Renewal Inspection Report

Assisted Conception Unit Guy's Hospital
0102

Date of Inspection: 5 February 2008
Date of Licence Committee: 12 May 2008

CENTRE DETAILS

Centre Name	Assisted Conception Unit. Guy's Hospital
Centre Number	0102
Licence Number	L0102/13/c
Centre Address	4th Floor Thomas Guy House Guy's Hospital London SE1 9RT
Telephone Number	020 7188 0501
Type of Inspection	Renewal
Person Responsible	Mr Yacoub Khalaf
Nominal Licensee	Mr Ian Abbs
Inspector(s)	Dr Vicki Lamb
	Mr Wil Lenton
	Mrs Janet Kirkland
	Mrs Ellie Suthers
	Mrs Carol Horner (observing)
Fee Paid – up-to-date	
Licence expiry date	30 June 2008
NHS/Private/Both	NHS

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About the Inspection:
This inspection visit was carried out on 5 February 2008 and lasted for 7.5 hours. The report covers the pre-inspection analysis, the visit and information received between 5 December 2006 and 4 February 2008.

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

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

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

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

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

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

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

Brief Description of the Centre and Person Responsible

The centre is part of Guys & St Thomas' Hospitals NHS Foundation Trust and provides licensed treatments to NHS funded and self funded patients from London and the surrounding area. The unit has an active research programme and provides an extensive pre-implantation diagnosis (PGD service).

The centre is open 7 days per week. The normal working hours are Monday-Friday: 0830-1630, Saturday and Sunday: flexible hours according to workload.

New premises are being built for the centre within the hospital. The new premises should be completed later in 2008.

The centre has no additional conditions on its licence.

Activities of the Centre

Licensed treatment cycles	1042
Donor insemination	6
IUI	70
Unlicensed treatments	Ovulation induction
Research	✓
Storage	✓

Summary for Licence Committee

Some improvements are required in the following areas: organisation, information and laboratory and clinical practice.

Improvements should be considered relating to the following aspects of the centre's practice:

- Payment of treatment fees to HFEA
- Validation of laboratory procedures and equipment
- Home sperm procurement
- Ensuring consents are fully completed

The centre should also risk assess their sperm preparation practice against the 7th Code of Practice. This has now been done.

The inspection team support the renewal of the centre's licence without additional licence conditions.

Risk Assessment

The risk assessment performed after the inspection was 11% - low.

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
The centre takes an average of 44 days to pay treatment fees. The HFEA payment terms are 28 days. Payment outside these terms is a breach of standard licence condition A13.3 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.	The PR should put procedures in place to ensure that payments are made to the HFEA within the 28 day limit.	By 30 June 2008

There is no SOP for sperm procured at home. This is a requirement under S.7.7.	An SOP should be developed.	By 30 June 2008
Validation for equipment and procedures has not been undertaken yet except for the microscope stages. This is a breach of S.6.4.2 and S.7.8.3.	Validation of equipment and procedures should be undertaken.	To be reviewed at next inspection
In two sets of records the consents were not complete. This is a breach of S.7.5.4.	Consent forms should always be completed and placed in the notes.	To be reviewed at next inspection

Non-Compliance

Area for improvement	Action required	Time scale
The centre employs the practice of having all unprocessed sperm samples in the work area at one time. This is not compliant with G.13.8.5.	The centre should risk assess their sperm preparation practice against the 7th Code of Practice.	By 30 April 2008. The risk assessment has been received from the centre.

Recommendations	Time scale
The telephone system for patients to contact the centre should be improved	When the centre has relocated to the new premises

Proposed licence variations by last LC

None

Changes/ improvements since last inspection

Recommendation from last inspection	Action Taken
Re-write information for patients donating or receiving treatment with donated gametes to bring it in to line with the Code of Practice.	Revised within 3 months of the inspection
Keep formal records of training and induction	These were seen to be in place during the inspection
The PR should consider monitoring telephone access to the unit as patient feedback to the HFEA indicated difficulty in contacting the unit by telephone.	There is an answering machine attached to the telephone and a business plan has been drawn up to address this issue.

