Executive Licensing Panel - minutes

Centre 0037 (Glasgow Royal Infirmary)

Renewal Inspection Report

Friday, 6 October 2017

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Juliet Tizzard (Chair) Ian Peacock Anna Quinn	Director of Strategy and Corporate Affairs Systems Manager Scientific 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 fertility clinic at Glasgow Royal Infirmary provides a full range of range of fertility services including storage and embryo testing.

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

1.4. The panel noted that, in the 12 months to 31 May 2017, the centre provided 1536 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a large sized centre.

1.5. The panel noted that almost all fresh treatments at this centre use ICSI to fertilise eggs. The centre provides too few IVF treatments for the success rates for this treatment to be statistically relevant.

1.6. The panel noted that HFEA held register data, for the year ending 28 February 2017, showed the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 8%: this represents performance that is not likely to exceed the 10% multiple live birth rate target.

1.7. The panel noted that an inspection was carried out at the centre on 11 and 12 July 2017.

1.8. The panel noted that at the time of the inspection there was one major and seven 'other' areas of practice which required improvement. The panel noted that the Person Responsible (PR) had provided evidence that actions have been taken to implement the recommendations concerning the pre-operative assessment and the surgical pathway, screening of donors and patients, the Quality Management System (QMS), process validation, incident reporting, obligations and reporting requirements and record keeping. The PR would audit the effectiveness of these actions within the prescribed timescales, where required.

1.9. The panel noted that that the PR has provided evidence that actions are being taken to address the non-compliance regarding staff, and this would be completed within the required timescales.

1.10. The panel noted that the inspectorate stated that some improvement is required for the centre to reflect suitable practices. The centre has a QMS and the PR is encouraged to use it to best effect to monitor and improve the success rates and the service provided to patients. The inspector will continue to monitor the centre's performance and the implementation of the report's recommendations within the required timescales.

1.11. The panel noted the inspectorate's recommendation to renew the centre's treatment (including embryo testing) and storage licence, for a period of four years without additional conditions, subject to the recommendations 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 non-compliances, acknowledging that actions had been taken to implement the recommendations made in the inspection report.

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

3. Chair's signature

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

Signature

Name

Juliet Tizzard

Date

18 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: 11/12 July 2017

Purpose of inspection: Renewal of a licence to carry out: Treatment (including embryo testing) 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: Andrew Leonard, Douglas Gray, Grace Lyndon

Date of Executive Licensing Panel: 6 October 2017

Centre name	Glasgow Royal Infirmary
Centre number	0037
Licence number	L/0037/14/d
Centre address	Assisted Conception Services Unit, Queen Elizabeth Building, Alexandra Parade, Glasgow, G31 2ER, United Kingdom
Person Responsible	Dr Rachel Gregoire (until 11 August 2017) Dr Helen Lyall (after 11 August 2017)
Licence Holder	Professor Scott Nelson
Date licence issued	01/01/2014
Licence expiry date	31/12/2017
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:

The fertility clinic at Glasgow Royal Infirmary has held a licence with the HFEA since 1992. The centre provides a full range of fertility services including storage and embryo testing services.

The centre provided 1536 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 May 2017. In relation to activity levels this is a large centre.

The centre's current licence was varied in July 2014 to reflect changes to the premises resulting from significant renovation and also to remove an additional licence condition which restricted licensed activity while the renovation was undertaken.

The licence was again varied in October 2015 to reflect a change of Person Responsible (PR).

The centre's licence was varied again on 11 August 2017 to reflect a change PR, this being after the renewal inspection visit but before the inspection report was provided to the centre.

No new activities are requested in this licence renewal application.

Pregnancy outcomes[1]

For ICSI and FET treatments, HFEA held register data for the year ending 28 February 2017 show the centre's success rates for these activities, in terms of the clinical pregnancy rates, are in line with national averages.

The inspection team notes that almost all fresh treatments at this centre use ICSI to fertilise eggs. The centre provides too few IVF treatments for the success rates for this treatment to be statistically relevant.

