Executive Licensing Panel - minutes

Centre 0078 (IVF Hammersmith) Renewal Inspection Report

Friday, 23 September 2016

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Juliet Tizzard (Chair) Joanne Anton Anna Rajakumar	Director of Strategy & Corporate Affairs Head of Regulatory Policy Scientific Policy Manager
Members of the Executive	Dee Knoyle	Secretary
External adviser		
Observers		

Declarations of interest

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

The panel had before it:

- 8th edition of the HFEA Code of Practice
- Standard licensing and approvals pack for committee members.

1. Consideration of application

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

1.2. The panel noted that IVF Hammersmith is located in London. The centre provides a full range of fertility services including embryo testing. In relation to activity levels this is a large centre.

1.3. The panel noted that the centre has been licensed by the HFEA since 31 July 1992.

1.4. The panel noted that in the 12 months to 31 May 2016, the centre provided 1242 cycles of treatment (excluding partner intrauterine insemination).

1.5. The panel noted that for IVF and ICSI, HFEA-held register data for the period 1 March 2015 to 29 February 2016 showed the centre's success rates were in line with national averages.

1.6. The panel noted that in 2015, the centre reported 26 cycles of partner insemination with four pregnancies. This represents a clinical pregnancy rate that is likely to be in line with the national average.

1.7. Between 1 March 2015 and 29 February 2016 the centre's multiple pregnancy rate for all IVF, ICSI and frozen embryo transfer (FET) cycles for all age groups was 17%. This represents performance that is not likely to be statistically different from the 10% maximum multiple live birth rate target for this period.

1.8. The panel noted that at the time of the renewal inspection on 12 and 13 July 2016, two major and four other areas of non-compliance were identified. The panel noted that since the inspection the Person Responsible (PR) has started to address the non-compliances and has committed to implementing all of the outstanding recommendations within the prescribed timescales.

1.9. The panel noted that the inspectorate recommends the renewal of the centre's treatment (including embryo testing) and 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.

2. Decision

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

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

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

2.4. The panel endorsed the inspectorate's recommendation to renew the centre's treatment (including embryo testing) and 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.

3. Chair's signature

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

Signature

Name

Juliet Tizzard

Date

5 October 2016

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

Date of inspection: 12 and 13 July 2016

Purpose of inspection: Renewal of a licence to carry out Treatment (including embryo testing) 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: Louise Winstone (lead), Polly Todd, Victoria Lamb, Cathy Hodgson and Tarek Hussain.

Date of Executive Licensing Panel: 23 September 2016

Centre name	IVF Hammersmith
Centre number	0078
Licence number	L/0078/15/b
Centre address	Wolfson Family Clinic, Hammersmith Hospital, Du Cane Road, London, W12 0HS, United Kingdom.
Person Responsible	Mr Stuart Lavery
Licence Holder	Mr Geoffrey Trew
Date licence issued	1 January 2013
Licence expiry date	31 December 2016
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:

IVF Hammersmith is located in London and has held a licence with the HFEA since 31 July 1992.

The centre provides a full range of fertility services including embryo testing to NHS and privately funded patients.

The centre provided 1242 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 May 2016. In relation to activity levels, this is a large centre.

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period 1 March 2015 to 29 February 2016 show the centre's success rates are in line with national averages.

In 2015, the centre reported 26 cycles of partner insemination with four pregnancies. Although data for 2015 has not yet been analysed, this represents a clinical pregnancy rate that is likely to be in line with the national average.

Multiple births[2]

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

Between 1 March 2015 to 29 February 2016 the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 17%: 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 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 his duty under section 17 of the HF&E Act 1990 (as amended);
- the premises (including those of relevant third parties) are suitable;
- the centre's practices are suitable;
- the application contains the supporting information required by General Direction 0008, in application for renewal of their licence;
- the centre has submitted an application fee to the HFEA in accordance with requirements.

The ELP is asked to note that at the time of the inspection there were recommendations for improvement in relation to two major and four 'other' areas of non compliance.

In responding to the report, the PR has provided assurance that the following recommendation has been implemented:

'Other' areas that require improvement:

- The PR should ensure that the centre's website meets the requirements of section 4.5 of the CoP.

