Licence Committee - minutes

Centre 0075
(London Women's Clinic, Darlington)
Renewal Licence

Thursday, 10 January 2019

Church House, Dean's Yard, Westminster, London SW1P 3NZ

Committee members	Kate Brian (Chair) Anita Bharucha (Deputy Chair) Ruth Wilde Gudrun Moore	
Members of the Executive	Dee Knoyle Sandrine Oakes (Observer) Nicola Lawrence (Observer) Sara Parlett (Observer)	Committee Secretary HFEA Inspector (induction) HFEA Inspector (induction) HFEA Inspector
Legal Adviser	Dawn Brathwaite	Mills & Reeve 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:
  - 11 January 2018 – renewal inspection report
  - 25 August 2017 – change of Person Responsible
  - 13 July 2017 – interim inspection report and media allegations report
  - 4 May 2017 – interim inspection report
  - 9 March 2017 – executive update
  - 14 July 2016 – unannounced inspection report
  - 21 March 2016 – interim inspection report

1. Background

1.1. The London Women's Clinic, Darlington, centre 0075 has held a treatment and storage licence with the HFEA since 1992 and provides a full range of fertility services.

Previous Licence

1.2. The centre's previous licence was granted on 1 April 2015 for a period of three years and was varied to reflect the following changes:

- Additional Licence Condition - 13 July 2017
- Change of Person Responsible (PR) - 25 August 2017

Current Licence

1.3. The centre's current licence was granted on 1 April 2018 for a period of one year, rather than the usual four years, which would be granted to centres that can demonstrate compliance at the licence renewal inspection. This was due to two critical non-compliances found during the inspection process, and other wide-ranging concerns identified, along with a poor history of compliance at the centre under the leadership of the previous PR.

1.4. The centre has an additional condition on the licence preventing treatments involving egg sharing at the centre.

Additional Condition:

The centre must not provide treatment services where a patient donates her eggs to receive 'benefits in kind' until the Executive is satisfied that there are appropriate procedures in place to ensure that this process is compliant with requirements.

2. Consideration of application

Renewal Inspection

Application

2.1. The committee noted that the centre had submitted an application for the renewal of the treatment and storage 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.

Inspection Process

2.3. The committee noted that in the 12 months to 30 September 2018, the centre provided 357 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a small centre.

2.4. The committee noted that for IVF and ICSI, HFEA-held register data for the period 1 July 2017 to 30 June 2018 showed the centre's success rates were in line with national averages.

2.5. The committee noted that in 2017, the centre reported eight cycles of partner insemination with one pregnancy. This is in line with the national average.

2.6. The committee noted that between 1 July 2017 and 30 June 2018, the centre's multiple pregnancy rate for all IVF, ICSI and FET (frozen embryo transfer) cycles for all age groups was 15%. This represents performance that is not likely to be statistically different from the 10% maximum multiple live birth rate target for this period.

2.7. The committee noted that the renewal inspection took place on 6 and 7 November 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 'other' areas of non-compliance identified. Since the inspection visit, the PR has committed to fully implementing all of the recommendations and will provide evidence that actions have been taken. The PR has also committed, where required, to audit the effectiveness of those actions within the required timescales.

2.8. The committee noted that the centre has a Quality Management System (QMS) and the PR is encouraged to continue to use it to monitor and improve their success rates and the quality of the service offered to patients.

Recommendations

Licence

2.9. The inspectorate recommends the renewal of the centre's treatment and storage licence for a period of four years, subject to the recommendations made in this report being implemented within the prescribed timescales.

2.10. During the current inspection, the additional licence condition preventing treatments involving egg sharing at the centre, was discussed with the PR who confirmed that she does not wish to have the condition removed at present. Therefore, the centre's egg sharing practices and procedures, were not reviewed at this inspection. The PR will provide the necessary information and documents required by the Executive at such time as she feels it appropriate to apply to have the licence condition removed. The inspectorate recommends that the additional condition remains on the current licence.

