Inspection Report

Date of Inspection: 20-21 March 2012
Purpose of inspection: Interim inspection of treatment (including embryo testing) and storage licence
Length of inspection: 6 hours
Inspectors: Vicki Lamb
Janet Kirkland

Inspection details:
The report covers the pre-inspection analysis, the visit and information received from the centre between 26 January 2010 and 1 June 2012.

Date of Executive Licensing Panel: 15 June 2012

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

Centre details

Centre Name	Guys Hospital
Centre Number	0102
Licence Number	L0102-14-e
Centre Address	Assisted Conception Unit 11th Floor Tower Wing Guy's Hospital St Thomas Street London, SE1 9RT
Person Responsible	Mr Yakoub Khalaf
Licence Holder	Dr John Scoble

Date Licence issued	1 July 2008
Licence expiry date	30 June 2013
Additional conditions applied to this licence	None

Contents

Report to Executive Licensing Panel

Brief description of the centre and its licensing history:

The centre is part of Guys & St Thomas' Hospitals NHS Foundation Trust and provides licensed treatments to NHS funded and private patients from London and the surrounding area. The unit has an active research programme and provides an extensive preimplantation genetic diagnosis (PGD) service. The unit is open 7 days per week and the normal working hours are Monday-Friday: 0830-1630 and between 0900 and 1500 on Saturday and Sunday.

This centre has been licensed to provide treatment since 1992 and the current Person Responsible (PR), Mr Khalaf, has been in post since April 2004 and is appropriately qualified for the role. Mr Khalaf has completed the PR entry programme.

Activities of the Centre:

Type of treatment	Number of treatment cycles for the period 1 March 2011 – 29 February 2012*
In vitro fertilisation (IVF) (including frozen embryo transfers)	554
Intracytoplasmic sperm injection (ICSI) (including frozen embryo transfers)	1345
Gamete intrafallopian transfer (GIFT)	0
Donor insemination (DI)	54
Partner insemination	97**
Egg share provider (sharer)	0
Egg share recipient	0
Egg donation (non-egg share)	17

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

*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.
** For the calendar year 2011

Outcomes*

For IVF/ICSI, HFEA held register data for the period 1 December 2010 to 30 November 2011 show the centre's success rates are in line with national averages with the following exceptions:

- in women aged 16-37 years undergoing ICSI using their own eggs, the clinical pregnancy rate is higher than the national average
- in women aged 16-39 years undergoing FET using IVF or ICSI produced thawed embryos created from their own eggs, the clinical pregnancy rate is higher than the national average

The centre reported 97 cycles of partner insemination with 13 pregnancies in 2011. This equates to a 13% pregnancy rate which is consistent with the national average.

Summary for licensing decision

In considering overall compliance, the inspection team considers that they have sufficient information drawn from documentation submitted by the centre prior to inspection and from observations and interviews conducted during the inspection visit to draw a conclusion on the continuation of the centre's licence.

The Executive Licensing Panel is asked to note that at the time of the inspection there was one other area of practice that required improvement.

The PR has given a commitment to fully implement the following recommendation:

Other areas of practice that require improvement:

- The PR should ensure that invoices are paid within the required timescale.

Recommendation to the Executive Licensing Panel

The inspection team considers that, overall there is sufficient information available to recommend the continuation of this centre's licence without additional conditions. In making this recommendation it is noted that the PR has responded to all recommendations made in this inspection report and further improvement is required in one area of practice.

