Executive Licensing Panel - minutes

Centre 0322 (Brighton Fertility Associates)

Renewal Inspection Report

Friday, 3 November 2017

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Juliet Tizzard (Chair) Ian Peacock Jessica Watkin	Director of Strategy and Corporate Affairs Systems 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 Brighton Fertility Associates has held a licence with the HFEA since 2012. The centre's licence was varied from a storage only to a treatment (insemination using partner/donor sperm) and treatment licence in March 2014. The centre provides basic fertility services and storage of gametes.

1.3. The panel noted that, in the 12 months to 30 June 2017, the centre provided 11 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a small centre.

1.4. The panel noted that HFEA held register data, in the 12 months to 30 June 2017, showed the centre reported 11 donor inseminations treatments with one pregnancy; this was not a multiple pregnancy. This represents a clinical pregnancy rate which is in line with the national average.

1.5. An inspection was carried out at the centre on 15 August 2017.

1.6. The panel noted that at the time of the inspection, there was one major area of non-compliance concerning the Quality Management System (QMS), and two 'other' areas of practice requiring improvement. Since the inspection, the Person Responsible (PR) has fully implemented the recommendations concerning the 'other' areas of non-compliance relating to CE marked devices and record keeping. The PR had given a commitment to fully implementing the recommendations concerning the QMS.

1.7. The panel noted that the PR had been encouraged to review the centre's QMS to ensure it can be used to best effect to monitor and improve the services provided to patients and donors.

1.8. The panel noted that inspector will continue to monitor the centre's performance and that implementation of the report's recommendations are made within the prescribed timescales.

1.9. The panel noted that the inspectorate recommends the renewal of the centre's treatment (insemination using partner/donor sperm) and storage licence for a period of four years, without additional conditions, subject to the recommendations being implemented within the prescribed timescales.

2. Decision

2.1. The panel had regard to its decision tree. It was satisfied that the appropriate applications 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 endorsed the inspectorate's recommendation to renew the centre's treatment (Insemination using partner / donor sperm) with storage licence for a period of four years, without additional conditions, subject to the recommendations 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

14 November 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: 15 August 2017

Purpose of inspection: Renewal of a licence to carry out Treatment (insemination using partner/donor sperm) 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) and Louise Winstone

Date of Executive Licensing Panel: 3 November 2017

Centre name	Brighton Fertility Associates
Centre number	0322
Licence number	L/0322/2/b
Centre address	Lower Ground Floor, Olivier House, 18 Marine Parade, East Sussex, Brighton, BN2 1TL, United Kingdom.
Person Responsible	Ms Suzanne Duffy
Licence Holder	Mrs Carolyn Croucher
Date licence issued	20 February 2014
Licence expiry date	19 February 2018
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:

Brighton Fertility Associates has held a licence with the HFEA since 2012. The centre's licence was varied from a storage only to a treatment (insemination using partner/donor sperm) and storage licence in March 2014. The centre provides basic fertility services.

The centre provided 11 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 30 June 2017. In relation to activity levels this is a small centre.

Other licensed activities at the centre include storage of gametes.

Pregnancy outcomes

In the 12 months to 30 June 2017, the centre reported 11 donor inseminations treatments with one pregnancy. This represents a clinical pregnancy rate which is in line with the national average.

In 2016, the centre reported two cycles of partner insemination with one pregnancy. This represents a clinical pregnancy rate which is in line with the national average.

Multiple births

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

The one pregnancy following donor insemination treatment in the 12 months to 30 June 2017 was not a multiple pregnancy.

In 2016, the one pregnancy following partner insemination treatment was not a multiple pregnancy.

Recommendation to the Executive Licensing Panel

Taking into account the essential requirements set out in the Human Fertilisation and Embryology (HF&E) Act 1990 (as amended), the HF&E Act 2008 and the HFEA Code of Practice (CoP), the inspection team considers that it has sufficient information to conclude that:

- the application has been submitted in the form required;
- the application has designated an individual to act as the Person Responsible (PR);
- the PR's qualifications and experience comply with section 16 (2) (c) of the HF&E Act 1990 (as amended);
- the PR has discharged her duty under section 17 of the HF&E Act 1990 (as amended);
- the premises (including those of relevant third parties) are suitable;
- the centre's practices are suitable;
- the application contains the supporting information required by General Direction 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 one major and two 'other' areas of non compliance.