Additional Condition:

The centre must not provide treatment services where a patient donates her eggs to receive 'benefits in kind' until the Executive is satisfied that there are appropriate procedures in place to ensure that this process is compliant with requirements.

3. Decision

3.1. The committee had regard to its decision tree, 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) – Mrs Jacqueline Biro

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) – Dr Kamal Ahuja

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 – Woodlands Hospital, Morton Park, Darlington, Durham, DL1 4PL, United Kingdom

3.6. The committee was satisfied that the premises and facilities are suitable for the conduct of the licensed activity applied for. The committee was also satisfied that the PR has confirmed that an external company will fit an extraction fan to an exterior wall to allow ventilation to the cryostore on 20 December 2018. The external company will also perform a risk assessment before and after installation and the PR will forward this to the inspectorate by 7 February 2019. The risk assessment should be to the satisfaction of the Executive.

3.7. The committee was satisfied that the third-party premises are also suitable.

Licence

3.8. The committee noted the level of engagement and progress made by the new PR, mindful of the centre's licensing history, and carefully 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 four-year licence subject to the implementation of the recommendations outlined in the renewal inspection report, was appropriate.

3.9. The committee noted that the inspectorate will continue to monitor the centre's performance and the implementation of the recommendations within the required timescales.

3.10. The committee endorsed the inspectorate's recommendation to add the additional condition from the current licence to the new licence:

Addition Condition:

The centre must not provide treatment services where a patient donates her eggs to receive 'benefits in kind' until the Executive is satisfied that there are appropriate procedures in place to ensure that this process is compliant with requirements'.

3.11. The committee commended the PR for her efforts to embed changes, act upon the recommendations set out in the last renewal report and sustain improvements. The committee encouraged the PR to continue working with the Executive to ensure that a good service is provided to patients.

3.12. The committee agreed that the centre's future interim inspection report should be considered by the Licence Committee.

4. Chair's signature

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

Signature

Name

Kate Brian

Date

5 February 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) will use 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: 6 and 7 November 2018

Purpose of inspection: Renewal of a licence to carry out treatment and storage

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: Dr Vicki Lamb, Lesley Brown, Julie Katsaros and Polly Todd

Date of Licence Committee: 10 January 2019

Centre name	London Women's Clinic, Darlington
Centre number	0075
Licence number	L/0075/16/a
Centre address	Woodlands Hospital, Morton Park, Darlington, Durham, DL1 4PL, United Kingdom
Person Responsible	Mrs Jacqueline Biro
Licence Holder	Dr Kamal Ahuja
Date licence issued	1 April 2018
Licence expiry date	31 March 2019
Additional conditions applied to this licence	a) The centre must not provide treatment services where a patient donates her eggs to receive 'benefits in kind' until the Executive is satisfied that there are appropriate procedures in place to ensure that this process is compliant with requirements.

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:

The London Women's Clinic, Darlington has held a treatment and storage licence with the HFEA since 1992 and provides a full range of fertility services.

The centre provided 357 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 30 September 2018. In relation to activity levels this is a small centre.

Other licensed activities at the centre include the storage of gametes and embryos.

The centre's previous licence was granted on 1 April 2015 for a period of three years, and was varied to reflect the following changes:

- 13 July 2017: Additional condition placed on licence
- 25 August 2017: Change of Person Responsible (PR)

The current licence was granted on 1 April 2018 for a period of one year, rather than the four years usually granted to compliant centres at licence renewal. This was due to two critical non-compliances being found during, or soon after, the renewal inspection and there being other wide-ranging concerns identified, along with a poor history of compliance at the centre under the leadership of the previous PR.

During the current inspection, the additional licence condition preventing treatments involving egg sharing at the centre, was discussed with the PR. She does not wish to have the condition removed at present. Therefore, the centre's egg sharing practices and procedures, were not reviewed at this inspection. The PR will provide the necessary information and documents required by the Executive at such time as she feels it appropriate to apply to have the licence condition removed.

