Interim Licensing Report

Centre name: Homerton Fertility Centre
Centre number: 0153
Date licence issued: 01/09/2010
Licence expiry date: 31/08/2014
Additional conditions applied to this licence: None
Date of inspection: 31/10/2012
Inspectors: Sara Parlett (Lead), Janet Kirkland and Dr Douglas Gray (Observer)
Date of Executive Licensing Panel: 11 January 2013

Purpose of the report

The Human Fertilisation and Embryology Authority (HFEA) is the UK's independent regulator of the fertility sector. The HFEA licenses centres providing in vitro fertilisation (IVF) and other fertility treatments and those carrying out human embryo research.

Licensed centres usually receive a licence to operate for up to four years and must, by law, be inspected every two years. The full inspection prior to a licence being granted or renewed assesses a centre's compliance with the law and the HFEA's Code of Practice (CoP) and Standard Licence Conditions (SLCs).

This is a report of an interim inspection together with our assessment of the centre's performance based on other information. We do this at the mid-point of the licence period. For 2012-14 the focus of an interim inspection is:

- **Quality of service**: the quality of service provided by a centre, including its success rates and performance in reducing multiple births – the biggest single risk of IVF.
- **Patient experience**: it is considered crucial that the experiences of service users feed into any evaluation of a centre's performance.

We also take into account the centre's own assessment of its service; the progress made in implementing the actions identified at the last inspection; and our on-going monitoring of the centre's performance.

The report represents a mid-term evaluation of a centre's performance based on the above. The aim is to provide the Authority's Executive Licensing Panel with information on which to make a decision about the continuation of the licence.

Summary for the Executive Licensing Panel

This report has enabled the inspection team to form a conclusion on the continuation of the centre's licence. The inspection team recommends the continuation of the centre's licence.

The team has made recommendations for improvement and these should be implemented within the times specified in the report.

The Executive Licensing Panel is asked to note that there are recommendations for improvement in relation to one critical, one major and four 'other' areas of non-compliance. Since the inspection, the Person Responsible (PR) has given a commitment to fully implement all of the following recommendations:

Critical areas of non compliance:

- **The PR must ensure that no gametes or embryos are kept in storage for longer than the consented period.**

Major areas of practice that require improvement:

- The PR should ensure that the data provided to the HFEA regarding patient consent to the disclosure of identifying information to researchers is accurate.

'Other' areas of practice that require improvement:

- The PR should seek the advice of local health and safety experts on the practice of using open centrifuge buckets for the centrifugation of sperm samples.
- The PR should review and revise the patient information leaflet regarding the use of gametes and embryos in staff training, to ensure that it only describes purposes that have been expressly authorised by the HFEA.
- The PR must ensure that licensed treatment data that the HFEA is required to hold on its register is submitted within the timeframes specified.

The PR has not given a specific commitment to fully implement the following recommendation:

'Other' areas of practice that require improvement:

- The PR must ensure that all notes made in patients' records are legible.

The PR has been asked to inform the centre's inspector of the action that will be taken in response to this area of practice.

Information about the centre

The Homerton Fertility Centre is located in London and has held a licence with the HFEA since 1995.

The centre provides a full range of fertility services.

The centre provided 1127 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 30 September 2012. In relation to activity levels this is a large centre.

Details of Inspection findings

Quality of Service

Each interim inspection focuses on the following themes: they are very important indicators of a centre's ability to provide high quality patient care and to meet the requirements of the law.

Outcomes[1]

HFEA held register data for the year ending June 2012 show the centre's success rates in terms of clinical pregnancy rates are in line with national averages.

For the year 2011, the centre reported 348 cycles of partner intrauterine insemination with 37 pregnancies. This equates to an 11% clinical pregnancy rate and is consistent with the national average.

Multiple births[2]

The single biggest risk of fertility treatment is a multiple pregnancy.

In 2010/11 the centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 24%. This represented performance that was not likely to be statistically different from the 20% live birth rate target.

For the time period April 2011 to July 2012 the centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 25%. This also represents performance that is not likely to be statistically different from the 15% live birth rate target.

