Executive Licensing Panel - minutes

Centre 0157 (Assisted Reproduction and Gynaecology Centre)

Renewal Inspection Report

Friday, 20 July 2018

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Clare Ettinghausen (Chair) Erin Barton Kathleen Sarsfield Watson	Director of Strategy and Corporate Affairs Policy Manager Communications Manager
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers	Catherine Burwood Richard Chamberlain	Senior Governance Manager Temporary Committee Clerk (Induction)

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 the Assisted Reproduction and Gynaecology Centre has held a licence with the HFEA since 1995. The centre provides a full range of fertility services, including embryo testing. The last inspection was on 27 and 28 January 2016; this was a licence renewal inspection and the centre was granted a three-year licence.

1.3. The panel noted that, in the 12 months to 31 January 2017, the centre provided 665 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a medium sized centre.

1.4. The panel noted that HFEA held register data, for the period October 2016 to September 2017, shows the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 31%. This represents performance that is likely to be statistically greater than the 10% multiple live birth rate target.

1.5. The panel noted that HFEA held register data, for the period September 2016 to August 2017, shows the centre's success rates for IVF and ICSI are in line with the national average. However, between October 2016 and September 2017, the Clinical Pregnancy Rate (CPR), by cycle for IVF treatment, involving fresh embryos, on patients aged 16 to 37 years, and 38 years and above age range on 2 January 2018 were both above average.

1.6. The panel noted that between October 2016 and September 2017, the CPR, by cycle for ICSI treatment, involving fresh embryos on patients aged 16 to 37, and 38 years and above age range, on 2 January 2018 were both above average.

1.7. An inspection was carried out at the centre on the 23, 24 and 25 January 2018.

1.8. The panel noted that at the time of the inspection, there was one critical area of non-compliance regarding the multiple birth rate.

1.9. There were also five major non-compliances concerning the Quality Management System (QMS) – standard operating procedures, incident reporting, counselling, the use of embryos in training, and obligations and reporting requirements.

1.10. There were two 'other' areas of non-compliance relating to information on the website and disclosure of information held on the HFEA Register for use in research.

1.11. The panel noted that since the inspection, the recommendations concerning the major non-compliances on incident reporting and use of embryos in training had been fully implemented. The panel noted that the PR had given a commitment to implementing the outstanding non-compliances relating to the multiple birth rate, the QMS – standard operating procedures, counselling, obligations and reporting requirements, information on the website and disclosure of information held on the HFEA Register for use in research within the prescribed timescales.

1.12. The inspection report noted that some improvement is required in order for the centre to reflect suitable practices. The centre has a QMS and the PR is encouraged to use this to best effect to monitor and improve the service provided within the centre

1.13. The inspector will continue to monitor the centre's performance and the implementation of the report's recommendations within the required timescales. Failure to implement the recommendations within the prescribed timescales will result in the submission of a further report to the Executive Licensing Panel with the recommendation that regulatory action be taken in accordance with the Authority's Compliance and Enforcement Policy.

1.14. The inspection team noted that the centres multiple clinical pregnancy live birth rates is unlikely to meet the target that no more than 10% of births are multiple births. The PR is encouraged to continue to use the QMS to best effect to monitor and improve its multiple clinical pregnancy live birth rates and to implement an effective strategy to reduce multiple birth rates to meet the target, so as to improve the quality of the service offered to patients

1.15. The panel noted the inspectorate's recommendation to renew the centre's treatment (including embryo testing) and storage licence for a period of four years, without any additional conditions, subject to the PR's engagement with the recommendations and his commitment to meeting the requirements 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 noted the unresolved issue regarding the multiple birth rate, encouraging dialogue, between the PR and inspectorate, to continue.

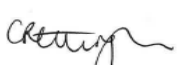
2.5. The panel acknowledged that the inspector will continue to monitor the centre's performance and the implementation of the report's recommendations within the required timescales. The panel reiterated the request to receive a further update report, with the recommendation that regulatory action should be taken, should the PR fail to implement the recommendations within the prescribed timescales, in accordance with the Authority's Compliance and Enforcement Policy.