The centre reported 48 cycles of partner insemination in 2016 with four pregnancies, performance which is in line with the national average.

Multiple births[2]

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

For treatments performed in the year ending 28 February 2017, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 8%; this represents performance that is not likely to exceed the 10% live multiple 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

The inspection team note that the centre's licence was varied to reflect a change of PR on 11 August 2017, this being after the renewal inspection visit but before the inspection report was provided to the centre. The out-going PR - Dr Rachel Gregoire - implemented many of the report's recommendations in response to feedback provided by the inspection team on inspection. The new PR - Dr Helen Lyall - has agreed to the submission of the licence renewal application and that it should be for a Treatment (including embryo testing) and Storage licence, as the centre currently has. She has also written the PR's responses in this report and will ensure final implementation of the recommendations in detail.

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 PR, albeit an ELP has subsequently approved a change of PR to Dr Helen Lyall;
- the new PR has agreed to the submission of the application;
- the new PR's qualifications and experience comply with section 16 (2) (c) of the HF&E Act 1990 (as amended);
- the out-going PR has discharged her duty under section 17 of the HF&E Act 1990 (as amended) and the new PR has done so to date;
- the premises (including those of relevant third parties) are suitable;
- the centre's practices are suitable;
- the application contains the supporting information required by General Direction 0008, in application for renewal of their licence;
- the centre has submitted an application fee to the HFEA in accordance with requirements.

The ELP is asked to note that at the time of the inspection there were a number of areas of practice that required improvement, comprising one major and seven 'other' areas of non compliance.

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 should ensure that allergies are properly considered and documented during the pre-procedural assessment.

'Other' areas that require improvement:

- The PR should ensure that the risks of Ebola virus are considered in the donor recruitment and patient treatment pathways.
- The PR should ensure that the witnessing audit and some standard operating procedures (SOPs) are compliant.
- The PR should ensure that all process validations are completed and contain evidence to support the safe and efficacious use of the processes in licensed activity.
- The PR should ensure that all adverse incidents and near misses are reported to the HFEA.

- The PR should ensure data submission to the register is timely and accurate.
- The PR should ensure that patient records include all required information.

The PR has provided evidence that actions are being taken to address the following non compliance and will be completed within the required timescales:

- The PR should ensure that a process is developed to assess and document the competence of all staff in all the activities they undertake.

Recommendation to the Executive Licensing Panel

The centre has no critical and one major area of concern.

The inspection team notes that the success rates are consistent with the national average and the multiple clinical pregnancy/live birth rates meet the target.

Some improvement is required in order for the centre to demonstrate the suitability of their practices. The centre has a quality management system and the PR is encouraged to use it to best effect to monitor and improve the success rates and the service provided to patients.

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 (including embryo testing) 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 broadly 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

Screening of donors (Guidance note 11)
The risks of Ebola virus are not considered in the donor recruitment pathway (SLC T52; recommendation 2). The inspection team accepts that the frequency of Ebola infection is very minimal, but the consequences merit compliance with Department of Health guidelines. It is important that patients are asked whether they have had a prior Ebola infection or have been travelling in an area in which Ebola virus is endemic, and act on the response according to Department of Health guidelines.

Suitable premises and suitable practices

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

What the centre does well

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

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

The centre has no transport or satellite facilities but the premises of the centre's laboratories conducting tests that impact on the quality and safety of gametes and/or embryos (and relevant third parties) are suitable.

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

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

Infection control (Guidance Note 25)
The centre has systems in place to manage and monitor the prevention and control of infection that are compliant with guidance.

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

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

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

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

The process for administering and monitoring patients during intralipid infusion was reviewed and considered to be suitable. Written information provided to patients offered intralipid therapy is also compliant with guidance. The inspection team notes that the centre provides intralipid therapy only to patients who have previously had the therapy and gone on to have a live birth, and who then ask for it in subsequent treatments.