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period 1 July 2017 to 30 June 2018 show the centre's success rates are in line with national averages.

In 2017, the centre reported eight cycles of partner insemination with one pregnancy which is in line with the national average.

Multiple births[2]

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

Between 1 July 2017 and 30 June 2018, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 15%. This represents performance that is not likely to be statistically different from the 10% multiple live birth rate target.

[1]The data in the Register may be subject to change as errors are notified to us by clinics, or picked up through our quality management systems. Centre success rates are considered statistically different from the national averages, and multiple pregnancy rates are considered statistically different from the 10% multiple live birth rate target, when $p \leq 0.002$.

[2]The HFEA use a conversion factor of 1.27 to convert the 10% multiple live birth rate (MLBR) target to a multiple pregnancy rate (MPR) target of 13%.

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 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, with the exception noted in the report;
- the centre's practices are suitable, with the exceptions noted in the report;
- 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 LC is asked to note that at the time of the inspection there were three 'other' areas of non-compliance, which have resulted in the following recommendations.

Since the inspection visit, the PR has given a commitment to fully implement all the recommendations, providing evidence that actions have been taken and making a commitment, where required, to audit the effectiveness of those actions within the required timescales.

'Other' areas of non-compliance:

- The PR should ensure that a record is kept of the check that donors have undergone appropriate selection and screening tests.
- The PR should review the cryostore.
- The PR should ensure that appropriate records are kept.

Recommendation to the Licence Committee

The centre has no critical or major areas of non-compliance.

The inspection team notes that the success rates are consistent with the national average and their multiple clinical pregnancy/live birth rates meet the target.

The PR is encouraged to continue to use the quality management system (QMS) to best effect to monitor and improve their success rates and the quality of the service offered to patients.

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 treatment and storage licence for a period of four years subject to the recommendations made in this report being implemented within the prescribed timescales. It also recommends that the current additional condition on the licence: 'the centre must not provide treatment services where a patient donates her eggs to receive 'benefits in kind' until the Executive is satisfied that

there are appropriate procedures in place to ensure that this process is compliant with requirements' remains in place.

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 embryos and the patient or donor to whom they relate are compliant with HFEA requirements. This ensures that patients receive treatment using the correct gametes or embryos.

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 broadly 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 or embryos. 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 or embryos from identifiable donors and keep records of donor characteristics. This is because patients using donated gametes and embryos 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

Screening of donors (Guidance note 11)
During a review of records related to imported donor sperm, for one donor of mixed race ethnicity the records indicated that no additional genetic screening tests had been carried out. A review of whether additional tests were required for this donor had not been documented (standard licence condition (SLC) T52 h and i, see recommendation 1).

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 broadly 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 satellite facilities and laboratories conducting tests that impact on the quality and safety of gametes and/or embryos (relevant third parties) are suitable.

The centre is compliant with HFEA requirements to process gametes and/or embryos 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, patients' partners or donors, or their gametes, embryos or

any material removed from them, are compliant with HFEA requirements to be accredited by UKAS, the national accreditation body for the UK, or another body 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 has arrangements in place for obtaining, recording, handling, using, keeping, dispensing, administering and disposing of medicines that are compliant with guidance.

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 has policies and procedures in place that are compliant with professional body guidelines for pre-operative assessment and management of the surgical pathway. This is important to ensure that all patients are safely assessed and cared for pre, peri and post operatively.

Multiple births (Guidance note 7; General Direction 0003)
The centre's procedures are compliant with HFEA multiple births minimisation strategy requirements for keeping a summary log of cases in which multiple embryos have been transferred and conducting regular audits and evaluations of the progress and effectiveness of the strategy. The single biggest risk of fertility treatment is a multiple pregnancy.

Procurement of gametes and embryos (Guidance note 15)
The centre's procedures are compliant with HFEA requirements to:

- document the justification for the use of the patient's gametes (or embryos created with their gametes) in treatment, based on the patient's medical history and therapeutic indications;
- where the sperm is procured at home, the centre keeps a record of this in the gamete provider's records.

