Executive Licensing Panel - minutes

Centre 0055 (The James Cook University Hospital) – Renewal Inspection Report

Friday 16 October 2015

HFEA, Finsbury Tower, 103-105 Bunhill Row, London, EC1Y 8HF

Panel members	Paula Robinson (Chair) Joanne Anton Ian Peacock	Head of Business Planning Policy Manager Analyst Programmer
Members of the Executive	Sam Hartley	Head of Governance and Licensing (Secretary)
External adviser	None	
Observers	Howard Ryan Jessica Watkin Polly Todd	

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 this is a treatment and storage centre which provides a full range of fertility services. The panel noted that in relation to activity levels this is a small centre.

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 30 June 2015, the centre provided 277 cycles of treatment (excluding partner intrauterine insemination).

1.5. For IVF and ICSI, HFEA-held register data for the period April 2014 – March 2015 showed the centre's success rates were in line with national averages.

1.6. The panel noted that in 2014, the centre reported six cycles of partner insemination with no pregnancies. This was consistent with the national average.

1.7. Between April 2014 and March 2015 the centre's multiple pregnancy rate for all IVF, ICSI and frozen embryo transfer (FET) cycles for all age groups was 21%. This means that the centre's multiple live birth rate is likely to be consistent with the 10% maximum target.

1.8. The panel noted that at the time of the inspection on 4 and 5 August 2015, one critical, eight major and four other areas of non-compliance were identified. The panel noted that, since the inspection, the Person Responsible (PR) had fully implemented one major and two other recommendations, and fully committed to implementing the remainder of the inspectorate's recommendations within the prescribed timescales.

1.9. The panel noted that significant improvement is required in order for the centre to demonstrate suitability of its practices and that a management review had been held by the inspectorate, in accordance with the Compliance and Enforcement Policy. The panel noted that, based on the information provided by the PR at the time of writing, the inspectorate had concluded that any likely risks to patients had been mitigated by the actions taken by the PR.

1.10. The panel noted that the inspectorate recommended the renewal of the centre's treatment and storage licence for a period of three years (rather than the standard four) without additional conditions, subject to the recommendations made in this report being implemented within the prescribed timescales. The panel also noted the inspectorate's recommendation that an interim inspection occurs within one year of the licence being granted.

2. Decision

2.1. The panel had regard to its decision tree.

2.2. The panel agreed it was in receipt of the appropriate documentation as required by the HFE Act 1990. 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.

2.3. 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 has discharged his duty under section 17 of the HFE Act 1990 (as amended).

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

2.5. The panel was encouraged by the conclusion of the inspectorate that any likely risks to patients had been mitigated by the actions taken so far by the PR. Nevertheless, the panel was concerned about the number and type of non-compliances identified at the renewal inspection, in particular

those relating to adverse incidents, the use of embryos in training, and the transfer of gametes and embryos. The panel encouraged the PR to use the QMS to best effect to monitor and improve the service provided. The PR is further reminded to ensure that the requirements in General Directions are fully adhered to, particularly in relation to adverse incidents and the transfer of gametes and embryos.

2.6. The panel also noted, and agreed with, the inspectorate's recommendation that an interim inspection occurs within one year of the licence being granted.

2.7. The panel endorsed the inspectorate's recommendation to renew the centre's treatment and storage licence for a period of three years, rather than the standard four, without additional conditions. The panel noted that a number of recommendations are due by 5 November 2015, and encouraged the inspectorate to report back to a licensing committee if it has significant concerns about the performance of the centre at that stage.

3. Chair's signature

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

Signature

Name

Paula Robinson

Date

16 October 2015

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: 4 and 5 August 2015

Purpose of inspection: Renewal of a licence to carry out treatment and storage

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

Inspectors: Vicki Lamb, Karen Conyers, Gill Walsh, Grace Lyndon

Date of Executive Licensing Panel: 16 October 2015

Centre name	The James Cook University Hospital
Centre number	0055
Licence number	L/0055/16/b
Centre address	Department of Reproductive Medicine, Marton Road, Middlesbrough, Cleveland, TS4 3BW, UK
Person Responsible	Mr Fayez Mustafa
Licence Holder	Mr Derek Cruickshank
Date licence issued	01/02/2012
Licence expiry date	31/01/2016
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:

The James Cook University Hospital has held a treatment and storage licence with the HFEA since July 1992 and provides a full range of fertility services. Other licensed activities of the centre included storage of gametes and embryos.

On 16 January 2015 an executive licensing panel approved a variation to the licence to reflect a change in premises. The changed premises mean that the centre is now on one floor with all the treatment and consultation rooms together.

The centre provided 277 cycles of treatment in the 12 months to 30 June 2015. In relation to activity levels this is a small centre.

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period April 2014 – March 2015 show the centre's success rates are in line with national averages.

In 2014, the centre reported 6 cycles of partner insemination with no pregnancies. This is in line with the national average.