Pre-operative assessment and the surgical pathway (Guidance Note 25)
The centre has policies and procedures in place that are partially 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, notwithstanding that the recall process is not documented in SOPs (see 'Quality Management System' section below). 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, notwithstanding some concerns regarding the associated SOPs and checklists which are discussed in 'Quality Management System'.

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

- to identify and locate gametes and embryos during any step from procurement to use for human application or disposal;

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

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

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

Transport and satellite agreements (General Direction 0010)
The centre is not the primary centre to any satellite or transport centres therefore these regulatory requirements 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 of the equipment and materials used in licensed activity are designated for the purpose and are appropriately maintained in order to minimise any hazard to patients and/or staff.

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

Process validation (Guidance note 15)
The centre's procedures are 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 broadly compliant with HFEA requirements. The centre reports some 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

Pre-operative assessment and the surgical pathway (Guidance Note 25)
Allergies documented in the medical history section in the records, were not consistently and for all patients also documented on the pre-procedure assessment form / drug chart, suggesting the allergies may not have been considered during the pre-procedural assessment (SLC T2 and CoP Guidance 25.25; recommendation 1).

Quality management system (QMS) (Guidance note 23)
The audits undertaken were of high quality with one exception: the audit of witnessing does not include a review of errors in the electronic witness system.

Some omissions were noted in SOP content:

- The transport SOP does not document a recall procedure, though staff said that a recall can be made if necessary.
- Laboratory process SOPs, in a small number of cases, do not fully specify all materials used to deliver the processes. All materials used in laboratory processing were however seen to be CE marked at an appropriate level.
- Transport and import/export SOPs and checklists do not ensure compliance with some of the requirements of General Direction 0006 or that the centre needs to receive/provide procurement reports with gamete and embryo imports, exports and transports.

(SLCs T31, T33b, T36, T110 and T122, General Direction 0006; recommendation 3).

Process validation (Guidance note 15)
Four of the process validation documents reviewed did not contain all necessary evidence to support validation (SLC T72; recommendation 4).

Adverse incidents (Guidance note 27)
The centre had not reported to the HFEA an adverse incident, as defined in CoP Guidance 27.1 (Interpretation of mandatory requirements 27A; SLC T118; recommendation 5). This was discussed with the PR on inspection. It was clear that a review and investigation of the adverse incident had been undertaken and consideration given to reporting it to the HFEA. It was not reported because the PR considered the event was a rare but predictable consequence of the egg collection procedure; the inspection team considered otherwise.

Staff engaged in licensed activity
Person Responsible (PR)
Staff

What the centre does well

Person Responsible (Guidance note 1)
The PR at the time of the inspection had academic qualifications in the field of embryology and more than two years of practical experience directly relevant to the activity to be authorised by the licence. The PR had successfully completed the HFEA PR Entry Programme. A new PR was appointed soon after the inspection who is also suitable qualified and experienced, and was acceptable to the ELP which approved the licence variation application.

Staff (Guidance note 2)
The centre is broadly 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

Staff (Guidance note 2)
Training and information provided to staff are documented but the assessment of staff competence, at an appropriate interval depending on the practice area, is not performed or documented for clinical and nursing staff (SLC T12; recommendation 6). The inspection team notes that some evidence for ongoing competence is available in the QMS (audit and quality indicator monitoring reports) and probably from other sources. That evidence and any other evidence the centre decides to collect, should be reviewed at an appropriate frequency to determine and document the competence of each staff member to perform their designated duties.

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)
The centre does not provide a preimplantation genetic screening service therefore these requirements were not relevant at this inspection.

Embryo testing and sex selection (Guidance note 10)
The centre's procedures for performing embryo testing for preimplantation genetic diagnosis are compliant with HFEA requirements. This ensures that:

- no embryo is transferred to a woman where that embryo or material removed from it, or the gametes that produced it, has been subject to genetic testing unless expressly authorised by the HFEA;
- no information derived from tests conducted has been used to select embryos of a particular sex for social reasons;
- no embryo is tested unless the statutory tests are met i.e. that the embryos is at a

significant risk of having a serious genetic condition.