The PR has also given a commitment to implement the following recommendations within the required timescales:

Major area of non compliance:

- The PR should ensure that patients are provided with adequate written information prior to giving consent for the use of embryos in training.
- The PR should ensure that all licensed treatment activity is reported to the HFEA within the timeframe required by General Direction 0005.

'Other' areas that require improvement:

- The PR should ensure that sperm donors are screened in accordance with current professional guidance, to include a physical examination for genital warts and herpes.
- The PR should ensure that a record keeping audit is completed and included in the audit schedule and should review the laboratory cleaning SOP to ensure that it accurately reflects practice.
- The PR should ensure that the disclosure consent information supplied to the HFEA accurately reflects that recorded on disclosure consent forms.

Recommendation to the Executive Licensing Panel

The centre has no critical areas of non compliance but does have two major areas of concern. 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 inspection team recommends the renewal of the centre's Treatment (including embryo testing) and Storage licence for a period of four years without additional conditions subject to the recommendations made in this report being implemented within the required 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 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)
A donor-conceived person is entitled to know details of their donor and any donor-conceived genetic siblings they may have. Parents of a donor-conceived child are able to access information on their child's donor (and about any donor-conceived genetic siblings) from the HFEA or the clinic where they received treatment.

Therefore, it is important that centres use donated gametes or embryos from identifiable donors. The centre's procedures are compliant with HFEA requirements to ensure the donor conceived will be able to receive this information.

What the centre could do better

Screening of donors (Guidance note 11)
A physical examination for herpes and genital warts is not carried out for known sperm donors prior to donation (SLC T52a; see recommendation 3).

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

What the centre does well

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

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

The premises of the centre's laboratories conducting tests that impact on the quality and safety of gametes 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 that 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 for accreditation by CPA (UK) Ltd or another body accrediting to an equivalent standard. This is important to assure the quality of the services provided.

Infection control
The centre has systems in place to manage and monitor the prevention and control of infection that are compliant with guidance.

Medicines management
The centre has arrangements in place for obtaining, recording, handling, using, keeping, dispensing, administering and disposing of medicines that are compliant with guidance.

Pre-operative assessment and the surgical pathway
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;
- if 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 note 15)
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 the gametes and embryos are appropriately labelled and has enough information to permit the gametes and embryos 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.

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 in place that is broadly 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 does not have transport or satellite agreements in place. Although the centre identified Boston Place (0326) as a satellite in the renewal application form, the PR has confirmed that this is the centre's sister clinic and not a satellite. Therefore, this area of practice is not applicable.

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

Quality management system (QMS) (Guidance note 23)
The centre has not undertaken a record keeping audit and this is not included in the audit schedule (SLC T36; see recommendation 4).

The laboratory cleaning SOP does not reflect current cleaning practice (SLC T26; see recommendation 4).

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 medicine and has more than two years of practical experience that is directly relevant to the activity to be authorised by the licence. The PR has successfully completed the HFEA PR Entry Programme (PREP number T/1046/7).

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 that 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 the welfare of any child who may be born as a result of the licensed treatment, and of any other child who may be affected by that birth before treatment is provided are compliant with HFEA requirements.

Safeguarding
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's procedures for performing embryo testing are compliant with HFEA requirements. This ensures that:

- no embryo is transferred to a woman where that embryo or material removed from it, or the gametes that produced it, has been subject to genetic testing unless expressly authorised by the HFEA;
- no information derived from tests conducted has been used to select embryos of a particular sex for social reasons;
- no embryo is tested unless the statutory tests are met i.e. that the embryo is at a significant risk of having a serious genetic condition.

The centre ensures that people seeking embryo testing are given written information, are given every opportunity to discuss the implications of their treatment and have access to clinical geneticists, genetic counsellors and infertility counsellors where required.

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

2. The experience of patients

Patient feedback

What the centre does well

During the inspection visit, no patients were available to speak to the inspectors about their experiences. Eight patients provided feedback directly to the HFEA in the time since the last inspection. Feedback was positive, with six of the individuals providing written feedback to the HFEA commenting that they have compliments about the care that they received. On this inspection, the centre's own patient questionnaire, recent patient feedback audit and the NHS Family and Friends test survey results were reviewed. Feedback in all cases was positive.