While it is acknowledged that the centre's clinical multiple pregnancy rate indicates performance not likely to be different from the relevant targets, the effectiveness of the centre's current strategy was discussed on inspection in consideration of the 10% live birth rate target that became effective on 1 October 2012. The PR confirmed that the centre's strategy had been revised in May 2012 and that the effectiveness of the changes would be audited in January 2013. Examples of further changes to the strategy that were being

[1] 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.
[2] The HFEA use a conversion factor of 1.27 to convert the multiple live birth rate (MLBR) target to a multiple clinical pregnancy rate (MCPR) target. The 2010/11 MLBR target of 20% is calculated as equivalent to a MCPR of 25%: the 2011/12 MLBR target of 15% is calculated as equivalent to a 19% MCPR.

considered were also given by the PR. It is suggested that the centre continues to closely monitor the effectiveness of their multiple birth minimisation strategy.

Witnessing

Good witnessing processes are vital in ensuring there are no mismatches of gametes or embryos and that identification errors do not occur. The following laboratory activities were observed in the course of the inspection: sperm preparation, transfer from tubes to dishes at egg collection and preparation for embryo transfer. The centre has installed an electronic witnessing system which is currently being used in parallel with their standard manual system whilst the system is being validated. All of the procedures observed were witnessed in accordance with HFEA requirements using the electronic and manual systems.

The inspection team was able to review records that were present in ten sets of patient notes and concluded that records of witnessing are accurately maintained.

Consent: Disclosure to researchers

A patient providing informed consent is one of the most important principles in healthcare. Since 1 October 2009, the HFEA has been able to release patient-identifying information held by the HFEA to researchers if patients give their permission. Patients are asked to give their consent to the disclosure of this information and this is recorded in their records and the HFEA is notified of their decision through the electronic data interface (EDI) system. It is important that the reporting through EDI is accurate so that patient information is not disclosed without consent.

The records of consent to disclosure to researchers given by ten patients were reviewed in the course of the inspection. The consents were not reported to the HFEA accurately in four instances in the patient records reviewed. In three instances where errors were found, the patients had consented to disclosure but the EDI entry recorded that they had not consented to disclosure. In one instance, the patient had not consented to disclosure but the EDI entry recorded that they had consented to disclosure (see recommendation 2).

Consent: To the storage of cryopreserved material

A review of the centre's records of consent to storage of gametes and embryos showed that all gametes and embryos currently in store are being stored in accordance with the consent of the gamete providers and are within the consented storage period with the following exceptions (see recommendation 1):

- Two sets of embryos are in storage past the consented storage period. In both cases, the gamete providers consented to five years storage in 2006/7. This was the statutory storage period at the time. In both cases the couples have since separated and one partner has consented to extending the storage period to the new statutory storage period of 10 years but the partner has not. The centre has invoked the cooling off procedure inappropriately in both of these cases. The cooling off period can be applied only when consent to storage has been withdrawn by one of the gamete providers, not when consent to extend the original storage period has not been given by one of the gamete providers.
- One set of sperm samples are in storage past the consented storage period. Samples were originally frozen in August 2002 and the gamete provider consented to storage for a period of 10 years. In 2008, further sperm samples from the gamete

provider were frozen and new consent to store these samples for 10 years was obtained. Centre staff considered incorrectly that this more recent consent extended the storage period of the first set of samples in storage.

The centre's bring forward system ensures sufficient advance notice is given to patients at the end of the consented storage period. It was demonstrated on inspection and was considered to be robust and comprehensive.

The storage periods recorded on the centre's database for three sets of embryos were cross checked against the consenting decisions made by the gamete providers. The storage period had been accurately recorded in all cases.

Staffing

Having the right numbers of staff, competent to carry out highly technical work in a non-pressured environment is important in infertility services.

Centre activity has increased by over 30% since 2009 and staffing levels have been increased in response to this. The PR confirmed that workforce assessments are performed regularly and that staffing levels are currently satisfactory. However, the centre is currently reviewing procedures with the aim of improving efficiency. For example, egg collections are currently performed only three days a week and workload may be managed more effectively with a five day egg collection list. It is suggested that the PR continues to closely monitor activity level versus staff complement.

