Licence Committee - minutes

Centre 0011 (London Sperm Bank)
Renewal Licence

Thursday, 7 March 2019

HFEA, 10 Spring Gardens, London, SW1A 2BU

Committee members	Kate Brian (Chair) Anita Bharucha (Deputy Chair) Ruth Wilde Jonathan Herring	
Members of the Executive	Dee Knoyle Moya Berry	Committee Secretary Committee Secretary (Observer)
Legal Adviser	Gerard Hanratty	Browne Jacobson LLP
Specialist Adviser		
Observers		

Declarations of interest:

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

The committee had before it:

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

The following papers were considered by the committee:

Papers enclosed:

- Renewal inspection report
- Application form
- Previous licensing minutes for the last three years:
  - Executive Licensing Panel Minutes - 12 February 2019 – Special Directions to permit continuation of licensed activity
  - Executive Licensing Panel Minutes - 15 July 2016 – Interim inspection report
  - Executive Licensing Panel Minutes - 12 December 2014 - Renewal inspection report
  - Executive Licensing Panel Minutes - 22 August 2014 - Change of Person Responsible

1. Background

1.1. The London Sperm Bank (LSB), centre 0011 is part of the London Women's Clinic (LWC) group, under the umbrella of JD Healthcare. The centre has held a storage only licence with the HFEA since 2010, when they took over a former HFEA licensed centre, Louis Hughes.

1.2. The centre is now mainly a storage and distribution centre for donor sperm, providing sperm to clinics within the LWC group and other fertility clinics within the UK and internationally. Centre 0011 stopped recruiting donors in May 2017. Donor recruitment for the LWC group now takes place at The Bridge Centre, centre 0070. However centre 0011 processes and stores samples for the final donors recruited, who are still in their donation cycle.

Current Licence

1.3. The current licence is due to expire on 31 March 2019.

1.4. Due to the complexity of a non-compliance relating to donor compensation, identified during the renewal inspection process, the renewal application was referred to the Licence Committee for consideration, instead of the Executive Licensing Panel.

1.5. However, due to the scheduling of the Licence Committee meeting on 7 March 2019 there is insufficient time to process this application before the licence expires on 31 March 2019, therefore the Executive Licensing Panel has issued Special Directions to allow the centre to continue activities should the licence expire before completion of this process.

2. Consideration of application

Renewal Inspection

Application

2.1. The committee noted that the PR had submitted an application for the renewal of the storage only licence.

2.2. The committee noted that the application contains the supporting information required by General Direction 0008 and that the appropriate fee has been paid.

2.3. The committee noted that the centre is in the process of applying for an Importing Tissue Establishment (ITE) certificate in accordance with the HF&E Act 1990 (as amended). Amendment made on 1 April 2018 by the Human Fertilisation and Embryology (Amendment) Regulations 2018 (the '2018 Regulations').

Inspection Process

2.4. The committee noted that the renewal inspection took place on 9 October 2018. The renewal inspection report covers the performance of the centre since the last inspection, the findings from the renewal inspection visit and communications received from the centre. The committee noted that at the time of the renewal inspection there were three major and two 'other' areas of non-compliance identified:

Major areas of non-compliance:

- The PR should ensure that import and export of donor gametes is compliant with General Directions 0006 and 0001.
- The PR should ensure that consent given by donors is compliant with requirements.
- The PR should ensure that adverse incidents are reported to the HFEA in the required time frame.

'Other' areas that requires improvement:

- The PR should ensure that the centre's recall procedure is sufficiently detailed to guide centre staff.
- The PR should ensure that all core requirements are included in any third party agreement (TPA).

2.5. The committee noted that the Executive considered adding a further non-compliance regarding poor leadership of the PR, however, given the PR's engagement and commitment to ensure compliance at the centre decided that this was not necessary.

2.6. The committee noted in particular, the non-compliances relating to incident reporting, the import and export of donor gametes and compensation.

2.7. The committee noted that since the inspection visit, the PR has provided evidence that actions have been taken to implement most of the recommendations and has committed, where required, to audit the effectiveness of those actions within the required timescales. The PR has committed to fully implementing the outstanding recommendation to ensure that consent given by donors is compliant with requirements.

General Directions 0006 – Import & Export of Gametes and Embryos and

General Directions 0001 – Gamete & Embryo Donation

2.8. The committee noted that section 24(4) of the HFEA Act 1990 (as amended) permits the Authority to issue directions to allow the import and export of gametes and embryos for countries outside of the United Kingdom.

2.9. **General Direction 0006** sets out the requirements that must be met before gametes can be imported into the UK.

2.10. Schedule 3 specifically refers to the import of gametes and embryos from outside of the EEA and Gibraltar.

Part 1 (h) requires that: no money or other benefits has been given or received in respect of the supply of the gametes or embryos unless the money or benefits paid or received is in accordance with Directions 0001 (Gamete and embryo donation) or any subsequent Directions given by the Authority relating to giving and receiving money or other benefits.

