 1 June 2009 |
| The protocol for air quality monitoring states that particle counting is performed quarterly and settle plates are assessed monthly. From the records provided to the inspection team it was apparent that the air quality testing had not been performed at this frequency. If air quality is not tested at the stated frequencies the centre is unable to demonstrate that processing has taken place in an environment of the required air quality at all times in compliance with standard licence condition A.10.19. | The frequency of air quality monitoring should be sufficient to ensure that the processing of gametes and embryos takes place in an environment of at least grade C air quality with a background of at least grade D air quality to ensure compliance with A.10.19. | By 1 June 2009 |
| In one set of patient records reviewed for a same sex couple, where one partner was donating to the other partner, the consent forms had been completed by the wrong partner. | Centre staff should ensure that consent forms are always completed correctly to ensure compliance with S.7.5.4 and A.12.2. | Immediately |
| There continue to be problems with data submissions to the HFEA. The centre is in breach of directions D.2008/6 as the HFEA form submission errors for November 2008 were not cleared within two months. | HFEA form submission errors should be cleared within two months to ensure compliance with directions D.2008/6. | By 1 June 2009 |

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|---|---|---|
| At the last stored sperm audit in January 2009 there were approximately 130 patients' storage consent forms that had expired or were missing from the storage paperwork and there were 106 cases where paperwork had not been completed. Storage of gametes without effective consent is a breach of schedule 3 section 8(1) of the Act. | Samples should only be kept in storage when there is effective consent in place to ensure compliance with schedule 3 section 8(1) of the Act. | By 1 September 2009 |
| No ongoing laboratory staff competencies have been performed. This is a breach of S.6.2.2(c) and S.6.2.7(a). | Staff competence assessments should be performed to ensure compliance with S.6.2.2(c) and S.6.2.7(a). | By the next inspection |
| Embryos that had been biopsied had been replaced with embryos that had not been biopsied. This is a breach of A.13.7(a). | Embryos that have been biopsied should not be replaced with embryos that have not been biopsied to ensure compliance with A.13.7(a). | Immediately |
| When reviewing records it was noted that chromosome 15 is included in the PGS screening. Screening for this chromosome is not included on the centre's licence and no application for approval to include this chromosome when performing PGS has been received by the HFEA. This is a breach of A.13.9(a). | PGS should only be carried out for the chromosomes that are authorised by the centre's licence to ensure compliance with A.13.9(a). | Immediately |
| Validation is being done for new equipment but validation of old equipment has not been done. This is a breach of A.10.13. | Validation of all equipment should be performed to ensure compliance with A.10.13. | By the next inspection |
| The payment log for sperm donors was reviewed by the inspection team. Sperm donors had been reimbursed | Sperm donors should be reimbursed in line with directions D.2006/1. | Immediately for new sperm donors |

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| a flat rate for each donation. No justification was provided to support this that could demonstrate compliance with directions D.2006/1. Therefore this appears to be a breach of directions D.2006/1. | | |

**Non-Compliance**

| Area for improvement | Action required | Time scale |
|---|---|---|
| The centre's procedure for handling patient complaints was provided to the inspection team. This included the statement: "It is important to keep a comprehensive and well-maintained record of any complaint that has been received, investigated and responded to." The inspection team did not consider that this part of the procedure was being followed effectively. This may indicate non-compliance with G.11.3.3 if not all communications are being recorded. | The PR should ensure that a record of all communications with complainants is maintained to ensure compliance with G.11.3.3. | Immediately |
| In one set of records reviewed there was only one witnessing signature for two of the procedures performed. | Witnessing should always be fully documented to ensure compliance with G.13.2.1. | Immediately |
| The inspection team noticed that welfare of the child forms are not being fully completed; the section where the clinician confirms they have checked the form was not completed in any of the forms seen by the team. | Welfare of the child forms should be fully completed to confirm that they have been checked to ensure compliance with G.3.1.1. | Immediately |
| Three patients who had PGS had had three embryos | Patients having PGS treatment should have a | Immediately |

| | | |
|---|---|---|
| transferred. This is non-compliance with G.8.5.3. | maximum of two embryos transferred to ensure compliance with G.8.5.3. | |

