Interim Inspection Report

The Bridge Centre
0070

Date of Inspection: 4th March 2008
Date of Licence Committee: 11th September 2008

CENTRE DETAILS

Centre Name	The Bridge Centre
Centre Number	0070
Licence Number	L0070-17-b
Centre Address	1 St Thomas Street London SE1 9RY
Telephone Number	0207 403 3363
Type of Inspection	Interim
Person Responsible	Professor Gedis Grudzinskas
Nominal Licensee	Mr Paul Williams
Inspector(s)	Wil Lenton (HFEA, Lead) Neelam Sood (HFEA, Executive) Parvez Qureshi (HFEA, Executive)
Fee Paid – up-to-date	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 04/03/2008 and lasted for 8 hours. The report covers the pre-inspection analysis, the visit and information received between January and December 2007.

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

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

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

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

NB: Where there are very minor issues to be addressed these are noted in the "minor issues to be addressed" section for each topic, and this will facilitate the evaluation of 'no improvements required'. Where recommendations are made the HFEA will provide details of what needs to be addressed but not how they should be carried out as this is the responsibility of the Person Responsible.

The report includes a response form for the Person Responsible to complete following the inspection.

The HFEA welcomes comments from patients and donors, past and present, on the quality of the service received. A questionnaire for patients can be found on the HFEA website www.hfea.gov.uk .

Brief Description of the Centre and Person Responsible

The Bridge centre is a privately-run unit which offers a wide range of treatments. The centre has been licensed since 1992, is well established and carried out approximately 1860 cycles of licensed treatments during January to December 2007. It is one of the largest licensed centres in the UK and one of only five to offer PGD/PGS.

The centre successfully implemented ISO9001/2000 in November 2007 and has a well developed quality management system (QMS) in place which underpins the clinical services.

The centre has an extensive network of satellite (7) and transport centres (4) which feed into the primary unit.

The PR is an experienced consultant Obstetrician & Gynaecologist and has completed the PREP.

Activities of the Centre (HFEA Registry 01/01/07 to 31/12/07)

Licensed treatment cycles	IVF	551
	ICSI	753
	FET	261
	DI	235
	Egg Donor	32
	Egg Recipient	26
Unlicensed treatments	N/A	
Research	No	
Storage	Yes	

Summary for Licence Committee

The centre appeared to be cohesive and well organised, with a good QMS in place which underpinned the clinical service. There appeared to be adequate numbers of qualified and trained staff in post to deliver the services provided.
During the course of the visit a number of regulatory issues were identified and are summarised below;

- Reporting errors concerning completeness and timeliness, identified on the previous inspection, are still occurring as illustrated in the last operational audit (reported 12 September 2007) although the centre is working closely with Registry to resolve this issue.

- During the audit of notes discrepancies were found concerning both Welfare of the Child (WoC) forms and witnessing of IUI procedures

- Only two out of nine third party agreements with satellite/transport centres were in place

- The witnessing of receipt of gametes from transport centres is not currently taking place and requires review/amendment

- The home procurement standard operating procedure (SOP) needs to be formalised

The inspection team support the renewal of the centre's licence.

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
Reporting errors concerning completeness and timeliness of information reaching the Authority. ***S.4.2.12(b) CoP7***	Resolve remaining issues concerning information supply and establish process for accurate and timely reporting to the Authority	3 months
Not all third party agreements with satellite/transport centres are in place ***S.4.2.10/ S.7.1.1 CoP7***	Formalise the outstanding third party agreements with satellite/transport centres	3 months
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***	Review/amend present practice	Immediately
Home procurement of gametes SOP to be developed ***S.7.7.9CoP7***	Develop SOP for home procurement of gametes.	Immediately

Non-Compliance

Area for improvement	Action required	Time scale
None		

Recommendations	Time scale
None	

Proposed licence variations by last L.C.