Since the inspection visit, the following recommendations have been fully implemented:

'Other' areas of non compliance:

- The PR should ensure that CE marked equipment is used where possible.
- The PR should ensure that the identity of a patient is reliably confirmed and documented.

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

Major areas of non compliance:

- The PR should ensure that the centre's quality management system (QMS) and auditing processes are effective.

The centre has no critical areas of concern but does have one major area of concern.

The PR is encouraged to review the centre's QMS to ensure that it can be used to best effect to monitor and improve the services provided to patients and donors.

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

The inspection team recommends the renewal of the centre's Treatment (insemination using partner/donor sperm) 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.

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) at this centre
4. How this centre looks after important information

1. Protection of the patient and children born following treatment

Witnessing and assuring patient and donor identification

What the centre does well

Witnessing (Guidance note 18)
The centre's procedures for double checking the identification of gametes and the patient or donor to whom they relate are compliant with HFEA requirements. This ensures that patients receive treatment using the correct gametes.

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

Donor selection criteria and laboratory tests

Screening of donors prior to procuring, processing gametes 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.

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. It is important that the principle of altruistic donation be upheld but at the same time donors receive appropriate compensation for their time and any inconvenience caused.

Donor assisted conception (Guidance note 20)
It is important that centres use donated gametes from identifiable donors and keep records of donor characteristics. This is because patients using donated gametes in treatment and the parents of donor-conceived children, are able to access non identifying

information regarding the donor from the clinic. Furthermore, donor-conceived persons are entitled to know non-identifying details about their donor and any donor-conceived genetic siblings they may have at the age of 16 years, and donor identifying information at 18 years.

The centre's procedures are compliant with HFEA requirements which ensure the donor-conceived and their parents will be able to receive all required donor-related information.

What the centre could do better
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 is compliant with HFEA requirements to process gametes 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, 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 does not keep or dispense medicines.

Pre-operative assessment and the surgical pathway (Guidance Note 25)
This area of practice is not relevant to this centre.

Multiple births (Guidance note 7; General Direction 0003)
The centre is providing only insemination treatments, but such treatments still expose patients to the risks of multiple pregnancies and births if incorrectly applied. The single biggest risk of fertility treatment is a multiple pregnancy and birth. Thus, it is important for centres providing insemination treatments to have a multiple births minimisation strategy. The centre's procedures are compliant with HFEA requirements to have a multiple births minimisation strategy and to conduct regular audits and evaluations of the progress and effectiveness of the strategy.

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 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 are compliant with HFEA requirements. This is important to ensure that all gametes sent to other licensed centres within or outside the UK are:

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

Receipt of gametes and embryos (Guidance note 15)
The centre's procedures for the receipt of gametes are compliant with HFEA requirements. This is important to ensure that the centre only accepts gametes from other centres if they are appropriately labelled and are accompanied by enough information to permit them to be stored or used in treatment in a way that does not compromise their quality and safety.

Imports and exports (Guidance note 16; General Direction 0006)
The centre does not import or export gametes.

Traceability (Guidance note 19)
The centre's procedures are compliant with HFEA traceability requirements. These requirements are important to ensure that the centre has the ability -

- to identify and locate gametes during any step from procurement to use for human application or disposal;
- to identify the donor and recipient of particular gametes;
- to identify any person who has carried out any activity in relation to particular gametes; and
- to identify and locate all relevant data relating to products and materials coming into contact with particular gametes and which can affect their quality or safety.

Quality management system (QMS) (Guidance note 23)
The centre has a QMS that is partially compliant with HFEA requirements. The establishment and use of a QMS is important to ensure continuous improvement in the quality of treatments and services.

Third party agreements (Guidance note 24)
The centre's third party agreements are compliant with HFEA requirements.

Transport and satellite agreements (Guidance note 24; General Direction 0010)
The centre does not have any transport or satellite arrangements.

Equipment and materials (Guidance note 26)
The centre uses equipment and materials that are broadly compliant with HFEA requirements.

Some 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 clinically ineffective or harmful to the recipient.

Adverse incidents (Guidance note 27)
The centre's procedures for reporting adverse incidents are compliant with HFEA requirements. The centre reports all adverse incidents (including serious adverse events and reactions) to the HFEA. The centre investigates all adverse incidents that have occurred. Reporting and investigation of adverse incidents is important to ensure that centres share the lessons learned from incidents and continuously improve the services it offers.