The centre ensures that people seeking embryo testing are given written information, are given every opportunity to discuss the implications of their treatment and have access to clinical geneticists, genetic counsellors and infertility counsellors where required.

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

2. The experience of patients

Patient feedback

What the centre does well

During the inspection visit, two patients were available to speak to the inspectors and twelve patients have provided feedback directly to the HFEA in the time since the last inspection. Feedback was generally positive, with seven of the individuals providing written feedback to the HFEA commenting that they have compliments about the care that they received.

An analysis of the centre's most recent patient survey was also reviewed, which detailed that 100% of 70 patients surveyed in May 2017 returned survey forms, at a satisfaction rate of 95%. Discussions with the PR showed the centre is responsive to patient feedback and acts to improve the patient experience.

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

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

What the centre could do better

Nothing identified at this inspection.

Treating patients fairly

Counselling
Egg sharing arrangements
Surrogacy
Complaints
Confidentiality and privacy

What the centre does well

Treating patients fairly (Guidance note 29)

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

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

Counselling (Guidance note 3)

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

Egg sharing arrangements (Guidance note 12; General Direction 0001)
The centre does not undertake egg share arrangements therefore these requirements were irrelevant at this inspection.

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

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

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

What the centre could do better
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, HFEA Chief Executive's letter CE(14)01 required centres to audit their parenthood consenting practices to ensure their suitability, to report the findings of the audit to the HFEA and to respond to those findings. The centre provided the audit report to the HFEA within the required timeframe. The report indicated that the centre had no parenthood consent non conformances and no corrective actions were needed.

As part of the HFEA's ongoing activities relating to legal parenthood consenting, all PRs were asked in October 2015 to confirm that all relevant cases had been included in the original audit in 2014. During the review, the PR discovered that the 2014 audit had been a sample audit, i.e. it had looked at a randomly selected proportion of relevant cases, rather than at all relevant cases as was required by CE(14)01. In response, the PR immediately conducted an audit of all relevant cases since April 2009. This audit identified five cases where effective consent to legal parenthood was questionable. One case should have been identified by the 2014 audit, the other four occurred after that audit was conducted.

At the last interim inspection in December 2015, the PR advised that preventative actions (training sessions for staff who take consent; additional consent form checks; SOP revisions; quarterly audits of relevant cases) had been implemented in response to the audit findings. The inspection team was also advised that centre staff had been liaising with hospital management and legal advisors regarding corrective actions, and to co-ordinate meetings with the five patient couples affected. These meetings went ahead in late February 2016. The interim inspection also found several discrepancies in an audit of 30 records of legal parenthood consent. These were notified to the PR, who undertook corrective actions including seeking legal advice, providing further staff training and competence assessment, and enforcing robust checking and auditing of the legal parenthood consent process.

The PR has subsequently provided to the centre's inspector quarterly audit reports of legal parenthood consenting and regular updates regarding the resolution of the cases identified with anomalous parenthood consents.

At this inspection, the process by which legal parenthood consents are collected, the checks of those consents before treatment and audits of the process were discussed. The inspection team considers the legal parenthood consenting process to be robust. To provide further assurance of its effectiveness, the inspection team reviewed four sets 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 all cases. The inspection team also considered the quarterly audits of legal parenthood consent provided by the centre in the last year; these provided further evidence of the compliance of the centre's procedures.

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 HFEA Register is a rich source of information about treatment using assisted reproductive technologies (ART). It can be used by researchers and linked to other health registers to improve knowledge about the health of patients who have undergone ART and those born following ART treatment. The HFEA is permitted to disclose non-identifying information to researchers but can only provide patient identifying information with the consent of the patient. Therefore, it is important that patients are asked to give their consent and that their wishes are accurately recorded and passed on to the HFEA.

Sixteen of seventeen completed patient/partner/donor disclosure consents in patient files matched to the equivalent consent data submitted for inclusion on the register. The centre's procedures for taking consent to disclosure to researchers are therefore broadly compliant with HFEA requirements.

