Interim Licensing Report

Centre name: The London Sperm Bank
Centre number: 0011
Date licence issued: 01 April 2011
Licence expiry date: 31 March 2015
Additional conditions applied to this licence: None
Date of inspection: 29 January 2013
Inspectors: Susan Jolliffe (Lead), Andrew Leonard
Date of Executive Licensing Panel: 05 July 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 (SLC's).

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 (ELP) 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. In particular we note the improvement to the centre's facilities following the change of premises in December 2012.

The team has made recommendations for improvement and these should be implemented within the time limits specified.

The ELP is asked to note that at the time of the inspection there were a number of areas of practice that required improvement, including one critical area of non-compliance, one major areas of non-compliance and six 'other' areas of non-compliance or poor practice.

Since the inspection the PR has provided evidence that the following recommendations have been fully implemented:

'Critical' areas of non compliance:

- **The Person Responsible (PR) should review the witnessing checks carried out during sperm procurement and processing and ensure they are compliant with HFEA CoP requirements and prevent any possibility of identification error.**

'Major' areas of non compliance:

- The PR must ensure that all stored sperm samples are audited against the storage consent forms to confirm they are all stored with effective consent.

'Other' areas of non compliance:

- The PR should develop and document a recall procedure that defines the responsibilities and all actions required when a gamete distribution is recalled.
- The PR should develop a third party agreement (TPA) with the establishment providing procurement facilities, to ensure that the practices are compliant with HFEA CoP requirements.
- The PR should ensure that a bring forward system is established to allow regular monitoring of the storage consent expiry dates of all stored samples.
- The PR should ensure that the time of the witnessed check of donor identification is recorded on the laboratory record sheet.
- The PR must ensure that sperm processing activities are undertaken in a laboratory with background air quality of at least Grade D.

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

'Other' areas of non compliance:

- The PR should ensure that where the gamete donors provide consent to disclosure of their identifying information to researchers, the centre should complete Part 4 of the HFEA CD consent form.

Information about the centre

The London Sperm Bank (LSB) has held a licence with the HFEA since April 2010 for the procurement, distribution, processing and storage of sperm; the centre actively recruits sperm donors and provides donated sperm to fertility clinics across the United Kingdom. The centre was formerly known as the Louis Hughes centre, which was originally licensed in 1992.

Following the last inspection on 23 November 2010 the centre has undergone a number of significant changes:

- A change of ownership; the LSB has joined the JD Healthcare group.
- New staff have been appointed and a new organisational structure developed.
- The centre changed premises in December 2012 from 99 to 112 Harley Street.

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]

This centre provides no treatment so no success rate data is available.

Multiple births

This centre provides no treatments.

Witnessing

Good witnessing processes are vital in ensuring there are no mismatches of gametes and that identification errors do not occur. During the course of the inspection, witnessing processes were discussed with staff and witnessing during sperm processing and placement into storage was observed in the laboratory. Ten sets of gamete donor records were also reviewed. The inspection team concluded that the centre has a manual witnessing scheme in place and records of manual witnessing checks are documented.

Review of the evidence led to recommendations being made to address three non-compliances: Identifiers on sperm samples and tubes were not witnessed at the beginning of the cryostorage preparation process, nor are such checks carried out if samples need to be centrifuged (recommendation 1); When a sperm donor attends the centre, staff did not cross-check identifying information provided by the donor against the donor records (recommendation 1); The time of the witnessed check of donor identification at sperm procurement was not recorded (recommendation 6).

Consent: Disclosure to researchers

A patient providing informed consent is one of the most important principles in healthcare.

[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.

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 through the electronic data interface (EDI) system.

From 1 August 2012 gamete donors can also provide consent to disclosure of their identifying information to researchers, and the centre should be aware that Part 4 of the HFEA CD consent form should be completed by all donors (recommendation 8)..

Consent: To the storage of cryopreserved material

A review of the centre's storage records showed that the centre could not reliably confirm that all sperm samples in store on the day of inspection were within their consented storage period. This is because the storage records do not state the consent expiry date and an effective bring-forward system is not in operation.