Staffing levels observed in the course of the on-site inspection appeared to be suitable for the activities being carried out: patients were seen promptly on arrival; the atmosphere in the clinic appeared calm at all times; staff in the laboratory were able to carry out their activities without distraction and were available to carry out witnessing activities when required.

Patient experience

During the inspection visit we observed interactions between centre staff and patients during three information giving sessions.

On the basis of these observations, it was possible to assess that the centre:

- has respect for the privacy and confidentiality of patients in the clinic;
- gives prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions. The inspection team observed information sessions for patients whose first language is not English. It was considered that these were managed effectively;
- maintains an effective system for responding to patient phone calls.

A further 27 patients also provided feedback directly to the HFEA in the time since the last inspection. Feedback was mixed with 19 patients providing written feedback to the HFEA commenting that they have compliments and 12 commenting that they have complaints about the care that they received.

Trends in negative comments received concerned:

- on arrival at the centre for a specific appointment time, patients commented on having to wait for an unsatisfactory length of time before being seen;
- poor provision of information.

These negative patient comments were discussed with centre staff on inspection. Feedback from patients is gathered by centre staff and the last survey was performed in 2011. Centre staff confirmed that the next survey is due in December 2012. It is suggested that the centre considers including in this survey the two common areas of dissatisfaction identified in patient feedback to the HFEA.

Monitoring of the centre's performance

In addition to commenting on evidence gathered on the inspection it is important to report on the centre's performance since the granting of the licence based on other evidence available to us.

Compliance with HFEA standard licence conditions

From the information submitted by the centre in their self assessment questionnaire and from observations during the visit to the centre, the inspection team identified the following non-compliances:

- Where multiple embryos have been transferred to a patient who meets the centre's criteria for a single embryo transfer, the centre does make a note in the patient's records confirming that the risks associated with multiple pregnancy have been fully discussed with the patient. However, the inspection team did not consider the writing to be appropriately legible in one set of patient records reviewed (see recommendation 3).
- Centrifugation of sperm samples is carried out in open centrifugation buckets. This could potentially be hazardous to laboratory staff (see recommendation 4).
- The centre's patient information leaflet regarding the use of gametes and embryos for the purposes of training staff states that one of the purposes would be to inject sperm into eggs. Creating embryos during training is prohibited and therefore injecting sperm into eggs is not an activity that has been authorised by the HFEA for staff training

purposes. The PR has provided assurance that eggs have not been used for this training purpose at the centre (see recommendation 5).

Compliance with recommendations made at the last inspection

Recommendations were made at the renewal inspection in 2010 in relation to one area of critical non-compliance and five areas of major non-compliance.

The PR provided information and evidence that all but one of the recommendations were fully implemented. The one outstanding recommendation regarding Clinical Pathology Accreditation (UK) Ltd (CPA) accreditation was discussed at this inspection.

The centre performs diagnostic semen analysis. Centre staff explained that they have applied for CPA accreditation and they are waiting to be given an inspection date. Evidence was provided demonstrating the significant amount of work that has been undertaken to meet CPA requirements. In the course of the inspection it was noted that the centre has a quality management system; has validated procedures and equipment; staff suitably qualified to perform and interpret the tests; and participates in the national external quality assessment scheme (NEQAS) for semen analysis. In consideration of this, the centre's semen analysis service is considered to have a status equivalent to that provided by CPA accreditation. In terms of HFEA requirements, no further action is required by the centre in relation to CPA accreditation.

On-going monitoring of centre success rates

The centre has had three performance alerts issued by the HFEA Risk Tool in 2012. The centre has responded to these alerts to the satisfaction of the inspector.

Provision of information to the HFEA

Clinics are required by law to provide information to the HFEA about all licensed fertility treatments they carry out.

This centre has a satisfactory record of data submission and of compliance with related regulatory requirements. Nevertheless, at the time of writing there are a small number of donor issues that need to be addressed as they potentially impact upon the ability of the Authority to meet statutory obligations to donors and the donor conceived.

