Executive Licensing Panel - minutes

Centre 0019 (Aberdeen Fertility Centre)

Renewal Inspection Report

Tuesday, 20 November 2018

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Clare Ettinghausen (Chair) Niamh Marren Helen Crutcher	Director of Strategy and Corporate Affairs Regulatory Policy Manager Risk and Business Planning Manager
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers	Catherine Burwood	Senior Governance Manager

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 Aberdeen Fertility Centre is located within Aberdeen Maternity Hospital and is part of Aberdeen University. The centre has held a treatment and storage licence with the HFEA since 1992. The centre's current licence was granted on 1 February 2015, for a period of four years, with no additional licence conditions. The centre provides a full range of fertility services.

1.3. The panel noted that following the centre's interim inspection in 2016, one recommendation concerning premises and infection control, remained outstanding. The Person Responsible (PR) had agreed this recommendation was appropriate, but NHS Grampian were unwilling to fund its implementation as there was an imminent new hospital build occurring which would comply with the recommendation made by the Executive. This issue was re-examined at the renewal inspection and the inspection team considered that, although the new hospital build had been delayed, appropriate preventative measures had been put in place and were monitored regularly with regards to safety.

1.4. The panel noted that, in the 12 months to 30 June 2018, the centre provided 951 cycles of treatment (excluding partner intrauterine insemination). In relation to activity this is a medium sized centre.

1.5. The panel noted that, between April 2017 and March 2018, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 6.6%. This represents performance that is not likely to be statistically different from the 10% multiple live birth rate target.

1.6. The panel noted that, for IVF and ICSI, HFEA held register data, for treatments in the year to 31 March 2018, show the centre's success rates are in line with national averages.

1.7. The panel noted that, in 2017, the centre reported 23 cycles of partner insemination with four pregnancies.

1.8. An inspection was carried out at the centre on the 5 and 6 September 2018.

1.9. The panel noted that at the time of the inspection, there were three major areas of non-compliance regarding the screening of donors, premises and the transport and distribution of gametes and embryos.

1.10. There were also three 'other' areas of non-compliance concerning medicines management, traceability and process validation.

1.11. Since the inspection, the PR has provided evidence that actions have been taken to implement the recommendations relating to the screening of donors, premises, the transport and distribution of gametes and embryos, medicines management and traceability, and has committed, where required to audit the effectiveness of these actions within the required timescales. The PR has given a commitment to fully implementing the non-compliance concerning process validation.

1.12. The panel noted that some improvement is required in order for the centre to demonstrate the suitability of their practices. The centre has a robust Quality Management System (QMS) and the PR is encouraged to use it to best effect to monitor and improve the service provided to patients. The centre was congratulated on their sustained low multiple birth rate. The centre's engagement with the HFEA is good, particularly in response to incidents and sector alerts.

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

1.14. The panel noted that, the inspection team recommended 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 noted the PR's positive engagement with the inspectorate, noting the particular challenges encountered by the centre in relation to the geographical spread of its patient group.

2.5. The panel endorsed the inspectorate's recommendation to renew the centre's treatment and storage only licence for a period of four years, without additional conditions, subject to the recommendations in the 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

23 November 2018

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: 5 and 6 September 2018

Purpose of inspection: Renewal of a licence to carry out Treatment & 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: Mhairi West, Lesley Brown, Janet Kirkland MacHattie

Date of Executive Licensing Panel: 20 November 2018

Centre name	Aberdeen Fertility Centre
Centre number	0019
Licence number	L/0019/15/a
Centre address	Department of Obstetrics & Gynaecology, Aberdeen Maternity Hospital, Foresterhill, Aberdeen, AB25 2ZL, UK
Person Responsible	Dr Abha Maheshwari
Licence Holder	Alison McTavish
Date licence issued	01/02/2015
Licence expiry date	31/01/2019
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:

Aberdeen Fertility Centre is located within Aberdeen Maternity Hospital and is part of Aberdeen University. The centre has held a Treatment and Storage licence with the HFEA since 1992. The centre's current licence was granted on 1 February 2015 for a period of four years with no additional licence conditions.