**Changes/ improvements since last inspection**

| Recommendations | Action Taken |
|---|---|
| Reporting errors concerning completeness and timeliness of information reaching the Authority. ***S.4.2.12(b) CoP7*** | Problems remain in the reporting of information to the HFEA. |
| Not all third party agreements with satellite/transport centres are in place ***S.4.2.10/ S.7.1.1 CoP7*** | The PR confirmed that third party agreements have been agreed with all the satellite/transport centres except one. The PR confirmed that he is continuing to attempt to reach an agreement with this centre. |
| The witnessing of the receipt of gametes from transport centres is not currently taking place and requires review/amendment ***S.7.3.1(a)/S7.7.1(a)(c) S.7.7.15 CoP7*** | Witnessing steps reviewed during the course of the inspection were seen to meet HFEA requirements. |
| Home procurement of gametes SOP to be developed ***S.7.7.9CoP7*** | This has been done and was seen on the day of the inspection |

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

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| The licence was issued with no additional conditions. |

## Report of inspection findings

### 1.Organisation

Desired Outcome: The centre is well-organised and managed and complies with the requirements of the HFE Act.

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

- Leadership and management
- Organisation of the centre
- Resource management
- Clinical governance
- Risk management
- Incident management
- Alert management
- Complaints management
- Contingency arrangements
- Establishment of third party agreements
- Meetings / dissemination of information
- Payment of licence/treatment fees

| Areas of firm compliance |
| --- |
| The PR at the centre has changed since the last inspection. The current PR has completed the PR entry programme satisfactorily and has been approved by a Licence Committee.<br><br>An organisation chart was provided showing clear lines of accountability.<br><br>The inspection team were informed that the centre had ISO recertification in October 2008. The report of this was provided to the team and the certificate was displayed in the reception area.<br><br>Staff reported that a risk assessment of the witnessing system was undertaken in August 2008 and 100% compliance was noted.<br><br>The team were informed that complaints are reviewed at quality team meetings. The minutes of one of these meetings and the annual quality management review meeting were provided and showed that complaints had been discussed.<br><br>The PR confirmed that he is having individual meetings with each transport/satellite centre one-two times per year. The minutes of the meetings held with four of these centres were provided to the inspection team.<br><br>Staff reported that regular staff meetings occur. Minutes of some of the most recent meetings were provided to the inspection team. These included: infection control, health and safety and theatre users meetings. Attendees were recorded for each of these meetings. The slides from the recent all staff meeting were also provided to the team. |
| Areas for improvement |
| The complaints log was provided to the inspection team. The information recorded relating to |

responses to complaints was brief. In ten sets of records reviewed, where incidents and complaints occurred, the documentation was considered to be weak, with signatures and dates missing. The centre's procedure for handling patient complaints was provided to the inspection team. This included the statement: "It is important to keep a comprehensive and well-maintained record of any complaint that has been received, investigated and responded to." The inspection team did not consider that this part of the procedure was being followed effectively. This may indicate non-compliance with G.11.3.3 if not all communications are being recorded. The inspection team were informed that there have been several changes of complaints officer due to changes of staff and this may have affected the way that complaints have been dealt with.

During the inspection the list of incidents reported internally within the centre and those reported to the HFEA were checked against each other. Some relevant incidents had not been reported to the HFEA and some incidents had been reported significantly in excess of the required HFEA reporting timeframes. The procedure for non-conformances and incident reports was provided to the inspection team. This procedure included staff who were responsible for dealing with incidents but did not refer to reporting incidents to the HFEA. This appears to be a breach of S.9.4.2.

A third party agreement was still outstanding for one of the transport/satellite centres. This was also noted as a breach at the previous inspection and the centre reported that all third party agreements would be in place by 31 August 2008. This is a breach of standard licence condition A.5.1.