2.6. 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 PR's engagement with the recommendations and his commitment to meeting the requirements of 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

Clare Ettinghausen

Date

30 July 2018

Inspection Report

Purpose of the Inspection Report

This is a report of an inspection at one of three centres under one ownership and leadership, carried out at the same time to assess whether it 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 application by the Person Responsible to renew the 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 new licences and, if so, whether any additional conditions should be applied to those licences.

Date of inspection: 23, 24 and 25 January 2018

Purpose of inspection: Renewal of a licence to carry out Treatment (including embryo testing) and Storage, at centre 0157

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: Susan Jolliffe (lead), Karen Conyers (scientific inspector), Shanaz Pasha (clinical inspector) and Sharon Fensome-Rimmer (chief inspector)

Executive Licensing Panel: 20 July 2018

Centre name	Assisted Reproduction and Gynaecology Centre
Centre number	0157
Licence number	L/0157/27/a
Centre address	13 Upper Wimpole Street, London, W1G 6LP
Person Responsible	Mr Mohamed Taranissi
Licence Holder	Mr Mohamed Taranissi
Date licence issued	1 July 2016
Licence expiry date	30 June 2019
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centres and their licensing history:

Assisted Reproduction and Gynaecology Centre (ARGC) 0157 which has held a licence with the HFEA since 1995. The centre provides a full range of fertility services including embryo testing. The last inspection was on 27 and 28 January 2016, this was a licence renewal inspection and the centre was granted a three-year licence. The centre provided 665 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 January 2017. In relation to activity levels this is a medium sized centre.

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period September 2016 to August 2017 shows that centre 0157 success rates are in line with national averages with the following exceptions:

Centre 0157 Clinical Pregnancy Rate (CPR) by cycle for IVF treatment involving fresh embryos between October 2016 and September 2017 on patients aged 16 to 37 years, and 38 years and above age range on 2 January 2018 were both above average.

Centre 0157 CPR by cycle for ICSI treatment involving fresh embryos between October 2016 and September 2017 on patients aged 16 to 37, and 38 years and above age range on 2 January 2018 were both above average.

The centre does not provide partner intrauterine insemination treatment.

Multiple births[2]

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

Between October 2016 and September 2017, centre 0157 multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 31%. This represents performance that is likely to be statistically greater than the 10% multiple live birth rate target (recommendation 1)

[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) for centre 0157
- 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 at 0157 (including those of relevant third parties) are suitable;
- the centre's practices are suitable;
- the application contains the supporting information required by General Direction 0008, in application for renewal of the centre's licence;
- the centre has submitted an application fee to the HFEA in accordance with requirements.

The ELP is asked to note that at the time of the inspection there were a number of areas of practice that required improvement including one critical five major and two 'other' areas of non-compliance which resulted in the following recommendations:

Since the inspection visit the PR has confirmed that the following recommendations have been fully implemented:

Major areas of non compliance:

- The PR should ensure that the centre's internal processes for identifying and reporting adverse incidents are effective.

- The PR should ensure that patients or donors considering donating embryos for use in staff training are provided with all the necessary information.

Since the inspection visit the PR has given a commitment to implementing the following recommendations in the prescribed timescales:

Critical areas of non compliance:

- **The effectiveness of the centre's multiple births minimisation strategy should be reviewed to ensure that it can meet the 10% multiple live birth rate target**

Major areas of non compliance:

- The PR should ensure that the centre's QMS is compliant with all relevant requirements.
- The PR should ensure that patients can access counselling services with an appropriately accredited counsellor.
- The PR should ensure that all licensed treatment activity is reported to the Authority within the timeframe required by General Direction 0005.

'Other' areas of non compliance:

- The PR should ensure the contents of the website are presented in accordance with guidance.
- The PR should review procedures and take appropriate corrective actions to ensure that the disclosure consent information supplied to the Authority accurately reflects that given and recorded on disclosure consent forms

Recommendation to the Executive Licensing Panel

The centre has one critical area of non-compliance, and five major areas of concern.

Some improvement is required in order for the centre to reflect suitable practices. The centre has a Quality Management System and the PR is encouraged to use this to best effect to monitor and improve the service provided within the centre.