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

- has respect for the privacy and confidentiality of patients in the clinic;
- gives patients sufficient, accessible and up-to-date information to enable them to make informed decisions;
- provides patients with satisfactory facilities for their care.

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 undertake egg or sperm sharing arrangements therefore this area of practice is not applicable.

Surrogacy (Guidance note 14)
The centre's procedures for treatment involving surrogacy are compliant with HFEA requirements. This is important to protect the surrogate and any children born as a result of the treatment.

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 broadly 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

The centre's website is not compliant with the requirements of section 4.5 of the CoP 'Responsible use of the centre's website' as the live birth rate per treatment cycle and the national rate for comparison are not listed (see recommendation 5).

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

What the centre does well

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

Legal parenthood (Guidance note 6)
Where a couple to be treated with donated gametes or embryos is not married or in a civil partnership, both the woman and her partner must give written consent in order for the partner to become the legal parent of any child born. If this consent is not documented properly or if proper information is not provided or counselling offered prior to both parties

giving consent, there may be doubt about its effectiveness and in some cases, it may be necessary for a patient couple to obtain a court declaration to establish legal parenthood.

In February 2014, the HFEA asked all centres to audit their practices in this area to ensure they are suitable, to report the findings of the audit to the HFEA and to respond to those findings. The centre did send the report of the audit to the HFEA within the required timeframe. The audit showed that two couples were affected by legal parenthood consent anomalies.

On this inspection, we reviewed the centre's audit and found that it had been performed according to the method specified by the HFEA. Actions had been taken in response to the audit findings.

As part of the HFEA's ongoing activities relating to legal parenthood, in October 2015 all PRs were asked to confirm that specific actions had been undertaken; that there are effective methods for assessing the on-going competence of staff to take this consent; and that effective audit procedures are in place to ensure on-going compliance with consent taking requirements. The PR responded to this communication and provided the required reassurances to the satisfaction of the Executive.

In February 2016, one of the couples affected by anomalies in their consent to legal parenthood had their case considered in the Family Court. Following receipt of the skeleton argument by the HFEA, it was decided that a meeting should be held between the centre with the key staff involved in the patients' care. The centre's inspector and senior inspector attended the centre on the 23 March 2016. The aim of this meeting was to discuss in more detail the actions that the centre took in terms of supporting and advising the patient and partner since discovering this anomaly. During this meeting, the PR provided assurance that corrective actions were in place. The PR also undertook a thorough root cause analysis (RCA). The report of this RCA has been provided to the HFEA.

To provide further assurance of the effectiveness of the centre's procedures, 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 and the offer of counselling was seen to be in place prior to consent and treatment in all cases.

In summary, the inspection team considers that the current processes used to collect legal parenthood consent at this centre are 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 broadly 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 assisted reproductive technologies (ART) and those born following ART treatment.

What the centre could do better

Disclosure of information, held on the HFEA Register, for use in research (General Direction 0005)

Four discrepancies were found between completed patient/partner disclosure consents on patient files and the related consent data submitted for inclusion on the Register. Therefore, the centre's procedures have failed to ensure that the HFEA holds an accurate record of consents to disclosure. This failing leads to a risk that the HFEA may release patient identifying information to researchers without consent (CH (10)05 and General Direction 0005; see recommendation 6).

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). This ensures that the centre has respect for the special status of the embryo when conducting licensed activities.

- 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
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 (Guidance note 22)

What the centre does well

Use of embryos for training staff (Guidance note 22)
The centre's procedures for using embryos for training staff are partially compliant with HFEA requirements. Embryos are only used for the purpose of training staff in those activities expressly authorised by the Authority.

What the centre could do better

Prior to seeking their consent, patients are not provided with adequate written information about the potential use of their embryos to train staff. Although a patient information sheet was available, this was not in use and staff were not aware of it (SLC T97a, b, c & d; see recommendation 1).

