Executive Licensing Panel - minutes

Centre 0170 (The Gateshead Fertility Unit)

Renewal Inspection Report

Friday, 22 September 2017

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Hannah Verdin (Chair) Howard Ryan Jessica Watkin	Head of Regulatory Policy Report Developer 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 The Gateshead Fertility Unit is located within the Queen Elizabeth Hospital, part of the Gateshead Health NHS Foundation Trust. The centre holds a treatment and storage licence and provides a full range of fertility services to NHS and self-funded patients from a wide geographical area.

1.3. The panel noted that the centre has been licensed by the HFEA since 1996.

1.4. The panel noted that, in the 12 months to 31 May 2017, the centre provided 683 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a medium sized centre. The panel noted the centre is commended on their progress and success in reducing the number of multiple births

1.5. The panel noted that HFEA held register data, for the period March 2016 to February 2017, showed the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 1%: this represents performance that is likely to be statistically lower than the 10% multiple live birth rate target. In 2015 the centre's MPR was 21%. The centre was alert to this and in the intervening period has revised their Multiple Birth Minimisation Strategy from both a clinical and embryology perspective. The efficacy of these changes was closely monitored.

1.6. The panel noted that an inspection was carried out at the centre on 27 and 28 June 2017.

1.7. The panel noted that at the time of the inspection there were five 'other' areas of practice which required improvement. The panel noted that, since the inspection, the Person Responsible (PR) had fully implemented the 'other' non-compliances recommendations concerning the Quality Management System (QMS) and equipment and materials. The panel noted that the PR had provided a commitment to implementing the recommendations regarding the remaining three 'other' areas of non-compliance surrounding third party agreements, laboratory staff and consent

1.8. The panel noted that the inspectorate commends the centre for their innovative work in meeting the needs of a section of the community who wish to receive assisted reproductive therapies while ensuring their requirements of their faith are also met. The inspectorate recommends the renewal of the centre's treatment and storage licence for a period of four years without additional conditions subject to the recommendations made in the report being implemented within the prescribed timescales.

2. Decision

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

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

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

2.4. The panel commended the centre on their low multiple birth rate and their positive patient feedback.

2.5. The panel endorsed the inspectorate's recommendation to renew the centre's treatment and storage licence for a period of four years without additional conditions subject to the recommendations made in this report being implemented within the prescribed timescales.

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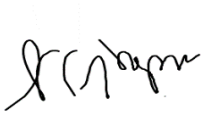
3. Chair's signature

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

Signature



Name

Hannah Verdin

Date

4 October 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: 27 and 28 June 2017

Purpose of inspection: Renewal of a licence to carry out Treatment and Storage

Inspection details: The report covers the performance of the centre since the last inspection, findings from the inspection visit and communications received from the centre.

Inspectors: Susan Jolliffe (lead), Gill Walsh and Douglas Gray

Executive Licensing Panel: 22 September 2017

Centre name	The Gateshead Fertility Unit
Centre number	0170
Licence number	L/0170/11/a
Centre address	Gateshead Health NHS Trust, Queen Elizabeth Hospital, Sheriff Hill, Gateshead, Tyne & Wear, NE9 6SX, United Kingdom
Person Responsible	Mr Ian Aird
Licence Holder	Gateshead Health NHS Foundation Trust
Date licence issued	01/01/14
Licence expiry date	31/12/17
Additional conditions applied to this licence	None

Contents

Section 1: Summary report 3

Section 2: Inspection findings 6

1. Protection of the patient and children born following treatment 6
2. The experience of patients 12
3. The protection of gametes and embryos 15
4. Information management 17

Section 3: Monitoring of the centre's performance 18

Areas of practice requiring action 19

Section 1: Summary report

Brief description of the centre and its licensing history:

The Gateshead Fertility Unit is located within the Queen Elizabeth Hospital, part of Gateshead Health NHS Foundation Trust and has been licensed with the HFEA since 1996. The centre provides a full range of fertility services to NHS and self-funded patients from a wide geographical area.

The centre provided 683 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 May 2017. In relation to activity levels this is a medium sized centre.

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

Pregnancy outcomes[1]

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

In 2016, the centre reported 17 cycles of partner insemination with two pregnancies, which is in line with the national average.

Multiple births[2]

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

Between March 2016 and February 2017, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 1%: this represents performance that is likely to be statistically lower than the 10% multiple live birth rate target. In 2015 the centre's MPR was 21%. The centre was alert to this and in the intervening period has revised their MBMS from both a clinical and embryology perspective. The efficacy of these changes was closely monitored. The centre is commended on their progress and success in reducing the number of multiple births.