Additional licence conditions and actions taken by centre since last inspection

The licence was issued without 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 findings from inspection:

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 organisation chart was provided to the inspection team showing clear lines of responsibility. The centre reports incidents promptly to the HFEA. The nurses and doctor interviewed knew how to report an incident and appropriate incident reporting was seen to be in place. To maintain patient confidentiality, if incidents occurring at the centre are reported to the Trust, only patient numbers are used. Risk assessments are performed and the most recent risk assessments were shown to the scientific inspector. A risk management file was seen to be in place. Risk assessments have so far concentrated on the lab but there are plans to move to risk assessments for the clinical area. Corrective risk assessments are performed in response to incidents. It was reported that CRB checks are undertaken on staff prior to employment according to Trust policy. A contingency arrangement is in place with centre 0006 and it was reported to the clinical inspector that there are regular meetings with this centre.
Areas for improvement
There is a single phone number, with an answering machine attached, for patients to call the centre staff. This is regularly highlighted as a problem in the patient questionnaires and it was reported that the centre are working to improve this. A business plan has been drawn up to address this issue, which involves programming the telephone system so that calls from different extensions are diverted appropriately. The centre takes an average of 44 days to pay treatment fees. The HFEA payment terms are 28 days. Payment outside these terms is a breach of standard licence condition A13.3 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 put in place procedures to ensure that fees due to the HFEA are paid within the 28 day limit.
Areas not covered on this inspection
None

Evaluation
Some 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. Document control
8. Live Birth Rates

Live Birth Rates
Pre-validation and pre-quality assured calculations on the HFEA held register data (31 March 2002-1st April 2005) show: • ICSI/IVF success rates are in line with the national average with the exception of age band <35 where they are shown to be significantly higher than the national average. • Frozen embryo transfer success rates are in line with the national average. • Donor insemination success rates are in line with the national average with the exception of age band 35-39 which is significantly lower than the national average.
Areas of firm compliance
There is a Quality Manager in post and the Quality Manual, which was seen to be comprehensive, was provided to the inspection team on the day of the visit. The quality management system was seen to be understood by all staff interviewed. Evidence of audits of success rates were seen by the scientific inspector. These are performed monthly and presented to the Senior Management meeting. Key performance indicators are assessed and corrective action taken if necessary. The list of forthcoming audits for 2008 was also shown to the inspection team. The centre has achieved ISO accreditation. SOPs were seen to be version controlled. Changes are discussed at the weekly multi-disciplinary meetings or within the department. SOPs are reviewed annually by the relevant team manager. The inspection team was informed that patient satisfaction surveys are completed and reviewed every 6 months. There was a notice on the wall of the waiting room explaining how to make a complaint. The complaints log was seen and the action which had been taken was documented.

Areas for improvement
None
Areas for consideration
Work on the third party agreements needs to be completed. Although some agreements are in place, many need to be completed and/or signed.
Executive recommendations for Licence Committee
None
Areas not covered on this inspection
Staff suggestions