None

Changes/ improvements since last inspection

Recommendations	Action Taken
An action-plan be devised and implemented to ensure better communication between the centre and its satellite/transport centres.	Implemented and ongoing.
The centre should identify, purchase and install a supplementary back-up power-supply.	Presently a structural engineer is assessing the siting of the 3-ton generator
With the increased number of cryostorage and supply vessels, the centre should undertake a new risk-assessment of cryostorage area.	Internal assessment completed
The centre should consider having a separate theatre log for procedures carried out at the London Bridge theatre in order to protect patient confidentiality	Any such activities now take place, under agreement at a near-by licensed centre, but is rarely required
Review of patient information relating to the Egg Donor/Recipient and Egg-Sharing Programmes, which takes into account the recommendations of the SEED review.	All information reviewed and now compliant
A consistent patient number format should be adopted for all documentation submitted to the HFEA.	In place
The centre should develop a process which ensures the timely reporting of treatment cycles to the HFEA (ie two months after the outcome of treatments are known)	Ongoing at present

Additional licence conditions and actions taken by centre since last inspection

Date	Action taken
N/A	

Report of Inspection findings

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

Summary of findings from inspection
Evidence is drawn from:

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

Areas of firm compliance
An organisational chart was provided which detailed the centre's lines of communication and reporting structure. A detailed staff list provided evidence that the centre had qualified/trained staff with which to deliver the range of patient services provided. The centre has recently achieved ISO-accreditation (November 2007) and it was evident during the inspection that this quality management system (QMS) underpinned the centre's activities/services. An SOP for the induction of new staff was in place. Staff interviewed on the day were able to discuss issues such as patient confidentiality, welfare of the child, privacy and respect. A complaints log and incident log were reviewed on the day of inspection and found to be in good order. A named individual is presently co-ordinating management of the centre's various satellite/transport centres. Minutes of meetings were viewed giving details of a number of meetings held between the primary centre and staff from its allied units. The minutes gave details of staff training and dissemination of information and results . A contingency arrangement is in place with centre 0094.
Areas for improvement
None

Areas for consideration
None
Executive recommendations for Licence Committee
None
Areas not covered on this inspection
Payment of treatment fees

Evaluation
No improvement required

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

Summary of findings from inspection:

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

Live Birth Rates (data from HFEA register 01/01/06 to 31/12/06)
Outcomes for the time period from 31st March 2003 -1st April 2006 were in line with national averages. Outcomes for the time period from 31st March 2004 -1st April 2007 were in line with national averages with the following exceptions: • Outcomes following frozen embryo transfer in patients aged less than 35 years were significantly less than national average; • Outcomes following donor insemination in patients aged less than 35 years were significantly less than national average. These data, which were extracted from the HFEA register, have not been verified by the centre and may be subject to change.
Areas of firm compliance
A designated quality manager is presently in place and the centre successfully implemented ISO9001/2000 in November 2007. The quality management system (QMS) is available to all staff via the pc network which is password protected. The QMS contains all policies/procedures, complaints log, incidents log, traceability log, air-quality monitoring log and equipment maintenance/service log. Any information requested, either to be viewed or printed off as a hard copy, was easily available. Minutes of the annual management review in 2007 were seen on the day and demonstrated the process of continual improvement now undertaken by the centre.
Areas for improvement
All third party agreements with satellite/transport centres to be formalised and put in place
Areas for consideration
None

Executive recommendations for Licence Committee
Third party agreements with satellite/transport centres to be formalised.
Areas not covered on this inspection
Live birth rates

Evaluation
Some improvement required

3. Premises and Equipment

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

Summary of findings from inspection:

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

Areas of firm compliance
The general premises have not changed since the previous inspection and were found to be fit for purpose. All critical care areas have restricted staff access and are secured when not in use. A counselling audit was supplied with the pre-inspection documentation which was found to be satisfactory. A genetic counsellor has recently been appointed by the centre to both support PGD/PGS patients and co-ordinate these services Patient records were seen to be kept securely either in the nurses office (current patients) or within the administration department (all others). Air quality within the laboratory is being monitored and found to be compliant with EUTD requirements. Equipment service/maintenance logs were reviewed during the inspection and found to be up-to-date in all areas. From analysis of the returned HFEA patient satisfaction questionnaires the majority of respondents described a positive experience when visiting the centre.
Areas for improvement
None
Areas for consideration
None