The inspector will continue to monitor the centre's performance and the implementation of this report's recommendations within the required timescales. Failure to implement the recommendations within the prescribed timescales will result in the submission of a further report to the ELP with the recommendation that regulatory action be taken in accordance with the Authority's Compliance and Enforcement Policy.

The inspection team also notes the centres multiple clinical pregnancy live birth rates is unlikely to meet the target that no more than 10% of births are multiple births. The PR is encouraged to continue to use the QMS to best effect to monitor and improve its multiple clinical pregnancy live birth rates and to implement an effective strategy to reduce multiple birth rates to meet the target, so as to improve the quality of the service offered to patients.

The inspection team recommends the renewal of the Treatment (including embryo testing) and Storage licence at centre 0157 for a period of four years without additional conditions subject to the PRs engagement with the recommendations and his commitment to meeting the requirements of made in this report being implemented within the prescribed timescales.

Section 2: Inspection findings

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

1. The protection of the patient, and children born following treatment at the centre
2. The experience of patients at the centre
3. The protection of gametes (sperm and eggs) and embryos at the centre
4. How the centre look 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 compliant with HFEA requirements. It is important that donors are appropriately screened to minimise the risks of cross infection during treatment, processing and storage of gametes and/or embryos.

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

Donor assisted conception (Guidance note 20)
It is important that centre uses 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 center'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 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 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 Clinical Pathology Accreditation (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 process for administering and monitoring patients during intralipid infusion was reviewed and considered to be suitable.

Written information provided to patients offered intralipid therapy is compliant with guidance.

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 partially compliant with HFEA multiple births minimisation strategy requirements for keeping a summary log of cases in which multiple embryos have been transferred and conducting regular audits and evaluations of the progress and effectiveness of the strategy. The single biggest risk of fertility treatment is a multiple pregnancy.

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

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

Transport and distribution of gametes and embryos (Guidance note 15; General Direction 0009)
The centre's procedures for the transport, distribution and recall of gametes and embryos are compliant with HFEA requirements. This is important to ensure that all gametes / embryos sent to other licensed centres within or outside the UK are:

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

Receipt of gametes and embryos (Guidance note15)
The centre's procedures for the receipt of gametes and embryos are compliant with HFEA requirements. This is important to ensure that the centre only accepts gametes and embryos from other centres if they are appropriately labelled and are accompanied by enough information to permit them to be stored or used in treatment in a way that does not compromise their quality and safety.

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

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

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 any transport or satellite arrangements therefore this area of practice is not relevant to this inspection.

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 partially compliant with HFEA requirements. The three centres report no adverse incidents (including serious adverse events and reactions) to the HFEA. The three centres investigate 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

Multiple births
Between 1 October 2016 and 30 September 2017, the multiple clinical pregnancy rates for all IVF, ICSI and FET cycles for all age groups at centre 0157 is 31%.

(General Direction 0003 and SLC T2) (recommendation 1).

The centre does not keep a summary log of all cases where more than one embryo was transferred to a patient who met their eSET criteria, or every treatment cycle that involves the placing in a woman of four eggs or three embryos.

(General Directions 0003 and SLC T2) (recommendation 1).

Quality management system (QMS)
The following issues were noted with the centres' SOPs:
- The SOP describing embryo biopsy did not include description of how the centre ensure compliance with SLCT86, SLC T87 and SLC T88. The inspection team were assured staff were aware of these licence conditions that practices are compliant.

- The SOP describing the transporting of gametes and/or embryos between licensed centres did not include a description of the information required on the labelling of the shipping container as required in SLC T107.
- The centre does not have a documented recall procedure that defines the roles and responsibilities and actions if a distribution is recalled (CoP 15C).

(SLC T33b) (recommendation 2)

Adverse incidents
Review of the centre's incident reporting log identified a breach of confidentiality at centre 0157 in May 2016 that should have been reported to the HFEA, but had not been reported.

(SLC T119, T121, and T43) (recommendation 3).