Details of Inspection findings

1. Focus of inspections for 2010-12

Providing information to patients in relation to costed treatment plans and parenthood
What the centre does well. **Costed treatment plans** Evidence was provided to demonstrate that costed treatment plans are provided to patients (Code of Practice 4.3). **Legal parenthood** There are procedures in place to ensure that women are not provided with treatment services using embryos or donated gametes unless they and their partners have been given appropriate information and have been offered counselling (Standard Licence Condition T60). Legal parenthood issues are included in this information (Standard Licence Condition T61), and discussions with staff demonstrated that staff understand the requirements relating to legal parenthood. In cases where donated gametes, or embryos created from donated gametes, are used in treatment the patient and her partner are given information about the importance of telling a child about its genetic origins and suitable methods for doing this (Standard Licence Condition T63). There is a process in place to deal with situations where consent to legal parenthood is withdrawn by the patient or her partner (Standard Licence Condition T64 and T65). An audit has been performed in the last two years checking that relevant information has been given to patients and their partners in relation to legal parenthood and that appropriate consent has been given (Standard Licence Condition T36).
What they could do better. Nothing noted

Consent - particularly consent to disclosure to researchers and consent to storage

What the centre does well.

Consent to disclosure
Five sets of patient notes were reviewed on inspection and appropriately completed consent to disclosure of identifying information was in place in all cases.

Consent to storage
The laboratory manager confirmed that there is written effective consent for all cryopreserved gametes and embryos in store at the centre. Additionally, it was demonstrated, via review of the centre's database, that all embryos currently in storage have valid consent (HF&E Act 1990 (as amended) Schedule 3, Paragraph 8 (2)).

What they could do better.

Nothing noted

Multiple births

For the 2010/11 time period the centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 18%[1]

The centre's multiple clinical pregnancy rate for 2010/11 represents performance likely to be better than the target rate at a statistically significant level, unlikely to be due to random variation.

What the centre does well.

Ongoing monitoring of the centre's multiple clinical pregnancy rate suggests that the centre is not likely to exceed the 2011/12 multiple birth rate target of 15% (Standard Licence Condition T123).

The PR has provided sufficient evidence to demonstrate compliance with HFEA Directions 0003 in that:

- staff were able to describe their progress towards reducing their multiple pregnancy rates and subsequent multiple birth rates;
- staff at the centre have audited their strategy and protocols as part of the quality management audit programme;
- staff have maintained a log of women receiving double and triple embryo transfers who meet the criteria for single embryo transfer;
- staff have maintained a log which indicates the reasons for variation from the single

[1] A multiple clinical pregnancy rate of 25% is calculated as likely to result in a multiple live birth rate of 20%.

embryo transfer policy and outcomes which are also recorded in the patients records.
What they could do better. Nothing noted

Validation of critical equipment and processes
What the centre does well. All equipment and processes have been validated and a procedure is in place which ensures that new equipment and processes will be validated before being brought into clinical use (Standard Licence Condition T24, T25, T72 and T73). Evidence of validation for one incubator was provided to the inspection team. The validation approach included temperature mapping studies and power failure simulation, and was considered by the inspection team to be comprehensive. Evidence was seen during the inspection which indicated that an audit of validation has been performed in the last two years (Standard Licence Condition T36). The audit has been documented and this included the necessary corrective and preventive actions and their implementation.
What they could do better. Nothing noted

Witnessing
What the centre does well. The centre uses electronic witnessing (Standard Licence Condition T71), with manual witnessing employed for mixing sperm and eggs, injecting sperm into eggs, and moving material into and out of cryostorage (CoP Guidance 18.33). Records of witnessing steps performed for each patient are retained and examples were provided to the inspection team. There is a standard operating procedure (SOP) for performing witnessing which covers all the critical points specified in CoP Guidance 18.4, and this was provided to the inspection team (Standard Licence Condition T33b). Witnessing of the transfer of embryos to the research licences held by centre 0102 is also performed. In a review of five electronic witnessing records on inspection, all records were found to include all required witnessing steps. Evidence of competence assessments for staff performing witnessing was seen on inspection (Standard Licence Condition T15a).

The centre has established quality indicators (QIs) for witnessing (Standard Licence Condition T35). An audit of witnessing procedures has been performed in the last two years and evidence of this was provided to the inspection team. The findings had been documented, with corrective actions recorded and implemented (Standard Licence Condition T36).

What they could do better.

Nothing noted

Gamete and embryo donation – reimbursement, information provision and screening

What the centre does well.

