Executive Licensing Panel - minutes

Centre 0086 (BMI Chelsfield Park ACU) - Renewal Inspection Report

Friday, 14 July 2017

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Juliet Tizzard (Chair) Anjeli Kara Jessica Watkin	Director of Strategy & Corporate Affairs Regulatory Policy Manager Policy Manager
Members of the Executive	Bernice Ash	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 BMI Chelsfield Park ACU holds a Treatment and Storage licence and provides a full range of fertility services.

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

1.4. The panel noted that, in the 12 months to 28 February 2017, the centre provided 193 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a small centre.

1.5. The panel noted that HFEA held register data for the period March 2016 to February 2017 showed that the centre's IVF and ICSI success rates are in line with national averages.

1.6. The panel noted that between December 2015 and November 2016, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 8%. This represents performance that is not likely to be statistically different from the 10% multiple live birth rate target.

1.7. An inspection was carried out at the centre on 19 and 20 April 2017.

1.8. The panel noted that at the time of the inspection there were three major and five 'other' areas of practice which required improvement. The panel noted that, since the inspection, the major area of non-compliance regarding process validation and the 'other' non-compliances concerning patient information and record and document control have been fully implemented. The PR has committed to fully implementing the non-compliances regarding storage of embryos, patient confidentiality and privacy, the Quality Management System (QMS), disclosure of information held on the HFEA register for use in research and obligations and reporting requirements.

1.9. The panel noted that the inspectorate recommends the renewal of the centre's Treatment and Storage licence for a period of four years without additional conditions subject to the recommendations made in the 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 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

25 July 2017

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: 19 and 20 April 2017

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: Shanaz Pasha (lead), Gill Walsh, Vicki Lamb. Register team: Cathy Hodgson and Zakia Ezzouyar.

Date of Executive Licensing Panel: 14 July 2017

Centre name	BMI Chelsfield Park ACU
Centre number	0086
Licence number	L/0086/17/e
Centre address	Bucks Cross Road, Chelsfield, Orpington, Kent, BR6 7RG, UK
Person Responsible	Mr Damian Pike
Licence Holder	Ms Susan Jones
Date licence issued	1 October 2013
Licence expiry date	30 September 2017
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:

The BMI Chelsfield Park ACU has held a Treatment and Storage licence with the HFEA since 1992 and provides a full range of fertility services.

The centre provided 193 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 28 February 2017. In relation to activity levels this is a small centre.

Other licensed activities of the centre included storage of gametes and embryos.

The centre's licence was varied in March 2016 to reflect change of Person Responsible.

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period March 2016 to February 2017 show the centre's success rates are in line with national averages.

In 2016, the centre reported two cycles of partner insemination with no pregnancies. This represents a clinical pregnancy rate which is in line with the national average.

Multiple births[2]

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

Between December 2015 and November 2016, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 8% 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 a number of areas of practice that required improvement, including three major and five 'other' areas of non-compliance which have resulted in the following recommendations which have been fully implemented:

Major areas of non compliance:

- The PR should ensure that all critical processing procedures are validated.

'Other' areas that requires improvement:

- The PR should ensure that identifying donor information is not kept in the medical records of the recipient; and when intralipids have been prescribed, this is recorded in medical records.
- The PR should ensure that information relating to intralipids and the use of embryos in training meets regulatory and professional body guidelines.

The PR has committed to fully implementing the following recommendations:

Major areas of non compliance:

- The PR should ensure that all embryos are stored with effective consent from both gamete providers.
- The PR should ensure the patient's consent to disclosure wishes as expressed on the consent to disclosure form are observed.

'Other' areas that requires improvement:

- The PR should ensure that the centre's Quality Management system and auditing processes are effective.
- The PR should ensure that the patient/partner consents to disclosing identifying information to researchers are accurately documented on the HFEA register.
- The PR should ensure that all licensed activity is reported to the HFEA within the timeframe required by General Direction 0005.

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 currently does not recruit, assess or screen donors.

Payments for donors (Guidance note 13; General Direction 0001)
The centre does not currently recruit donors.

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
Nothing identified at this inspection.

