# Executive Licensing Panel Minutes

## Centre 0070 (London Sperm Bank (LSB) London Bridge)

## Renewal Inspection Report

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| Date: | 1 June 2021 | |
| Venue: | HFEA Teleconference Meeting | |
| Attendees: | Helen Crutcher (Chair)<br>Anna Coundley<br>Niamh Marren | Risk and Business Planning Manager<br>Policy Manager<br>Regulatory Policy Manager |
| Executive: | Bernice Ash | Secretary |
| Observers: | Catherine Burwood | Licensing Manager |

## Declarations of interest

- Members of the panel declared that they had no conflicts of interest in relation to this item.

## The panel had before it:

- 9th edition of the HFEA Code of Practice.
- Standard licensing and approvals pack for committee members.

## 1. Consideration of Application

**1.1.** The panel considered the papers, which included a completed application form, inspection report and licensing minutes for the last five years.

**1.2.** The panel noted that London Sperm Bank (LSB) London Bridge is located in central London and holds a treatment (insemination using partner/donor sperm) and storage licence. The centre has been licensed by the HFEA since 1992.

**1.3.** The panel noted that the centre has not provided any insemination treatment during the current reporting period, therefore no pregnancies were stated in 2020.

**1.4.** The panel noted that the centre followed professional body guidance to suspend all non-essential treatments in response to Covid-19 and is compliant with GD0014 Version 2 for resuming treatment services.

**1.5.** The panel noted that the centre was due a renewal of licence inspection during the period of suspension of fertility treatments, due to the Covid-19 pandemic. In April 2020, the Person Responsible (PR) applied for a variation to extend the duration of the centre's current treatment (insemination using partner/donor sperm) and storage licence by one year. This was initially issued for a period of four years; following the grant of the licence variation, the centre's licence duration was extended to five years.

**1.6.** The panel noted that the centre's interim inspection occurred in April 2018 and a renewal inspection was scheduled to be undertaken by April 2020. However, due to the Covid-19 pandemic, a Desk Based Assessment and Risk Based Approach (DBA/RBA), was conducted. Following this, it was established that any items of concern identified were of relatively low risk and could be reviewed effectively using virtual technology, rather than an on-site inspection. This process removed the risks to patients and staff, associated with a HFEA team attending the clinic for an on-site inspection during the Covid-19 pandemic.

**1.7.** The panel noted that a DBA, followed by a virtual inspection, was conducted on 13 April 2021.

**1.8.** The panel noted that, at time of the inspection, there were no areas of poor practice that required improvement, and this was commended by the inspectorate.

**1.9.** The panel noted that centre activities are currently focused on the recruitment, procurement, processing and storage of donor sperm. At this inspection, the PR outlined a plan to re-introduce insemination treatment using donor sperm later in the year. The inspection team considered this plan, noting that its implementation would not require an application to vary the centre's licence.

**1.10.** The panel noted that the centre is well led and provides a good level of patient support.

**1.11.** The panel noted that, as a result of the UK's departure from the European Union (EU) a relicensing exercise is currently under way. This follows approval by the Licence Committee of a variation without application on 4 March 2021. This means that new offer licences are being sent to all clinics, incorporating changes to some of the standard licence conditions. The varied licences will all come into effect on 1 July 2021, after the transition period ends on 30 June 2021.

**1.12.** The panel noted that this renewal is being considered during that relicensing period. However, since this renewal licence (if approved) will begin on 1 October 2021, which is after 1 July 2021, the renewal licence will simply follow on in the normal way from the centre's current active licence, which by that date will be the new varied licence.

**1.13.** The panel noted that the inspection team recommends the renewal of the centre's treatment (insemination using partner/donor sperm) and storage licence, for a period of four years, without additional conditions.

**1.14.** The panel noted that the centre has been issued with an Importing Tissue Establishment (ITE) import certificate by the HFEA, pursuant to section 24(4AD). Such certificates are generally synchronised to the centre's HFEA licence. The executive therefore recommends the renewal of the centre's ITE import certificate in line with the centre's licence.