To check storage consents were effective would have required the review of storage consent forms for each donor with samples in store. Such an audit of storage consents against the stored sperm samples has not been performed in the last two years (recommendation 2).

The inspection team consider this non-compliance low risk, because the centre does not keep sperm samples in storage for long periods of time since it is a donor sperm supplying centre. The inspection team considers however this situation needs to be addressed because some samples are consented for storage for less than 10 years and the consequences of storage beyond the consented time are significant, i.e. a breach of HF&E Act 1990 (as amended) Schedule 3, 8 (1).

A bring-forward system would allow regular monitoring of the consent expiry dates and prevent the storage of sperm without effective consent (recommendation 5).

Staffing

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

Staffing levels observed in the course of the on-site inspection appeared to be suitable for the activities being carried out: gamete donors were seen promptly on arrival and the atmosphere in the centre 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 the team were able to look around the premises and noted the attention to privacy for gamete donors, the production rooms had internal door locks and a system to ensure discretion was maintained at all times. There is a comfortable waiting area and a separate room where conversations can be held in private.

The team were only able to talk with one gamete donor on the day of the inspection, the feedback was therefore considered together with eight satisfaction survey reports (provided by the centre) which revealed a high level of satisfaction with the premises, the staff, and

the communication provided by the centre. There has been no direct feedback to the HFEA from donors at this centre in the last two years.

On the basis of this feedback and observations made in the course of the inspection it was possible to assess that the centre:

- has respect for the privacy and confidentiality of gamete donors in the clinic;
- gives their donors accessible and up-to-date information to enable them to make informed decisions;

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 two non-compliances (recommendations 3, and 4).

- A recall procedure is not in place for the recall of distributed gametes.
- A third party agreement is required with the establishment providing the premises for the procurement facilities.

Compliance with recommendations made at the last inspection

Following the renewal inspection in November 2010, recommendations for improvement were made in relation to two areas of 'major' non-compliance and one 'other' area of non-compliance. The PR provided information and evidence that all but one recommendation had been fully implemented within the prescribed timescales. The following non-compliance was not corrected:

- The laboratory background air quality is not Grade D.

In responding to the report immediately after the inspection in 2010, the PR agreed to implement the recommendations and measures were explored at that time to address the background air quality. The centre then relocated to the current premises in December 2012, where the PR has completed daily monitoring of the air quality in the laboratory.

Following the approval of the variation to change the location of the licensed premises, the centre was asked to provide evidence that the air quality was compliant. Evidence was provided which showed air of Grade C or better in the critical work area, but that the laboratory background air was not consistently achieving the required quality of Grade D. Given the compliance of air in the critical work area and that the background air quality was never substantially less than the required Grade D, the Executive approved the centre commencing activity with the proviso that remedial actions are taken to improve the background air quality.

Further review of air quality testing data during this inspection confirmed that the background air quality in the new laboratory does achieve Grade D or better, but this is not consistent (recommendation 7).

Discussions with staff at the inspection showed that the centre is implementing actions to address this issue. The inspection team also notes that gamete processing occurs within an air flow cabinet in grade C air quality or better, which will minimise any impact of the deficient background air on gamete quality and safety.

On-going monitoring of centre success rates

This sperm donor recruitment centre is not subject to on-going monitoring through the HFEA risk tool and has not therefore been issued with any performance alerts in the last six months.

Provision of information to the HFEA

Clinics are required by law to provide information to the HFEA about all the licensed fertility treatments they carry out. The HFEA Register team report that the centre provides information in a timely and accurate manner.