Suitable premises and suitable practices

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

What the centre does well

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

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

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

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

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

The centre does not administer intralipids, however one clinician does prescribe intralipids which are administered off-site by a third-party provider.

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 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 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 currently does not have any transport and satellite arrangements.

Equipment and materials (Guidance note 26)
The centre uses equipment and materials that are compliant with HFEA requirements. All 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 partially compliant with HFEA requirements to validate critical processes. Validation 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 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

Prescription of intralipid 'off label'
Patient information does not describe that intralipids are being prescribed off-label for this group of women. Clinic Focus, July 2015, see recommendation 5.

In two records seen where intralipids had been prescribed, the rationale for prescribing this therapy had not been documented. Clinic Focus, July 2015, see recommendations 6.

Quality management system (QMS) (Guidance note 23)
A number of audits undertaken by the centre were reviewed, at least two audits identified issues however these were not cited as non-conformances. SLC T32, see recommendation 4.
The centre has not undertaken an audit of the provision of information to patients in the last two years. SLC T36, see recommendation 4.

Process validation (Guidance note 15)
The centre had initiated process validation; however, this had not been completed. SLC 72, 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 biological sciences and has more than two years of practical experience which is directly relevant to the activity to be authorised by the licence. The PR has successfully completed the HFEA PR Entry Programme.

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

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

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

Welfare of the child and safeguarding

What the centre does well

Welfare of the child (Guidance note 8)
The centre'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 does not undertake pre-implantation genetic screening or embryo testing and sex selection.

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

2. The experience of patients

Patient feedback

What the centre does well

Three patients provided feedback directly to the HFEA in the time since the last inspection. Feedback was positive, with two of the individuals providing written feedback to the HFEA commenting that they have compliments about the care that they received.

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 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 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 currently undertake egg or sperm sharing arrangements.

Surrogacy (Guidance note 14)

The centre does not currently undertake treatments that require a surrogate.

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 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 written patient information regarding the use of gametes or embryos in training does not include whether any information will be fed back to patients. SLC T97, see recommendation 6.

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 sent the report of the audit to the HFEA within the required

timeframe. The audit showed that no couples were affected by legal parenthood consent anomalies.

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.

On this inspection, we reviewed the centre's most recent audit of consent to legal parenthood which showed that it had been performed according to the method specified by the HFEA. There were no anomalies identified.

To provide further assurance of the effectiveness of the centre's procedures, the inspection team reviewed five randomly selected sets of records where treatment with donor sperm had recently been provided in circumstances where consent to legal parenthood may have been required. In each case consent to legal parenthood was not required as the couples were either married or civil partners or single women. The centre's processes for ensuring the offer of counselling is provided and for seeking consent to legal parenthood were discussed with the PR and staff. From these discussions and a review of documentation, 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 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 fertility treatment and those born following fertility treatment.

What the centre could do better
Disclosure of information, held on the HFEA Register, for use in research (General Direction 0005)
Of 35 records reviewed, in five cases discrepancies were found between completed patient/partner disclosure consents on patient files and the related consent data submitted for inclusion on the HFEA register. In each case the patient and her partner had given consent to disclosure to researchers but the consent decision submitted to the HFEA register was that consent to disclosure was withheld. Whilst this does not pose a risk of inadvertent disclosure of information to researchers without consent, it does not reflect the consent provider's wishes. CH(10)05 and Gen Dir 0005, see recommendation 7.

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
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 partially 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

Storage of gametes and embryos (Guidance note 17)

An audit of patient records identified that embryos for one couple had been in storage for two years without consent by the male gamete provider, and three weeks by the female

gamete provider. This was not identified in the centre's own consent to storage records audit. This was drawn to the attention of the PR who immediately began the process to contact the male gamete provider. HF&E Act (as amended) 1990, sch 3, 8(2), see recommendation 1.

Since the inspection the PR has informed the HFEA that the male gamete provider has provided consent and therefore effective consent to storage of the embryos is now in place.

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 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
Nothing identified at this inspection.

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 broadly 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 broadly 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 some 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)
In one set of patient records reviewed by the inspection team, identifying information about the donor had been filed within the patient records. The inspection team considered that this could increase the risk of potential breach of donor confidentiality. SLC T44c, see recommendation 5.