## 2. Decision

**2.1.** The panel had regard to its decision tree. It was satisfied that the appropriate application and fee had been submitted and that the application contained the supporting information required by General Directions 0008.

**2.2.** The panel noted that the premises to be licensed are suitable for the conduct of licensed activity.

**2.3.** The panel was satisfied that the qualifications and character of the PR are such as is required for the supervision of licensed activities and the PR will discharge his duty under section 17 of the HFE Act 1990 (as amended).

**2.4.** The panel particularly noted that all relevant staff will receive refresher training on taking legal parenthood consent before donor inseminations recommence at the centre; regular audits of these consents will be conducted to ensure it incorporates the centre's multiple birth strategy.

**2.5.** The panel commended the centre on responses received to its patient and donor satisfaction survey, completed between 8 March 2021 and 14 March 2021; 24 donors had provided responses during this period and 100% provided the highest rating of '5'.

**2.6.** The panel endorsed the inspectorate's recommendation to renew the centre's treatment (insemination using partner/donor sperm) and storage licence for a period of four years, without additional conditions. The panel agreed that if no representations or any other information is received within 28 days, the final renewal licence should be issued.

**2.7.** The panel endorsed the executive's recommendation to renew the ITE's import certificate, in line with the centre's licence.

## 3. Chair's signature

**3.1.** I confirm this is a true and accurate record of the meeting.

### Signature

### Name

Helen Crutcher

### Date

7 June 2021

# Inspection Report

## Purpose of the Inspection Report

This is a report of an inspection, carried out to assess whether this centre complies with essential requirements in providing safe and high quality care to patients and donors.

The report provides information on the centre's application to renew its existing licence. Licensed centres usually receive a licence to operate for up to four years, although some centres have had their licence extended to five years due to the Covid-19 pandemic (five years being the maximum length of a treatment licence permitted by law).

The Authority's Executive Licensing Panel (ELP) uses the application and this report to decide whether to grant a new licence and, if so, whether any additional conditions should be applied to the licence.

**Date of inspection:** 13 April 2021

**Purpose of inspection:** Renewal of a licence to carry out Treatment (Insemination using partner / donor sperm) and Storage licence

**Inspection details:** The report covers the performance of the centre since the last inspection, findings from the inspection and communications received from the centre.

In March 2020, the World Health Organisation declared a world-wide pandemic of Coronavirus (Covid-19). In response to UK measures to contain and mitigate the spread of the virus, new inspection methodologies were developed and implemented.

These methods enable compliance to be reviewed through desk based assessment (DBA) and the use of virtual technology where available and appropriate. A risk based approach (RBA) can then be applied, balancing the risks of on-site inspection during the Covid-19 pandemic against those resulting from potential non compliances, identified during DBA, if not adequately investigated.

HFEA licensed premises must be inspected on site every two years in accordance with Schedule 3B paragraph (4)(1) of the Human Fertilisation and Embryology (HF&E) Act 1990 (as amended). Whilst the current restrictions of the pandemic do not prohibit on-site inspection, the risks of doing so must be balanced against the need for the Authority to fulfil its legal duties.

This centre was last inspected in April 2018, therefore an on-site inspection should usually be conducted by April 2020. However, following the DBA/RBA for this clinic, it was concluded that any items of concern identified during the DBA were of relatively low risk and could be reviewed effectively using virtual technology rather than on-site inspection. This removed the risks to patients and staff, associated with a HFEA team attending the clinic for an on-site inspection during the Covid-19 pandemic.

This inspection was therefore carried out by DBA followed by a virtual inspection, which included videoconferencing with key members of centre staff.

**Inspectors:** Louise Winstone (lead), Bernadette O'Leary and Karen Campbell (HFEA observer)

**Date of Executive Licensing Panel:** 1 June 2021

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| **Centre name** | London Sperm Bank (LSB) London Bridge |
| **Centre number** | 0070 |
| **Licence number** | L/0070/20/f |
| **Centre address** | 1, St Thomas Street, London Bridge, London, SE1 9RY, United Kingdom |
| **Person Responsible** | Dr Kamal Ahuja |
| **Licence Holder** | Mr David Williams |
| **Date licence issued** | 1 October 2016 |
| **Licence expiry date** | 30 September 2021 |
| **Additional conditions applied to this licence** | None |

# Contents

# Section 1: Summary report

### Brief description of the centre and its licensing history:

London Sperm Bank (LSB) London Bridge is located in central London and holds a Treatment (Insemination using partner / donor sperm) and Storage licence. The centre has been licensed by the HFEA since 1992.