The centre provides a full range of fertility services. The centre provided 951 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 30 June 2018. In relation to activity levels this is a medium-size centre.

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

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for treatments in the year to 31 March 2018 show the centre's success rates are in line with national average.

In 2017, the centre reported 23 cycles of partner insemination with 4 pregnancies.

Multiple births[2]

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

Between April 2017 and March 2018, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 6.6%. This represents performance that is not likely to be statistically different from the 10% multiple live birth rate target.

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

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

Summary for licensing decision

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

- the application has been submitted in the form required;
- the application has designated an individual to act as the Person Responsible (PR);
- the PR's qualifications and experience comply with section 16(2)(c) of the HF&E Act 1990 (as amended);
- the PR has discharged 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 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 three major and three 'other' areas of non compliance.

Since the inspection visit, the PR has provided evidence that actions have been taken to implement the following recommendations and has committed, where required, to audit the effectiveness of those actions within the required timescales:

Major areas of non compliance:

- The PR must ensure that gamete donors are screened in accordance with regulatory requirements and professional body guidelines.
- The PR should ensure medical gases and liquid nitrogen are stored safely and securely.
- The PR should ensure that the documented procedure for gamete and embryo distribution is compliant with regulatory requirements, and that a written agreement is in place with all third parties providing goods or services that affect the quality and safety of gametes and embryos, including the process of distribution.

'Other' areas of non compliance:

- The PR should ensure that dispensing of medication is performed in accordance with statutory and regulatory requirements.
- The PR should ensure that all data relating to anything coming into contact with gametes or embryos are traceable from procurement of gametes to patient treatment or disposal and vice versa.

The PR has given a commitment to fully implement the following recommendation:

'Other' areas of non compliance:

- The PR should ensure that validation processes are complete for all critical processes.

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

Some improvement is required in order for the centre to demonstrate the suitability of their practices. The centre has a robust quality management system (QMS) and the PR is encouraged to use it to best effect to monitor and improve the service provided to patients. The centre should be congratulated on their sustained low multiple birth rate. Their engagement with the HFEA is good, particularly in response to incidents and sector alerts.

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 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 partially 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

Egg donors are not screened for syphilis at the time of donation, contrary to licence condition requirements and current guidance produced by the relevant professional bodies (SLC T52; CoP Guidance 11.23; UK guidelines for the medical and laboratory screening of sperm, egg and embryo donors, 2008; see recommendation 1).

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 partially suitable. Suitable premises are 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 partially 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 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 broadly compliant with guidance.

Prescription of intralipid 'off label'
Intralipid is an intravenous nutritional supplement sometimes prescribed to facilitate IVF treatment in a particular 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 single biggest risk of fertility treatment is a multiple pregnancy. 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.

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

- packaged and transported in a manner that minimises the risk of contamination and preserves the characteristics and biological functions of the gametes or embryos;
- shipped in a container that is designed for the transport of biological materials and that maintains the safety and quality of the gametes or embryos;
- appropriately labelled with the transport conditions, including temperature and time limit being specified;

- the container/package is secure and ensures that the gametes or embryos are maintained in the specified conditions. All containers and packages are validated as fit for purpose.

Receipt of gametes and embryos (Guidance note 15)
The centre's procedures for the receipt of gametes and embryos are broadly 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 broadly compliant with HFEA traceability requirements. These requirements are important to ensure that the centre has the ability -

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

Quality management system (QMS) (Guidance note 23)
The centre has a QMS that is 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 no transport or satellite agreements therefore requirements related to these types of activities were not relevant at this inspection.

Equipment and materials (Guidance note 26)
The centre uses equipment and materials that are compliant with HFEA requirements. All 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 broadly compliant with HFEA requirements to validate critical processes. This ensures that these processes are effective and do not render the gametes or embryos clinically ineffective or harmful to the recipient.