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, SLCs, Directions or the CoP, 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 PR.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team’s response to the PR’s statement
1. Identifiers on sperm samples and tubes were not witnessed at the beginning of the cryostorage preparation process, nor are witness checks carried out if samples need to be centrifuged (SLC T71. Staff also did not cross-check identifying information provided by the donor against the donor records when the donors attend the centre to provide sperm (CoP Guidance 5.11).	The PR should review the identification checks of samples and donors carried out during sperm procurement and processing and ensure they are compliant with HFEA CoP requirements, and prevent any possibility of identification error. The corrective actions taken and the revised witnessing SOP should be provided to the HFEA by 28 April 2013	The witnessed donor identification check at the start of procurement now includes verification of the donors identity against the donors photograph held at the reception desk. (See attached Recruitment Manual SOP) Sperm samples are witnessed by two members of staff when they enter the critical work area and when transferring tube-tube where centrifugation is required. (See attached "Quarantine donor sample record" worksheet	Corrective action has been taken, and the amended SOP and worksheet have been submitted to the executive. The effectiveness of these changes must be monitored by the centre through their audit process. No further action required.

‘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 PR 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. The centre could not reliably confirm that all sperm samples in store on the day of inspection were within their consented storage period and has not audited records of storage consent against the stored sperm samples in the last two years (SLC T36; CoP Guidance 17.18).	The PR should ensure that all stored sperm samples are audited against their storage consent forms, to confirm effective consent for storage is in place for all samples. This audit should be completed by the 28 April 2013 and a summary report provided to the HFEA by the 28 July 2013.	An audit of consent forms and storage periods will be completed by the 28th of April 2013 and reported to the HFEA by the 28th of July 2013. The 'Quarantine Donor sample record' includes a section recording i) date of CD and MD forms ii) period of sperm/embryo storage consent & iii) date of end of storage.	The centre has submitted a 'Quarantine Donor sample record' to the lead inspector, showing the fields required to collect the data. The centre has assured the executive that it will complete the audit by April as agreed, and the outcome of the audit and any corrective actions will be shared with the lead inspector. Audit completed and shared with the HFEA. No further action required.

‘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. The centre does not have a recall procedure that defines the responsibilities and actions required when a gamete distribution needs to be recalled (SLC T122)	The PR should develop and document a recall procedure that defines the responsibilities and all actions required when a gamete distribution is recalled. The recall procedure should be supplied to the HFEA by 28 April 2013.	Completed and submitted.	A copy of the laboratory manual including a recall procedure was submitted on 1 February 2013. No further action is required.
4. Sperm processing and storage are carried out on the licensed premises, but sperm is actually procured from donors in an unlicensed building across the road from the licensed premises (SLC T1). When a sample is ready, a member of the laboratory team collects the sample and takes it to the laboratory. The procurement facilities are	The PR should develop a TPA with the establishment providing procurement facilities, to ensure that the practices are compliant with HFEA CoP requirements. The TPA should be provided to the HFEA by 28 April 2013.	Completed and submitted.	A compliant TPA was submitted on 11 February 2013. No further action is required.

considered as a third party to the licensed centre but no TPA has been established (SLC T111).			
5. The centre could not reliably confirm that all sperm samples in store on the day of inspection were within their consented storage period, in part because an effective bring-forward system is not in operation (CoP Guidance 17.18).	The PR should ensure that a bring forward system is established, to allow regular monitoring of the storage consent expiry dates of all stored samples. An action plan to address this recommendation should be implemented by 28 April 2013 and the HFEA informed of the corrective actions taken.	An effective bring forward system has been implemented and the HFEA will be informed of any required corrective actions by the 28th of April 2013.	The centre has implemented a bring-forward system, which is being checked to ensure it is robust. Any corrective actions will be notified to the lead inspector. The bring forward system has been established. No further action required.
6. The time of the witnessed check of donor identification at sperm procurement is not recorded (CoP guidance 18.71).	The PR should ensure that the time of the witnessed check of donor identification is recorded on the laboratory record sheet. This recommendation should be implemented immediately. Witnessing documentation should be audited on 28 April 2013 or soon thereafter to verify that all witnessed checks are compliantly documented. The results of this audit should be supplied to the HFEA by 28	The requirement for documenting the time of a witnessing check has been implemented. An audit will be completed and submitted to the HFEA by the required timeframe.	The centre has implemented the recommendation as requested, and is now required to audit the effectiveness of the introduction of documenting the time of a witness check being recorded on the laboratory record sheet. An audit was sent showing 100% compliance was sent to the lead inspector. No further action required.