Evaluation
No improvements 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

Areas of firm compliance
The centre is situated on the fourth floor of Guy's Hospital. The premises have not changed since the last inspection and consist of 3 consulting rooms, 1 scanning room, laboratory, cryostore, theatre, recovery area, men's room and patient's waiting room in addition to several offices and toilets. Swipecard and keypad lock systems were seen to be in place for security. The inspection team was informed that the unit is alarmed outside working hours. The counselling room was considered to be suitable for its purpose and the staff room at the centre was seen to be well equipped. Critical laboratory equipment is monitored; temperature is monitored constantly and CO_2 levels are measured weekly. The records for this were seen during the course of the inspection. There is a protocol in place for situations where equipment is operating outside the optimum parameters. Liquid nitrogen levels are checked and topped up weekly. A log of this is maintained and was seen by the scientific inspector. A log for all equipment is maintained and service contracts are in place. The scientific inspector saw that equipment had been serviced within the last year. There is an uninterrupted power supply to provide power in an emergency and the new unit will have UPS for all power sockets in the laboratory. Storage dewars are individually locked as well as being stored in a keypad locked room. The temperature of the dewars is constantly monitored and an autodialler was seen to be in place to dial out in an emergency. The low nitrogen alarms are tested monthly and this is recorded. A low oxygen monitor is in place in the cryostore. The quality manager confirmed that the air quality in the laboratory meets the requirements in the Code of Practice: S.6.3.6(b) and G.9.4.3. This is assessed using settle plates, and particle counts are performed once a week. The SOP for this was provided to the inspection team.

Areas for improvement
None
Areas for consideration
The main office was seen to be busy and the nurses' office was small. Consideration should be given to the size and suitability of these facilities in planning the new premises.
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. Surrogacy
11. Procurement and distribution and receipt of gametes and embryos
12. Home procurement report documentation
13. Labelling of packages containing procured gametes
14. Receipt of gametes

Areas of firm compliance
The records were seen to be stored in locked cupboards in a locked office. Patient information evenings are held and the content of these evenings was demonstrated to the lead inspector. The clinical inspector was informed that counsellors are introduced to the patients at this evening. In the waiting room on display was the HFEA licence, a complaints notice, counselling notice with contact details and a support group notice. The emergency contact number is given out on the answering machine when patients ring in out of hours. The patients are also given a card with the number on. The emergency number is a mobile phone carried by the doctors. Unit meetings are held weekly. Incidents are discussed at this meeting. The minutes are kept on the knowledge hub, on the centre's computer system, and are emailed to staff. Also a paper copy of meeting minutes is put on the board in the staff room. There is also a clinical meeting every lunchtime. Department specific meetings are held monthly. The minutes are held on the knowledge hub which all staff have access to. Academic meetings for presentations are held weekly. The clinical inspector was informed that HFEA alerts are printed out and discussed at meetings and pinned up in the staff room. The procedure for investigating concerns about welfare of the child was explained to the clinical and lead inspectors. The inspection team was informed that as the centre performs very few surrogacy cycles there is a nominated doctor to deal with these cases. The SOP for ensuring batch traceability was made available to the inspection team.

There is an interpretation service in the Trust if required.
Areas for improvement
None
Areas for consideration
None
Executive recommendations for Licence Committee
None
Areas not covered on this inspection
Donor registration Packaging &distribution Transportation, labelling of shipping container and recall

Evaluation
No 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	8
HPC registered scientists	3.5
Scientists working towards registration	4
Support staff (receptionists, record managers, quality and risk managers etc)	11
Counsellors	3

Summary of laboratory audit / audit of records
The SOP for the audit of stored material was seen by the scientific inspector. In the last audit there were 17 errors noted for the stored embryos and 34 errors for the stored sperm. All the errors were reported to be related to record keeping. Eight sets of patient records were reviewed to check for appropriately completed consents. In two sets of records the consents were not complete.
Summary of spot check of stored material
One sperm sample and one embryo sample were tracked from records to tank and one sperm and one embryo sample were tracked from tank to records. No discrepancies were noted.
Areas of firm compliance
Evidence of an induction scheme was seen for one of the pre-registration embryologists and the newest nurse. The training logs for one of the doctors, one of the nurses and the quality manager were seen. Training had been undertaken in the last year and evidence of BLS training within the last year was seen by the clinical inspector. All the embryologists are registered on the ACE CPD scheme and the junior embryologists undertake the ACE certificate. Training logs were seen that showed evidence of meetings attended and appropriate training. The inspection team were informed that funding for CPD comes from the hospital or the unit. There was recently a workshop held on embryo transfer as part of the continual learning at the centre.

Ultrasound training is given by the unit ultrasonographer and via BFS training. This forms part of the competencies for the clinical staff.