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

What the centre could do better

Safety and suitability of premises and facilities (Guidance note 25)
On the day of inspection, the outside medical gas storage area was not clearly labelled or secured from public access, and was surrounded by cigarette ends. The indoor gas store had limited ventilation and was very warm, owing to the computer server within the gas store; this presented a possible risk of overheating and ignition. The room on the embryology corridor which was used to contain a liquid nitrogen storage tank was not secured or labelled with appropriate safety signage. (SLC T17; DH Health Technical Memorandum 02-01: Medical gas pipeline systems; Operational management (2006); see recommendation 2).

Medicines management (Guidance Note 25)
Registered nurses at the centre dispense patients' medication against a signed prescription. NMC guidelines state that nurses can dispense in 'exceptional circumstances and represents an extension to professional practice. However, the dispensing of medication by members of the nursing team is standard practice at the centre. The charge nurse is aware of the guidelines and informed the clinical inspector that the exceptional circumstances are that many patients come from the islands of Scotland and cannot get home delivery service. In addition the centre can provide the medication at a lower cost than local pharmacies (NICE Guideline [NG46] April 2016 'Controlled drugs: safe use and management'; NMC (2015) 'Standards for medicines management'; see recommendation 4).

Transport and distribution and receipt of gametes and embryos (Guidance note 15; General Direction 0009)
The standard operating procedure (SOP) to guide the distribution of gametes and embryos is currently under review. However the draft SOP does not document a process for recall of gametes, how to handle returned gametes and embryos, or that any such recall should be investigated as an adverse incident (SLC T107, SLC T110, CoP Interpretation of mandatory requirements 15C; see recommendation 3).

Traceability (Guidance note 19)
On the day of the inspection the ICSI rig used for processing gametes was not recorded in the patients' records for traceability purposes (SLC T99; see recommendation 5).

Third party agreements (Guidance note 24)
The centre does not have a third party agreement with their gamete / embryo transportation courier. Patients oversee their own transportation arrangements, including organising the courier. However the centre still has responsibility for all arrangements with third parties which provide goods or services that affect the quality and safety of gametes and embryos, including distribution, and so should have an agreement with an

identified distribution service (SLC T111; CoP Interpretation of mandatory requirements 15C; see recommendation **Error! Reference source not found.**).

Process validation (Guidance note 15)
The validation documentation for the following critical processes was reviewed: storage and cryopreservation of gametes and embryos, and preparation of culture dishes. Process validation evidence was provided at the end of the relevant SOPs but was scant in detail and did not provide good evidence that the process, as applied at the centre, was efficacious and compliant (SLC T72; see recommendation 6).

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 has an organisational chart which clearly defines accountability and reporting relationships.

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

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

Welfare of the child and safeguarding

What the centre does well

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

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

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

Embryo testing

Preimplantation genetic screening
Embryo testing and sex selection

What the centre does well

Preimplantation genetic screening (Guidance note 9);
Embryo testing and sex selection (Guidance note 10)
The centre does not perform embryo testing and therefore the requirements surrounding this were not relevant to this inspection.

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

2. The experience of patients

Patient feedback

What the centre does well

Patient experience
The HFEA website has a facility on its 'Choose a Fertility Clinic' page enabling patients to provide feedback on their experience of their clinic. Only seven patients have provided feedback in the last 12 months, giving an average four star rating to the clinic. This suggests that the clinic does not actively seek patient feedback for comparison purposes. For the system to work well, it's important that every patient knows about the rating system. The PR is asked to consider ways to promote the use of this facility, and this will be followed up at the next inspection. The website also gives the ability for patients to comment on the cost of treatment. All patients confirmed that they had paid what they expected to, or less. Several patients provided individual comments to the HFEA complimenting the nursing staff at the clinic.

The centre also collects patient feedback and the most recent survey of this feedback was considered by the inspection team. Feedback was comparable to that provided to the HFEA.

During the inspection, the inspectors were unable to speak to any patients.

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

- treats patients with privacy and dignity;
- provides a clean and well organised environment for patient treatment;
- has staff who are supportive and professional;
- gives patients sufficient, accessible and up-to-date information to enable them to make informed decisions;
- treats patients with empathy and understanding.