Until January 2015, the centre provided a full range of fertility services, including embryo testing. In 2016, the Person Responsible (PR) informed the HFEA that treatments offered at the centre were limited to partner insemination treatment and an additional condition was applied to the licence, removing the licensing of activities involving the creation of embryos. It permitted storage and distribution to allow embryo cryostorage and transport to centre 0105 for use in treatment to continue. On 9 March 2020, the PR submitted an application to vary the centre's licence to a Treatment (insemination using partner / donor sperm) and Storage licence. The PR confirmed that all frozen embryos had been transferred to centre 0105. This application was approved by ELP on 16 June 2020 and the additional condition applied to the licence was removed.

On 17 March 2020, the Chief Executive of the HFEA wrote to all PRs informing them that all on-site inspections were suspended until the end of August 2020. This action was in response to UK measures to maintain and mitigate the spread of the Coronavirus (Covid-19), and in line with the actions taken by other national regulators.

This centre was due a renewal of licence inspection during the period of suspension of fertility treatments. In April 2020, the PR applied for a variation to extend the duration of the centre's current Treatment (Insemination using partner / donor sperm) and Storage licence by one year. The clinic's licence was issued for a period of four years and following the grant of the licence variation, the centre's licence duration was extended to five years.

The centre's licence has also been varied to reflect the following:

- January 2021 – change of centre name
- July 2020 – change of centre name
- June 2020 – extension of licence and variation of licensed activities
- August 2018 – change of Licence Holder

The centre activities are currently focussed on the recruitment, procurement, processing and storage of donor sperm. At this inspection, the PR outlined a plan to re-introduce insemination treatment using donor sperm at the London Sperm Bank (LSB), London Bridge later in the year. The inspection team considered this plan and noted that its implementation would not require an application to vary the centre's licence.

| Pregnancy outcomes |
| --- |
| The centre has not provided insemination treatment during the current reporting period, therefore no pregnancies were reported for the year 2020. |

## Summary for licensing decision

Taking into account the essential requirements set out in the Human Fertilisation and Embryology (HF&E) Act 1990 (as amended), the HF&E Act 2008 and the HFEA Code of Practice (CoP) and standard licence conditions (SLCs), the inspection team considers that it has sufficient information to conclude that:

- the application has been submitted in the form required;
- the application has designated an individual to act as the PR;
- the PR's qualifications and experience comply with section 16(2)(c) of the HF&E Act 1990 (as amended);
- the PR has discharged his duty under section 17 of the HF&E Act 1990 (as amended);
- the premises (including those of relevant third parties) are suitable;
- the centre's practices are suitable;
- the application contains the supporting information required by General Direction 0008, in application for renewal of the centre's licence;
- the centre has submitted an application fee to the HFEA in accordance with requirements.

The ELP is asked to note that at the time of the virtual inspection there were no areas of practice that required improvement.

## Recommendation to the Executive Licensing Panel

This inspection identified no areas of non compliance or areas of poor practice that required improvement, for which the centre is to be commended.

The centre is well led and provides a good level of support to donors.

The inspection team recommends the renewal of the centre's 'Treatment (Insemination using partner / donor sperm) and Storage' licence for a period of four years without additional conditions.

Centre 0070 has been issued with an Importing Tissue Establishment (ITE) import certificate by the HFEA, pursuant to the Human Fertilisation and Embryology (Amendment) Regulations 2018. Such certificates are generally synchronised to the centre's HFEA licence. The inspection team therefore recommends the renewal of the centre's ITE import certificate in line with the centre's licence.