The doctor interviewed stated that she had competencies signed off and the competency folders for the nurses were seen by the clinical inspector. The clinical inspector was also informed that nurses are to undergo recovery competencies in the new unit.

An anaesthetist is present to administer sedation during egg collections.

The centre treats HIV positive patients if they are suitable in the opinion of a virologist.

The inspection team were informed that the incidence of OHSS has decreased substantially at the centre over the last year due to extra monitoring.

The centre reported that 45 three embryo transfers had been performed since the last inspection. Two of these transfers were performed in women under the age of 40. The reasons for these transfers were seen by the inspection team to be appropriately documented.

Extra appointments are held to see private patients. The nurses get overtime payment for these clinics.

NHS or passport numbers are used for identification purposes if the patient is not referred by their GP.

If patients are refused treatment they have an appointment with the consultant to discuss this.

The emergency trolley was seen by the clinical inspector. It is located in the recovery room and was seen to be checked daily. An emergency dewar is in place and is kept full of liquid nitrogen and is alarmed.

The pre-inspection questionnaire reported that patients producing samples at home are required to sign a form stating that the sample is his own. The signature is checked against the signatures in the notes.

Areas for improvement

An SOP for sperm procured at home needs to be developed. This is a requirement under S.7.7.

Witnessing protocols were seen to be in place but the centre employs the practice of having all unprocessed sperm samples in the work area at one time. This is not compliant with G.13.8.5. The centre has previously risk assessed this practice against the witnessing guidance in the 6th Code of Practice.

In two sets of records the consents were not complete. This is a breach of S.7.5.4.

Validation for equipment and procedures has not been undertaken yet except for the microscope stages. This is a breach of S.6.4.2 and S.7.8.3.

Areas for consideration
The inspection team were informed that electronic witnessing will be introduced in the new unit. The centre has signed up to NEQAS but have not participated in any assessments yet. It was reported that they may also participate in FERTAID. In the last audit there were 17 errors noted for the stored embryos and 34 errors for the stored sperm. All the errors were reported to be related to record keeping. The inspection team were informed that due to an expected increase in patients and move to new premises a business plan has been drawn up to recruit an extra 2 nurses, 1 embryologist, 1 doctor and 2 administration staff.
Executive recommendations for Licence Committee
An SOP for home sperm procurement needs to be developed. The centre should risk assess their sperm preparation practice against the 7th Code of Practice. This risk assessment has now been received. Staff should ensure that consents are fully completed in patients' notes. Validation of equipment and procedures should be undertaken.
Areas not covered on this inspection
PGD The PGD service was considered in detail during an additional visit to this centre in March 2008 and was not reviewed at this inspection.

Evaluation
Some improvement required

Report compiled by:

Name…Vicki Lamb……..……..…….

Designation…HFEA Inspector…….……

Date…28 February 2008……

Appendix A: Centre Staff interviewed

The PR and seven members of staff were interviewed in the course of the inspection.

Appendix B: Licence history for previous 3 years

Licence	Status	Type	Valid from	Valid to
L0102/13/c	Active	Treatment with storage	01/09/2007	30/06/2008
L0102/13/b	Replaced by new version	Treatment with storage	01/08/2007	30/06/2008
L0102/13/a	Expired	Treatment with storage	05/07/2007	30/06/2008
L0102/11/f	Replaced by new version	Treatment with storage	01/03/2007	30/06/2008
L0102/11/d	Replaced by new version	Treatment with storage	01/07/2006	30/06/2008
L0102/11/b	Replaced by new version	Treatment with storage	01/10/2005	30/06/2008
L0102/10/a	Replaced by new version	Treatment with storage	01/07/2005	30/06/2008
L0102/9/u	Expired	Treatment with storage	31/01/2005	30/06/2005

Appendix C:

RESPONSE OF PERSON RESPONSIBLE TO THE INSPECTION REPORT

Centre Number…0102……

Name of PR…Mr Yacoub Khalaf……..