What the centre could do better

Disclosure of information, held on the HFEA Register, for use in research
One discrepancy was found between 17 completed patient/partner/donor disclosure consents in patient files and the equivalent consent data submitted for inclusion on the register. This reporting error led to a risk that the HFEA may release patient identifying information, to researchers, without consent (General Direction 0005; recommendation 7).

3. The protection of gametes and embryos

Respect for the special status of the embryo

What the centre does well

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

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

What the centre could do better

Nothing identified at this inspection.

Screening of patients
Storage of gametes and embryos

What the centre does well

Screening of patients (Guidance note 17)

The centre's procedures for screening patients are broadly 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. 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

Screening of patients (Guidance note 17)

The risks of Ebola virus are not considered in the patient treatment pathway (SLC T50; recommendation 2). The inspection team accepts that the frequency of Ebola infection is very low, but the consequences merit compliance with Department of Health guidelines. It is important that patients are asked whether they have had a prior Ebola infection or have been travelling in an area in which Ebola virus is endemic, and act on the response in accordance with Department of Health guidelines.

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, notwithstanding the non compliance in the information provided to patients discussed in the 'Information' section. 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 broadly compliant with HFEA requirements to ensure that accurate medical records are maintained. Good medical records are essential for the continuity of the patient's care.

Obligations and reporting requirements (Guidance note 32; General Direction 0005)
The HFEA has a legal responsibility to maintain a register containing information about all licensed activities. To facilitate this, centres are required to provide information to the HFEA about all licensed fertility treatments they carry out. The primary purpose for keeping this information is to allow the donor conceived and their parents to access information about the donor and about any donor-conceived genetic siblings.

All IVF and DI treatments reviewed had been submitted to the HFEA. All (121/121) IVF and 95% of DI treatments had been reported within the timescales required by General Direction 0005. The centre's procedures for submitting information about licensed activities to the Authority are therefore broadly compliant with HFEA requirements.

What the centre could do better

Record keeping and document control (Guidance note 31)
A review of patient records showed that they do not always document effectively:

- discussions regarding the offer of counselling, though the patients' decisions were clearly documented in all records reviewed;
- checks when patients re-attend the centre regarding the accuracy of records of their personal details, including their marital / civil partnership status;
- the off-site location at which sperm is procured by testicular biopsy.

(SLCs T46 and T100d; recommendation 8)

Obligations and reporting requirements (Guidance note 32; General Direction 0005)
The following non compliances were noted during the audit of register data submission (General Direction 0005; SLC T41; recommendation 7).

- Seven of 148 DI treatments were reported to the HFEA register outside of the required timeframe.
- Data submission errors were identified in relation to the recording of surrogacy treatments and dates in a small number of treatment cycles. The centre has been advised of these errors so they can be corrected.

Section 3: Monitoring of the centre's performance

Following the interim inspection in 2015, four recommendations for improvement were necessary to address major non compliances. The PR implemented the report's recommendations within the required timeframes.

On-going monitoring of centre success rates

The centre received alert emails for IVF treatments in October 2015, April 2016, August 2016, November 2016 and December 2016. These emails were discussed with the PR when they were released. She advised that the centre had suspended IVF treatment in May 2015, except where specifically requested by patients. From that time virtually all patients have been treated with ICSI rather than IVF alone.

These risk tool alerts were investigated and were found to be false alarms triggered because treatments cancelled between the start of stimulation and egg collection are automatically assigned in the register as IVF treatments. All such treatments have negative outcomes but because the centre performed virtually no other IVF treatments which could produce pregnancies, the risk tool issued sporadic alert emails in response to the negative outcomes from the cancelled cycles.