	July 2013.		
7. The centre provided evidence the air quality in the critical work area is compliant, but could not provide evidence that the background laboratory environment is consistently of at least Grade D air quality (SLC T20).	The PR must ensure that sperm processing activities are undertaken in a laboratory with background air quality of at least Grade D. An action plan to achieve this should be submitted to the HFEA by 28 April 2013, and should be implemented so that air quality monitoring data supporting compliant air quality can be provided to the HFEA by 28 July 2013.	An air filter has been purchased for the laboratory in order to ensure the provision of the required background air quality. It is anticipated that this will be fitted and validated by the 22nd of March 2013. Purchase order attached. Weekly air quality monitoring will be implemented when the equipment has been validated. This will be achieved by the required timeframe and monitoring data supporting compliant air quality will be provided to the HFEA by 28th of July 2013.	The centre has provided evidence of purchasing a filter kit. Air quality monitoring results, showing a laboratory with background air quality of at least Grade D is required by 28 July 2013 at the latest. Centre submitted an 'Air monitoring with CODA' log to show daily air quality in the lab at rest and in operation CODA 700 air filtering unit. Compliant with Grade D. No further action required.
8. The centre should offer all gamete donors the opportunity to give consent to the disclosure of information to researchers (Chair's Letter CH(12)03).	The PR must ensure that where the gamete donor agrees to the disclosure of information to researchers, the centre must complete the HFEA CD form, section 4. The centre should ensure all relevant staff are aware of the Chair's Letter CH(12)03).	The audit for sperm donors agreeing to the disclosure of information to researchers in section 4 of the HFEA-Cd form is ongoing and will be submitted on or before 28th October 2013.	The executive is satisfied with this response. Audit expected October 2013. Further action required.

	A retrospective audit of patient records should be completed to ensure the recommendation is implemented. The findings of the audit and any corrective action should be shared with the lead inspector by 28 October 2013.		

Additional information from the Person Responsible
Please note that an RI Witnessing system will have been installed and validated by the end of April 2013. This will include all the areas and witnessing points discussed at the time of inspection. Documented evidence will be provided to the HFEA Executive.

HFEA Executive Licensing Panel Meeting

5 July 2013

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

Minutes – Item 5

Centre 0011 – (London Sperm Bank) – Interim Inspection Report

Members of the Panel:	Committee Secretary:
Juliet Tizzard – Head of Policy and Communications (Chair) Hannah Darby – Senior Policy Manager David Moysen – Head of IT	Rebecca Loveys

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 is a storage only centre and has held an HFEA licence since April 2010. It was formerly known as the Louis Hughes centre which was originally licensed in 1992.

2. The Panel noted that the centre, being a storage, process and distribution only centre, has no outcomes because it does not offer treatment.

3. The Panel noted that following the last inspection on 23 November 2010 the centre has undergone a number of significant changes:

    i. A change of ownership; the LSB has joined the JD Healthcare group;
    ii. New staff have been appointed and a new organisational structure developed;
    iii. The centre changed premises in December 2012 from 99 to 112 Harley Street.

4. The Panel noted that the inspection took place on 29 January 2013.

5. The Panel noted that at the time of inspection one critical, one major and five other areas of non-compliance were identified.

6. The Panel noted that since the inspection all but one of the other areas of non-compliance have been addressed.

7. The Panel noted in particular the non-compliances relating to air quality and consent to storage of sperm, but acknowledged that they have been addressed.

Decision

8. The Panel had regard to its decision tree. It was satisfied that there were no issues preventing the continuation of the centre's licence.

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

Signed: J Tizzard. Date: 17 July 2013

Juliet Tizzard (Chair)