The centre does not directly recruit egg donors. They do however use known egg donors introduced by patients, who are not reimbursed for expenses, and also use an independent organisation that recruits egg donors and deals with the reimbursement.

There is a third party agreement with the organisation that recruits egg donors. The agreement was provided to the inspection team and was seen to contain all the required elements (Standard Licence Condition T111, T113, T114 and T116).

The centre does not directly recruit sperm donors. They purchase donor sperm from licensed sperm banks in the UK and abroad. Donor sperm purchased from centres outside the UK is imported under General Directions 0006. Four sperm imports were reviewed during the inspection and all met the requirements of General Directions 0006.

Three egg donor records and two sperm donor records were reviewed during the inspection and all five showed evidence that appropriate screening had been performed (Standard Licence Condition T52 and T53).

QIs have been set and audits of donor selection, screening and information provision have been performed in the last two years. The findings have been recorded, and corrective actions documented and implemented (Standard Licence Condition T35 and T36). Evidence of this was provided to the inspection team.

What they could do better.

Nothing noted

Embryo testing
What the centre does well. The embryo biopsy procedure is documented in a SOP (Standard Licence Condition T33b). QIs have been established (Standard Licence Condition T35) and audits of biopsy processing have been performed and recorded; no corrective actions were required (Standard Licence Condition T36). The biopsy procedure has been validated, as a well established procedure is used and audits conducted in house have demonstrated good embryo survival (Standard Licence Condition T72). The Laboratory Manager is satisfied that staff are competent to carry out embryo biopsy (Standard Licence Condition T12). This is based on annual assessment of embryologist competence (Standard Licence Condition T15a) and monthly audits of embryo survival after biopsy (Standard Licence Condition T36). A system is in place to ensure that embryo testing is only carried out for those genetic conditions that are authorised by the Authority (Standard Licence Condition T89). The laboratory where testing takes place is accredited by Clinical Pathology Accreditation (UK) Ltd. The certificate to demonstrate this was shown to the inspection team (Standard Licence Condition T21).
What they could do better. Nothing noted

2. Changes / improvements since the previous inspection on 26 January 2010

Area for improvement	Action required	Action taken as evidenced during this inspection
Documentation of staff competence. Competence assessments have not been documented for members of the administration team or for all members of the nursing and laboratory teams **Standard Licence Condition T12:** Personnel in the centre must be available in sufficient number and be qualified and competent for the tasks they perform. The competency of the personnel must be evaluated at appropriate intervals. **Standard Licence Condition T15a:** The training programme must ensure and document that each individual has demonstrated competence in the performance of their designated tasks.	The PR must ensure that all personnel have demonstrated competence in the performance of their designed tasks. Assessments undertaken should be documented in each individual staff member's training records. 26 April 2010	Evidence of this issue being resolved was provided prior to the inspection. No further action required.
Validation of critical processes and equipment. The centre is not yet fully compliant with the requirement to validate critical processing procedures or equipment. **Standard Licence Condition T72:** The critical processing procedures must be validated and must not render the gametes or embryos clinically ineffective or harmful to the recipient.	Critical processes and equipment must be validated in accordance with T72, T24 and T25. By 26 January 2011. The PR should submit to the HFEA a quarterly report on, progress until it is complete.	Regular correspondence from the centre demonstrated that this issue was being addressed and was resolved in summer 2011. Evidence of effective validation of equipment and processes was provided during the inspection. No further action required.