4. Information management

Record keeping
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, however see recommendation 4. 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 HFEA are partially compliant with HFEA requirements. This is important to ensure that the HFEA can supply accurate information to a donor-conceived person and their parents or donors.

What the centre could do better

Obligations and reporting requirements (Guidance note 32; General Direction 0005)
The HFEA register audit team found some evidence of problems with the timeliness and accuracy of the centre's submission of data to the Register. All of the IVF treatments reviewed at inspection had been reported to the HFEA with 97% (128/132) reported within timeframes required by General Direction 0005. 62% (8/13) of the DI treatments reviewed at inspection had not been reported to the HFEA with only one being submitted in the period required by General Direction 0005 (General Direction 0005, SLC T41; see recommendation 2).

Section 3: Monitoring of the centre's performance

Following the interim inspection in 2014, recommendations for improvement were made in relation to one area of critical non compliance, five areas of major non compliance and one 'other' area of non compliance.

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

On-going monitoring of centre success rates

The centre has not received any success rate risk tool alerts since the last inspection.

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 Direction 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.

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.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
1. Use of embryos for training staff Prior to seeking their consent, patients are not provided with adequate written information about the potential use of their embryos to train staff. Although a patient information sheet was available, this was not in use and staff were not aware of it. This was cited as a non compliance in the last inspection report. SLC T97a, b, c & d.	The PR should ensure that patients are provided with adequate written information prior to giving consent for the use of embryos in training. Once corrective action has been taken, within three months an audit should be undertaken. A summary report of the audit should be submitted to the centre's inspector by 13 October 2016. The PR should provide a comment when responding to this report to address why this recommendation was not fully implemented following their previous inspection.	Registration packs for all patients commencing licenced treatment now include additional written information regarding use of embryos in training. The audit will be undertaken and a summary report submitted to our inspector by 13 October 2016. I am aware that this issue was cited as non-compliance during our interim inspection in 2014. I can confirm that following that previous inspection action was taken and a new document (IVFHH-	The PR has taken appropriate action and we await the audit summary report by 13 October 2016. Further action is required.

		CON-CLN-001-Consent to training) was drafted and implemented. The document provided patients with written information and the option to provide consent to the use of their embryos in training. In addition to this written document, information was provided verbally by an embryologist during the patient co-ordination/information session. Following the implementation of the information and consent document, issues arose where the consent provided by patients on this new document would often differ from that they provided on their MT or WT form. The team then made a considered decision to archive this document and continue to provide detailed verbal information during the information session. We are confident that the action implemented as a result of our most recent inspection will ensure compliance with SLC T97a, b, c &d.	

2. Obligations and reporting requirements The HFEA register audit team found evidence of problems with the timeliness and accuracy of the centre's submission of data to the Register, as discussed in the body of the report. SLC T41; General Direction 0005.	The PR should ensure that all licensed treatment activity is reported to the HFEA within the timeframe required by General Direction 0005. The procedures used to submit donor insemination treatment data should be reviewed to identify and address the reasons for non-reporting. A summary of this review should be submitted to the centre's inspector by 13 October 2016. The PR should conduct an audit six months after implementing any corrective actions, to confirm that the actions have had the desired effect. A summary of the audit should be provided to the centre's inspector by the 13 January 2017.	A review of DI treatment cycle submissions and reasons for inconsistent reporting has commenced. Our quality manager is working closely with our nurse manager to ensure the system of identifying these cycles and reporting them in the timeframes set by the HFEA is robust and includes a failsafe step. Full details will be submitted to our inspector as required by the 13th of October 2016. An audit of DI data submission will be completed to ensure the review of processes has been effective. We will submit this audit to our inspector by 13 January 2017.	The PR has taken appropriate action and we await the review by 13 October 2016 and the audit summary report by 13 January 2017. Further action is required.