Executive recommendations for Licence Committee
None
Areas not covered on this inspection
None

Evaluation
No improvements required

4. Information

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

Summary of findings from inspection:

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

Areas of firm compliance
The HFEA licence, ISO accreditation and HCC certificates were prominently displayed within the main waiting area, together with details on the centre's complaints procedure, counselling and chaperone services. All patient information assessed during the inspection was found to be accurate and concise. Staff have access to patient information via a password protected electronic database whose data is backed-up on a daily basis.
Areas for improvement
Reporting errors concerning the completeness and timeliness of information reaching the Authority are still occurring as was demonstrated via the Operational Audit report finalised in September 2007. The centre is currently working with both the Registry and IT departments at the Authority in order to resolve these issues. A home procurement SOP needs to be developed.
Areas for consideration
None
Executive recommendations for Licence Committee
The centre should work closely with the IT and Registry teams at the Authority in order to resolve the remaining issues over information supply. A home procurement SOP needs to be developed.

Areas not covered on this inspection
Surrogacy

Evaluation
Some improvements required

5. Laboratory and Clinical Practice

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

Summary of findings from inspection:

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

Full time equivalent staff

GMC registered doctors	8
NMC registered nurses	10
HPC registered scientists	7
Scientists working towards registration	5
Support staff (receptionists, record managers, quality and risk managers etc)	27
Counsellors	2

Summary of laboratory audit / Audit of records
The centre has initiated a rolling audit of their embryo and sperm storage vessels. Two tanks were audited during January 2008 with no discrepancies found. All except four tanks (2 containing embryos and 2 containing sperm samples) are now located in the Cryoservices store (0171)
Summary of spot check of stored material
One sperm sample and one embryo was tracked from database to cryotank and vice versa. No discrepancies were found.
Areas of firm compliance
Laboratory training and CPD logs were seen to be up-to-date. Any new staff member undergoes a general induction course prior to undergoing specific laboratory training which is monitored and signed off by a supervisor. Laboratory equipment such as incubators/heated surfaces/blocks are monitored and parameters such as temperature and $\%CO_2$ recorded regularly in a hard-log as part of a quality control policy. This data is then scanned and filed as part of the QMS. Key Performance Indicator's (KPI's) which give details of individual performance within the laboratory are scrutinised monthly. Evidence of annual appraisals was seen.

The laboratory has a traceability system in place for recording all media, laboratory consumables and equipment used when processing gametes/embryo's.
Areas for improvement
The receipt of gametes from transport centres is not currently being witnessed. The witnessing procedure for the receipt of gametes from transport centres requires review/amendment.
Areas for consideration
None
Executive recommendations for Licence Committee
The witnessing procedure for the receipt of gametes from transport centres requires review/amendment.
Areas not covered on this inspection
Validation

Evaluation
Some improvements required

Report compiled by:

Name ……Wil Lenton……..

Designation…Inspector……..

Date……04/03/08……

Appendix A: Centre Staff interviewed

The PR plus six other staff.

Appendix B: Licence history for previous 3 years

2007

Licence Committee 13th September 2007
Variation of licence to include PGD for the exclusion of early onset Alzheimers disease

Licence Committee 26th July 2007
Renewal of licence for 3 years

Licence Committee 9th July 2007
Variation of licence to include PGD for beta thalassaemia major with HLA typing
Variation of licence to include PGD for Marfan Syndrome

Licence Committee 7th June 2007
Variation of licence to include storage of eggs

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

2006

Licence Committee 1st November 2006
The Committee agreed to continue the Centre's licence, to expire on 30th September 2007 with no conditions and no recommendations
A variation to include PGD Beta Hydroxyisobuyryl CoA Hydrolase Deficiency approved

Licence Committee 1st September 2006
A variation to include PGD Charcot Marie Tooth approved

Licence Committee 1st May 2006
A variation to include PGD to avoid Congenital Fibrosis of the Extraocular Muscles

Licence Committee 1st January 2006
Re-licensing project and PGD Conditions added to licence

2005

Licence Committee 18th February 2005
Licence continued with no conditions

Appendix C:

RESPONSE OF PERSON RESPONSIBLE TO THE INSPECTION REPORT

Centre Number.....