Multiple births[2]

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

Between April 2014 and March 2015 the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 21%: this represents performance that is likely to be consistent with the 10% multiple live birth rate target for this period.

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

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

Summary for licensing decision

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

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

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

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

Major areas of non compliance:

- The PR should ensure that medicines supplied to patients are always labelled with the name of the patient and are accompanied by an information sheet.

'Other' areas that requires improvement:

- The PR should ensure the premises do not pose a breach of confidentiality risk and/or a risk to privacy and dignity for the centre's patients.
- The PR should establish an SOP to direct staff regarding action in the case of equipment malfunction or failure and should establish quality indicators or objectives for administration activities.

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

Critical area of non compliance:

- **The PR should ensure that embryos are only used for training purposes if both gametes providers have consented, and that embryos intended for training purposes are not used for any other purpose.**

Major areas of non compliance:

- The PR should ensure that the temperature and time limits of shipping containers are specified, that individuals using the containers understand the significance of these limits in maintaining the viability of gametes/embryos and that the shipper is secured before release to the courier.

- The PR should ensure that imports and exports of gametes and embryos only take place in compliance with General Directions 0006 or Special Direction as appropriate.
- The PR should ensure that all relevant data about anything coming into contact with gametes or embryos is traceable.
- The PR should establish a third party agreement with the main theatres of the hospital.
- The PR should establish as system of appropriate monitoring and alarms to ensure that the critical parameters within the incubators are maintained within acceptable limits at all times.
- The PR should ensure that all adverse incidents are appropriately reported to the HFEA.
- The PR should ensure that all licensed treatment activity is reported to the Authority within the timeframe required.

'Other' areas that requires improvement:

- The PR should update the centre's inspector as each CE marked consumable is brought into use.
- The PR should ensure that the disclosure consent information supplied to the Authority accurately reflects that given and recorded on disclosure consent forms.

Recommendation to the Executive Licensing Panel

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

However, the centre has one critical and eight major areas of concern and significant improvement is required in order for the centre to reflect suitable practices.

In response to these concerns a management review meeting was held on 3 September 2015 in accordance with the HFEA's compliance and enforcement policy. The review concluded that informal action, informing the PR in writing of the minimum levels of remedial action that must be undertaken and the timescales for doing so as documented in this report, was warranted in the first instance.

Based on all the information provided to date, the Executive considers that immediate actions taken by the PR have mitigated any likely immediate risks to patients (with particular reference to use of embryos in training and import of embryos). As a result the Executive recommends the renewal of the centre's treatment and storage licence for a period of three years (rather than the standard four) without additional conditions subject to compliance with the recommendations made in this report being implemented within the prescribed timescales. An interim inspection should be conducted at the discretion of the Executive but within one year of this licence being granted. This will enable the centre's progress in implementing the recommendations to be evaluated within a shorter than usual timescale. Should there be any concerns about the effectiveness of any corrective action taken this can be referred to a licensing committee. Alternatively, if the centre is able to demonstrate good progress after the interim inspection, the usual biennial inspection frequency can be resumed.

The PR is encouraged to continue to use the Quality Management System (QMS) to best effect to monitor and improve the quality of the service offered to patients.

The inspector will continue to monitor the centre’s performance.

Section 2: Inspection findings

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

1. The protection of the patient, and children born following treatment at this centre
2. The experience of patients at this centre
3. The protection of gametes (sperm and eggs) and embryos at this centre
4. How this centre looks after important information

1. Protection of the patient and children born following treatment

Witnessing and assuring patient and donor identification

What the centre does well

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

What the centre could do better

Nothing identified at this inspection.

Donor selection criteria and laboratory tests

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

What the centre does well

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

Payments for donors (Guidance note 13; General Directions 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)
A donor-conceived person is entitled to know details of their donor and any donor-conceived genetic siblings they may have. Parents of a donor-conceived child are able to access information on their child's donor (and about any donor-conceived genetic siblings) from the HFEA or the clinic where they received treatment.

Therefore it is important that centres use donated gametes or embryos from identifiable donors. The centre's procedures are compliant with HFEA requirements to ensure the donor conceived will be able to receive this information.

What the centre could do better

Nothing identified at this inspection.

Suitable premises and suitable practices

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

What the centre does well

Safety and suitability of premises and facilities (Guidance note 25)
The centre's premises are broadly 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 to ensure patients and staff are in safe surroundings that prevent harm.

The centre is compliant with HFEA requirements to processes gametes and 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 for accreditation 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
The centre has systems in place to manage and monitor the prevention and control of infection that are compliant with guidance.

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

Pre-operative assessment and the surgical pathway
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 Directions 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 Directions 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 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 the gametes and embryos are appropriately labelled and has enough information to permit the gametes and embryos be stored or used in treatment in a way that does not compromise their quality and safety.

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

Traceability (Guidance note 19)
The centre's procedures are partially 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,
- 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 in place 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 partially compliant with HFEA requirements.