2.11. **General Direction 0001** sets out the requirements for giving and receiving money or other benefits in respect to any import of gametes or embryos from outside the UK, specifically:

> 12. When considering whether to import gametes donated overseas, the centre should ensure the donor has not received compensation which exceeds:
>
> a) reasonable expenses incurred by the donor in connection with the donation of gametes provided to that centre; and
> b) loss of earnings (but not for other costs or inconveniences) incurred by the donor up to a daily maximum of £61.28 but with an overall limit of £250 for each course or cycle of donation (local currency equivalent).

13. When receiving donated gametes from overseas, the centre must keep a record (provided by the overseas centre) of:

a) the actual expenses incurred by the donor;
b) the amount reimbursed to the donor; and
c) the receipts produced by the donor, and/or the steps taken by the person responsible to satisfy themselves that the excess expenses claimed by the donor have in fact been incurred.

2.12. The committee further noted that if the conditions outlined in General Directions 0006 are not satisfied, in relation to the import and export of gametes and embryos outside of the European Economic Area and Gibraltar, transactions can only be permitted under Special Directions, which require the centre to submit an application.

2.13. The committee noted that on the day of the inspection, the centre was unable to provide the inspection team with evidence to show that the import of a donor sperm sample from Seattle Sperm Bank (SSB) in the United States of America (via the European Sperm Bank) was compliant with General Directions 0006, since compensation provided to the donors appeared not to be compliant with General Directions 0001.

2.14. The Executive held a Management Review meeting with the PR on 10 January 2019 in accordance with the HFEA's Compliance and Enforcement policy. The review found that the evidence supported the inspection team's significant concerns and considered that a meeting with the PR and LH would be useful to clarify the compensation scheme and to determine what actions to take. A recommendation was also made for the centre's renewal inspection report to be considered by the Licence Committee rather than the Executive Licensing Panel, due to the complexity of this non-compliance.

2.15. On 11 January 2019, the Executive contacted the PR setting out the HFEA's position and requested that the centre should not import any further samples until both the centre and the HFEA were satisfied with the donor compensation arrangements. A further meeting was held with the PR and LH to discuss the issues highlighted by the submitted evidence, which suggested fixed rate compensation per visit with no limit per course of donation, with a request to bring further evidence of compliance.

2.16. On 28 January 2019 a meeting was held with the PR and LH to review the further evidence they presented. The Executive's view at this point was that the fixed rate compensation was not compliant with General Direction 0001. The Executive recommended that the centre seeks further information and advice from SSB.

2.17. Further information was submitted to the Executive on 11 February 2019. This consisted of evidence showing that the compensation, although a fixed rate, was likely to represent an amount for each visit which would cover only limited expenses and loss of earnings incurred by each donor during each visit to SSB, in the context of the cost of living in the area in which SSB is based. Therefore, the donations could be deemed altruistic as the donors were unlikely to be making money on the compensation provided. The Executive considered that it is proportionate to conclude that the evidence confirms that the compensation arrangements do not undermine the altruistic nature of the donation.

2.18. The PR also supplied an action plan to address how the centre will ensure that future gamete imports will be compliant with General Directions 0006 and General Directions 0001. The Executive reviewed the action plan and is satisfied that this demonstrates understanding and a commitment to ensuring the centre is compliant.

2.19. The committee noted that some improvement is required in order for the centre to demonstrate the suitability of its practices. The centre has a Quality Management System (QMS) and the PR is encouraged to use it to monitor and improve the service provided to donors.

Adverse Incident Reporting

2.20. The committee noted that the centre has failed to report two adverse incidents to the HFEA. The Executive was made aware of these two incidents because they had been reported by the other centres involved.

2.21. The committee noted that in one of these incidents, the use of a donor was blocked pending investigation of a negative outcome. This block was not disseminated to receiving centres in a timely manner, with the consequence that a patient's treatment had to be cancelled at short notice. There was also a risk that blocked samples were used elsewhere in the six months between the donor being blocked and the sector being informed, albeit fortunately, subsequent investigation found the negative outcome was unrelated to the donor. The root cause analysis (RCA) provided by the centre, identified the reason for the delay in informing receiving clinics as being due to a delay in the treating centre informing centre 0011 about the negative outcome. However, during a discussion on inspection, the PR provided a different reason, this being that the genetic counsellor for centre 0011 was responsible for informing the receiving centres but had not done so.

2.22. The Executive has been supplied with a new SOP 'Adverse Incident Management', which includes a revised procedure and risk assessment tool for identifying which incidents should be submitted to the HFEA.

Recommendations

2.23. The inspectorate recommends the renewal of the centre's storage licence for a period of four years without additional conditions subject to the recommendations made in the renewal inspection report being implemented within the prescribed timescales.