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

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

Summary for licensing decision

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

- the application has been submitted in the form required;
- the application has designated an individual to act as the Person Responsible (PR);
- the PR's qualifications and experience comply with section 16 (2) (c) of the HF&E Act 1990 (as amended);
- the PR has discharged his duty under section 17 of the HF&E Act 1990 (as amended);
- the premises (including those of relevant third parties) are suitable;
- the centre's practices are suitable;
- the application contains the supporting information required by General Direction 0008, in application for renewal of their licence;
- the centre has submitted an application fee to the HFEA in accordance with requirements.

The ELP is asked to note that at the time of the inspection there were no critical or major non-compliances, there were five 'other' areas of non-compliance.

The PR has provided evidence that the following recommendations have been implemented:

'Other' areas that requires improvement:

- The PR should ensure the 'screening of donors' SOP is updated to reflect their practices, that screening is conducted within the time frame specified by the Authority and that screening takes account of professional body guidance.
- The PR should ensure that servicing and validation of the centrifuge is completed and documented.

The PR has provided a commitment to implement the following recommendations:

'Other' areas that requires improvement:

- The PR should ensure that there is a third party agreement (TPA) with the theatre used by the centre to perform testicular biopsies.
- The PR should ensure that competencies for laboratory staff obtaining consent are completed and documented.
- The PR should ensure that patient/partner consents to disclosure of identifying information to researchers are accurately reported to the HFEA register.

Recommendation to the Executive Licensing Panel

The centre has no critical or major areas of non-compliance. The centre's success rates are in line with the national average. At 1%, the multiple clinical pregnancy rate is significantly below the no greater than 10% target, for which the centre is to be commended

The inspection team also commends the centre for their innovative work in meeting the needs of a section of the community who wish to receive assisted reproductive therapies while ensuring their requirements of their faith are also met. The inspection team recommends the renewal of the centre's treatment and

storage licence for a period of four years without additional conditions subject to the recommendations made in 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 and eggs) and embryos at this centre
4. How this centre looks after important information

1. Protection of the patient and children born following treatment

Witnessing and assuring patient and donor identification

What the centre does well

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

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

Donor selection criteria and laboratory tests

Screening of donors prior to procuring, processing gametes and embryos
Payments for donors
Donor assisted conception

What the centre does well

Screening of donors (Guidance note 11)
The centre's procedures for screening donors are compliant with HFEA requirements. It is important that donors are appropriately screened to minimise the risks of cross infection during treatment, processing and storage of gametes and/or embryos.

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

Donor assisted conception (Guidance note 20)
It is important that centres use donated gametes or embryos from identifiable donors and keep records of donor characteristics. This is because patients using donated gametes and embryos in treatment and the parents of donor-conceived children, are able to access non identifying information regarding the donor from the clinic. Furthermore, donor-conceived persons are entitled to know non-identifying details about their donor

and any donor-conceived genetic siblings they may have at the age of 16 years, and donor identifying information at 18 years.

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

What the centre could do better
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 considered so that patients and staff are in safe surroundings that prevent harm.

The premises of the centre's laboratories conducting tests that impact on the quality and safety of gametes and/or embryos (relevant third parties) are suitable.

The centre is compliant with HFEA requirements to process gametes and/or embryos in an environment of appropriate air quality.

Laboratory accreditation (Guidance note 25)
The centre's laboratories and/or third party laboratories which undertake the diagnosis and investigation of patients, patients' partners or donors, or their gametes, embryos or any material removed from them, are compliant with HFEA requirements to be accredited by CPA (UK) Ltd or another body accrediting to an equivalent standard. This is important to assure the quality of the services provided.

Infection control (Guidance Note 25)

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

Medicines management (Guidance Note 25)
The centre has arrangements in place for obtaining, recording, handling, using, keeping, dispensing, administering and disposing of medicines that are compliant with guidance.

Prescription of intralipid 'off label'
Intralipid is an intravenous nutritional supplement sometimes prescribed to facilitate IVF treatment in a subset of women. This centre does not prescribe intralipid therapy therefore requirements related to its use were not relevant at this inspection.

Pre-operative assessment and the surgical pathway (Guidance Note 25)
The centre has policies and procedures in place that are compliant with professional body guidelines for pre-operative assessment and management of the surgical pathway. This is important to ensure that all patients are safely assessed and cared for pre, peri and post operatively.