Transport and distribution of gametes and embryos (Guidance note 15; General Direction 0009)
The centre's procedures for the transport, distribution and recall of gametes and embryos are compliant with HFEA requirements. This is important to ensure that all gametes / embryos 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 or embryos;
- shipped in a container that is designed for the transport of biological materials and that maintains the safety and quality of the gametes or embryos;
- appropriately labelled with the transport conditions, including temperature and time limit being specified;
- the container/package is secure and ensures that the gametes or embryos are maintained in the specified conditions. All containers and packages are validated

as fit for purpose.

Receipt of gametes and embryos (Guidance note15)
The centre's procedures for the receipt of gametes and embryos are compliant with HFEA requirements. This is important to ensure that the centre only accepts gametes and embryos 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 and embryos are compliant with HFEA requirements.

The centre has not yet been allocated an importing tissue establishment (ITE) import certificate, however imports of gametes and embryos from third country suppliers (TCS) outside the EU/EEA have not been made since the introduction of the ITE/TCS import certification scheme on 1 April 2018.

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 and embryos during any step from procurement to use for human application or disposal;
- to identify the donor and recipient of particular gametes or embryos;
- to identify any person who has carried out any activity in relation to particular gametes or embryos; and
- to identify and locate all relevant data relating to products and materials coming into contact with particular gametes or embryos 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 are compliant with HFEA requirements.

Transport and satellite agreements (Guidance note 24; General Direction 0010)
The centre has systems in place to manage satellite activities that are compliant with HFEA requirements. This is important to ensure that activities performed by satellite clinics on behalf of the licensed centre are suitable and meet the HFEA requirements.

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 or embryos 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

Safety and suitability of premises and facilities (Guidance note 25)
The cryostore, containing 11 storage dewars, has low oxygen alarms but does not have any extraction system. There is a push bar opening fire door, leading outside, from the cryostore. The embryologists described opening this external door to ensure adequate ventilation when filling dewars. The cryostore is situated next to the embryologist office area of the laboratory, with a windowed fire door between. The inspector could not be assured that the ventilation within the cryostore is adequate, nor were they assured that the fire door between the cryostore and the embryology office would prevent oxygen depletion in the embryologists' work station area (SLC T17, British Compressed Gases Association's (BCGA) (2000) Code of Practice 30 (CP30) – 'The safe use of liquid nitrogen dewars up to 50 litres, see recommendation 2).

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.

The PR has academic qualifications in the field of nursing 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's procedures to ensure that the centre takes into account 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, 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 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 does not perform embryo testing, therefore this area was not inspected.

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

2. The experience of patients

Patient feedback

What the centre does well

The HFEA website has a facility on its 'Choose a Fertility Clinic' page enabling patients to provide feedback on their experience of their clinic. Only eight patients have provided feedback in the last 12 months, giving an average 4.5 star rating to the clinic. This suggests that the clinic does not actively seek patient feedback for comparison purposes. For the system to work well, it is important that every patient knows about the rating system. The PR is asked to consider ways to promote the use of this facility, this will be followed up at the next inspection. The website also gives the ability for patients to comment on the cost of treatment. The majority of patients confirmed that they had paid what they expected to.

The centre's own most recent patient survey responses were also reviewed. Feedback was comparable to that provided to the HFEA.

During the inspection no patients were available to speak to the inspectors about their experiences.

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

- treats patients with privacy and dignity;
- provides a clean and well organised environment for patient treatment;
- has staff who are supportive and professional;
- gives patients sufficient, accessible and up-to-date information to enable them to make informed decisions;
- treats patients with empathy and understanding.

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 patients and 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 patients and donors providing relevant consent and prior to consenting to legal parenthood.