Date of Inspection…2 February 2008……..

Date of Response…27 March 2008……

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

Signed……

Name……..

Date……

1. Correction of factual inaccuracies

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

Being the largest and most successful PGD unit in the country, the unit were surprised that no attention was given during the inspection to this area. PGD requires additional safeguards to be in place over and above those needed for IVF/ICSI for infertility, and for which the HFEA recommends CPA accreditation, which has been obtained by this unit. The unit's PGD results have not been published by the HFEA as required by the Act.

The following comments were made by the PR when reviewing the report and have been transcribed to this section by the author of the report.

As we have done in the past, the centre is happy to perform a risk assessment against the 7th Code of Practice. The centre does not agree that this fulfils the definition of "some improvement required" as this has been approved by a licence committee following a previous inspection

In relation to the breach of S.7.5.4 the PR commented:
Consents are always placed in notes. This does not require action.

In relation to the recommendation about the telephone system the PR commented:
This has already been dealt with in a previous report and is an ongoing quality objective (as seen by inspectors). It is not a new recommendation and thus should not be present in this section of the report.

In relation to 'areas for consideration' in section 3 the PR commented:

Consideration has already been given to this. The plans for the new Unit were available to the inspection team should they have wished to view them. This section should be revised to reflect this.

Under ‘areas for improvement’ in section 5, after the comment about witnessing the PR added:
and the report taken to HFEA License Committee in 2007; the practice was found to be acceptable.

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

Licence Committee Meeting

12 May 2008
21 Bloomsbury Street London WC1B 3HF

MINUTES Item 1

Guys Hospital, 0102
Licence Renewal

Members of the Committee:	In Attendance:
Walter Merricks, Lay Member – Chair	Debra Bloor, Head of Inspection
David Archard, Lay Member	Claudia Lally, Committee Secretary
Sally Cheshire, Lay Member	
Jennifer Hunt, Senior Infertility Counsellor, IVF Hammersmith	Providing Legal Advice to the Committee:
(Present via conference telephone:)	
Neva Haites, Professor of Medical Genetics, University of Aberdeen	Andrew Lidbetter, Herbert Smith, LLP

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

The following papers were considered by the Committee:

- papers for Licence Committee (35 pages)
- no papers were tabled.

1. The papers for this item were presented by Vicki Lamb, HFEA Inspector. Dr Lamb informed the Committee that this centre is part of Guys and St Thomas' Hospitals NHS Foundation Trust and provides licensed treatments to NHS funded and self funded patients. The centre is well established and comparatively few areas for improvement were identified at the renewal inspection. These related to payment of treatment fees to the HFEA, validation of laboratory procedures and equipment, procedures for home sperm procurement and completion of consent forms. Dr Lamb directed the Committee to pages 6 and 7 in the inspection report where the points for improvement are summarised. She further directed the Committee to the Person Responsible's response to the findings of the inspection, at page 21 of the report.

2. The Committee noted the areas of improvement identified in the report and also the response from the Person Responsible. The Committee reminds the

Person Responsible that it expects compliance with standard licence condition A13.3 which states that the Person Responsible agrees to pay HFEA fees within 28 days of the date of notice of the fee.

3. The Committee asked Dr Lamb about the risk assessment the centre was requested to complete in relation to the practice of having different unprocessed sperm samples in the work area at one time. Dr Lamb confirmed that this has now been received.

The Committee's Decision

4. The Committee agreed that it was satisfied as to the suitability of the Person Responsible, the suitability of the centre premises and the use of suitable practices at the centre. The Committee noted that a signed application had been received from the centre but that the licence fee had not been paid. The Committee further agreed that it was satisfied that it had sufficient and satisfactory information on which to make a decision on the licence renewal.

5. The Committee decided to renew the licence for a period of five years, with no additional conditions, subject to payment of the licence fee.

Signed…… … Date……..
Walter Merricks (Chair)