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

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

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

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

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

Receipt of gametes and embryos (Guidance note15)
The centre's procedures for the receipt of gametes and embryos are compliant with HFEA requirements. This is important to ensure that the centre only accepts gametes and embryos from other centres if they are appropriately labelled and are accompanied by

enough information to permit them to be stored or used in treatment in a way that does not compromise their quality and safety.

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

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 gametes or embryos;
- to identify any person who has carried out any activity in relation to gametes or embryos; and
- to identify and locate all relevant data relating to products and materials coming into contact with particular gametes or embryos and which can affect their quality or safety.

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

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

Transport and satellite agreements (Guidance note 24; General Direction 0010)
The centre has one satellite agreement with Hexham General Hospital which is compliant with HFEA requirements. The centre has no transport arrangements.

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, with one exception noted below.

The centre is broadly compliant with HFEA requirements to validate critical equipment. The centre has documented procedures for the operation of critical equipment and procedures to follow if equipment malfunctions.

Process validation (Guidance note 15)
The centre's procedures are compliant with HFEA requirements to validate critical processes. This ensures that these processes are effective and do not render the gametes or embryos clinically ineffective or harmful to the recipient.

Adverse incidents (Guidance note 27)
The centre's procedures for reporting adverse incidents are compliant with HFEA requirements. The centre reports all adverse incidents (including serious adverse events and reactions) to the HFEA. The centre investigates all 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
Third party agreements (Guidance note 24)
The centre infrequently uses the main theatres for testicular biopsy cases; however, there is no third party agreement in place between the centre and the main theatres for this licensed activity (SLC T111, recommendation 1).

Quality management system
The centre has an excellent QMS system. However, one SOP had not been updated to reflect practices at the centre for the screening of donors to be conducted within the time frame specified by the Authority and that screening takes account of professional body guidance. An audit of patient records confirmed that practices are within the timeframe and staff were aware of the correct procedures (SLC T33b, recommendation 2).

Equipment and materials
There was no documented evidence of the maintenance and validation of the centrifuges used for sperm preparation (SLC T23, recommendation 3).

Staff engaged in licensed activity

Person Responsible (PR)

Staff

What the centre does well

Person Responsible (Guidance note 1)
The PR has complied with HFEA requirements.

The PR has academic qualifications in the field of medicine and has more than two years of practical experience 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 is however broadly compliant with HFEA requirements to provide updated training as required. 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
Staff
Medical and nursing staff had documented competencies; however, the embryology team was unable to provide documented evidence of competence assessment for obtaining consent (SLC T15, recommendation 4).

Welfare of the child and safeguarding

What the centre does well

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

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

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

Embryo testing

Preimplantation genetic screening
Embryo testing and sex selection

What the centre does well

Preimplantation genetic screening (Guidance note 9);
Embryo testing and sex selection (Guidance note 10)
The centre does not undertake embryo testing therefore these guidance notes are not applicable to this inspection.

What the centre could do better
Not applicable to this inspection.

2. The experience of patients

Patient feedback

What the centre does well

During the inspection visit the inspectors spoke to three couples who provided feedback on their experiences. In the last 12 months to June 2017, 185 patients provided feedback directly to the centre which was shared with the inspection team, the feedback was all positive, thanking staff for their friendly and professional support.

Based on this feedback and observations made during the inspection it was possible to assess that the centre:

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

What the centre could do better

Nothing identified at this inspection.

Treating patients fairly

Counselling
Egg [and sperm] sharing arrangements
Surrogacy
Complaints
Confidentiality and privacy

What the centre does well

Treating patients fairly (Guidance note 29)

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

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

Counselling (Guidance note 3)

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

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

The centre does not undertake egg sharing therefore this guidance note is not applicable to this inspection.

Surrogacy (Guidance note 14)

The centre does not offer treatment involving surrogacy, therefore this guidance note is not applicable to this inspection.

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 no one was affected by legal parenthood consent anomalies.

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

On this inspection, we reviewed the centre's audit of consent to legal parenthood dated May 2017 and found that it had been performed according to the method specified by the HFEA.

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

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 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 (General Direction 0005)
The records of consent to disclosure to researchers given by 10 patients were reviewed in the course of the inspection. One discrepancy was found where the patient had consented to contact research but the data submitted by the centre to the HFEA indicated that the patient had not. This does not present a risk that the HFEA could inadvertently disclose information to researchers without consent (recommendation 5).

3. The protection of gametes and embryos

Respect for the special status of the embryo

What the centre does well

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

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

What the centre could do better

Nothing identified at this inspection.