As a result of the UK's departure from the EU, there is currently a relicensing exercise under way. This follows approval by the Licence Committee of a variation without application on 4 March 2021. This means that new offer licences are being sent to all clinics, incorporating changes to some of the standard licence conditions. The varied licences will all come into effect on 1 July 2021, after the transition period ends on 30 June 2021.

This licence renewal application is being considered during that relicensing period. However, since this renewal licence (if approved) will begin on 1 October 2021, which is after 1 July 2021, the renewal licence will simply follow on in the normal way from the centre's current active licence which, by that date will be the new, varied licence.

# Section 2: Inspection findings

This section details what the centre does well and which areas need to be improved to meet essential requirements. We break this down in to four areas covering all the activities of a licensed centre:

1. The protection of the patient, and children born following treatment at this centre
2. The experience of patients at this centre
3. The protection of gametes (sperm and eggs) and embryos at this centre
4. How this centre looks after important information

## 1. Protection of the patient and children born following treatment

### Witnessing and assuring patient and donor identification

**What the centre does well**

**Witnessing (Guidance note 18)**
The centre's procedures for double checking the identification of gametes and the patient or donor to whom they relate are compliant with HFEA requirements. This ensures that patients receive treatment using the correct gametes.

**What the centre could do better**
Nothing identified at this inspection.

### Donor selection criteria and laboratory tests

Screening of donors prior to procuring, processing gametes and embryos
Payments for donors
Donor assisted conception

**What the centre does well**

**Screening of donors (Guidance note 11)**
The centre's procedures for screening donors are compliant with HFEA requirements. It is important that donors are appropriately screened to minimise the risks of cross infection during treatment, processing and storage of gametes and/or embryos.

**Payments for donors (Guidance note 13; General Direction 0001)**
The centre's procedures are compliant with HFEA requirements for giving and receiving money or other benefits in respect to any supply of gametes. It is important that the principle of altruistic donation be upheld but at the same time donors receive appropriate compensation for their time and any inconvenience caused.

**Donor assisted conception (Guidance note 20)**
It is important that centres use donated gametes from identifiable donors and keep records of donor characteristics. This is because patients using donated gametes in treatment and the parents of donor-conceived children, are able to access non identifying information regarding the donor from the clinic. Furthermore, donor-conceived persons are entitled to know non-identifying details about their donor and any donor-conceived

genetic siblings they may have at the age of 16 years, and donor identifying information at 18 years.

The centre's procedures are compliant with HFEA requirements which ensure the donor-conceived and their parents will be able to receive all required donor-related information.

**What the centre could do better**
Nothing identified at this inspection.

## Suitable premises and suitable practices

Safety and suitability of premises and facilities
Laboratory accreditation
Infection control
Medicines management
Pre-operative assessment and the surgical pathway
Multiple births
Procuring gametes and embryos
Transport and distribution of gametes and embryos
Receipt of gametes and embryos
Imports and exports
Traceability
Quality management system
Third party agreements
Transports and satellite agreements
Equipment and materials
Process validation
Adverse incidents

**What the centre does well**

**Safety and suitability of premises and facilities (Guidance note 25)**
The centre's premises are suitable. This is important to ensure that all licensed activities are conducted in a suitable environment that is fit for purpose.

The centre has procedures in place that are compliant with requirements to ensure that risks are taken into account so that patients and staff are in safe surroundings that prevent harm.

The premises of the centre's laboratories conducting tests that impact on the quality and safety of gametes (relevant third parties) are suitable.

The centre is compliant with HFEA requirements to process gametes in an environment of appropriate air quality.

**Laboratory accreditation (Guidance note 25)**
The centre's laboratories and/or third party laboratories which undertake the diagnosis and investigation of patients and donors are compliant with HFEA requirements to be accredited by UKAS, the national accreditation body for the UK, or another accreditation body recognised as accrediting to an equivalent standard. This is important to assure the quality of the services provided.

**Infection control (Guidance Note 25)**
The centre has systems in place to manage and monitor the prevention and control of infection that are compliant with guidance.