What the centre could do better

Quality management system (QMS) (Guidance note 23)
The following was noted regarding the centre's audits:

- The audit reports do not systematically document the timescales for the

implementation of corrective actions and the dates of implementation. For audits involving a review of patient notes, the number of notes reviewed and the timeframe of the audit, were not clearly documented
- The centre has not undertaken the following audits within the last two years:
    - traceability of consumables
    - provision of information to patients
    - record keeping and document control
    - submission of data to the HFEA
    - confidentiality and privacy
    - CE marking of consumables and media

The following was noted regarding the centre's SOPs:
- The adverse events SOP does not provide information/instructions about reporting adverse events to the HFEA.

The centre has developed quality statements but has not expanded this to include statistically based quality objectives, against which the quality of activities can be monitored and assessed.

SLC T32, T33b, T35 and T36; see recommendation 1.

Equipment and materials (Guidance note 26)
The centre has recently obtained and are using sperm collection pots that are not CE marked to the appropriate standard.

SLC T30; 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)
This area of practice is not relevant to this centre.

2. The experience of patients

Patient feedback

What the centre does well
During the inspection visit there were no patients available to provide feedback on their experiences. The centre collects patient feedback through a questionnaire and feedback received for the last three months was reviewed on this inspection. The feedback was positive and patients complimented the care 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 sharing arrangements
Surrogacy
Complaints
Confidentiality and privacy

What the centre does well

Treating patients fairly (Guidance note 29)
The centre's procedures are compliant with the HF&E Act 1990 (as amended) to ensure that staff members understand the requirements for a conscientious objection to providing a particular licensed activity governed by the Act.

The centre's procedures are compliant with requirements to ensure that prospective and current patients and donors are treated fairly and that all licensed activities are conducted in a non discriminatory way.

Counselling (Guidance note 3)
The centre's counselling procedures are compliant with HFEA requirements. This is important to ensure that counselling support is offered to patients and donors providing relevant consent and prior to consenting to legal parenthood.

Egg sharing arrangements (Guidance note 12; General Direction 0001)
This area of practice is not relevant to this centre.

Surrogacy (Guidance note 14)
This area of practice is not relevant to this centre.

Complaints (Guidance note 28)
The centre's procedures are compliant with HFEA requirements to seek patient feedback and to be responsive to patient complaints. This is important to ensure that the centre uses patient feedback and any complaints as an opportunity to learn and improve their services.

Confidentiality and privacy (Guidance note 30)
The centre's procedures are compliant with HFEA requirements to ensure it has respect for the privacy, confidentiality, dignity, comfort and wellbeing of prospective and current patients and donors.

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

Information

What the centre does well

Information (Guidance note 4; Chair's Letter CH(11)02)
The centre's procedures for providing information to patients and / or donors are compliant with HFEA requirements. This ensures that the centre gives prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions.

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

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

What the centre does well

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

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

On this inspection we reviewed the center's most recent audit and found that it had been performed according to the method specified by the HFEA. No corrective actions were identified in the audit findings.

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

The PR informed the inspection team that no treatments requiring the collection of legal parenthood consent have been carried out since the last inspection, when all requirements related to legal parenthood consent were being met. An audit of recent legal parenthood consenting records could therefore not be performed on this inspection but current policies and procedures for obtaining legal parenthood consent were discussed with staff.

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

Disclosure of information, held on the HFEA Register, for use in research (General Direction 0005)
The centre's procedures for taking consent to disclosure to researchers are compliant with HFEA requirements.

This is important to ensure that the HFEA holds an accurate record of patients' consent, so that it only releases the patients identifying information, to researchers, with their consent. Information can be used by researchers to improve the knowledge about the health of patients undergoing ART and those born following ART treatment.

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

3. The protection of gametes and embryos

Respect for the special status of the embryo

What the centre does well
This area of practice is not relevant to this centre.

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 are compliant with HFEA requirements. These measures ensure that the gametes are stored appropriately to maintain their quality and safety. Furthermore, the centre only stores gametes in accordance with the consent of the gamete providers. The storage of gametes 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.

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

Use of embryos for training staff (Guidance note 22)

What the centre does well

Use of embryos for training staff (Guidance note 22)
This area of practice is not relevant to this centre.

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 broadly compliant with HFEA requirements to ensure that accurate medical records are maintained. Good medical records are essential for the continuity of the patient's care.

Obligations and reporting requirements (Guidance note 32; General Direction 0005)
The centre's procedures for submitting information, about licensed activities to the Authority are compliant with HFEA requirements This is important to ensure the HFEA can supply accurate information to a donor-conceived person and their parents or donors.