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 consents to treatment and/or legal parenthood.

Egg sharing arrangements (Guidance note 12; General Direction 0001)
The centre's procedures for egg sharing arrangements are compliant with HFEA requirements. This is important to ensure that:

- care is taken when selecting egg providers donating for benefits in kind
- egg providers are fully assessed and medically suitable, and
- the benefit offered is the most suitable for the egg provider and recipient(s) (where relevant).

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

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

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

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

Information

What the centre does well

Information (Guidance note 4; Chair's Letter CH(11)02)
The centre's procedures for providing information to patients and / or donors are 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 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 inspection in 2016 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. Two 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 processes used to collect legal parenthood consent at this centre are compliant with HFEA requirements.

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

This is important to ensure that the HFEA holds an accurate record of patients' consents, so that it only releases patient identifying information, to researchers, with a patient's 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
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 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

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 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 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 2016, recommendations for improvement were made in relation to one major and two 'other' areas of non compliance.

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

In responding to the report immediately after the inspection in 2016, the PR had agreed that the outstanding recommendation related to premises and infection control was appropriate, but NHS Grampian were unwilling to fund its implementation, as there was an imminent new hospital build taking place which would comply with the recommendation made by the Executive. This issue was re-examined at the recent inspection and the inspection team considered that, although the new hospital build had been delayed, appropriate preventative measures had been put in place and were monitored regularly with regards to safety.

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
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.

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
1. Screening of Donors Egg donors are not screened for syphilis at the time of donation. SLC T52. Guidance Note 11.23. UK guidelines for the medical and laboratory screening of sperm, egg and embryo donors, 2008 (Association of Biomedical Andrologists, Association of Clinical Embryologists, British Andrology Society, British Fertility Society & Royal	The PR must ensure that gamete donors are screened in accordance with regulatory requirements and professional body guidelines. The PR should provide the centre's inspector with confirmation of revised screening practices, a copy of the updated donor screening SOP and evidence of relevant staff training when responding to this report. As this non-compliance was not identified in the centre's routine audit, the PR should	Egg donors have always been screened at the time of screening but we did not screen them at time of donation for syphilis. We apologize for missing this. The practice was changed immediately after inspection. All staff have been advised. It was communicated in relevant meetings. SOP is going through the due quality management process, which has been delayed to add the NAT testing for Egg donors (in accordance with the 9th Code of practice). We will submit the	The Executive acknowledges the PR's response and commitment to implementing this recommendation. For reference, Annex III to European Directive 2006/17/EC, which is embedded in the HF&E Act 1990 (as amended), states that "In the case of living donors … blood samples must be obtained at the time of donation". The Executive has now received a copy of the updated SOP. The PR has

College of Obstetricians and Gynaecologists).	conduct an audit of the centre's screening practices and procedures for egg donors to ensure that they are compliant with regulatory requirements and professional body guidelines. The PR should provide the centre's inspector with a copy of this audit report, including any corrective actions identified, by 6 November 2018. Within three months of the implementation of revised practices, the centre should carry out an audit of gamete donor screening to ensure that the 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 December 2018, or within three months of implementation. The PR should seek the advice of an expert microbiologist to assess the risk to patients who have received treatment with eggs	SOP once the full process is completed by 5th Nov. Last UK guidance are old (last version 2008). We have Scottish Guidance developed in 2018, which are followed for all donors. I have attached the donor questionnaire we use to risk assess any potential donor backed up with the guidance (attached). We firmly believe that given the stringency of donor screening questionnaire along with virology screening testing, ensures patient safety. Last Audit undertaken (just prior to inspection) shows compliance with all mandatory It was also fedback at inspection that the repeat screening for syphilis was recommended in a clinic focus which is not linked to the HFEA Code of Practice that is possibly why it was missed whereas all mandatory screening required was done.	also confirmed that she, in conjunction with their microbiologist, is currently implementing a plan to retrospectively screen egg donors, to assess if there has been any risk of transmission to recipients. No further action is required, other than an update on the results of the retrospective screening exercise when complete, and submission of an audit of revised practice by 15 December 2018.