Egg and sperm sharing arrangements (Guidance note 12; General Direction 0001)
The centre does not perform egg or sperm sharing, therefore this area was not inspected

Surrogacy (Guidance note 14)
The centre does not perform surrogacy, therefore this area was not inspected.

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 patients and 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 patients and / or 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 the effectiveness of the consent and in some cases it may be necessary for a patient couple to obtain a court declaration to establish legal parenthood.

This centre has been inspected since 2014 and 2015 when significant failings were reported across the sector regarding the collection and documentation of consent to legal parenthood. At the inspections on 5 December 2016 and 26/27 October 2017, legal parenthood consenting processes were found to be robust.

At this inspection, to provide assurance of the continued effectiveness of the centre's procedures related to legal parenthood consent, the inspection team reviewed five sets of records where treatment with donor sperm had recently been provided in circumstances where consent to legal parenthood was required. Effective consent to legal parenthood with a prior offer of counselling was seen to be in place before treatment.

In summary, the inspection team considers the processes used to obtain consent to legal parenthood at this centre to be compliant with HFEA requirements.

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 patients' consent, so that it only releases the patients 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
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's procedures are compliant with the requirements of the HF&E Act 1990 (as amended) and ensure that the special status of the embryo is respected when licensed activities are conducted at the centre because:

- licensed activities only take place on licensed premises;
- only permitted embryos are used in the provision of treatment services;
- embryos are not selected for use in treatment for social reasons;
- embryos are not created by embryo splitting;
- embryos are only created where there is a specific reason to do so which is in connection with the provision of treatment services for a particular woman and
- embryos are only stored if those embryos were created for a woman receiving treatment services or from whom a third party agreement applies.

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 17)

The centre's procedures for screening patients 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 and/or embryos.

Storage of gametes and embryos (Guidance note 17)

The centre's procedures for storing gametes and embryos are compliant with HFEA requirements. These measures ensure that the gametes and embryos are stored appropriately to maintain their quality and safety. Furthermore, the centre only stores gametes and embryos in accordance with the consent of the gamete providers. The storage of gametes and embryos is an important service offered by fertility clinics, as it can enable patients to preserve their fertility prior to undergoing other medical treatment such as radiotherapy. The storage of embryos not required for immediate use also means that women can undergo further fertility treatment without further invasive procedures being performed.

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 has not used embryos for training since the last inspection, therefore this area was not inspected.

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 broadly 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

Record keeping and document control (Guidance note 31)
The centre performs an annual SOP review followed by a process revalidation. The conclusion to each process validation stated "all OK", without the rationale for this judgement being clearly documented, though it was recounted by the person who had performed the validation (SLC T72 and T73, see recommendation 3).

The senior embryologist was able to describe the acceptable limits of critical parameters for items of critical equipment, however these are not documented within validation or equipment monitoring or maintenance documents (SLC T24, see recommendation 3).

The centre does not label each individual egg collection tube. Instead, they follow a process to check and witness that the work area is clear between patients. However, there is no documentation to evidence that this check has occurred (SLC T99, see recommendation 3).

Section 3: Monitoring of the centre's performance

Following the renewal inspection in 2017, recommendations for improvement were made in relation to two areas of critical non-compliance, one area of major non-compliance and one 'other' area of non-compliance.

The PR provided information and evidence that the recommendations for one of the critical non-compliances and both of the 'other' non-compliances were fully implemented within the prescribed timescales.

The remaining critical non-compliance related to storage of gametes. This recommendation was implemented as far as the PR was able. The PR sought legal advice as recommended but their legal advisor was not able to reconcile the scenario with the law. He contacted the HFEA's legal advisor for assistance and currently a barrister's opinion is being sought. The Chief Executive and the Director of Compliance and Information at the HFEA have agreed that we do not expect the clinic to take any further action regarding this stored sample until we have counsel's opinion. The PR has continued to cooperate and engage with the executive throughout this time.

On-going monitoring of centre success rates

Since the last inspection, the centre has not received any alerts relating to success rates.

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 partially compliant with requirements.