That the centre has used only ICSI to inseminate eggs for fresh treatments since May 2015, unless IVF alone is specifically required by a patient, was discussed on inspection with the centre team. They stated that this was a decision made to provide the best treatment to their patients. The Licence Holder (LH), who is the accredited medical practitioner at the centre, cited in support of this approach a published academic paper in which he had applied multivariant analysis to almost 145000 treatment cycles documented in the HFEA register, and shown that a live birth outcome was 1.27 times more likely if ICSI rather than IVF alone was used to create the embryos used in treatment. The LH recognises that some academic studies associate ICSI with some risks but also that other studies have found no such association and that it is suspected that any risks observed are due to the characteristics of the patient group in which ICSI has been applied rather than to the ICSI procedure itself. The LH considers that the evidence regarding risk is equivocal and that the evidence of benefit in terms of live birth rates is strong. A decision was therefore taken by the centre management team in May 2015 to use ICSI in all cases at the centre.

The PR and LH noted that patients are advised in writing of the potential risks associated with ICSI, in line with HFEA guidance, but also that the evidence in support of these risks is equivocal and that, in their opinion, the strong evidence for improved success rates in ICSI cases justifies its use. In the event that patients specifically request IVF alone, they are referred to the PR or LH for further discussion of the evidence for risk and benefit, to ensure they are fully aware of the information provided. The PR advised that virtually all patients in this situation are reassured and progress to have ICSI in treatment. The PR also said that the centre would provide IVF to those patient who insisted upon it, noting that this had happened in a very limited number of cases. Regarding the cost of ICSI, the PR outlined that the costs of ICSI are not charged to the organisations commissioning NHS treatments. Private patients only pay for ICSI if their clinical characteristics fulfil the criteria for ICSI previous applied by the clinic before it moved to using ICSI in all cases.

A review of register data by the inspection team has shown that embryo transfers in IVF cases declined almost to zero in May 2015, confirming the PR's assertion that IVF

treatments virtually stopped at this time. The register data set for the centre between June 2015 and March 2017, includes 169 IVF cases but only 11 embryo transfers, which is consistent with there having been a few IVF cases progressing to embryo transfer and a larger number of cases cancelled before egg collection and wrongly ascribed as having had IVF treatment.

The inspection team notes that: the centre's success rates for ICSI and FET in all age groups are comparable with the national averages; that information provision generally, and concerning ICSI specifically, was considered compliant; that patient feedback to the HFEA and the centre includes no comments regarding the centre providing only ICSI based treatment; the centre has clear justification for the use of ICSI in all treatments based on a published academic analysis of a HFEA register data set and the equivocal evidence for risk. The inspection team is therefore minded to make no recommendations on this matter at present.

The inspection team also notes however that the Scientific and Clinical Advances Advisory Committee is currently reviewing the evidence available regarding the risks associated with ICSI and indicators for its use. When this review is completed and any recommendations have been implemented in the CoP, the PR at centre 0037 will be contacted if necessary to provide evidence of the on-going compliance of the centre's practices.

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
No issues identified			

Major area of non compliance

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

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
1. Pre-operative assessment and the surgical pathway In some records, allergies were documented in the medical history but were not documented in the pre-procedure assessment form / drug chart, suggesting they may not have been considered during the pre-procedural assessment (SLC T2, CoP Guidance 25.25).	The PR should ensure that allergies are properly considered and documented during the pre-procedural assessment. The PR should review the circumstances which led to information about allergies not being documented in the pre-procedural assessment or on the drugs record card in some cases. A report of the review, including corrective actions with timescales for implementation, should be provided to the centre's inspector by 11 October 2017. The PR should thereafter audit patient records to determine whether allergies are being effectively recorded on the pre-procedure assessment form. A report of this audit should be provided to the centre's inspector by 11 January 2018.	Corrective actions were taken immediately after the inspection to address this concern and the required audit will be submitted within the deadline stated.	28 July 2017: The out-going PR advised that a review had been performed and provided the 'post-screening' SOP to show it has been amended to include that allergy details are recorded on the pre-procedure assessment form / drug chart. Nursing staff have been advised of this change. A baseline audit of records was provided which found that allergy details were missing from the pre-procedure assessment form / drug chart in two of 20 records. The out-going PR advised that a further audit will be performed to determine the effectiveness of the corrective actions taken. No further actions are required beyond completion of the required audit by 11 January 2018.