Name of PR.....

Date of Inspection.....

Date of Response.....

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

Signed..... P. Williams

Name..... PAUL WILLIAMS

Date..... 13/5/08

1. Correction of factual inaccuracies

Please let us know of any factual corrections that you believe need to be made (NB we will make any alterations to the report where there are factual inaccuracies. Any other comments about the inspection report will be appended to the report).

On Page 17 of the report support staff are numbered at 42, this number should be 27.

Bridge feel it is unfair for the HFEA to continue referring to the operational audit undertaken in 2007 in this 2008 inspection report. The operational audit undertaken by the HFEA in 2008 showed a substantial improvement, with very few errors identified and we believe this should be reflected in this inspection report.

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

Reporting errors concerning completeness and timeliness of information reaching the Authority. ***S.4.2.12(b) CoP7*** Bridge staff have worked tirelessly to resolve the issues surrounding reporting data via EDI to the HFEA. All outstanding issues now need to be resolved by the HFEA IT department in collaboration with Nick Pulsford.

Not all third party agreements with satellite/transport centres are in place ***S.4.2.10/ S.7.1.1 CoP7*** We are continuing to work with our Transport and Satellite partners in order to obtain signed copies of these agreements. We now have 50% of these agreements signed and completed and will have the rest completed within the next 3 months.

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*** Our current practice when male partners arrive at Bridge with the Transport incubator is they are recorded as attended on our ACU appointments system. Time of arrival and incubator temperature is also recorded on our laboratory witnessing sheet. All identifying information on tubes is witnessed on removal from the transport incubator. In light of comments made by the HFEA during this inspection we have now added an additional witnessing

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step that requires the partner to sign and print his name when delivering the incubator. The embryologist receiving the incubator witnesses this step.

Home procurement of gametes SOP to be developed ***S.7.7.9CoP7*** - A SOP has been completed.

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

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

Licence Committee Meeting

11 September 2008
21 Bloomsbury Street London WC1B 3HF

MINUTES Item 6

The Bridge (0070)
Interim Inspection

Members of the Committee:

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

In Attendance:

Debra Bloor, Head of Inspection
Claudia Lally, Committee Secretary

Providing Legal Advice:

Graham Miles, Morgan Cole Solicitors

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.

1. The papers for this item were presented by Debra Bloor, Head of Inspection. Dr Bloor informed the Committee that this centre is privately run and offers a wide range of treatment services. The centre has been licensed since 1992, is well-established and carried out approximately 1860 cycles in the past year. The interim inspection visit to the centre took place on 4 March 2008. It found the centre to be well organised, with a good Quality Management System in place. However, the following areas for improvement were also identified:
   - submission of timely and accurate treatment information to the HFEA
   - establishment of third party agreements with satellite and transport centres
   - witnessing procedures at the time of the receipt of gametes

- procedures for home procurement.

2. Dr Bloor drew the Committee's attention to the response provided to the report by the Nominal Licensee (NL) who wished to draw attention to the outcome of an operational audit visit that took place post inspection and found substantial improvement in the submission of information to the HFEA.

3. Dr Bloor confirmed that the report of a recent operational audit inspection of the centre supported the Nominal Licensee's assertion that improvements have been made in the reporting of register information.

4. Dr Bloor summarised the response by the Nominal Licensee, who acknowledged the deficiency in third party agreements and gave a commitment to having all agreements in place within 3 months. He also confirmed that an extra witnessing step has now been included at the time of receipt of gametes; and an SOP has been produced for home procurement.

The Committee's Decision

5. The Committee noted that the Person Responsible has addressed all the points raised in the inspection report and decided that the centre's licence should continue with no additional conditions. However, the Committee noted the centre's low success rates and asked that these be a focus of the next inspection.

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