Staff engaged in licensed activity

Person Responsible (PR)
Staff

What the centre does well

Person Responsible (Guidance note 1)

The PR has academic qualifications in the field of medicine 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
The PR should ensure that patients can access counselling services with an appropriately accredited counsellor. This non-compliance is described in the counselling section below.

Welfare of the child and safeguarding

What the centre does well

Welfare of the child (Guidance note 8)
The centre's procedures to ensure that the centre takes into account before licensed treatment is provided, the welfare of any child who may be born as a result of that treatment and of any other child who may be affected by that birth, are compliant with HFEA requirements.

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

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

Embryo testing

Preimplantation genetic screening
Embryo testing and sex selection

What the centre does well

Preimplantation genetic screening (Guidance note 9);
Embryo testing and sex selection (Guidance note 10)
The centre'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 embryos is at a significant risk of having a series 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
The SOP for embryo biopsy does not include description of how the centre ensures compliance with SLC T86, SLC T87 and SLC T88. This non-compliance is described in the 'Quality Management System' section above.

2. The experience of patients

Patient feedback

What the centre does well

During the inspection visit no patients were available to speak with the inspectors about their experiences at the centre., The centre does ask patients to complete a patient satisfaction survey, between January 2017 and November 2017, 60 patients from all three centres completed a survey. Feedback was positive, with 100% of the individuals providing written feedback to the centre 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 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)

It is important to ensure that counselling support is offered to patients and donors providing relevant consent and prior to consenting to legal parenthood. The centre's counselling procedures are partially compliant with HFEA requirements.

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

The center does not offer egg and/or sperm sharing arrangements therefore this area of practice is not relevant to this inspection.

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
Counselling
The PR should ensure that patients can access counselling services with an appropriately accredited counsellor. The centre's counsellor is not accredited by British Infertility Counselling Association (BICA) and sufficient evidence to demonstrate that the counsellor meets full equivalence to BICA accreditation was not seen.

(SLC T14, CoP 2.12(b)) (recommendation 4)

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 partially 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
Information (Guidance note 4; Chair's Letter CH (11)02)
Success rates on the centre's website are not presented in accordance with HFEA guidance.
The centre's website does not provide data less than three years old.

(CoP 4.12 (a)) (recommendation7)

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

What the centre does well

Consent (Guidance note 5;6)

The centre's procedures for obtaining consent are compliant with HFEA requirements. This ensures that patients and donors have provided all relevant consents before carrying out any licensed activity.

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

This centre has been inspected since 2014 and 2015 when significant failings were reported across the sector regarding the collection and documentation of consent to legal parenthood. At those inspections, legal parenthood consenting processes were found to be robust.

To provide assurance of the continued compliance and effectiveness of the centre's legal parenthood consenting procedures, the inspection team discussed these procedures with staff and reviewed the results of recent legal parenthood consenting audits. Five sets of records where treatment with donor sperm had recently been provided in circumstances where consent to legal parenthood was required were also audited by the inspection team. These activities enabled the inspection team to conclude that the process used to collect legal parenthood consent at this centre is 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 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
Five discrepancies were found between eight completed; Centre 0157 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 in these instances.
In all five discrepancies, the patients had consented to non contact research but the data submitted by the centre to the HFEA indicated that the patients had not.

(CH (10)05 and General Directions 0005 5) (recommendation 8)

3. The protection of gametes and embryos

Respect for the special status of the embryo

What the centre does well

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

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

What the centre could do better

Nothing identified at this inspection.

Screening of patients and Storage of gametes and embryos

What the centre does well

Screening of patients (Guidance note 17)

The centre's procedures for screening patients are compliant with HFEA requirements. It is important that gamete providers are appropriately screened to minimise the risks of cross infection during treatment, processing and storage of gametes and/or embryos.

Storage of gametes and embryos (Guidance note 17)

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

What the centre could do better

Nothing identified at this inspection.

Use of embryos for training staff

What the centre does well

Use of embryos for training staff (Guidance note 22)
The centre'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
The centre's do not provide sufficient information to patients regarding the use of embryos in training.

(SLC T97) (recommendation 5).