2.24. The committee noted that the inspectorate will continue to monitor the centre's performance and the implementation of the recommendations.

3. Decision

3.1. The committee had regard to its decision tree, General Directions 0006 and 0001, the HFEA Compliance and Enforcement Policy and HFEA Guidance on licensing.

Administrative Requirements

Supporting Information under General Direction 0008

Application

3.2. The committee was satisfied that the application was submitted in the form required and contained all the supporting information required by General Direction 0008. Furthermore, it was satisfied that the appropriate fees had been paid.

Proposed Person responsible (PR) – Dr Meheranghiz Minbattiwalla

3.3. The committee was satisfied that the proposed PR possesses the required qualifications and experience and that the character of the proposed PR is such as is required for supervision of the licensed activities. It was further satisfied that the proposed PR will discharge her duties under section 17 of the HFE Act 1990 (as amended).

Proposed Licence Holder (LH) – London Sperm Bank

3.4. The committee was satisfied that the proposed LH is suitable.

Activities

3.5. The committee was satisfied with the suitability of the activities applied for.

Premises – 112 Harley Street, London, W1G 7JQ

3.6. The committee was satisfied that the premises and facilities are suitable for the conduct of the licensed activity applied for.

3.7. The committee noted the recommendation made by the Executive that the PR should ensure written agreements with all third parties who provide goods or services that influence the quality and safety of gametes and embryos are compliant with requirements.

Licence

3.8. The committee agreed that the PR should have been aware of HFEA requirements for the import and export of gametes in relation to compensation, prior to inspection, especially as the centre's primary activities are the storage and distribution of donor sperm within the UK and internationally, and the centre has been operating for many years.

3.9. The committee was deeply concerned that the PR had failed to report two incidents that occurred and also failed to respond to one of the incidents in a timely manner, not acting in the best interest of the patients concerned.

3.10. The committee noted the PR's current level of engagement and commitment to ensure compliance at the centre.

3.11. The committee considered the duration of licence it should offer with reference to the 'Guidance on licensing'. Carefully weighing all factors in the balance, the committee agreed that a three-year licence with no conditions, subject to the implementation of the recommendations outlined in the renewal inspection report, was appropriate.

3.12. The committee noted that a three-year licence would allow the centre to be subject to an interim inspection within one year, which could be scheduled or unannounced, to review evidence of implementation of recommendations and quality of service.

4. Chair's signature

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

Signature

Name

Kate Brian

Date

4 April 2019

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 inspection was scheduled (rather than unannounced) and the report provides information on the centre's application for a renewal of its existing licence. Licences are usually granted for a period of four years. The Authority's Licence Committee (LC) 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: 9 October 2018

Purpose of inspection: Renewal of a licence to carry out Storage only.

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

Inspectors: Mhairi West and Sara Parlett

Date of Licence Committee: 7 March 2019

Centre name	London Sperm Bank
Centre number	0011
Licence number	L/0011/20/a
Centre address	112 Harley Street, London, W1G 7JQ, United Kingdom
Person Responsible	Dr Meheranghiz Minbattiwalla
Licence Holder	London Sperm Bank
Date licence issued	1 April 2015
Licence expiry date	31 March 2019
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:

The London Sperm Bank (LSB) has held a storage only licence with the HFEA since 2010, when they took over the former Louis Hughes licensed centre. The centre is part of the London Women's Clinic (LWC) group, under the umbrella of JD Healthcare. The centre is now mainly a storage and distribution centre for donor sperm, providing sperm to clinics within the LWC group, and other fertility clinics within the UK and internationally. The centre ceased actively recruiting donors in May 2017 but is processing and storing samples for the final donors recruited, who are still in their donation cycle. Donor recruitment for the LWC group now takes place at The Bridge Centre (centre 0070). LSB also imports sperm from Seattle Sperm Bank (SSB) in the United States of America and is in the process of applying for an Importing Tissue Establishment (ITE) certificate to allow this to continue.

Pregnancy outcomes
Treatment services leading to pregnancies are not provided at this clinic.

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), 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 Person Responsible (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 her 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 (GD) 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 LC is asked to note that at the time of the inspection there were a number of areas of practice that required improvement, including three major and two 'other' areas of non compliance.

Since the inspection visit, the PR has provided evidence that actions have been taken to implement the following recommendations and has committed, where required, to audit the effectiveness of those actions within the required timescales:

Major areas of non compliance:

- The PR should ensure that import and export of donor gametes is compliant with General Directions 0006 and 0001.

- The PR should ensure that adverse incidents are reported to the HFEA in the required time frame.

'Other' areas that requires improvement:

- The PR should ensure that the centre's recall procedure is sufficiently detailed to guide centre staff.
- The PR should ensure that all core requirements are included in any third party agreement (TPA).

The PR has given a commitment to fully implementing the following recommendations:

Major areas of non compliance:

- The PR should ensure that consent given by donors is compliant with requirements.