The average payment time for treatment fees is 39 days. HFEA payment terms are 28 days and payment outside these terms is a breach of standard licence condition A.13.3 which states that in consideration of the grant of the licence (or its variation to designate the individual named in this licence as Person Responsible), the Person Responsible agrees that s/he will pay to the Authority any additional fee, as defined in section 16(6) of the Act, within 28 days of the date of the notice of such additional fee.

Areas for consideration

None

Executive recommendations for Licence Committee

The PR should ensure that a record of all communications with complainants is maintained to ensure compliance with G.11.3.3.

The PR is responsible for notifying the HFEA of any incidents or near misses as stated in S.4.1.9. He should ensure that all staff are aware of their roles and responsibilities for reporting incidents and that procedures meet the requirements of S.9.4.2

The PR should ensure that third party agreements are in place and up to date to ensure compliance with A.5.1.

The PR should take steps to ensure that in future fees are paid within 28 days in compliance with A.13.3.

| Evaluation |
| --- |
| Significant improvement required |
| Areas not covered on this inspection |
| Alert management<br>Contingency arrangements |

## 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 from the 1 January 2005 to 31 December 2007 the centre's outcomes were in line with the national average, except for frozen embryo transfer treatments for patients aged below 35 where the outcomes were significantly below the national average. |
| Areas of firm compliance |
| The inspection team were given full access to the electronic quality management system. SOPs were seen to be in place and available electronically. Document control was seen to be in place and documents that were provided to the inspection team were seen to have been reviewed in the last twelve months.<br><br>A scientific review was commissioned by the centre and undertaken by an external consultant. The inspection team were provided with a copy of this report. Several recommendations were made in the report and centre staff are meeting to consider what action should be taken in response to these recommendations.<br><br>No patient questionnaires have been received at HFEA since the last inspection.<br><br>One patient was interviewed and gave positive feedback on her experience of treatment and provision of information at the centre. She reported that she felt she could ask questions about her treatment. |
| Areas for improvement |
| None |
| Areas for consideration |
| The Licence Committee that considered the previous inspection report asked that success rates be the focus of this inspection. The analysis of three years of data held at the HFEA showed that all the parameters assessed were in line with national averages except for frozen embryo transfer rates for patients under the age of 35, which were significantly below the national average. This is an improvement since the last inspection, when analysis of three years of data showed that donor insemination success rates for patients under the age of 35 were also below the national average. The inspection team were informed that a large number of key performance indicators are monitored on a monthly basis. These include: |

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| normal fertilisation rates, cleavage rates, implantation rates and clinical pregnancy rates. Live birth rates are monitored every three months. Additionally inter-operator comparisons are assessed for the clinical and scientific staff. |
| Executive recommendations for Licence Committee |
| None |
| Evaluation |
| No improvements required |
| Areas not covered on this inspection |
| Quality policy<br>Quality manual<br>Quality objectives and plans |

### 3. Premises and Equipment

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

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

- Premises
- Clinical facilities
- Counselling facilities
- Laboratory facilities
- Air quality
- Management of equipment and materials
- Storage facilities for gametes and embryos
- Staff facilities
- Storage of records

| Areas of firm compliance |
| --- |
| The premises were seen to be secure. Keypad locks were present and in use to provide security for critical areas such as the administration floor, theatre area and laboratory.<br><br>The theatre and recovery area was considered to be well run and theatre appeared clean and well-equipped. There are four recovery bays with alarms on the wall in all bays. There is oxygen on the patient trolleys and portable suction is available. The monitors in the recovery bay had all been tested in the last year. The emergency trolley and portable suction were seen to be checked on a daily basis and the daily checklist was fully signed. The anaphylaxis kit at the nurses' station was in date and had been checked as per protocol.<br><br>In discussion it was established that the counsellor considers the counselling facilities to be satisfactory.<br><br>Cryovessels were seen to be secure and alarmed. The log for monitoring incubator $CO_2$ and temperature was seen and was fully completed. Flow hoods and incubators had been serviced in the last year. The scientific inspector was informed that service/maintenance contracts are in place.<br><br>There is a staff changing area with lockers. The door to this room has a keypad lock. A staff room with kitchen area and first aid kit is available on the third floor.<br><br>The toilets were being refurbished when the inspection took place. It had been arranged that this would be done in stages so that adequate facilities remained available at all times.<br><br>During discussion the PR confirmed that he is confident that transport/satellite centres store their records appropriately. |
| Areas for improvement |
| The low oxygen monitor in the IVF laboratory was not functional. As cryovessels are stored in this area a functional low oxygen monitor should be in place to ensure compliance with S.6.3.2. |