4. Information management

Record keeping and Obligations and reporting requirements

What the centre does well

Record keeping and document control (Guidance note 31)
The centre's procedures for keeping records are compliant with HFEA requirements to ensure that accurate medical records are maintained. Good medical records are essential for the continuity of the patient's care.

Obligations and reporting requirements (Guidance note 32; General Direction 0005)
The centre's procedures for submitting information, about licensed activities to the Authority are partially 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
The PR should ensure that all licensed treatment activity is reported to the Authority within the timeframe required by General Direction 0005.

(General Direction 0005 SLC T41) (recommendation 6)

Section 3: Monitoring of the centre's performance

Following the last inspection, the PR had not commented on the report and had not engaged or provided evidence to show that recommendations were implemented.

Areas of practice requiring action

The section sets out matters which the Inspection Team considers may constitute areas of non compliance. These have been classified into critical, major and others. Each area of non compliance is referenced to the relevant sections of the Acts, Regulations, Standard Licence Conditions, General Directions or the Code of Practice, and the recommended improvement actions required are given, as well as the timescales in which these improvements should be carried out.

Critical area of non compliance

A critical area of non compliance is an area of practice which poses a significant risk of causing harm to a patient, donor, embryo or to a child who may be born as a result of treatment services, or a significant shortcoming from the statutory requirements. A critical area of non compliance requires immediate action to be taken by the Person Responsible.

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
1.Multiple birth rate Between 1 October 2016 and 30 September 2017, the multiple clinical pregnancy rates for all IVF, ICSI and FET cycles for all age groups at centre 0157 is 31%. If there is no change to centre's 0157 multiple pregnancy rate, our analysis suggests that the 10%	The effectiveness of centre's multiple births minimisation strategy should be reviewed to ensure that the centre can meet the 10% multiple live birth rate target. The PR should arrange to have the effectiveness of centre 0157 multiple births minimisation strategy reviewed by an independent	Our position on this matter has been clear and consistent over many years, and extensively discussed with various inspectors and the Executive both informally and formally (including in legal challenges). We simply follow the criteria set up by the professional bodies (for clinicians and clinics to strictly follow) which determine the number of	The Executive acknowledges the PR's response. The PR should provide the centre's inspector with an update by 25 October 2018 on his review and the implementation of any corrective actions required to improve the effectiveness of the centre's multiple birth minimisation strategy

multiple live birth target is likely to be exceeded. The centre does not keep a summary log of all cases where more than one embryo was transferred to a patient who met their eSET criteria, or every treatment cycle that involves the placing in a woman of four eggs or three embryos. A copy of the centre's audit of their multiple pregnancy rate was not available at the inspection. General Directions 0003 SLCT2 Performance within the target from centres 0206 and 0088 may be a good opportunity for sharing and learning.	expert, and establish, and ensure the accurate use of, summary logs for treatment cycles in which multiple embryos have been transferred to a patient who meets the criteria for single embryo transfer. A summary report of the findings of the review including corrective actions and the timescale for their implementation should be submitted to the HFEA by 25 September 2018. The PR should provide the centre's inspector with an update by 25 October 2018 on the review and the implementation of any corrective actions required to improve the effectiveness of the centre's multiple birth minimisation strategy. The PR should audit and evaluate the progress and effectiveness of the three centres multiple births minimisation strategy.	embryos to be transferred in individual patients based on their specific characteristics. Because most of our patients have had often multiple failed cycles elsewhere, it follows that they no longer fulfill the criteria for eSET. As with any clinic or clinician in the UK, we are not in a position to deviate from those criteria (despite being told informally on a previous occasion by a member of the Executive to do so because we are "too good" compared to the others). We would be happy however to collaborate with an independent expert, should the HFEA choose to appoint one, to discuss the position. We also don't have cases where more than 1 embryo is transferred to patients who have met the criteria for eSET. Moreover, a copy hadn't be requested during the inspection, or after in the correspondence that followed.	Further action is required

	Following this the PR should provide quarterly updates on the actions taken, including audit findings, to address these success rates with an aim to address this area of practice by 25 January 2019,		

Major area of non compliance

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

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

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
2. Quality Management System- Standard operating procedures	The PR should ensure that the centre's QMS is compliant with all relevant requirements.	Most if not all of this information was already available in our patients' information leaflets. We have now further incorporated the	The Executive acknowledges the PR's response and commitment to meet the requirement in the agreed time.