Recommendation to the Licence Committee

The centre has no critical areas of concern but does have three major of areas of concern. One non compliance resulted because on the day of inspection, the centre could not provide the inspection team with evidence to show that the import of a donor sperm sample from SSB (via the European Sperm Bank) was compliant with GD 0006, since compensation provided to the donors appeared non compliant with GD0001.

General Direction 0006 sets out the requirements that must be met before gametes can be imported into the UK. Schedule 3 specifically refers to the import of gametes and embryos from outside of the EEA and Gibraltar. Part 1 (h) requires that: *no money or other benefits has been given or received in respect of the supply of the gametes or embryos unless the money or benefits paid or received is in accordance with Directions 0001 (Gamete and embryo donation) or any subsequent Directions given by the Authority relating to giving and receiving money or other benefits;*

General Direction 0001 sets out the requirements for giving and receiving money or other benefits in respect to any import of gametes or embryos from outside the UK, specifically:
12. *When considering whether to import gametes donated overseas, the centre should ensure the donor has not received compensation which exceeds:*

a) *reasonable expenses incurred by the donor in connection with the donation of gametes provided to that centre; and*
b) *loss of earnings (but not for other costs or inconveniences) incurred by the donor up to a daily maximum of £61.28 but with an overall limit of £250 for each course or cycle of donation (local currency equivalent).*

13. *When receiving donated gametes from overseas, the centre must keep a record (provided by the overseas centre) of:*

a) *the actual expenses incurred by the donor;*
b) *the amount reimbursed to the donor; and*
c) *the receipts produced by the donor, and/or the steps taken by the person responsible to satisfy themselves that the excess expenses claimed by the donor have in fact been incurred.*

On 10 December 2018, when responding to the report, the PR supplied documentary evidence from SSB, stating that donors were compensated 'never more than £35 per clinic visit', accompanied by an itemised payment list for a donor, showing that they were paid $40 per clinic visit. On 8 January 2019, the PR provided further documents detailing similar compensation arrangements and confirmed there were equivalent records for all of the 59 donors imported from SSB.

The inspection team was concerned that the imports of multiple donor sperm samples from SSB to LSB were seriously non compliant with GD 0006, because the compensation provided to the donors was apparently non compliant with GD 0001. A management review meeting was therefore held on 10 January 2019 in accordance with the HFEA's Compliance and Enforcement policy.

The review found that the evidence supported the inspection team's significant concerns and considered that a meeting with the PR and LH would be useful to clarify the compensation scheme and to determine what actions to take. The management review also recommended that this inspection report be considered by the Licence Committee rather than the Executive Licensing Panel, due to the complexity of this non-compliance.

On 11 January 2019, the executive emailed the PR setting out the HFEA's position and requesting that the centre should not import any further samples until both the centre and the HFEA were satisfied with the donor compensation arrangements. The PR and LH were invited to attend a meeting with the HFEA executive, to discuss the issues highlighted by the submitted evidence, which suggested fixed rate compensation per visit with no limit per course of donation, with a request to bring further evidence of compliance.

On 23 January 2019, the PR confirmed by email that she would not import any donor sperm until both the centre and the HFEA were satisfied with the compensation arrangements.

The HFEA executive met with the PR and the LH on 28 January 2019 to review the further evidence they presented. The information suggested that donors are each paid a flat fee of $40USD per visit, irrespective of the actual loss of earnings and expenses. The executive's view at this point was that this fixed rate compensation was not compliant with General Direction 0001. The executive emailed the PR and LH with a summary of the meeting, and a recommendation that they seek further information and advice from SSB, with a deadline for submission of two weeks.

Further evidence was submitted to the executive on 11 February 2019. This consisted of evidence showing that the compensation, although fixed rate, represented an amount for each visit which would cover only limited expenses and loss of earnings in the cost of living environment in which SSB is based, highly likely to have been incurred by each donor during each visit to SSB. Therefore the donations could be deemed altruistic as the donors were unlikely to be making money on the compensation provided. The executive considered that it is proportionate to conclude that the evidence confirms that the compensation arrangements do not undermine the altruistic nature of the donation.

The PR also supplied the centre's action plan to address how the centre will ensure that future gamete imports will be compliant with GD 0006 and GD 0001. The executive reviewed the action plan and is satisfied that this demonstrated understanding and commitment to attaining compliance, and address the elements of the major non compliance recorded in the section 'areas to be addressed by the PR'.

In response to the information provided by the PR soon after the inspection, the inspection team had considered adding a further recommendation to the report regarding the leadership of the centre. The meetings with the PR and LH have assured the executive that the PR now has the understanding necessary to ensure future compliance at the centre, as well as the support of the centre's Licence Holder. The executive considered

that adding a further non-compliance regarding poor leadership by the PR was unnecessary, given the PR's engagement and commitment to ensure compliance at the centre.