	or embryos created with donated eggs, from donors where the screening has not been compliant with regulatory requirements. The PR should inform the centre's inspector of the timeline for obtaining this expert advice when responding to this report.	We would suggest that the HFEA updates could be linked to code of practice so that anytime we access it electronically we can see the latest changes. We will submit a revised audit by Dec 2018. A meeting with Microbiologists has been requested. This will be arranged in Nov due to relevant people on leave. We will update HFEA with the report immediately after that.	
2. Premises The following issues were noted regarding the suitability of gas and liquid nitrogen storage within the centre: The outdoor and indoor gas and liquid nitrogen storage areas were not appropriately labelled with safety signage or secured. There were discarded cigarette ends in close proximity to the cylinders in the outdoor storage area.	The PR should ensure medical gases and liquid nitrogen are stored safely and securely. The PR should ensure that gas safety assessments of all storage areas should be carried out, particularly regarding access, ventilation, risk of ignition and appropriate signage, including no smoking. The PR should inform the centre's inspector of the	We have discussed with Estates who will ensure that the area will be kept clean and have appropriate signage. We have since reviewed the site multiple times. It has been clean.	The Executive acknowledges the PR's response and commitment to implementing this recommendation. The PR has provided a subsequent update, confirming that temporary appropriate safety signage is in place and a project application has been submitted to implement more permanent corrective actions. The outdoor storage area has been assessed and measures put in place to increase

The indoor storage area also appeared to have limited ventilation and a significant amount of electrical cables within the store. It should be noted that the centre acted to address the outdoor gas store security issue on the day of inspection. SLC T17. DH Health Technical Memorandum 02-01: Medical gas pipeline systems; Operational management (2006).	actions taken to comply with this recommendation when responding to the inspection report. The PR should provide documentation of the safety assessments, and updates on any changes to processes, to the centre's inspector by 6 November 2018.		security. A safety assessment of the indoor gas storage area has been commissioned. No further action is required beyond the submission of the indoor gas storage area safety assessment, when it is completed.
3. Transport and distribution of gametes and embryos The SOP for distribution of gametes and embryos did not document a process for recall of gametes, how to handle returned gametes and embryos, or that any such recall should be investigated as an adverse incident.	The PR should ensure the documented procedure for gamete and embryo distribution is compliant with regulatory requirements. The PR should also ensure that a written agreement is in place with all third parties providing goods or services that affect the quality and safety of gametes and	The process of third party agreement with courier has been initiated and we await a response from the company.	The Executive acknowledges the PR's response and commitment to implementing this recommendation. The PR has provided a subsequent update, assuring the Executive that the identified courier has agreed to sign and return the third party agreement. The PR has also provided a copy of the revised gamete and embryo

The centre does not have a Third Party Agreement with a gamete / embryo transportation courier. SLC T107, T110, T111. CoP Interpretation of Mandatory requirements 15C.	embryos, including the process of distribution. The PR should review the gamete and embryo distribution procedure and provide a copy of the review, along with a copy of a written agreement with a courier service by 6 November 2018.		distribution procedure and the Executive are assured that it is compliant with regulatory requirements. No further action is required, other than the submission of a copy of the signed third party agreement to the centre's inspector when it is available.