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| The protocol for air quality monitoring states that particle counting is performed quarterly and settle plates are assessed monthly. From the records provided to the inspection team it was apparent that the air quality testing had not been performed at this frequency, although the results that were present showed that the air quality when tested had met the required criteria. If air quality is not tested at the stated frequencies the centre is unable to demonstrate that processing has taken place in an environment of the required air quality at all times in compliance with standard licence condition A.10.19. |
| Areas for consideration |
| None |
| Executive recommendations for Licence Committee |
| A functional low oxygen monitor should be in place in the IVF laboratory to ensure compliance with S.6.3.2.<br><br>The frequency of air quality monitoring should be sufficient to ensure that the processing of gametes and embryos takes place in an environment of at least grade C air quality with a background of at least grade D air quality to ensure compliance with A.10.19. |
| Evaluation |
| Some improvement required |
| Areas not covered on this inspection |
| None |

## 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

| Audit of records |
| --- |
| Five sets of patient records were checked for consents. In one set for a same sex couple, where one partner was donating to the other partner, the consent forms had been completed by the wrong partner. This means that gametes had been used for treatment purposes without effective consent. In the other four sets of records the consent forms had been correctly completed.<br><br>Five sets of patient records were checked for witnessing documentation. In one set of records there was only one signature for two of the procedures performed.<br><br>The inspection team noticed that welfare of the child forms are not being fully completed; the section where the clinician confirms they have checked the form was not completed in any of the forms seen by the team. However, centre staff informed the inspection team that a new form had been devised and is coming into use shortly. |
| Areas of firm compliance |
| The HFEA licence and ISO certificate were displayed in the reception area and complaints information was displayed in the waiting room. Information on counselling was also available.<br><br>The centre's multiple birth minimisation strategy has been submitted to the HFEA.<br><br>The finance manager confirmed that the financial database is password protected. Patients' first names are used when addressing them to maintain confidentiality. |
| Areas for improvement |
| Centre staff should ensure that consent forms are always completed correctly (see audit of records above).<br><br>Witnessing should always be fully documented (see audit of records above).<br><br>Welfare of the child forms should always be fully completed (see audit of records above).<br><br>There continue to be problems with data submissions to the HFEA. This appears to be due to staff shortages and the inspection team were informed that an additional member of staff may be recruited to do EDI returns. Additionally, the inspection team were informed that there have been problems with the IT equipment and EDI interface which has created a considerable backlog. The centre is in breach of directions D.2008/6 as the HFEA form |

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| submission errors for November 2008 were not cleared within two months. |
| Areas for consideration |
| None |
| Executive recommendations for Licence Committee |
| Centre staff should ensure that consent forms are always completed correctly to ensure effective consent is in place and compliance with section 12(1)(c) of the Act, S.7.5.4 and A.12.2.<br><br>Witnessing should always be fully documented to ensure compliance with G.13.2.1.<br><br>Welfare of the child forms should be fully completed to confirm that they have been checked to ensure compliance with G.3.1.1.<br><br>HFEA form submission errors should be cleared within two months to ensure compliance with directions D.2008/6. |
| Evaluation |
| Significant improvement required |
| Areas not covered on this inspection |
| None |