The centre's licence expires on 31 March 2019 but Special Directions have been granted to allow the centre's activities to continue lawfully until 30 June 2019 or the coming into effect of a renewed licence, whichever is the sooner.

In summary, the centre has no critical areas of concern but does have three major of areas of concern.

Some improvement is required in order for the centre to demonstrate the suitability of its practices. The centre has a quality management system (QMS) and the PR is encouraged to use it to monitor and improve the service provided to donors.

The inspector will continue to monitor the centre's performance and the implementation of this report's recommendations within the required timescales.

The inspection team recommends the renewal of the centre's storage licence for a period of four years without additional conditions subject to the recommendations made in this report being implemented within the prescribed timescales.

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
2. The experience of donors at this centre
3. The protection of gametes (sperm) 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 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
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.

Payments for donors (Guidance note 13; General Direction 0001)
The centre's procedures are partially 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

Payments for donors (Guidance note 13; General Direction 0001)
Refer to the imports and exports section of this report and recommendation 1.

Suitable premises and suitable practices

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 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 third party laboratories which will undertake the diagnosis and investigation of donors, or their gametes, are compliant with HFEA requirements for accreditation 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)
The centre is providing sperm storage services only therefore this area of practice was not relevant to this inspection.

Prescription of intralipid 'off label'
Intralipid is an intravenous nutritional supplement sometimes prescribed to facilitate IVF treatment in a particular subset of women. This centre does not prescribe intralipid therapy therefore requirements related to its use were not relevant at this inspection.

Pre-operative assessment and the surgical pathway (Guidance Note 25)
The centre is providing sperm storage services only therefore this area of practice was not relevant to this inspection.

Multiple births (Guidance note 7; General Direction 0003)
The centre is providing sperm storage services only, therefore this area of practice was not relevant to this inspection.

Procurement of gametes (Guidance note 15)
The centre's procedures are compliant with HFEA requirements.

Transport and distribution of gametes (Guidance note 15; General Direction 0009)
The centre's procedures for the transport, distribution and recall of gametes are broadly 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 (Guidance note 15)
The centre's procedures for the receipt of gametes are 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 partially compliant with HFEA requirements.

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 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 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 are broadly compliant with HFEA requirements.

Transport and satellite agreements (Guidance note 24; General Direction 0010)
The centre does not have any transport or satellite activities, therefore this area of practice was not relevant to this inspection.

Equipment and materials (Guidance note 26)
The centre uses equipment and materials that are compliant with HFEA requirements. All 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 partially compliant with HFEA requirements. The centre reports some 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

Transport and distribution of gametes (Guidance note 15; General Direction 0009)
The centre's recall procedure is insufficiently detailed to cover more unusual scenarios such as when a transportation shipper is delivered to the wrong address. It is acknowledged that recall is likely to be infrequent, but the inspection team considered that due to the centre being a large distribution hub for donor sperm, a more comprehensive protocol is warranted.

SLC T122, CoP Guidance Note 15; see recommendation 4.

Imports and exports (Guidance note 16; General Direction 0006)
Records for the import of donor sperm from the European Sperm Bank (ESB) in Denmark and the export of donor sperm to Vietnam and Israel, were reviewed to assess compliance with the requirements of General Direction (GD) 0006. Additional documentation was provided post inspection and was also reviewed. None of the three imports/exports were fully compliant with GD 0006 because:

1. **Import of donor sperm from the ESB:** This donor sperm originated from Seattle Sperm Bank (SSB) in USA. Evidence was not available on inspection to demonstrate the amount of compensation given to the sperm donor. Post inspection, centre staff forwarded correspondence from ESB stating that ESB sperm donors (and this particular sperm donor from SSB) all receive compensation equivalent to £35 per visit as received for UK donors and that they do not request receipts for expenses. This correspondence and the fixed rate compensation it describes, are not compliant with General Direction 0001, paragraphs 12 and 13, and therefore the import of this sperm was not compliant with GD 0006.

   This finding potentially has wider sector implications, because ESB donor sperm is imported to many UK clinics.

2. **Export of donor sperm to Vietnam:** No evidence was available on inspection to demonstrate compliance with GD 0006. Centre staff assured the inspection team that the evidence had been collected and assessed prior to export, but the records were with a member of staff that was currently on annual leave. The evidence was subsequently provided post inspection. This was reviewed and found to be non compliant with GD 0006 because there was no evidence that the QMS at the centre in Vietnam had been certified by an internationally recognised body (GD 0006, Schedule 4, Part 1 (b)).

   Due to this non-compliance with a requirement of GD 0006, Schedule 4, an application for a Special Direction should have been submitted in order for this export to be considered.

3. **Export of donor sperm to Israel:** The centre has not provided evidence to demonstrate compliance with Schedule 4, Part 1 (a), (b) and (c). Again an application for a Special Direction should have been submitted in order for this export to be considered

GD 0006, SLC T69; see recommendation 1.