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
4. Medicines Management Dispensing of medication by nurses in the centre is against Professional Body Guidelines, which state that nurses should only dispense medicines in exceptional circumstances. The reasoning which underpins the dispensing of medication by nurses is that many patients come from the islands of Scotland and cannot get home delivery service. In addition the centre can provide the medication at a reduced cost relative to local pharmacies. NICE Guideline [NG46] April 2016 'Controlled drugs: safe use and management'.	The PR should ensure that dispensing of medication is performed in accordance with statutory and regulatory requirements. The PR should review the process for dispensing medicines and risk assess the circumstances under which nurses are dispensing medicines. A summary of this review, and risk assessment should be provided to the centre's inspector, along with a copy of any revised processes, by 6 November 2018. The PR should also consult the NMC for professional advice on the suitability of the nurse's current practice and	We work with two organisations NHS and University. University is the licence holder. This issue of dispensing medication has been raised with NHS pharmacy and an agreement was produced (attached) which uses pragmatic approach. We are well aware of the NMC guidance and 'dispensing' medications, and currently supply and dispense within defined protocols and NHSG pharmacy approved labels. Previously, we have explored different options: 1. Direct supply from NHSG Pharmacy, however	The Executive acknowledges the PR's response and commitment to implementing this recommendation. The centre's policy now documents that nurse dispensing is not in line with NMC guidance and that the centre is working in conjunction with the local Pharmacy towards a solution. The Executive are assured that nurses are aware of the NMC guidance. It is also evident that the process in place, although against professional guidelines, is a considered one, and risks and alternative options have been adequately assessed and documented.

NMC (2015) ‘Standards for medicines management’.	inform the centre’s inspector of the outcome and any proposed actions by 6 November 2018.	this would incur 28% surcharge as the University of Aberdeen is seen as third party 'customer'. This additional cost would be passed to patients and the NHS health boards, reduce the number of cycles provided within annual budget allocated for tertiary services. Where patients require 'top up' prescriptions on day of monitoring scans, NHSG cannot guarantee immediate supply, therefore patients who do not reside within the Grampian area would be at a disadvantage (ACRM receives referrals from Highlands and Islands - Orkney & Shetland). 2. Direct supply from National Pharmaceutical Organisation - surcharge would be incurred as above. 3. Home Care Agreement - issues as discussed above in the context of geographical layout of North of Scotland At the time of reviewing our Medicines Management OP and external document	No further action is required.

		relating to NHSG guidance and supplying and dispensing on site, we sought guidance and advice from Pharmacy Manager, approved our protocol on the basis that currently, NHSG Pharmacy has no alternative to offer at this stage.	
5. Traceability On the day of the inspection the ICSI equipment used during treatment was not documented for traceability purposes. It should be noted that laboratory documentation was revised on the day of inspection to allow records of ICSI equipment to be kept. It is also noted that the HFEA's assessment framework recommends classification as a major non compliance but in consideration that this is only one instance, and was addressed immediately, it has been classified as an 'other' non compliance.	The PR should ensure that any equipment or materials used in processing gametes or embryos, which may influence their quality and safety, are traceable from procurement of gametes to patient treatment or disposal and vice versa. An audit of ICSI laboratory sheets should be performed within three months to ensure this practice has been embedded, and this audit provided to the centre's inspector by 6 November 2018.	An audit will be submitted by 6th Nov	The Executive acknowledges the PR's response and commitment to implementing this recommendation. In an update to the Executive, the revised laboratory sheets have been provided and the PR has committed to provide an audit of the amended practice once sufficient numbers of patients have undergone treatment. No further action is required other than the submission of an audit of revised practice when it is completed.

SLC T99.			
6. Process validation Several of the validation documents are scant in detail. It should be noted that this had already been identified by the centre and process validations are currently being reviewed and updated. SLC T72.	The PR should ensure that validation documentation has been completed for all critical processes. Once the review of process validation documentation is completed, a selection of documents will be requested by the centre's inspector for review. This should be completed by 6 February 2019.	I confirm that the process has already started and this will be completed in the stated time scale.	The Executive acknowledges the PR's response and commitment to implement this recommendation by completing the necessary process validation documentation and providing a sample of the documents to the centre's inspector. Further action is required.

Reponses from the Person Responsible to this inspection report

Thanks for the report and positive feedback. We found inspection very useful. As mentioned above some things would help sector- i.e. any updates should be linked to online lastest version of code of pratcice similar to JPAC guidance for blood transfusion.

We are the only centre in the country where university is licence holder which has issues such as pharmacy and we try to deal with it in pragmatic way so that patient care do not get affected. Our geopgraphical location and area covered (up until Shetland islands produces different challenges).

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