The HFEA register audit team found no evidence of problems with the timeliness and accuracy of the centre's submission of data to the Register.

What the centre could do better

Record keeping and document control (Guidance note 31)
The centre uses photographic identification to reliably identify its patients and donors but does not maintain a record of how, and by whom, each patient/donor has been reliably identified.

SLC T46b, see recommendation 3.

Section 3: Monitoring of the centre's performance

Following the interim inspection in 2015, no recommendations for improvement were made.

On-going monitoring of centre success rates

The centre has not been asked to review procedures for the provision of treatment since the last inspection.

Areas of practice requiring action

The section sets out matters which the Inspection Team considers may constitute areas of non compliance. These have been classified into critical, major and others. Each area of non compliance is referenced to the relevant sections of the Acts, Regulations, Standard Licence Conditions, General 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. Quality management system The following were noted regarding the centre's audits: • The audit reports do not systematically document the timescales for the implementation of corrective actions and the dates of implementation. For audits involving a review of patient notes, the number of notes reviewed and the timeframe of the audit, were not clearly documented; • The centre has not undertaken in the last two years the following audits: o traceability of consumables o provision of information to patients	The PR should ensure that the centre's QMS and auditing processes are effective. The PR should review the centre's audit programme to ensure that it is compliant in the range of audits performed, the methodology used and the documentation of corrective and preventative actions and their implementation. The PR should provide the centre's inspector with a copy of the review and an action plan for the implementation of this recommendation by 15	The audit SOP will be updated to reflect the changes suggested by the inspectors. i.e precise dated timescales for any corrective actions. The remaining audits were on a schedule for the end of the year . However we will bring them forward and will be completed in the updated formats and sent by the 15th November.	The Executive acknowledge the PR's commitment to implementing this recommendation. Further action is required.

o record keeping and document control o submission of data to the HFEA o confidentiality and privacy o CE marking of consumables and media. The following was noted regarding the centre's SOPs: • The adverse events SOP does not provide information/instructions about reporting adverse events to the HFEA. The centre has not developed statistically based quality objectives for key activities. SLC T32, T33b and T36.	November 2017. The centre should develop statistically based quality objectives for activities and submit evidence of this by 15 November 2017. The PR should provide copies of the audits and SOP identified in this report as non-compliant to the centre's inspector, by 15 February 2018.	The adverse events SOP has already been updated and forwarded to our inspector. All QI indictaors were qualified and described how to achieve and monitor them, but we had not put a numerical number on this. These will be amended and sent by 15th November.	

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
2. CE Marking The centre has recently obtained and is using sperm collection pots that are not CE marked to the appropriate standard. SLC T30.	The PR should ensure that CE marked equipment is used where possible. It is expected that sperm collection pots, CE marked to the appropriate standard, are in use by 15 November 2017 2017.	This has been corrected and the previous medical CE marked appropriate types purchased. The staff member was not helped by the supplier which stated CE marked product. As a learning exercise the staff member has undertaken a CE marking audit of consumables and found no further issues. This will be forwarded when staff returned from annual leave.	The Executive are satisfied that the PR has taken the recommended action. No further action is required.
3. Record Keeping The centre does not maintain a record of how, and by whom, each patient/donor has been reliably identified. SLC T46b	The PR should ensure that the identity of a patient is reliably confirmed and documented. The PR should undertake a review of the centre's processes for establishing the identity of patients. A summary of the findings of the review including corrective actions and the timescales for implementation should be	We have always taken photo ID and this has been noted on all patient and donor notes. We have not however signed on the photocopy itself to confirm this is the person. We have amended our SOP and all are now signed and dated at the time of checking. An audit will be undertaken by the end of November to confirm 100% compliance with this	The Executive are satisfied that the PR has taken the recommended action. No further action is required beyond the completion of the audit to check that the corrective actions already taken have been effective.

	provided to the centre's inspector by 15 November 2017. Within three months, the centre should carry out an audit of records to ensure that the proposed corrective actions have been effective in ensuring compliance. A summary report of the findings of the audit should be provided to the centre's inspector by 15 February 2018.	recommendation.	

Responses from the Person Responsible to this inspection report
I think the suggestions as usual from our inspectors were fair and useful. The recommendations for specific dates and targets make the QI and the audit reports more definitive and therefore stronger. We had previously taken photo ID to verify the clients and donors, and signed it had been done. However, we had not done the extra step of signing and dating on the actual photocopy , so the inspectors suggestion makes this process documented and therefore stronger.