The centre has a relationship with SSB; donor sperm is received from SSB and LSB, in turn, exports UK donor sperm to SSB. Imports are on hold currently because the centre has not yet successfully applied to the HFEA for a certificate to import, following implementation of EU Directive 2015/566. However, post inspection, the centre's current TPA with SSB was reviewed. This states that compensation given to donors is no more than £35 per visit. This fixed rate compensation scheme is non compliant with GD 0001, paragraph 12, thus the import of sperm from donors so compensated is non compliant with GD 0006, as detailed above.

Third party agreements (Guidance note 24)

The content of the TPA with The Doctors Laboratory (TDL) did not include how information in terms of tests / diagnostic results is relayed to the commissioning centre including sign off and confirmation that the result applies to the correct sample.

SLC T114; see recommendation 5.

Adverse incidents (Guidance note 27)
The centre has failed to report two adverse incidents to the HFEA. The inspection team was aware of these two incidents because they had been reported by the other centres involved.

In one of these incidents, usage of a donor was blocked pending investigation of a negative outcome. This block was not disseminated to receiving clinics in a timely manner, with the consequence that a patient's treatment had to be cancelled at short notice. There was also a risk that blocked samples were used elsewhere in the six months between the donor being blocked and the sector being informed, albeit fortunately, subsequent investigation found the negative outcome was unrelated to the donor. The root cause analysis (RCA) provided by the centre, identified the reason for the delay in informing receiving clinics as being due to a delay in the treating centre informing LSB about the negative outcome. However, the PR provided a different reason during discussion on inspection, this being that the LSB genetic counsellor was responsible for informing receiving clinics but had not done so.

SLC T118; see recommendation 3.

Staff engaged in licensed activity

Person Responsible (PR)
Staff

What the centre does well

Person Responsible (Guidance note 1)
The PR has complied with HFEA requirements, notwithstanding the concerns related to moving gametes under GD0006.

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.

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 providing sperm storage services only therefore this area of practice was not relevant to this inspection.

Safeguarding (Guidance Note 25)
The centre's procedures are compliant with safeguarding guidance. This ensures that the centre's patients 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)
The centre is providing sperm storage services only and therefore requirements related to embryo testing were not relevant at this inspection.

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

2. The experience of patients

Patient feedback

What the centre does well

Only a very small number of donors remain donating at this centre; it is mainly a storage and distribution centre for donor sperm procured at another centre in the LWC group and overseas. Therefore donor feedback was not reviewed in detail at this inspection.

What the centre could do better

Nothing identified at this inspection.

Treating patients fairly

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 donors are treated fairly and that all licensed activities are conducted in a non discriminatory way.

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 donors providing relevant consent. The inspection team was impressed with the centre's approach to counselling: historic donors, even those from before the group took over the centre and for whom samples are no longer stored, can access the centre's counselling service as often as required and free of charge.'

Egg and sperm sharing arrangements (Guidance note 12; General Direction 0001)

The centre is providing sperm storage services only therefore this area of practice was not relevant to this inspection.

Surrogacy (Guidance note 14)

The centre is providing sperm storage services only and therefore requirements related to surrogacy were not relevant at this inspection.

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.

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

Information

What the centre does well

Information (Guidance note 4; Chair's Letter CH(11)02)
The centre's procedures for providing information to donors are compliant with HFEA requirements. This ensures that the centre gives prospective and current 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 partially compliant with HFEA requirements. This ensures that donors have provided all relevant consents before carrying out any licensed activity.

Legal parenthood (Guidance note 6)
The centre is providing sperm storage services only and therefore requirements related to legal parenthood were not relevant at this inspection.

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' consent, so that it only releases the donor's identifying information, to researchers, with their consent. Information can be used by researchers to improve the knowledge about the health of patients undergoing ART and those born following ART treatment.

What the centre could do better

Consent (Guidance note 5;6)

The consent form completed by a donor of sperm imported from ESB was reviewed on inspection. This donor sperm originated from SSB. Under the 'withdrawal of consent' section of the form it states:

"*I understand that I have the right to withdraw my consent to the Seattle Sperm Bank's donor program up until such time that a specific recipient has begun an assisted reproductive cycle in reliance on the availability of my donor sperm".* This is non-compliant with UK law, which allows for donors to withdraw their consent up until the point their gametes are used in treatment.

The form goes on to state:

"In the event I elect to withdraw from the program, I understand that Seattle Sperm Bank may seek to recover any and all direct fees lost by Seattle Sperm Bank as a result of my withdrawal, including, without limitation, the compensation I have received for all specimens in quarantine, costs paid by Seattle Sperm Bank for genetic testing and processing, direct labor costs, as well as reimbursement for legal fees incurred in the process of enforcement and collection.'