## 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 | 9 |
| NMC registered nurses | 10 |
| Non NMC registered clinical staff | 5 |
| HPC registered scientists | 5 |
| Scientists working towards registration | 7 |
| Support staff (receptionists, record managers, quality and risk managers etc) | 27 |
| Counsellors | 2 |

| Summary of laboratory audit |
|---|
| The latest audit of sperm was provided to the inspection team. This audit had been performed in January 2009. There were a number of discrepancies noted. Approximately 130 patients' storage consent forms had expired or were missing from the storage paperwork and there were 106 cases where paperwork had not been completed. |
| **Summary of spot check of stored material** |
| This was not performed as this was an interim inspection. |
| **Areas of firm compliance** |
| The state registered embryologists are participating in the ACE CPD programme. The counsellor is a member of BICA. GMC and NMC registration numbers were provided for relevant members of staff. The operating theatre nurse has received recent training, including a sedation course and mandatory training. The junior clinic nurse has had her competencies assessed and signed off. This was seen in her orientation folder. The competencies included venepuncture, drug storage and dispensing.<br><br>Two sets of sperm donor notes were reviewed and appropriate screening was seen to have been performed. |

The inspection team was provided with the three embryo transfer log for patients having treatment, excluding PGS. All the patients were seen to be aged 40 or over.

The clinical inspector saw some patient checks being undertaken and they were seen to meet the requirements.

The PR and donor coordinator confirmed that gametes and embryos are not imported from overseas egg donor centres.

The home procurement SOP and traceability log was seen by the scientific inspector.

The counsellor reported that the counselling protocol was reviewed 4-5 months ago. He feels well integrated within the centre. Counselling records are computerised and no-one else has access to them. There are 2 other counsellors who can provide back-up and there is a separate genetic counsellor.

Areas for improvement

At the last stored sperm audit in January 2009 there were approximately 130 patients' storage consent forms that had expired or were missing from the storage paperwork and there were 106 cases where paperwork had not been completed. Storage of gametes without effective consent is a breach of schedule 3 section 8(1) of the Act.

Laboratory staff confirmed that an audit against SOPs was performed in 2008 but no ongoing laboratory staff competencies have been performed. This is a breach of S.6.2.2(c) and S.6.2.7(a).

Three patients who had PGS had had three embryos transferred. This is non-compliance with G.8.5.3. However, centre staff confirmed that of these nine embryos replaced, only one gave a normal result, two gave an abnormal result, three gave no result and three of the embryos replaced had not been biopsied. Replacing both embryos from which biopsies have been taken, and embryos which have not been biopsied is a breach of A.13.7(a).

When reviewing records it was noted that chromosome 15 is included in the PGS screening. Screening for this chromosome is not included on the centre's licence and no application for approval to include this chromosome when performing PGS has been received by the HFEA. This is a breach of A.13.9(a).

Validation is being performed for new equipment but existing equipment has not been validated. This is a breach of A.10.13.

The payment log for sperm donors was reviewed by the inspection team. Sperm donors had been reimbursed a flat rate for each donation. No justification was provided to support this that could demonstrate compliance with directions D.2006/1. Therefore this appears to be a breach of directions D.2006/1.

Areas for consideration

There have been a number of staff changes since the last inspection with an overall net loss of five staff members.

| Executive recommendations for Licence Committee |
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| Samples should only be kept in storage when there is effective consent in place to ensure compliance with schedule 3 section 8(1) of the Act.<br><br>Staff competence assessments should be performed to ensure compliance with S.6.2.2(c) and S.6.2.7(a).<br><br>Patients having PGS treatment should have a maximum of two embryos transferred to ensure compliance with G.8.5.3.<br><br>Embryos that have been biopsied should not be replaced with embryos that have not been biopsied to ensure compliance with A.13.7(a).<br><br>PGS should only be carried out for the chromosomes that are authorised by the centre's licence to ensure compliance with A.13.9(a).<br><br>Validation of all equipment should be performed to ensure compliance with A.10.13.<br><br>Sperm donors should be reimbursed in line with directions D.2006/1. |
| Evaluation |
| Significant improvement required |
| Areas not covered on this inspection |
| Coding/ identification of samples |

**Report compiled by:**

Name……Vicki Lamb…….