Obligations and reporting requirements (Guidance note 32; General Direction 0005)
31% (33/106) of the IVF treatments reviewed at inspection had been reported to the HFEA outside the period required by General Direction 0005. SLC T41, see recommendation 8.

Section 3: Monitoring of the centre's performance

Following the interim inspection in 2015, recommendations for improvement were made in relation to three areas of major non compliance and two 'other' areas of non compliance.

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

On-going monitoring of centre success rates

In the last year the centre has received two RBAT alerts in relation pregnancy rate per cycle of ICSI for patients under 38 years. The centre responded to these alerts and there are currently no ongoing concerns regarding the centre's success rates.

Section 5: Areas of practice that require the attention of the person responsible

The section sets out matters which the Inspection Team considers may constitute areas of non compliance. These have been classified into critical, major and others. Each area of non compliance is referenced to the relevant sections of the Acts, Regulations, 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.

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

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. Storage of embryos In one instance, there was a 'gap' of approximately three weeks whereby consent to extend storage of embryos was not in place for the patient (the female gamete provider). During the time since the embryos were placed into storage, the patient had extended storage twice, however it was noted that the corresponding consent to extend storage had not been provided by her partner (the male gamete provider) during that time. The embryos had therefore been stored for nearly two years without effective consent from both gamete providers.	The PR should ensure that all embryos are stored with effective consent from both gamete providers. Whilst it is recognised that the PR took swift action to try to resolve this issue, the fact remains that this consent failure was not prevented by the centre's mechanisms for monitoring the extension of storage consent nor was it identified by the centre's own audit of consent to storage. The PR should instigate a thorough route cause analysis of events that lead to this failing, including a review of procedures and process for		The Executive are satisfied that the PR has taken appropriate action and await the outcome of the centre's re-audit due in October 2017.

HF&E Act (as amended) 1990, sch 3, 8(2). Since the inspection the PR has informed the HFEA that consent has now been provided by the male gamete provider.	the management of storage consent and the efficacy of the centre's audit. The PR should provide a copy of the analysis and details of actions to be taken and learning in response to the analysis findings by 19 July 2017. As this finding sheds doubt on the provenance of the centre's previous consent to storage audit, this should be repeated for all gametes and embryos where storage has been extended. A summary of the findings of that audit and details of any actions to be taken as a result should be provided to the centre's inspector by 19 July 2017. Within three months of implementing corrective actions, the centre should undertake an audit of storage consents. A summary of the report should be sent to the centre's inspector by 19 October 2017.		

2. Process validation The centre had initiated process validation; however this had not been completed. SLC 72	The PR should ensure that all critical processing procedures are validated by 19 July 2017. The PR should inform the centre's inspector when this has been completed and the centre's inspector will request a sample of the documentation to review.	The validation of equipment and procedures is an on-going process as new processes, procedures and equipment are introduced to help meet the needs of our patients. This dynamic process reflects BMI`s commitment to update and improve the service we provide. The validation processes were completed, as anticipated, shortly after the inspection.	Since the inspection the PR has provided evidence of the validation of all critical procedures. No further action required
3. Patient confidentiality and privacy An audit of patient records by the inspection team identified that in one set of patient records the patient's consent to disclosure wishes had not been observed in that the treating clinician appeared to have written to the patient's GP regarding her treatment. SLC T43	The PR should ensure that patient confidentiality is maintained and the patient's consent to disclosure wishes as expressed on the consent to disclosure form are observed. The PR should investigate the circumstances which resulted in the treating clinician failing to know that the patient did not wish for her GP to be contacted when this was clearly marked on her record.	We have taken this opportunity to review our practice regarding GP contact. GP letters play an important role in the management and contiuation of patient care. We recognise the importance of GPs and the extent they help and support their patients. However, we understand that some patients may not want	The Executive acknowledge the PR's commitment to implementing this recommendation. Further action is required

	Following this, the PR should review procedures and take appropriate corrective actions to ensure that a recurrence is prevented. The PR should provide a summary of the outcome of the investigation and review along with details of actions taken to the centre's inspector by 19 July 2017. Within three months of implementing corrective actions the PR should conduct an audit of patient confidentiality. A summary report of the audit should be sent to the centre's inspector by 19 October 2017.	their GPs to be aware of their treatment. We will investigate how this event occurred and notify HFEA of our investigation findings before 19th July 2017. As an interim measure ; we changed our practice, and currently GP letters are given to the patient to review and pass onto their GP. This enables the patient to make an informed decision regarding the sharing of important clinical information with their GP. As with any change in process, we will will audit within three months to determine the effectiveness of the changes. The results of this audit will be shared with HFEA.	