Linking financial penalties to a withdrawal of consent could be considered a pressure to continue to consent to usage of their gametes. The inspection team considers that this consenting policy does not meet HFEA consenting principles, including that consent (including the withdrawal of consent) should not be restricted in any way, and therefore does not meet the requirements of Schedule 3 of the HF&E Act 1990 (as amended) (see recommendation 2).

3. The protection of gametes and embryos

Respect for the special status of the embryo

What the centre does well
The centre is providing sperm storage services only and therefore requirements related to the special status of the embryo were not relevant at this inspection.

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

Screening of donors and Storage of gametes

What the centre does well

Screening of patients (Guidance note 17)
These requirements are not relevant to the centre's activities.

Storage of gametes (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)
The centre is providing sperm storage services only and therefore requirements related to the use of embryos for training staff were not relevant at this inspection.

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 **Record keeping and document control (Guidance note 31)** 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. **Obligations and reporting requirements (Guidance note 32; General Direction 0005)** 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. The HFEA register audit team found no evidence of problems with the timeliness and accuracy of the centre's submission of data to the Register.
What the centre could do better Nothing identified at this inspection.

Section 3: Monitoring of the centre's performance

Following the interim inspection in 2016, recommendations for improvement were made in relation to two areas of major non compliance and two 'other' areas of non compliance.

The PR provided information and evidence that all the recommendations were fully implemented.

On-going monitoring of centre success rates

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

Areas of practice requiring action

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, 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 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 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			

Major area of non compliance

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

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

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
1. Imports and exports; Payment of donors The centre has imported donor sperm from the USA via Denmark under GD 0006, without having evidence that all requirements of this GD have been met; i.e. the record of compensation paid to the donor and the fixed rate compensation it describes, were not compliant with GD 0001, paragraphs 12 and 13. This finding potentially has wider sector implications,	The PR should ensure that import and export of donor gametes are compliant with General Directions. The PR should ensure compliance with GD 0001, in particular with respect to compensation given to donors of gametes procured outside the UK then imported into the UK. The PR should review donor compensation arrangements at the banks in Denmark and the USA and provide evidence of compliance with GD requirements, when responding	1. Please ref to email attached as received from ESB in regards to compensation of their donors #8637 & #8133. ESB has confirmed compensating their donor with 300DKK per donation, which is equivalent to UK £35/donation. SSB has also confirmed separately of the same; please ref attached document. 2. Compensation for all imported donors from 2016 will be reviewed and a report will be submitted by 9th July.	The executive acknowledges the PR's response and also the evidence supplied in order to demonstrate compliance with this recommendation. The PR has supplied email communications from SSB, and from ESB, confirming compensation to the donors as equivalent to £35 per visit. The same payment at each visit implies a flat rate is being paid per visit, rather than payment depending on incurred expenses. Since the report, the PR has confirmed that the centre has imported samples

because donor sperm from ESB in Denmark is imported to many UK clinics. The centre also could not provide evidence that all the requirements of GD 0006 (Schedule 4) had been met for the two gamete export cases reviewed. GD 0001, GD 0006, SLC T69.	to this report. The PR should retrospectively audit all gamete imports and exports from the last two years for compliance with GDs 0001 and 0006, and submit a report to the centre's inspector by 9 July 2019. It is acknowledged that this may be a time-consuming task, however because issues were noted with all three imports/exports reviewed on inspection, it is considered necessary to determine the scale of non compliance in this area. The PR should contact the centre's inspector if they anticipate any difficulties in meeting this target. The TPA with SSB should be reviewed against all relevant CoP requirements. A revised and compliant TPA should be provided to the centre's inspector by 9 January 2019. The PR should review the centre's procedures to ensure that evidence required to demonstrate compliance with the requirements of GD 0006 is	3. TPA with SSB is being reviewed & a compliant TPA will be submitted by 9th Jan 2019. 4-5. Lab manual is under review to include import and export of gametes to and from LSB. This wil be submitted to the inspector by 9th Jan 2019. 6. A report will be submitted of the revised procedures to ascertain viability with respect to GD 0006 as suggested.	from 59 donors, compensation for all of whom is similar to that indicated by the evidence above. This compensation of overseas donors is non compliant with GD 0001 paragraphs 12 and 13, which describe maximum daily and cycle of donation payments for such donors, and that reimbursed expenses should have been incurred. **Update 8 February;** The PR and LH have met with the executive, and subsequently retrospectively reviewed the compensation records for the donor sperm imports from SSB. The PR has supplied the executive with evidence that the amount paid to the overseas donors represents an amount which covers likely expenses and loss of earnings, indicating that the donors were not donating because of a financial inducement to donate, and the donations were meeting the fundamental principle that