Other areas of practice that require improvement

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
2. Screening of donors Screening of patients The risks of Ebola virus are not considered in the donor recruitment and patient treatment pathways (SLCs T50 and T52). The inspection team accept that the frequency of Ebola infection is minimal, hence have graded this as an 'other' non compliance.	The PR should ensure that the risks of Ebola virus are considered in the donor recruitment and patient treatment pathways. The centre's inspector should be informed of the actions taken to implement this recommendation when the report is returned with the PR's comments.	The following have been amended and attached: post-screen SOP (reflecting modified practice), patient information and staff notice.	28 July 2017: The out-going PR advised that the patient information leaflets regarding travel and viral exposure would need to be updated to account for the risks of Ebola. 5 September 2017: The new PR provided evidence that patient and donor information and the patient and donor review processes, have been updated so that possible exposure to Ebola virus is now considered by clinical staff prior to treatment commencing. No further actions are required.
3. The QMS The audit of witnessing does not include a review of any errors in the electronic witness system. Flaws were noted in SOP	The PR should ensure that the witnessing audit includes a review and trend analysis of the reasons for any errors in the electronic witnessing system. The PR should also ensure that the SOPs are updated to	Corrective actions were taken immediately after the inspection to address this concern.	28 July 2017: The out-going PR provided documentary evidence (updated SOPs and an audit proforma) that these matters have all been effectively addressed.

content: • The transport SOP does not document a recall procedure; • Laboratory process SOPs, in a small number of cases, do not fully specify all materials used to deliver the processes; • Transport and import/export SOPs and checklists do not include some aspects of the requirements of General Direction 0006 or that the centre needs to receive/provide procurement reports with gamete and embryo imports, exports and transports. SLCs T31, T33b, T110 and T122; General Direction 0006.	address the matters of concern documented in this report. This recommendation should be implemented by 11 October 2017 and the centre's inspector provided with evidence of the actions taken.		No further actions are required.
4. Process validation Four of the process validation documents reviewed did not contain appropriate evidence to support validation (SLC T72).	The PR should ensure that the four process validations are completed and contain effective evidence to support the safe and efficacious use of the processes in licensed activity. This recommendation should be	Corrective actions were taken immediately after the inspection to address this concern.	28 July 2017: The out-going PR provided documents which show that validation evidence has been inserted into the SOPs for the processes. No further actions are required.

This non compliance has been downgraded to 'other' because the remaining process validations were of good quality and the omitted evidence – the literature basis for using the methods – can be easily sourced and was likely available elsewhere in the QMS.	implemented by 11 October 2017 and the centre's inspector advised when this occurs. A sample will then be reviewed by the centre's inspector.		
5. Incident reporting The centre has not reported to the HFEA an adverse incident, as defined in CoP Guidance 27.1 (Interpretation of mandatory requirements 27A; SLC T118). This non compliance has been downgraded to 'other' because the inspection team accepts that incident reporting and investigation at the centre is thorough and generally compliant. In this case, the PR and laboratory manager mis-interpreted guidance.	The PR should ensure that all adverse incidents, including serious adverse events and reactions, as well as near misses, are reported to the HFEA in line with SLC T118 and the centre's incident reporting SOP. The PR should review all adverse incidents in the centre's incident register in the last year and should report retrospectively to the HFEA any which fulfil the criteria of adverse incidents or near misses, as defined in CoP Guidance 27.1. This recommendation should be implemented by 11 October 2017 and the centre's inspector advised of the actions taken.	Corrective actions were taken immediately after the inspection to address this concern.	28 July 2017: The out-going PR reported the incident to the HFEA and confirmed that the incident log at the centre had been reviewed and that no further incidents or near misses needed to be reported to the HFEA. No further actions are required.