**Medicines management (Guidance Note 25)**
These requirements are not relevant to the centre's activities.

**Prescription of intralipid 'off label'**
Intralipid is a sterile liquid soybean and egg yolk based fat emulsion which is licensed as an intravenous nutritional supplement for adults and children. Some healthcare professionals consider intralipid therapy may be beneficial to a particular subset of women having IVF. Intralipid is not however licensed for use in fertility treatment and if prescribed in this context, it represents 'off-label' use. Healthcare professionals' responsibilities when prescribing a medicine off-label may be greater than when prescribing a medicine for use within the terms of its licence.

In April 2015, the President of the Royal College of Obstetricians and Gynaecologists, published concerns regarding the evidence base for the use of intralipid in IVF treatment, in terms of its safety and efficacy. In July 2015, the HFEA published guidance to centres regarding the prescribing of intralipid (or other 'off label' therapies) to patients. This guidance required centres to take responsibility for prescribing the medicine and for overseeing the patient's care by:

- reviewing and recording the information provided to patients about intralipid therapy to ensure that the reasons for prescribing it 'off-label' are explained, including that there is currently little evidence to support its use in fertility treatment;
- recording the reasons for prescribing intralipid in the patient's records and;
- ensuring that patients who are prescribed intralipid are properly monitored and followed up.

The centre does not prescribe intralipids, therefore this area of practice is not relevant to this inspection.

**Pre-operative assessment and the surgical pathway (Guidance Note 25)**
These requirements are not relevant to the centre's activities.

**Multiple births (Guidance note 7; General Direction 0003)**
The centre is not currently providing insemination treatments but intends to resume these activities later in 2021. Such treatments still expose patients to the risks of multiple pregnancies and births if incorrectly applied. The single biggest risk of fertility treatment is a multiple pregnancy and birth. Thus, it is important for centres providing insemination treatments to have a multiple births minimisation strategy. The centre has procedures in place which are compliant with HFEA requirements to have a multiple births minimisation strategy and to conduct regular audits and evaluations of the progress and effectiveness of the strategy.

**Procurement of gametes and embryos (Guidance note 15)**
The centre's does not procure embryos however the procedures for procuring gametes are compliant with HFEA requirements.

**Transport and distribution of gametes and embryos (Guidance note 15; General Direction 0009)**

The centre does not transport embryos. The centre's procedures for the transport, distribution and recall of gametes are compliant with HFEA requirements. This is important to ensure that all gametes sent to other licensed centres within or outside the UK are:

- packaged and transported in a manner that minimises the risk of contamination and preserves the characteristics and biological functions of the gametes;
- shipped in a container that is designed for the transport of biological materials and that maintains the safety and quality of the gametes;
- appropriately labelled with the transport conditions, including temperature and time limit being specified;
- the container/package is secure and ensures that the gametes are maintained in the specified conditions. All containers and packages are validated as fit for purpose.

**Receipt of gametes and embryos (Guidance note 15)**
The centre does not receive embryos. The centre's procedures for the receipt of gametes is compliant with HFEA requirements. This is important to ensure that the centre only accepts gametes from other centres if they are appropriately labelled and are accompanied by enough information to permit them to be stored or used in treatment in a way that does not compromise their quality and safety.

**Imports and exports (Guidance note 16; General Direction 0006)**
The centre's procedures for import and export of gametes are compliant with HFEA requirements.

The Human Fertilisation and Embryology Act 1990 (as amended) was amended on 1 April 2018 by the Human Fertilisation and Embryology (Amendment) Regulations 2018, to incorporate procedures for assuring the quality and safety of gametes and embryos imported into licensed centres in the UK, i.e. 'importing tissue establishments' (ITEs), from tissue establishments outside of the EU, EEA or Gibraltar, i.e. 'third country suppliers' (TCS). UK clinics must apply to the HFEA for an ITE import certificate to allow imports from specified TCSs, a clinic's certificate being synchronised in lifespan with the treatment licence. The centre has been allocated an ITE import certificate and imports of gametes and embryos from TCSs outside the EU/EEA have been made since the introduction of the ITE import certification scheme on 1 April 2018. No imports have been made from TCS which are not specified on the centre's ITE import certificate. The centre is therefore compliant with General Direction 0006.