Three SOP's need to be updated or written, to meet licence conditions: The following issues were noted with the centre's SOP: • The SOP describing embryo biopsy did not include a description of how the centre ensures compliance with SLCT86, SLC T87 and SLC T88. The inspection team were assured staff were aware of these licence conditions that practices are compliant. • The SOP describing the transporting of gametes and/or embryos between licensed centres did not include a description of the information required on the labelling of the shipping container as required in SLC T107. • The centre does not have a documented recall procedure that defines the roles and responsibilities and actions if a distribution is recalled (CoP 15C).	The PR should address the SOP non-compliances within three months and send the updated version to the centre inspector by 25 September 2018.	same information into the text of the relevant SOPs to make them clearly reflective of our actual practices (which were acknowledged as compliant during the last, as well as in earlier inspections, in relation to those matters). As such, this matter has now been resolved.	A copy of the SOP's have been requested by 25 September 2018 and once they have been reviewed the non-compliance can be closed. Further action is required.

(SLC T33b)			
3.Incident reporting The PR did not notify the HFEA about a breach of confidentiality at centre 0157 in May 2016. SLC T119, T121, and T43.	The PR should ensure that the centre's internal processes for identifying and reporting adverse incidents are effective. In responding to this report, the PR should explain why the breach of confidentiality was not reported to the HFEA at the time of occurrence. The PR must immediately notify the HFEA of the incident that occurred in May 2016, using the HFEA incident reporting process; outlining the conclusion of the investigation to analyse the cause of the incident and recommendations for preventive and corrective actions at that time.	Verbal feedback from the PR on 22nd June; that having investigated the breach it was considered to be a patient undergoing Gynaecological treatment and not HFEA licensed treatment.	The breach of confidentiality was recorded on the centres incident log. The PR should ensure that the centre's internal processes for identifying and reporting adverse incidents are effective, which includes recording if the incident is reportable to the HFEA. Staff training and awareness had been undertaken post the breach, to ensure staff are aware of cases to be reported to the HFEA. No further action required.
4.Counselling The centres' counsellor (providing counselling services to each of the three clinics) is not accredited by BICA and sufficient evidence to demonstrate that the counsellor meets full	The PR should ensure that patients can access counselling services with an appropriately accredited counsellor. A report should be provided to the HFEA documenting how	As explained during the last, as well as in earlier inspections, all our patients are generally free to access any appropriate counselling service of their choice. Historically however for over 15 years, the vast majority of	The Executive acknowledges the PR's response. A report has been requested by 25 July 2018. Further action is required

equivalence to BICA accreditation was not seen. SLC T14, CoP 2.12(b).	the relevant individual's skills are equivalent to those conferred by the BICA accreditation scheme **or** how the centre plans to ensure compliance with this guidance when responding to this report.	them have opted to choose the services of an independent and very experienced counsellor with the full knowledge of the HFEA (without objection). We have had no problems or received any complaints relating to those services at any time throughout this long period of time; quite the opposite, many patients have complemented the care and advice received from this counsellor.	
5. Use of embryos in training The centre does not provide information to patients regarding the use of embryos in training. SLC T97	The PR should ensure that patients or donors considering donating embryos for use in staff training are provided with all the necessary information. A copy of the written patient information should be provided to the centre's inspector by 25 September 2018.	This is incorrect as the Centre has always had a separate information sheet which is routinely provided to patients at the start of their treatment. Moreover, the potential use of left over embryos for training purposes is clearly documented in the consent forms which the patients sign.	The Executive has received the patient information sheet. No further action is required
6.Obligations and reporting requirements The HFEA has a legal responsibility to maintain a register containing information about all licensed activities. In order to do this, centres are	The PR should ensure that all licensed treatment activity is reported to the Authority within the timeframe required by General Direction 0005.	It is to be noted, as we explained for many years in previous inspections, that a large number of centres find it difficult to provide the information within the allocated time frame	The Executive acknowledges the PR's response. The PR should ensure that all licensed treatment activity is reported to the Authority within