Designation……Inspector…….…….

Date……25 March 2009……

**Appendix A: Centre staff interviewed**

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|---|
| The PR and seven members of staff were interviewed |

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

| Licence | Status | Type | Valid from | Valid to |
|---|---|---|---|---|
| L0070/17/f | Active | Treatment with storage | 01/12/2008 | 30/09/2010 |
| L0070/17/e | Replaced by new version | Treatment with storage | 25/06/2008 | 30/09/2010 |
| L0070/17/d | Replaced by new version | Treatment with storage | 21/05/2008 | 30/09/2010 |
| L0070/17/c | Replaced by new version | Treatment with storage | 25/02/2008 | 30/09/2010 |
| L0070/17/b | Replaced by new version | Treatment with storage | 01/10/2007 | 30/09/2010 |
| L0070/17/a | Replaced by new version | Treatment with storage | 01/10/2007 | 30/09/2010 |
| L0070/16/b | Expired | Treatment with storage | 05/07/2007 | 30/09/2007 |
| L0070/16/a | Replaced by new version | Treatment with storage | 05/07/2007 | 30/09/2007 |
| L0070/15/d | Replaced by new version | Treatment with storage | 01/11/2006 | 30/09/2007 |
| L0070/15/c | Replaced by new version | Treatment with storage | 01/09/2006 | 30/09/2007 |
| L0070/15/b | Replaced by new version | Treatment with storage | 01/05/2006 | 30/09/2007 |
| L0070/15/a | Replaced by new version | Treatment with storage | 01/01/2006 | 30/09/2007 |

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

Centre Number.....0070.....

Name of PR.....Professor Alan Handyside.....

Date of Inspection...17 February 2009.....

Date of Response...15th April 2009.....

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

Signed.....A.H Handyside.....

Name.....Professor Alan H Handyside.....

Date.....15th April 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. Organisation
   The Bridge Centre 0070 has incorporated the licensed activities of the cryobank which was previously licensed separately and the Bridge Cryoservices licence (0171) was discontinued.
2. Changes/improvements since last inspection
   The annual HFEA Operational Audit documented an improvement in our data submission as a result of our extra effort in this area.
   We have installed a backup power system for essential equipment.

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

Quality of service

The outcomes for frozen embryo transfers for Jan-Sept, 2008 are significantly improved. For women under 35, positive hCG rates are 29.8% per thaw and clinical pregnancy rates 19.5% per thaw.

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

1. HFEA Incident Reporting
All incidents at Bridge are recorded and logged according to our internal Incident/Non-compliance SOP.
ACTION: An additional HFEA Incident Report SOP is being drafted and training for all staff will be incorporated in our weekly training sessions. In the absence of specific guidance from the HFEA on what it defines as a reportable incident, guidelines will be included in the SOP and discussed with our Inspector before the SOP is adopted.

2. Third Party Agreement
A third party agreement was held up pending a decision on awarding the contract with one of our NHS based transport partners and then following the decision to continue with Bridge the new EUTD/HFEA compliant agreement/contract has been held up for technical reasons and not signed despite repeated requests. (We have previously always had a formal contract with them). A planned meeting in Feb was cancelled twice by them for important local clinical management reasons.
ACTION: The PR will write to the consultant concerned to remind them of the need for a signed agreement and that this is a requirement of standard licence condition A.5.1.

3. HFEA Fees
ACTION: Accounts have been reminded of the requirement to pay HFEA fees within 28 days.

4. Low Oxygen Monitor
ACTION: Both Monitors have been sent away for repair and recalibration and should be returned within two weeks.