**Traceability (Guidance note 19)**
The centre's procedures are compliant with HFEA traceability requirements. These requirements are important to ensure that the centre has the ability:

- to identify and locate gametes during any step from procurement to use for human application or disposal;
- to identify the donor and recipient of particular gametes;
- to identify any person who has carried out any activity in relation to particular gametes; and
- to identify and locate all relevant data relating to products and materials coming into contact with particular gametes and which can affect their quality or safety.

**Quality management system (QMS) (Guidance note 23)**

The centre has a QMS that is compliant with HFEA requirements. The establishment and use of a QMS is important to ensure continuous improvement in the quality of treatments and services.

**Third party agreements (Guidance note 24)**
The centre's third party agreements, including those associated with ITE/TCS import certificates, are compliant with HFEA requirements.

**Transport and satellite agreements (Guidance note 24; General Direction 0010)**
These requirements are not relevant to the centre's activities.

**Equipment and materials (Guidance note 26)**
The centre uses equipment and materials that are compliant with HFEA requirements. All of the equipment and materials used in licensed activity are designated for the purpose and are appropriately maintained in order to minimise any hazard to patients and/or staff.

The centre is compliant with HFEA requirements to validate critical equipment. The centre has documented procedures for the operation of critical equipment and procedures to follow if equipment malfunctions.

**Process validation (Guidance note 15)**
The centre's procedures are compliant with HFEA requirements to validate critical processes. This ensures that these processes are effective and do not render the gametes clinically ineffective or harmful to the recipient.

**Adverse incidents (Guidance note 27)**
The centre's procedures for reporting adverse incidents are compliant with HFEA requirements. The centre reports all adverse incidents (including serious adverse events and reactions) to the HFEA. The centre investigates all adverse incidents that have occurred. Reporting and investigation of adverse incidents is important to ensure that centres share the lessons learned from incidents and continuously improve the services it offers.

**What the centre could do better**
Nothing identified at this inspection.

## Staff engaged in licensed activity

Person Responsible (PR)
Leadership
Staff

**What the centre does well**

**Person Responsible (Guidance note 1)**
The PR has complied with HFEA requirements.

The PR has academic qualifications in the field of biological sciences and has more than two years of practical experience which is directly relevant to the activity to be authorised by the licence. The PR has successfully completed the HFEA PR Entry Programme.

**Leadership**
The centre is compliant with HFEA guidance regarding effective leadership.

Good leadership improves patient care and is encouraged by the HFEA. A PR should have the necessary authority and autonomy to carry out the role. The PR should ensure that staff understand their legal obligations, are competent, have access to appropriate training and development, and can contribute to discussions and decisions about patient care. The PR is legally accountable for the overall performance of the centre and should establish clear responsibilities, roles and systems of accountability to support good governance, including ensuring that appropriate action is taken following all forms of feedback from the HFEA or patients.

**Staff (Guidance note 2)**
The centre is compliant with HFEA requirements to have suitably qualified and competent staff, in sufficient number, to carry out the licensed activities and associated services. The centre has an organisational chart which clearly defines accountability and reporting relationships.

The centre has access to a nominated registered medical practitioner and scientist, within the UK, to advise on and oversee medical and scientific activities respectively.

**What the centre could do better**
Nothing identified at this inspection.

## Welfare of the child and safeguarding

**What the centre does well**

**Welfare of the child (Guidance note 8)**
The centre is not currently providing treatment. In anticipation of this resuming, the centre has procedures in place to ensure that before licensed treatment is provided, the welfare of any child who may be born as a result of that treatment and of any other child who may be affected by that birth is taken into account, which are compliant with HFEA requirements.

**Safeguarding (Guidance Note 25)**
The centre's procedures are compliant with safeguarding guidance. This ensures that the centre's patients, donors and staff are protected from harm where possible.

**What the centre could do better**
Nothing identified at this inspection.

## Embryo testing

Preimplantation genetic screening
Embryo testing and sex selection

**What the centre does well**

**Preimplantation genetic screening (Guidance note 9);**
**Embryo testing and sex selection (Guidance note 10)**
These requirements are not relevant to the centre's activities.