Area for improvement	Action required	Action taken as evidenced during this inspection
This validation may be based on studies performed by the establishment itself, or on data from published studies or from well-established processing procedures, by retrospective evaluation of the clinical results of tissues provided by the establishment. **Standard Licence Condition T24**: All critical equipment and technical devices must be identified and validated, regularly inspected and maintained in accordance with the manufacturer's instructions. **Standard Licence Condition T25**: New, repaired and recommissioned equipment must be tested and validated before use. Test results must be documented.		
Submission of data to the HFEA Of the 124 IVF treatments sampled within the period 01/01/2009- 31/12/2009, 3 were found to be unreported to the Authority. Of the treatment forms sampled for the audit, only 20% were reported within 5 working days. This means that 80% of treatments were reported late (i.e. outside the period stipulated in applicable Directions during the period (D2008/06 para.5 D2007/07 para.4; and Direction 0005 para.3).	The PR must ensure that patient and partner registration forms are submitted to the Authority five days after the patient has confirmed intention to undergo treatment. The PR must also ensure that where errors are identified they are corrected within two calendar months. With immediate effect.	The centre has put measures in place to ensure that forms are submitted to the HFEA within the timescales specified and that errors are corrected within two calendar months. The mechanisms for doing this were discussed during the inspection. No further action required.

Area for improvement	Action required	Action taken as evidenced during this inspection
General Direction 0005: All licensed centres must ensure that EDI forms submitted to the Authority are completed according to the guidance issued by the Authority (the most recent versions of which are available, alongside the forms, on the HFEA website). Where an error is identified, centres must correct the error within 2 calendar months. **Correcting error reports.** In the period 01/11/08 to 04/11/09 6907 EDI forms had been submitted to the HFEA and within these were 448 errors. These errors had not been cleared on the 4 January 2010.		
Audit of activities At inspection it was noted that audits have not yet been conducted in the following areas of practice: selection and recruitment of donors, submission of data to the HFEA and confidentiality and privacy. **Standard Licence Condition T36:** Trained and competent persons must audit the activities authorised by this licence, and other activities carried out in the course of providing treatment services that do not require a licence, against compliance with the approved protocols, the regulatory requirements and	The PR must ensure that licensed activities and other activities related to unlicensed treatment services are audited at least every two years. As identified on this inspection, the PR should ensure that this programme of audits includes: > Selection and recruitment of donors. > Submission of data to the HFEA. > Confidentiality and privacy. 26 April 2010.	A programme of audits was submitted to the inspector and documented audits of activities were reviewed during this inspection. No further action required

Area for improvement	Action required	Action taken as evidenced during this inspection
quality indicators. These audits must be performed in an independent way, at least every two years. Findings and corrective actions must be documented.		
Establishing Quality Indicators Quality indicators have not yet been set for the following areas of practice: storage of gametes/embryos and confidentiality and privacy **Standard Licence Condition T35:** Required standards of quality and safety, in the form of quality indicators for all activities authorised by this licence and other activities carried out in the course of providing treatment services that do not require a licence, must be established.	Quality indicators must be established for all licensed activities, including the storage of gametes and embryos and confidentiality and privacy, and other activities carried out in the course of providing treatment services that do not require a licence. 26 April 2010.	A list of quality indicators was submitted to the inspector and quality indicators were reviewed during this inspection. No further action required
Payment of Treatment Fees The centre took an average of 36 days to pay its invoices in 2009 **Standard Licence Condition T9d:** Ensure fees are paid to the Authority within the timescales specified in Directions or in writing	The PR should ensure that HFEA fees are paid in accordance with invoice requirements Immediately	The centre has reduced the number of days taken to pay invoices. In 2011 they took an average of 30 days to pay. There is an action plan in place to reduce this time to 28 days and this action plan was discussed during the inspection. Further action required.

3. Areas of concern

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

Area of concern	Inspection findings	Assessment of whether the findings meet the requirement or whether any further action is required
SAQ – Guidance Note 2 Is your centre operating with a full staff complement?	The PR explained that he was satisfied with staffing levels at present. None of the staff interviewed expressed concern over staffing levels.	No further action required

Areas of practice that require the attention of the Person Responsible

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

Critical area of non compliance

A critical are of non compliance is an area of practice which poses a significant direct risk of causing harm to a patient, donor, embryo or to a child who may be born as a result of treatment services. A critical area of non-compliance requires immediate action to be taken by the Person Responsible.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
None			