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
4. QMS A number of audits undertaken by the centre were reviewed, at least two audits identified issues however these were not cited as non-conformances in these audits. The centre has not undertaken an audit of the provision of information to patients in the last two years. SLC T32 and T36	The PR should ensure that the centre's Quality Management system and auditing processes are effective. The PR should review the centre's audit process to ensure that where anomalies are found, these are identified as non-conformances and that corrective and preventative actions are implemented. A summary of the review should be sent to the centre's inspector by 19 July 2017. An audit of the provision of information should be completed and a summary forwarded to the centre's inspector by 19 July 2017.	The Team has undergone a period of significant change in terms of composition and process. The value of the QMS requires that any areas of improvement are identified and actions enacted. We undergo three internal levels of audit : Fertility Unit: We have an audit calender and findings of audits are reported at Fertility Team Meetings and at regular Quality Review Meetings. Chelfield Park Hospital audit calender. As we are part of a larger hospital we participate in their audit process, eg Infection Prevention.	The Executive acknowledge the PR's commitment to implementing this recommendation. Further action is required.

		Corporate : BMI Healthcare is the largest independent healthcare provider in the UK and has a strong governance structure. The Fertility Unit submit local Key Performance Indicators (KPI`s) and audit outcome to the corporate lead to enable actioning and promote shared learning within the group. Review of Audits : The Quality Manager will review all audits within the last 12 months and the outstanding actions identified and implemented. This information will be shared with HFEA by 19th July 2017. BMI Healthcare has reviewed the information we provide and how this information is provided, eg. we have recently updated our fertility website. BMI Healthcare has invested in a specially trained Fertility team who work at the National Enquiry Centre.	

		The information we provide patients is evolving to meet their needs and the on going changes to fertility treatments. As with any change in process; we will audit the provision of patient information. The results of this audit will be shared with HFEA by 19th July 2017.	
5. Record keeping and document control In one set of patient records reviewed by the inspection team, identifying information about the donor had been filed within the patient records. This increases the risk of potential breach of donor confidentiality. SLC T44c In two records seen where intralipids had been prescribed, the rationale for prescribing this therapy had not been documented. Clinic Focus, July 2015	The PR should ensure that the centre has robust procedures for maintaining the confidentiality of donor records. The PR should conduct a review of the centre's procedures for donor records. A summary of the review should be sent to the centre's inspector by 19 July 2017. The PR should ensure that the rationale for prescribing 'off-label' therapies is documented in the patient's records.	Although no breach of confidentiality had occurred , we accept HFEA`s position that there is a potential risk that it may occur. Consequently, donor records are no longer kept within patient records. In terms of intralipid, HFEA are aware that BMI Healthcare do not provide Intralipid therapy. However, we recognise that some patients may pursue Intralipid therapy as in addition to their fertility treatment -this is their right.	The Executive have reviewed the revised patient information and require no further action in relation to this. The Executive are satisfied with the summary of actions taken with respect to donor records and require no further action in relation to this.