In addition, submission of a number (40+) of intention to treat forms and (20+) outcome forms is outstanding; the latter potentially impacts upon the HFEA's ability to monitor success rates and multiple births (see recommendation 6).

Annex 1

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 required are given, as well as the timescales in which these improvements should be carried out.

Critical area of non compliance

A critical area of non compliance is an area of practice which poses a significant risk of causing harm to a patient, donor, embryo or 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	Inspection team's response to the PR's statement
1. The centre does not have written effective consent for two sets of embryos in storage. The cooling off period has been applied inappropriately in these cases. HF&E Act 1990 (as amended), Schedule 3, 8 (2). One set of sperm samples is being stored after the consent for storage has expired. HF&E Act 1990 (as amended) Schedule 3, 8 (1).	The PR must ensure that sperm and embryo samples are stored within the terms of the gamete provider's consent and within the statutory storage period. The PR must take appropriate action regarding the continued storage of the two sets of embryos and one set of sperm samples. The PR should inform the inspector of the action to be taken (including timeframes) by the time the PR responds to this report.	Both sets of embryos and one set of sperm samples were discarded and the patients were informed accordingly. The SOP will be amended so that the staff are very clear about the cooling off period. It will emphasise that the cooling off period does not apply to embryos where the consent has expired (even within the statutory storage period). All laboratory staff will be trained accordingly.	The inspection team acknowledges the PR's response and will continue to monitor progress in implementing the full recommendation.

	The PR should review staff understanding of consent to storage in general and the application of the cooling off period and of the requirements of the HF&E (statutory storage period for embryos and gametes) Regulations 2009 with respect to extending storage past the statutory period in particular. Training should be provided as required. Confirmation that this training has been provided should be given to the inspector by 31 January 2013. The centre's standard operating procedure for consent to storage should be reviewed and revised as appropriate and submitted to the inspector by 31 January 2013.		

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 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	Inspection team's response to the PR's statement
2. In four cases the records of consent to disclosure to researchers had been incorrectly reported to the HFEA. General Direction 0005.	The errors identified during the inspection should be corrected immediately. The centre should review its related systems and processes by which these consenting decisions are communicated to the HFEA. Where appropriate, the cause(s) of these discrepancies should be addressed. Three months after the inspection, the PR should audit a random sample of ten sets of patient records to ensure that consent to disclosure to researchers taken from	We have decided to conduct a training session for the doctors and the nurses regarding counselling patients about the consent to disclosure, the recording of data and communicating this data to the HFEA. We plan to conduct this in early January 2013. We will also be auditing this data in the middle of February where 10 patients records, the information supplied to the HFEA will be audited and this audit will be given to the HFEA.	The inspection team acknowledges the PR's response and will continue to monitor progress in implementing the recommendation.

	patients has been correctly communicated for entry on to the HFEA register. The records audited should have had this consent completed within the previous three months. This audit should be submitted to the HFEA by 28 February 2013. The HFEA may require the centre to perform an audit of individual consent records against the consent decision held by the HFEA in the future if an application is made by researchers for the release of that information.		

Other areas of practice that requires improvement

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

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team's response to the PR's statement
3. In one set of relevant patient records reviewed, the centre had not recorded legible notes confirming that the risks associated with multiple pregnancy had been fully discussed with the patient. General Direction 0003, SLC T38 and T47.	The PR must ensure that, prospectively, all notes made in patients' records are legible. This recommendation should be implemented immediately.	All the doctors have been explained that as per protocol, we will document risks of multiple pregnancy before starting treatment. This will also be documented in the embryo transfer sheet and explained to the patient. The embryo transfer sheet has been changed to reflect the advice given	The inspection team acknowledges the PR's response. However, the PR is reminded that the specific action required is to ensure that all notes made in patients' records are legible. The PR is asked to inform the centre's inspector of the action that will be taken in response to this area of practice.
4. Centrifugation of sperm samples is carried out in open centrifuge buckets. CoP Guidance 25.14.	The PR should seek the advice of local health and safety experts on the practice of using open centrifuge buckets for the centrifugation of sperm samples. A copy of the advice and a summary report on the implementation of any suggested corrective actions	The lids for the centrifuge buckets will be purchased and the SOPs will be changed so that all the buckets will have lids on during operation.	The inspection team acknowledges the PR's response. The PR is asked to inform the centre's inspector when the centrifuge buckets are in use.