5. Air Quality Monitoring
The Bridge SOP specifies monitoring every quarter and this was not completed in the last quarter of last year. Settle plates are also renewed monthly.
ACTION: Review SOP and consider reducing particle monitoring to half yearly and settle plates bimonthly on the basis that our experience to date indicates that is sufficient to maintain adequate air quality. Lab Manager to check that the monitoring company have a standing order to visit at the appropriate intervals.

6. Consent and WoC forms and Witnessing
The lack of countersignatures on our old WoC forms had been recognised before inspection and new forms are now in place.
ACTION: Training of all appropriate staff on completing these tasks accurately. Regular audit to be carried out.

7. HFEA data submission
Problems continue with the EDI system for data submission and although progress has been made in keeping pace with current entry, errors from previous months continue to accumulate.
ACTION: Extra resource will be allocated to ensure errors are cleared within two months. The cost of this ongoing effort will be monitored and may have to be passed on to patients as an HFEA admin fee. Progress with data entry will be a standing item on the agenda of monthly Quality Management meetings.

8. Gamete storage without consent
A relatively large number of sperm samples are being stored with expired or no consents some of which were taken over from another licensed centre when it closed several years ago. Hence many of the samples any of the samples
ACTION: These samples are already highlighted on the storage spreadsheet. However, a separate spreadsheet of sperm samples in these categories with includes details of progress in contacting the patients and/or discard has been set up. To date, 47 samples have now been reviewed and discarded and 44 more have been reviewed (including 26 without paperwork) and will be discarded following checking in the next week. Progress with the remining 39 samples will be monitored monthly at regular Quality Management meetings.

9. Staff Competency Assessment
Lab staff are not formally assessed following completion of ACE accreditation except for ongoing competency assessment for ICSI and embryo biopsy.
ACTION: A competence assessment plan is being drafted and will be implemented to assess each embryologists competence after they become accredited. Similar schemes are being considered for the clinical staff.

10. Testing for chromosomal aneuploidy
(a) Chromosome 15 is well established as frequently aneuploid in preimplantation embryos and testing is licensed in other centres in the UK. It was therefore assumed that by analogy with single gene defects previously licensed that all that was required was to write requesting an executive decision to license including testing of this extra chromosome. Following validation, we failed to do this before incorporating this chromosome into the improved panel.
ACTION: An application will be submitted to extend our licence to cover chromosome 15.
(b) Transfer of biopsied and non-biopsied embryos and transfer of three embryos following chromosome testing (in women over 40)
Following a highly publicised randomised multicentre clinical trial, we (and other centres) adopted a policy of minimising the possibility of failing to transfer an embryo with a false positive aneuploid result by recommending the possible transfer of embryos identified as having a non-viable monosomy after detailed analysis of our follow up data showed there were an excess of these errors in this class of embryo. Also, we have a 15-20% rate of failing to get any test result and if no other embryo with a normal number of chromosomes is available we believe this embryo should not be excluded for consideration for transfer. This has led in a small fraction of cases in which biopsied and non-biopsied embryos or three have been transferred (in women over 40) as case by case consideration is given to optimising the chance of pregnant in these mostly poor prognosis patients.
ACTION: The patient information has been altered to specify that a maximum of two embryos will be transferred following chromosome testing and training on decision making after chromosome testing will be scheduled for the clinical staff. We will write to the HFEA to request that they review the regulations in this area as we believe they are not in the patients' best interest. The limitation on the number of tested normal embryos to be returned was based on the expectation that implantation rates would be substantially improved which is now known not to be the case particularly in poor prognosis patients. As an interim measure, please advise on whether it would be acceptable to adopt a similar policy to mixing IVF and ICSI embryos for a specified and small fraction of cases in which we record the reasons for non-compliance. Alternatively we may seek removal of this

condition on our Licence for the specified reasons.

11. Validation of equipment
Prospective validation of all new equipment is now routine.
ACTION: Validation of existing equipment has been started and will be completed over a number of months. The Lab Manager is finalising a schedule. This will be a standing item on the agenda for the monthly Quality Management meetings.