**What the centre could do better**
Nothing identified at this inspection.

## 2. The experience of patients

### Patient and Donor feedback

**What the centre does well**

The centre has effective systems in place to seek patient and donor feedback. Donor satisfaction survey responses completed between 8 March 2021 and 14 March 2021 were reviewed as part of the DBA process. 24 donors provided responses during this time period and 100% gave the highest rating of '5'. When treatment activities recommence, this system will also provide a mechanism for patients to provide their feedback.

On the basis of documents provided as part of the DBA assessment and discussions with staff it was possible to assess that the centre:

- has respect for the privacy and confidentiality of patients and donors in the clinic;
- gives patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions;
- provides patients and donors with satisfactory facilities for their care;
- has mechanisms in place to effectively respond to patient and donor calls and queries in a timely manner.

**What the centre could do better**

Nothing identified at this inspection.

### Treating patients fairly

Patient support
Counselling
Egg and sperm sharing arrangements
Surrogacy
Complaints
Confidentiality and privacy

**What the centre does well**

**Treating patients fairly (Guidance note 29)**

The centre's procedures are compliant with the HF&E Act 1990 (as amended) to ensure that staff members understand the requirements for a conscientious objection to providing a particular licensed activity governed by the Act.

The centre's procedures are compliant with requirements to ensure that prospective and current patients and donors are treated fairly and that all licensed activities are conducted in a non-discriminatory way.

**Patient support (Guidance note 3)**

New HFEA guidance strengthens support provided by staff at all levels to patients, so as to improve their emotional experience of care. All clinics should have a policy outlining how appropriate psychosocial support from all staff is provided to patients, donors and their partners, before, during and after treatment. All staff should understand their responsibilities and be provided with appropriate training, information and functional aids to assist them. Patient feedback should be collected to enhance the patient / donor support procedures.

The centre's patient support procedures are compliant with HFEA guidance.

**Counselling (Guidance note 3)**
The centre's counselling procedures are compliant with HFEA requirements. This is important to ensure that counselling support is offered to patients and donors providing relevant consent.

**Egg and sperm sharing arrangements (Guidance note 12; General Direction 0001)**
These requirements are not relevant to the centre's activities.

**Surrogacy (Guidance note 14)**
These requirements are not relevant to the centre's activities.

**Complaints (Guidance note 28)**
The centre's procedures are compliant with HFEA requirements to seek patient feedback and to be responsive to patient complaints. This is important to ensure that the centre uses patient feedback and any complaints as an opportunity to learn and improve their services.

**Confidentiality and privacy (Guidance note 30)**
The centre's procedures are compliant with HFEA requirements to ensure it has respect for the privacy, confidentiality, dignity, comfort and wellbeing of prospective and current donors and patients.

**What the centre could do better**
Nothing identified at this inspection.

## Information

**What the centre does well**

**Information (Guidance note 4**
The centre's procedures for providing information to patients and donors are compliant with HFEA requirements. This ensures that the centre gives prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions.

**What the centre could do better**
Nothing identified at this inspection.

## Consent and disclosure of information, held on the HFEA Register, for use in research

**What the centre does well**

**Consent (Guidance note 5;6)**
The centre's procedures for obtaining consent are compliant with HFEA requirements. This ensures that patients and donors have provided all relevant consents before carrying out any licensed activity.

**Legal parenthood (Guidance note 6)**
Where a couple to be treated with donated gametes or embryos is not married or in a civil partnership, both the woman and her partner must give written consent in order for the partner to become the legal parent of any child born. If this consent is not documented properly or if proper information is not provided or counselling offered prior to both parties giving consent, there may be doubt about its effectiveness and, in some cases, it may be necessary for a patient couple to obtain a court declaration to establish legal parenthood.

The centre is not currently providing insemination treatment using donated sperm however the centre does intend to resume this treatment later this year. The PR has confirmed that refresher training will be provided to all staff taking consent to legal parenthood prior to treatments commencing and regular audits of legal parenthood consent will take place.

**Disclosure of information, held on the HFEA Register, for use in research (General Direction 0005)**
The centre's procedures for taking consent to disclosure to researchers are compliant with HFEA requirements.