		The "intralipid" patient information sheet has been reviewed and was made available to HFEA on 26th April 2017. The "off licence" consent form exists for those patients who may seek Intralipid therapy elsewhere. The purpose of the "off licence" consent form is to document the rationale for prescribing off licence therapies within the patients records. BMI Healthcare`s position on intralipid has remained the same but we accept that patients have the right to seek additional medical treatment, albiet , elsewhere.	
6. Patient information The written patient information does not describe that intralipids are being prescribed off-label for this group of women. SLC T58, Clinic Focus, July 2015	The PR should ensure that patients are provided with "proper" information. The PR should review the information about reproductive immunology treatments provided to patients to ensure it is in line with professional	In terms of intralipid, HFEA are aware that BMI Healthcare do not provide Intralipid therapy. However, we recognise that some patients may pursue Intralipid therapy as in addition to their fertility treatment -this is their right.	The Executive have reviewed the revised patient information. No further action required

The written patient information regarding training does not include whether any information will be fed back to patients. SLC T97	body guidance and that provided by the MHRA on the off-label use of medicines. The PR should update the patient information regarding the use of gametes and embryos in training to include whether any information will be fed back to patients regarding their use. Copies of the revised patient information should be submitted to the centre's inspector by 19 July 2017	The "intralipid" patient information sheet has been updated and was made available to HFEA on 26th April 2017. In addition to the Intralipid information sheet , the patient also signs the "off licence" Intralipid consent form which clearly identifies the rationale for the prescription. BMI Healthcare`s position on intralipid has remained the same but we accept that patients have the right to seek additional medical treatment, albiet, elsewhere. We continue to work with HFEA in regard to how best to meet the needs of our patients The patient information sheet regarding gametes / embryos used in training has been reviewed. The patient information sheet has been ammended by the inclusion of a single additional	

		sentence. The ammended patient information sheet was made available to HFEA on 26th April 2017.	
7. Disclosure of information, held on the HFEA Register, for use in research. Five discrepancies were found between completed patient/partner disclosure consents on patient files and the related consent data submitted for inclusion on the register. In each case the patient and her partner had given consent to disclosure to researchers but the consent decision submitted to the HFEA register was that consent to disclosure was withheld. Whilst this does not pose a risk of inadvertent disclosure of information to researchers without consent, it does not reflect the consent provider's wishes CH(10)05 and Gen Dir 0005	The PR should review procedures for submitting consent to disclosure decisions to the HFEA register 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. The PR should also correct the submissions that have been identified as being incorrect. 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 19 October 2017.	As part of a comprehensive process review in 2016, we improved the pathway regarding EDI data entry and have appropriately trained our team on EDI. We have acted openly and proactively to clear data errors and have involved HFEA`s Register personal to great effect. The errors the Register Team discovered were historical and were cleared. We notified HFEA of this on 22nd May 2017. To help avoid future errors, especially as EDI is not a commonly available computer programme, we ask that HFEA support our endeavour by providing an on-site training day.	The Executive acknowledge the PR's commitment to implementing this recommendation. We await the summary of the centre's audit due October 2017.

		To support our change in process, we would consider it normal to re-audit and accept HFEA`s proposed timeframe. We will share the audit report with HFEA.	
8. Obligations and reporting requirements 31% (33/106) of the IVF treatments reviewed at inspection had been reported to the HFEA outside the period required by General Direction 0005. These findings indicate that the centre's procedures for submitting information about licensed activities, to the HFEA are broadly compliant with HFEA requirements. General Direction 0005 and SLC T41	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 licensed treatment data should be reviewed to identify and address the reasons for delayed submissions. 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 19 October 2017.	The register submissions are made through a specific computer programme , known as HFEA Electronic Data Interface (EDI). This programme is supplied by and maintained by HFEA. For a period of approx 3months in 2016 the EDI programme was not funtional and this was fed back to HFEA . HFEA`s IT support for the EDI programme eventually resolved the issue. To help avoid future errors or delays , especially as EDI is not a common computer programme, we ask that HFEA support our endeavour by providing an on-site training day.	The Executive acknowledge the PR's commitment to implementing this recommendation. We await the summary of the audit due in October 2017.

		To support our change in process, we would consider it normal to re-audit and accept HFEA`s proposed timeframe. We will share the audit report with HFEA.	

Reponses from the Person Responsible to this inspection report
We support the need for effective regulation and support HFEA`s approach to promote quality improvement. We endeavour to work with the HFEA in an open and proactive manner. Fertility services are provided by a team and we encourage all of our Team to engage with HFEA . This was especially evident during the Inspection which provided an excellent learning opportunity for all members of the Team. The initial / verbal feedback identified areas we should review and we have done so in a timely manner.