12. Payment of Sperm Donors
Compliance with directions on the payment of donors is known to vary widely between licensed centres and we have provided the HFEA evidence of this. Our policy has been pragmatic and intended to minimise administration time. The limit on remuneration of donors was set more than a decade ago. We will be writing to the HFEA to request a review.
ACTION: A new expense form will be introduced and will be used for all new donors.

13. Complaints procedure
As a private centre, we take patient complaints very seriously. We believe we have a very thorough and responsive procedure for handling complaints. Serious illness of the member of staff coordinating the process, together with other staff changes have caused a temporary hiatus.
ACTION: PR will review the operation of the process particularly the recording of all communications.

**Update on Appendix C (0070)** - received 8 May 2009

1. HFEA Incident Reporting

The SOP for HFEA Incident reporting will be completed after I return from annual leave later this month. A comprehensive training schedule for staff is being organised which will take place on a weekly basis and be repeated quarterly. All of the issues including this which have been raised at the Inspection will be included in this programme and staff will be tested for their knowledge and comprehension at each session.

2. Third Party Agreement

Following discussion with the transport partner involved, it was decided to remove all of the financial aspects of the agreement which had been preventing the PCT agreeing to sign the document. The modified agreement has now been signed by both parties.

3. HFEA Fees

Our Accounts section has been reminded of the need to pay HFEA fees within 28 days.

4. Low Oxygen Monitor

Both of the monitors have been repaired and returned. One has been placed in the IVF Lab and one just outside by the cylinders. An additional monitor is now in place in the LN storage area on the 3rd floor.

5. Air Quality Monitoring

Based on a review of the results of air quality monitoring over the last 2 years, which have always been satisfactory, theSOP for particle counting and settle plates have been modified. Particle counts will now be done at least twice a year and settle plates every other month.

6. Consent and WoC forms and Witnessing

Training on these issues will be incorporated into the schedule. An audit on the new WoC forms will be undertaken to confirm that they are now countersigned by one of the clinical staff.

7. HFEA data submission

A meeting between the embryology staff, who have responsibility for HFEA data entry, and the senior nursing staff has identified some frequent sources of errors resulting from inaccurate records completed by the nurses. A nurse coordinator has been appointed to train the nursing staff and monitor the accuracy of the information. The nursing team have also been co-opted into helping clear the backlog of errors, which remains unsatisfactory:

Clearing error reports

| 2008 | |
|---|---|
| Nov | Most completed |
| Dec | Work ongoing |

| 2009 | |
|---|---|
| Jan | Work ongoing |
| Feb | Most completed |

Progress will be reviewed at the next Quality Management meeting on May 20th and a decision taken on what extra resources and/or training are required to resolve this on an ongoing and sustainable basis.

8. Gamete storage without consent

Of the remaining 39 sperm samples, 22 have now been reviewed and discarded and 17 are still in the review process.

9. Staff Competency Assessment

A programme of competency assessments for clinical embryology staff has been scheduled and assessments began two weeks ago.

10. Testing for chromosomal aneuploidy
    (a) An application to include chromosome 15 in our FISH based test has been submitted this week. Pending variation of our licence we have suspended testing for this chromosome.
    (b) Transfer of biopsied and non-biopsied embryos and transfer of three embryos following chromosome testing (in women over 40)
    Our patient information has been amended to make clear the limitations on the number of tested embryos which can be transferred and that biopsied and non-biopsied embryos cannot be transferred together. We are considering applying for special directions to remove these conditions in the patients' interest in certain situations.

11. Validation of equipment

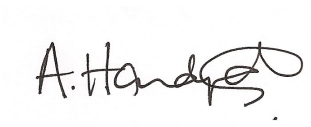
Historical validation of all equipment has begun and a schedule organised to complete this by June.

12. Payment of Sperm Donors

From now on details of donor expenses and receipts will be recorded and reimbursed in compliance with the relevant Chair's letter.

13. Complaints procedure

A review of our complaints procedure led by the PR will be undertaken in June.



Prof Alan H Handyside
Person Responsible

8th May 2009