6. Staff The assessment of staff competence at an appropriate interval depending on the practice area, is not performed and documented for some staff members and activities (SLC T12).	The PR should ensure that the competence assessment process consistently and reliably assesses and documents the competence of all staff in all the activities they undertake. A plan to implement this recommendation should be developed and provided to the centre's inspector by 11 October 2017. The plan should be fully implemented by 11 January 2018 and the centre's inspector advised when this occurs.	The plan for staff competency assessments will be fully implemented by the timescale required. The staff competency assessment form is attached together with annual competency reassessment matrices.	28 July 2017: The out-going PR provided evidence that effective competence assessment, and documentation thereof, has commenced for the staff group which concerned the inspection team. 5 September 2017: The new PR provided evidence that competence matrices have been documented for each staff group, to direct and record the assessment of the competence of each member of staff to deliver their key functions. A timeline for implementation by the end of December of each year is included. The centre's inspector will follow up with the PR to ensure that the competence assessment programme is completed by 11 January 2018. **Further actions are required.**
7. Obligations and reporting requirements Several non compliances were noted during the audit of register data submission:	The PR should ensure data submission to the register is timely and accurate. The PR should investigate the	Data entry for the relevant surrogate couples have been corrected. The RBAT received relating to this issue is now clear. The	28 July 2017: The out-going PR responded: 'All outstanding donors have now been registered'.

• seven of 148 DI treatments were reported to the register outside of the required timeframe; • one discrepancy was found between 17 completed disclosure consents in patient files and the equivalent consent data submitted to the register; • data submission errors were identified in relation to the recording of surrogacy treatments and dates in a small number of treatment cycles.	data errors identified and the relevant data submission procedures and take appropriate corrective actions. A report of the investigation should be provided to the centre's inspector by 11 October 2017. The PR should correct the data submissions that have been identified as being incorrect and should advise the centre's inspector when this has been completed. The PR should conduct an audit six months after implementing corrective actions, to confirm that data submission to the register is timely and accurate. A summary of the audit should be provided to the centre's inspector by 11 April 2018.	relevant SOP (attached) has been amended. We will carry out a records audit for the EDI data submission. We will randomly select a group of patients having undergone HFEA related treatments (i.e.no partner IUI) and validate the EDI register information against the clinical and laboratory paperwork. If the outcome reveals problematic issues, we will run a rolling schedule for auditing. We will also run a long-term validation error check (going back a number of years) to determine any historical issues. The Quality Manager has run the missing donor report for the period over the last 15 years to generate the historical list of missing donors. We will formulate a plan for these once we know whether records are obtainable.	No risk tool alerts concerning unregistered donors were issued in August 2017 indicating that no donors remain unregistered. 5 September 2017: The new PR provided a revised SOP for reporting surrogacy treatments which should avoid the data submission errors associated with such treatments. The PR has also confirmed that the transmission error concerning a consent to disclosure to researchers decision has been corrected. No further actions are required beyond completion of the planned audit discussed in the PR's response by 11 April 2017.
8. Record keeping A review of patient records	The PR should ensure patient records are kept which include	Corrective actions were taken immediately after the	28 July 2017: The PR advised that the templates used to collect

showed that they do not always document effectively: • discussions regarding the offer of counselling; • checks when patients re-attend the centre regarding the accuracy of records of their personal details, including their marital / civil partnership status; • the off-site location at which sperm is procured by testicular biopsy. SLCs T46, T99 and T100	all required information. The PR should review current record keeping practices and relevant SOPs and take appropriate corrective actions, to ensure this. A copy of the review should be provided to the centre's inspector by 11 October 2017. An audit of patient records should subsequently be performed to confirm the corrective actions have been effective. A report of the audit should be provided to the centre's inspector by 11 January 2018.	inspection to address this concern and the required audit will be submitted within the deadline stated.	patient information have been revised to allow more effective record keeping. The templates were provided and the centre's inspector agrees that the template should aid effective record keeping. Nursing staff have been advised of the changes. No further actions are required beyond completion of the required audit by 11 January 2018.

Reponses from the Person Responsible to this inspection report