	provided should be submitted to the inspector by 31 January 2013.		
5. The centre's patient information leaflet regarding the use of gametes and embryos for the purposes of training staff states that one of the purposes would be to inject sperm into eggs. This is not an activity that has been authorised by the HFEA for staff training purposes. The PR has provided assurance that eggs used in staff training have not been used for this purpose at the centre. SLC T93.	The PR should review and revise the patient information leaflet regarding the use of gametes and embryos for the purposes of staff training to ensure that it only describes purposes that have been expressly authorised by the Authority. A copy of the revised patient information should be submitted to the inspector by 31 January 2013.	The patient information leaflet has already been amended in the Q-Pulse (our quality management system) I can confirm that we have not injected any sperm into eggs for training. This has been changed in the protocol.	The inspection team acknowledges the PR's response. The PR is asked to submit a copy of this revised patient information leaflet to the centre's inspector.
6. A number of intention to treat and early pregnancy outcome forms have not been submitted to the HFEA within the timescales required.	The PR must ensure that any remaining outstanding forms are submitted immediately and that, in future, licensed treatment data is submitted within the required timescales.	The operational manager is reviewing any outstanding forms and arranging for the submission if any of these have been missed. The procedure has got better and we are planning to appoint an	The inspection team acknowledges the PR's response and will continue to monitor progress in implementing the recommendation.

General Direction 0005.	The process for submitting licensed treatment data to the HFEA should be reviewed and enhanced to ensure compliance. The review should include an evaluation of resources to ensure staff are available in sufficient numbers to perform this activity. Confirmation that the review has been completed and details of any action taken should be submitted to the inspector by 31 January 2013.	administrative person to support the team in completing the data on time and transmitted to the HFEA we have also bought a new version of the IDEAS which will inform us of any entries which come back as incomplete and are listed as tasks A review will be done in the 3rd week of January specifying the process, the responsible individuals and the cover for these activities when on leave This entire review will be sent to the HFEA before the 31st of January	

Additional information from the Person Responsible
We have also been reveiwing the number of staff and the the proposal has been sent to the senior trust and we are awaiting their decision

HFEA Executive Licensing Panel Meeting

25 January 2013

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

Minutes – Item 1

Centre 0153 – (Homerton Fertility Centre) – Interim Inspection Report

Members of the Panel:	Committee Secretary:
Juliet Tizzard, Head of Policy & Communications (Chair) Ian Peacock, Analyst Programmer Matthew Watts, Regulatory 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 by the HFEA since 1995, and provides a full range of fertility services.

2. The Panel noted that the centre's current licence is due to expire on 31 August 2014.

3. The Panel noted that in the 12 months to September 2012 the centre provided 1127 cycles of treatment (excluding partner intrauterine insemination) and in relation to activity levels this is a large centre.

4. The Panel noted that the centre was inspected in October 2012, and at the time of the inspection the Inspectorate identified one critical, one major and four other areas of non-compliance.

5. The Panel noted that since the inspection the Person Responsible (PR) had given a commitment to implement all areas of non-compliance that were identified on the inspection.

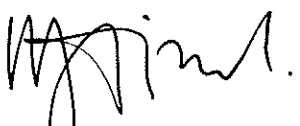
6. The Panel noted the centre's multiple clinical pregnancy rate of 25% for all IVF, ICSI, and FET cycles for the period 2011-2012. The Panel urged the PR to work closely with the Inspectorate to reduce this rate in order to meet the 10% target now in force.

7. The Panel noted that the centre did not have written effective consent for two sets of embryos that are in storage. The Panel note the PR's response and the misinterpretation of the law regarding the 'cooling off' period, but urged the PR to ensure that staff are trained and procedures are reviewed in relation to this requirement.

8. The Panel note the Inspectorate's recommendation to continue the centre's licence with no additional conditions.

Decision

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

Signed:  Date: 18 February 2013

Juliet Tizzard (Chair)