	obtained and kept on file, before gametes are imported or exported. A summary of the review and any changes implemented as a result, should be provided to the centre's inspector by 9 January 2019. Three months after implementation, the PR should audit the revised procedures. A report of the audit, including any further necessary corrective actions with timescales for implementation, should be provided to the centre's inspector by 9 April 2019.		donation must be altruistic. No further action required. The PR has supplied the executive with a revised TPA from SSB which contains a statement agreeing that donors will be compensated in line with the appropriate requirements of GD 0001. The PR has also provided an action plan for future imports of donor gametes, requiring the supplying centre to provide evidence of compliance with the requirements of GD 0001 and GD 0006, in the form of a requirement for the supplying donor bank to provide detailed breakdown of compensation provided to that donor. Once the ITE certification is granted to allow this centre to recommence importing donor gametes from SSB, the PR should monitor the imports for six months to ensure that they are compliant with the requirements of GD 0001 and GD 0006, and submit the results of that monitoring to the

			centre's inspector. The PR should note that a course of sperm donation, referred to in GD 0001, has been previously defined by the HFEA as the period beginning at the first consultation and ending once the sample has been released for use in treatment. The PR should ensure that compliance is assessed using this definition. Further action required.
2. Consent The centre could not provide evidence that donors of gametes imported from SSB were able to withdraw their consent to the use of their gametes in donation, freely, without hindrance and up to the point of use of their gametes in treatment. Human Fertilisation and Embryology (HF&E) Act 1990 (as amended) Schedule 3.	The PR should ensure that consent given by donors is compliant with requirements. The PR should review the consents completed by donors providing imported samples from SSB and provide an update to the centre's inspector when responding to this report.	Please see attached report summarising SSB withdrawal of consent and verbal confirmation from SSB. We have contacted SSB to report this area of practice as non-compliant in its present nature. SSB has agreed to review & redress their 'withdrawal of consent' policy and forward revised documentation pertaining to current donors imported & stored a LSB.	The executive acknowledges the PR's response and commitment to implementing this recommendation. Further action is required; submission of the revised consent form used by SSB and an audit to determine if any donors who could not be contacted, or declined to sign the new consent forms, are in storage at LSB, and an action plan for that scenario.
3. Adverse incidents	The PR should ensure that	Incident IN06207 occurred	The executive acknowledges

The centre has failed to report two adverse events to the HFEA. For one of these incidents there was also a discrepancy between the submitted RCA and the PR's verbal account provided during the inspection. SLC T118.	adverse incidents are reported to the HFEA within the required time frame. The PR should review the documented procedure used to identify which incidents are reportable to the HFEA, to ensure it supports compliant incident reporting. It should be provided to the centre's inspector by 9 January 2019. The PR should review why the RCA submitted to the HFEA differed in its explanation of the incident involving blocked donor sperm from that provided by the PR on inspection. A written summary of the review should be provided to the centre's inspector with the PR's response to this report.	from a centre within the JDH group, therefore it was decided that the treating clinic will report the incident to the HFEA. Moving forward if LSB is made aware of the any adverse outcomes, the PR will report them independently. Please see attached 'summary of events re adverse incident' doc. All email correspondences mentioned in the summary can be provided upon request.	the PR's response to this recommendation. However, IN016207 reports that a treating centre did not relay an adverse birth outcome back to LSB. This non-compliance is not related to the reporting of the adverse outcome, it is related to the incident where LSB later became aware that the blocking of the donor had not been communicated to centres who had purchased that donor and therefore that LSB procedures had failed. It is this incident that should have been reported to the HFEA. **Update 28 January 2019;** The centre's inspector has been supplied with a new SOP 'Adverse Incident Management', which includes a revised procedure and risk assessment tool for identifying which incidents should be submitted to the HFEA. No further action required.

Other areas of practice that requires improvement

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

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
4. Transportation The centre's recall procedure is insufficiently detailed to cover more unusual scenarios, such as when a transportation shipper is delivered to the wrong address. SLC T122, CoP Guidance Note 15.	The PR should ensure that the centre's recall procedure is sufficiently detailed to guide centre staff. A revised copy of the recall procedure should be provided to the centre's inspector by 9 January 2019.	The recall procedure will be redressed in the lab manual and presented by 9th January 2019	The executive acknowledges the PR's response and commitment to implementing this recommendation. The PR has supplied evidence that the recall procedure has been reviewed and is now sufficiently detailed. No further action required.
5. Third party agreements The content of the TPA for TDL reviewed during the inspection did not include how information in terms of tests / diagnostic results is relayed to the commissioning centre including sign off and confirmation that the result applies to the correct sample. SLC T114f.	The PR should ensure that all core requirements are included in any TPA. The PR should review this TPA, to ensure it is compliant with SLCs and provide a copy with the necessary amendments, to the centre's inspector by 9 January 2019.	TPA with SSB is in revision to be compliant with SLC T114f. Acompleted TPA will be presented by 9th January 2019	The PR has supplied a response which is related to the TPA with SSB, not TDL Update 19 February; The PR has supplied the executive with a compliant TPA for TDL. No further action.

Reponses from the Person Responsible to this inspection report