required by law to provide information to the HFEA about all licensed fertility treatments they carry out. The primary purpose for keeping this information is to allow the donor conceived and their parents to access information about the donor and about any donor-conceived genetic siblings. At centre 0157 all 108 IVF treatments and four Donor Insemination (DI) treatments reviewed at inspection had been reported to the HFEA by the inspection date (General Direction 005). 79% (85/108) of the IVF treatments and 75% (3/4) of the DI treatments reviewed at the time of inspection had been reported to the HFEA outside the ten working day period required by General Direction 0005. A small number of data input errors or omissions for centre 0157 were observed.	The procedures used to submit licensed treatment data should be reviewed to identify and address the reasons delayed submissions. This recommendation should be implemented by the time the inspection report is considered by a licensing committee and the inspector informed of the results of the review and actions taken. 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 Authority. The PR should review the causes of the donor registration issues identified and if they are not the result of simple data entry errors take appropriate corrective actions to prevent recurrence.	requested by the HFEA. At our Centre, this information is routinely submitted by the embryologists who generally elect to prioritise their clinical duties over their administrative responsibilities. Given the arbitrary nature of the time frame chosen by the HFEA, and the fact that all the required information had always been fully reported by our centres before any publication of the corresponding data throughout our 23 years licencing history, we therefore respectfully invite the HFEA to recomsider the timeline in those directions	the timeframe required by General Direction 0005. The PR should conduct an audit six months after implementing corrective actions. A summary of the audit should be provided to the Authority by 25 November 2018. Further action is required

These findings indicate that the centre's procedures for submitting information about licensed activities, to the Authority are partially compliant with HFEA requirements. General Direction 0005 SLC T41			

Other areas of practice that requires improvement

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

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
7. Information on the website at 0157 The centre's website does not provide data less than three years old. CoP Guidance 4.12 (a).	The PR should ensure the contents of the website for centre 0157 are presented in accordance with guidance. The PR should audit the centre's website against the	We have always published only verified data by the HFEA on our website to avoid confusion and contradiction. The data currently displayed on our website is the latest verified data published by the	The Executive acknowledges the PR's response. Further action is required

	regulatory requirements and promptly arrange for any amendments required. A summary of findings and action taken should be received from the PR by 25 September 2018.	HFEA for our Centre. We also understand that the HFEA, contrary to their practice for many years in updating the published statistics every 6 months, have now failed to do so on at least 3 successive occasions over the last 18 months or so, and we've been told that no updated publication is imminent. It is also ironic that the HFEA doesn't appear to follow its own guidance in relation to this matter as all the live birth rates data currently displayed on the HFEA's website are more than 3 years old, for example the live birth rate per egg collection published currently on the Authority's website is 5 years old as it covers the period from 01/07/2012 to 30/06/2013	
8. Disclosure of information, held on the HFEA Register, for use in research Five discrepancies were found between eight completed; Centre 0157 patient/partner disclosure consents on patient files and the related consent data submitted for inclusion on	The PR should review procedures and take appropriate corrective actions to ensure that the disclosure consent information supplied to the Authority accurately reflects that given and recorded on disclosure consent forms.	Verbal feedback from the PR on 22nd June that he required patient details, these were re-sent on 22nd June as requested.	The Executive acknowledges the PR's response. Further action is required

the register. Therefore, the centre's procedures have failed to ensure that the HFEA holds an accurate record of consents to disclosure in these instances. In all five discrepancies, the patients had consented to non contact research but the data submitted by the centre to the HFEA indicated that the patients had not. (NB. The Centre's designated HFEA Form Returnee has been provided with the relevant patient and partner numbers so that the form data can be reviewed and corrected). CH (10)05 and General Directions 0005	The PR should also correct the submissions that have been identified as being incorrect. These recommendations should be implemented by the time the inspection report is considered by a licensing committee and the inspector informed of the results of the review and actions taken. 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 Authority.		

Reponses from the Person Responsible to this inspection report