Major area of non compliance

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

- which poses an indirect risk to the safety of a patient, donor, embryo or to a child who may be born as a result of treatment services
- which indicates a major shortcoming from the statutory requirements;
- which indicates a failure of the Person Responsible to carry out his/her legal duties
- a combination of several "other" areas of non-compliance, none of which on their own may be major but which together may represent a major area of non compliance.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
None			

Other areas of practice that require improvement

Other areas of practice that require improvement is any area of practice which cannot be classified as either a critical or major area of non compliance, but which indicates a departure from statutory requirements or good practice.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
In 2011 the centre took an average of 30 days to pay invoices, which is in excess of the timescale of 28 days set out in CH(10)02 (Standard Licence Condition T9d). This was an issue at the last inspection.	The PR should ensure that invoices are paid within the required timescale. Immediately	The centre is trying all it can to ensure that HFEA invoices are paid within the required timescale. It should be noted, however, that the centre is only 2 days off the target 28 days timescale.	The Executive considers that this is an appropriate response.

Additional information from the Person Responsible
I am generally very pleased with the report which reflects the hard work of the team in ensuring full compliance in all but one aspect of the areas that were covered by the inspection.

HFEA Executive Licensing Panel Meeting

15 June 2012

Finsbury Tower, 103-105 Bunhill Row, London, EC1Y 8HF

Minutes – Item 4

Centre 0102 – (Guy's Hospital) – Interim Inspection Report

Members of the Panel:	Committee Secretary:
Juliet Tizzard, Head of Policy & Communications (Chair) Rachel Hopkins, Head of Human Resources Hannah Darby, Senior Policy Manager	Joanne McAlpine

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

The Panel also had before it:

- HFEA Protocol for the Conduct of Meetings of Executive Licensing Panel
- 8th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- Decision trees for granting and renewing licences and considering requests to vary a licence (including the PGD decision tree)
- Guidance for members of Authority and Committees on the handling of conflicts of interest approved by the Authority on 21 January 2009.
- Guidance on periods for which new or renewed licences should be granted
- Standing Orders and Instrument of Delegation
- Indicative Sanctions Guidance
- HFEA Direction 0008 (where relevant), and any other relevant Directions issued by the Authority
- Guide to Licensing
- Compliance and Enforcement Policy
- Policy on Publication of Authority and Committee Papers

Consideration of Application

1. The Panel noted that this centre has been licensed since 1992 and offers a range of treatments, including in vitro fertilisation (IVF), intra cytoplasmic sperm injection (ICSI), gamete intafallopian transfer (GIFT), donor insemination (DI), partner insemination and egg donation, to NHS and privately funded patients.

2. The Panel noted that the centre carried out 554 IVF and 1345 ICSI cycles between 1 March 2011 and 29 February 2012 and that, based on the latest Register data available, the centre's success rates are in line with the national average (with two exceptions where the centre's success rates are higher than the national average).

3. The Panel noted that at the time the inspection took place the Inspectorate identified one other area of practice that required improvement, in relation to the payment of invoices during the required timescale.

4. The Panel noted that the Inspectorate recommend the continuation of the centre's licence with no conditions.

5. The Panel noted that the Person Responsible (PR) has been in post since 2004 and is appropriately qualified for the role, and has completed the PR Entry Programme.

6. The Panel noted the PR's response to all recommendations in the report and were encouraged that the centre has been proactive in implementing all of them.

7. The Panel noted that the centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 18% for the period 2010/11. The Panel noted that the monitoring of the centre's multiple clinical pregnancy rate suggests that the centre is not likely to exceed the 2011/12 multiple birth rate target of 15%.

8. The Panel was encouraged by the centre's low multiple pregnancy rate, achieved whilst having success rates within the national average and commended the PR for the centre's performance in this area.

9. The Panel noted that the Inspectorate recommended the continuation of the centre's licence without additional conditions.

Decision

10. The Panel endorsed the Inspectorate's recommendation to continue the centre's licence, with no additional conditions.

Signed: Date: 25 June 2012
Juliet Tizzard (Chair)