Screening of patients
Storage of gametes and embryos

What the centre does well

Screening of patients (Guidance note 17)

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

Storage of gametes and embryos (Guidance note 17)

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

What the centre could do better

Nothing identified at this inspection.

Use of embryos for training staff (Guidance note 22)

What the centre does well

Use of embryos for training staff (Guidance note 22)

The centre’s procedures for using embryos for training staff are compliant with HFEA requirements. Embryos are only used for the purpose of training staff in those activities expressly authorised by the Authority.
What the centre could do better Nothing identified at this inspection.

4. Information management

Record keeping
Obligations and reporting requirements

What the centre does well

Record keeping and document control (Guidance note 31)
The centre's procedures for keeping records are compliant 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
Nothing identified at this inspection.

Section 3: Monitoring of the centre's performance

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

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

On-going monitoring of centre success rates

The centre has not received any risk based alerts relating to success rates.

Areas of practice requiring action

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

Critical area of non compliance

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

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

Major area of non compliance

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

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

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

Other areas of practice that requires improvement

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
1 **Third party agreements** The PR should ensure that there is a TPA with the theatre used by the centre to perform testicular biopsy. (SLC T111)	The PR should ensure that where activities are carried out on the premises of a third party, there should be a TPA completed. The PR should send a copy of the completed TPA to the lead inspector by 27 September 2017.	TPA with theatre services has been drafted (see attachments ; service provision letter theatres QEH and Product manager letter) and sent to Service Line manager in theatres. Awaiting return of document from theatre to confirm. This will be forwarded to HFEA on completion.	The executive acknowledges the PR's response and his commitment to fully implementing this recommendation. A copy of the draft TPA has been provided, a signed copy should be sent to the centre inspector on completion. Further action required
2 **Quality management system** The PR should ensure the 'screening of donors' SOP is updated to reflect their practices; that screening is conducted within the time frame specified by the Authority and that screening takes account of professional body guidance. (SLC T33b)	The PR should ensure that the screening SOP is updated. The donor screening SOP should be reviewed to ensure it is compliant with regulatory requirements and takes account of professional body guidance. Evidence of this should be submitted to the centre's inspector by 27 September 2017.	Relevant SOP's (screening and Egg donation have been appropriately updated - see attached	The PR has sent the revised screening procedures which are now compliant. **No further action is required**.

3 **Equipment and materials** There was no documented evidence of the maintenance and regular inspection of the centrifuges used for sperm preparation. (SLC T23)	The PR should ensure that servicing and validation of the centrifuges are completed and documented. Confirmation of this should be sent to the lead inspector by 27 September 2017.	Centrifuge being serviced 31st August 2017. Will forward relevant documentation when available and prior to 27 September 2017.	The PR has submitted the servicing and validation documents as requested. **No further action is required.**
4 **Staff** Laboratory staff were unable to provide documented competencies for taking consent. (SLC T15)	The PR should ensure staff competencies are completed and documented for all staff. Laboratory staff competencies should be reviewed, implemented and completed for consent taking by 27 September 2017, and a copy sent to the lead inspector.	Competency has been drafted Laboratory staff in process of being competency assessed. Copy of confirmation will be sent on completion and prior to 27 September 2017.	The executive acknowledges the PR's response and his commitment to fully implementing this recommendation within the timescale. Further action required
5**. Consent to disclosure** In one of the ten patient consent to disclosure forms reviewed, the patients had consented to contact research but the data submitted by the centre to the HFEA indicated that the patients had not. (General Direction 0005)	The PR should correct the submission that was identified as incorrect and review the procedures for checking and submitting consent to disclosure decisions to the HFEA to ensure that consent to disclosure decisions made by patients are accurately reported to the HFEA.	Consent form corrected. The SOP for consent to disclosure has been reviewed and appropriate changes made. A further audit of 30 patients has been conducted and the report will be forwarded - see attached.	The executive acknowledges the PR's response and his commitment to fully implementing this recommendation within the timescale. Further action required

	A summary of the findings and any corrective actions identified should be submitted to the centre's inspector by 27 September 2017.		

Reponses from the Person Responsible to this inspection report
We feel the Inspection report accurately reflects our interpretation of the findings of the inspection. We were grateful to receive such positive feedback from the inspection team at the feedback session at the end of the inspection. The tone of the report does not reflect this positivity and tends to focus on the small number of areas where the clinic practice may not have complied with the code of practice. We feel that the report would be better balanced if more emphasis was given to include ggod practice. The report is available to be viewed by the general public via the HFEA website and we feel a more balanced report would be more helpful to the publics understanding of how the clinic is run.