Other areas of practice that requires improvement

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
3. Screening of donors Known sperm donors are not screened in accordance with current professional guidance produced by the relevant professional bodies, to include a physical examination for genital warts and herpes. SLC T52a.	The PR should ensure that known sperm donors are screened in accordance with current professional guidance. This recommendation should be immediately implemented and the centre's inspector advised of the actions taken when the PR responds to this report. Copies of the updated SOP and confirmation of relevant staff training should be provided to the centre's inspector by 13 October 2016.	I have reviewed the current professional guidance provided in Association of Biomedical Andrologists/Association of Clinical Embryologists/British Andrology Society/ British Fertility Society/Royal College of Obstetricians and Gynaecologists – UK guidelines for the medical and laboratory screening of sperm, egg and embryo donors (2008). Following this review our practice has been amended to include a physical examination of known sperm donors. Staff involved in the screening of donors have been informed of this change. Our revised SOP and training records confirming the implementation of these cahnges will be provided to	The PR has taken appropriate action and we await a copy of the revised SOP and training records by 13 October 2016. Further action is required.

		our inspector by 13 October 2016.	
4. Quality Management System The centre has not undertaken an audit of record keeping within the last two years and this is not included in the audit schedule. SLC T36. The laboratory cleaning SOP does not reflect current cleaning practice. SLC T26.	The PR should review the centre's audit programme to ensure that it is compliant in the range of audits performed. The PR should perform the record keeping audit identified as outstanding and a summary of this should be provided to the centres inspector by 13 October 2016. The PR should review the laboratory cleaning SOP to ensure that it accurately reflects practice and submit this to the centre's inspector by 13 October 2016.	I have reviewed the annual audit plan compiled by our quality manager and am reassured that the plan is compliant. Although a specific record keeping audit has not been undertaken many of the audits completed include an element of recordkeeping and this has provided assurance that our recordkeeping processes are robust and compliant with requirements. These audits include, traceability, consent, welfare of the child, witnessing and selection and recruitment of donors. At the time of providing this response I can confirm that a specific recordkeeping audit is underway and that we will submit a summary to our inspector by 13 October 2016. The laboratory cleaning SOP has been revised to ensure	The PR has taken appropriate action and we await the audit summary report by 13 October 2016. Further action is required.

		this reflects the cleaning programme undertaken by laboratory staff. The revised SOP is included with this submission.	
5. Website The centre's website is not compliant with the requirements of section 4.5 of the CoP 'Responsible use of the centre's website' as the live birth rate per treatment cycle and the national rate for comparison are not listed. CoP section 4.5.	The PR should ensure that the centre's website meets the requirements of section 4.5 of the CoP 'Responsible use of the centre's website'. The PR should inform the HFEA of actions that can be taken to ensure that the centre's website is compliant with requirements when responding to this report.	I can confirm that we have reviewed our website and have updated it to ensure compliance with CoP requirements. This includes raw numbers not just percentages for our published success rates, we refer to the HFEA as a source of national information and have included a link through to HFEA information for patients on the interpretation of success rates. We have also provided a link to our most recent live birth data published by the HFEA.	The PR has taken appropriate action to address this non compliance. No further action is required.
6. Disclosure of information, held on the HFEA Register, for use in research Four discrepancies were found between completed patient/partner disclosure consents on patient files and the related consent data	The PR should review procedures and take appropriate corrective actions to ensure that the disclosure consent information supplied to the HFEA accurately reflects that given and recorded on disclosure consent forms. A summary of this review should	We are undertaking a review of the pathway whereby patients are registered on the EDI to ensure correct consent to disclosure information is submitted to the register. This will be provided to our inspector by 13 October 2016	The PR has taken appropriate action and we await the outcome of the review by 13 October 2016 and the audit summary report by 13 January 2017. Further action is required.

submitted for inclusion on the Register. CH (10)05 and General Direction 0005.	be submitted to the centre's inspector by 13 October 2016. The PR should correct the submissions that have been identified as being incorrect and confirm that these have been completed when responding to this report. The PR should conduct an audit six months after implementing any corrective actions, to confirm that the actions have had the desired effect. A summary of the audit should be provided to the centre's inspector by 13 January 2017.	 I can confirm that the submissions identified as being incorrect have been corrected and submitted via EDI Consent to disclosure and EDI submission form part of our audit programme and I will ensure that an additional audit is undertaken by 13 January 2017.	

Response from the Person Responsible to this inspection report