This is important to ensure that the HFEA holds an accurate record of donors' consents, so that it only releases patient identifying information, to researchers, with the consent of the patient. Information can be used by researchers to improve knowledge about the health of patients undergoing licensed fertility treatment and those born as a result of it.

**What the centre could do better**
Nothing identified at this inspection.

## 3. The protection of gametes and embryos

### Respect for the special status of the embryo

**What the centre does well**

The centre does not create of store embryos therefore these requirements are not relevant to the centre's activities.

**What the centre could do better**

Nothing identified at this inspection.

### Screening of patients and Storage of gametes and embryos

**What the centre does well**

**Screening of patients (Guidance note 15)**

The centre is not currently providing patient treatments. Ahead of patient treatment resuming, the centre has procedures in place for screening patients which are compliant with HFEA requirements. It is important that gamete providers are appropriately screened to minimise the risks of cross infection during treatment, processing and storage of gametes.

**Storage of gametes and embryos (Guidance note 17)**

The centre's procedures for storing gametes are compliant with HFEA requirements. These measures ensure that the gametes are stored appropriately to maintain their quality and safety. Furthermore, the centre only stores gametes in accordance with the consent of the gamete providers.

**What the centre could do better**

Nothing identified at this inspection.

### Use of embryos for training staff

**What the centre does well**

**Use of embryos for training staff (Guidance note 22)**

These requirements are not relevant to the centre's activities.

**What the centre could do better**

Nothing identified at this inspection.

## 4. Information management

| Record keeping and Obligations and reporting requirements |
|---|
| **What the centre does well**<br><br>**Record keeping and document control (Guidance note 31)**<br>The centre's procedures for keeping records are compliant with HFEA requirements to ensure that accurate medical records are maintained. Good medical records are essential for the continuity of the patient's care.<br><br>**Obligations and reporting requirements (Guidance note 32; General Direction 0005)**<br>The centre's procedures for submitting information, about licensed activities to the Authority are compliant with HFEA requirements This is important to ensure the HFEA can supply accurate information to a donor-conceived person and their parents or donors. |
| **What the centre could do better**<br>Nothing identified at this inspection. |

## Section 3: Monitoring of the centre's performance

Following the interim inspection in 2018, recommendations for improvement were made in relation to two 'other' areas of non compliance.

The PR provided information and evidence that both of the recommendations were fully implemented within the prescribed timescales.

### On-going monitoring of centre success rates

Treatment services that result in success rates monitored by the HFEA are not currently provided at this centre.

## Areas of practice requiring action

This 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, General 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 areas 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 to a child who may be born as a result of treatment services, or a significant shortcoming from the statutory requirements. A critical area of non compliance requires immediate action to be taken by the Person Responsible.

A critical area of non compliance is identified in the report by a statement that an area of practice is not compliant with requirements.

| Area of practice and reference | Action required and timescale for action | PR response | Executive review |
|---|---|---|---|
| None identified. | | | |

## Major areas 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.

A major area of non compliance is identified in the report by a statement that an area of practice is partially compliant with requirements.

| Area of practice and reference | Action required and timescale for action | PR response | Executive review |
|---|---|---|---|
| None identified. | | | |

## Other areas of practice that require improvement

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

An ‘other’ area of non compliance is identified in the report by a statement that an area of practice is ‘broadly’ compliant with requirements.

| Area of practice and reference | Action required and timescale for action | PR response | Executive review |
|---|---|---|---|
| None identified. | | | |

| Responses from the Person Responsible to this inspection report |
| --- |
| We have placed a reminder to ensure that all relevant staff have refresher training on taking Legal Parenthood consent before we begin DI inseminations at LSB London Bridge as well as incorporating regular audits of taking of legal parenthood consents.We will also incorporate JDH Multiple births mimisation strategy to apply to LSB London Bridge when DI inseminations commence.We will also ensure a procedure is in place to take Welfare of the Child consents before any DI insemination takes place, in line with the JDH procedures.We will also ensure that all patients that have DI inseminations will be screened in line with HFEA requirements. |