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

Other areas of practice that requires improvement

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

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
1. Screening of donors During a review of records related to imported donor sperm, for one donor of mixed race ethnicity the records indicated that no additional genetic screening tests had been carried out. A review of whether additional tests were required for this donor had not been documented (SLC T52 h and i).	The PR should ensure that a record is kept of the check that donors have undergone appropriate selection and screening tests. The PR should inform the centre's inspector of actions taken when responding to this report. Within three months of the implementation of corrective actions, the PR should audit a selection of donor gamete records to ensure that this step is fully documented. A summary report of the findings of the audit should be provided to the centres inspector by 7 April 2019.	There is already a donor gamete-in checklist that covers additional screening tests required according to ethnicity and race. On the day of the inspection, rather than the check being marked as not applicable it was left blank. Therefore, this cannot be confirmed as being checked for this patient. A full audit for the completion of these forms will be done before 7 April 2019.	The PR has provided assurances that staff are aware that forms should be completed appropriately. The PR will perform an audit of these forms and a summary report of that audit will be requested from the PR by 7 April 2019. Further action required.
2. Premises and facilities	The PR should risk assess the	An external company called	The PR has confirmed that the

The cryostore does not have any extraction system. There is a push bar opening fire door, leading outside which is opened when filling dewars. The cryostore is situated next to the embryologist office area of the laboratory, with a windowed fire door between. The inspector could not be assured that the ventilation within the cryostore is adequate, nor were they assured that the fire door between the cryostore and the embryology office would prevent oxygen depletion in the embryologists' work station area (SLC T17, British Compressed Gases Association's (BCGA) (2000) Code of Practice 30 (CP30) – 'The safe use of liquid nitrogen dewars up to 50 litres).	cryostore to ensure it is safe to use and presents no risk to staff in the vicinity. The risk assessment should include a calculation of the ventilation requirements given the number and capacity of dewars stored, including if a dewar was to fail, and also the safety of those working adjacent to the cryostore. A copy of this risk assessment, including any corrective actions and timescales for implementation, should be provided to the centre's inspector by 7 February 2019.	Britannia has been contacted and will be performing a risk assessment and the instalment of an extraction fan before the end of 2018. A copy of this report and the work that has been carried out will be forwarded before 7 February 2019.	external company are fitting an extraction fan to the exterior wall on 20 December 2018. The external company will also perform the risk assessment pre- and post-installation and the PR will forward this to the inspector by 7 February 2019. Further action required.
3. Record keeping The centre performs an annual SOP review followed by a process revalidation. The conclusion to each validation stated "all OK", without the rationale for this judgement being clearly documented	The PR should ensure that appropriate records are kept. The PR should inform the centre's inspector of actions taken when responding to this report.	An audit has been added to the 2019 audit schedule for revalidation of processes and equipment to ensure acceptable limits of critical parameters are met. This will be completed and	The PR has provided assurances that staff are aware that forms should be completed appropriately. The PR will perform audits of this documentation and has agreed to provide a copy of

(SLC T72 and T73). The acceptable limits of critical parameters for items of critical equipment, are not documented within the validation or equipment monitoring or maintenance documents (SLC T24). The centre does not label each individual egg collection tube. Instead, they follow a process to check and witness that the work area is clear between patients. However, there is no documentation to evidence that this check has occurred (SLC T99).	Within three months of the implementation of corrective actions, the PR should audit the relevant documentation. A summary report of the findings of the audit should be provided to the centres inspector by 7 April 2019.	provided by 7 April 2019. A new lab record has been created to document that the work area is clear after an egg collection (please see attached). The completion of this section will be audited by 7 April 2019.	those audits by 7 April 2019. The PR has provided a copy of the new lab record which includes a section to be completed to confirm that the work area is clear after each egg collection. The PR will perform an audit of these forms and a summary report of that audit will be requested from the PR by 7 April 2019. Further action required.

Reponses from the Person Responsible to this inspection report