Transport and satellite agreements (Guidance note 24; General Directions 0010)
The centre has no transport or satellite arrangements.

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

The centre is compliant with HFEA requirements to validate critical equipment.

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

Adverse incidents (Guidance note 27)
The centre's procedures for reporting adverse incidents are partially compliant with HFEA requirements. The centre reports most adverse incidents (including serious adverse events and reactions) to the HFEA. The centre investigates 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
The fire escape for the adjacent ward requires access through the centre. As the access doors are not secured this could pose a risk of inadvertent breach of confidentiality and/or a risk to privacy and dignity for the centre's patients, although the inspection team recognise that there is no evidence that this has occurred (SLC T17). See recommendation 10.

Medicines management
Drugs supplied to self-funding patients are not labelled with the name of the patient and in some cases an information sheet for the medicine is not supplied (SLC T2). See recommendation 2.

Transport and distribution of gametes and embryos
When gametes/embryos are transported from this centre the transport conditions do not specify the temperature and time limits or the date and time of the start of transportation (SLC T107). Additionally, the shipper is not secured prior to release to the courier (SLC T108). See recommendation 3.

Imports and exports
One sample of sperm has been exported and one set of embryos has been imported under General Directions 0006 when the requirements for import/export under General Directions 0006 were not met. The requirements of General Directions 0006 were not met because the sperm was exported with the intention of using the sperm to inseminate eggs from a donor who has not agreed to be identifiable, and the imported embryos were created using eggs from a donor who has not agreed to be identifiable. The imported embryos have not yet been used for treatment (General Directions 0006). See recommendation 4.

Traceability
The sperm gradient medium had a 'first use' date that was in the future so it was not possible to know when this medium had first been used or for which patients (SLC T99). At egg collection not all containers (dishes, vials, ampoules, tubes etc) used during the procurement of eggs are labelled with the patient's/donor's full name and a further identifier (SLC T101). See recommendation 5.

Quality management system (QMS)
There is no SOP to direct staff regarding action in the case of equipment malfunction or failure (SLC T27 and T33b). Additionally, the centre has not established quality indicators or objectives relevant to administration activities (SLC T35). See recommendation 11.

Third party agreements
The centre occasionally undertakes procurement of sperm and/or eggs in the main theatres of the hospital but there is no third party agreement in place (SLC T111). See recommendation 6.

Equipment and materials

The incubators are not subject to continuous monitoring and there is no external alarm system to alert staff to malfunctions outside normal working hours (SLC T24). See recommendation 7.

Some of the consumables in use currently are not CE marked. However, CE marked alternatives have already been identified where they are available and will be in use within the next six months (SLC T30). A list of the consumables that are currently not CE marked, along with the CE marked alternatives was provided to the inspection team. See recommendation 12.

Adverse incidents
During discussions with the PR the inspection team discovered that a letter had been sent to the wrong patient in the past year. This had not been reported to the HFEA as an adverse incident as the PR and staff were not aware that a breach of confidentiality of this nature constituted an adverse incident reportable to the HFEA. This incident had not therefore been investigated and followed up (SLC T118). See recommendation 8.

Staff engaged in licensed activity

Person Responsible (PR)
Staff

What the centre does well

Person Responsible (Guidance note 1)
The PR has academic qualifications in the field of medicine and has more than two years of practical experience which is directly relevant to the activity to be authorised by the licence. The PR has successfully completed the HFEA PR Entry Programme (PREP number T/1031/7).

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 the welfare of any child who may be born as a result of the licensed treatment, and of any other child who may be affected by that birth before treatment is provided are compliant with HFEA requirements.

Safeguarding
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 preimplantation genetic screening or embryo testing and sex selection.

What the centre could do better

Not applicable

2. The experience of patients

Patient feedback

What the centre does well

During the inspection visit the inspectors were not able to speak to any patients about their experiences as there were no patients available who had had treatment. However, 10 patients provided feedback directly to the HFEA in the time since the last inspection. Feedback was positive, with eight of the individuals providing written feedback to the HFEA commenting that they have compliments about the care that they received.

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

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

What the centre could do better

Nothing identified at this inspection.

Treating patients fairly

Counselling
Egg sharing arrangements
Surrogacy
Complaints
Confidentiality and privacy

What the centre does well

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

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

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

Egg sharing arrangements (Guidance note 12; General Directions 0001)
The centre does not provide egg sharing arrangements.

Surrogacy (Guidance note 14)
The centre does not provide treatment involving surrogacy arrangements.

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 broadly 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

It was noted that there was one breach of confidentiality whereby a patient letter was send to the wrong address (see 'Adverse incidents' section).

Information

What the centre does well

Information (Guidance note 4; 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.

Disclosure of information, held on the HFEA Register, for use in research (General Directions 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.

No discrepancies were found in four patient/partner disclosure consents completed post April 2015[1] on patient files and the related consent data submitted for inclusion on the register.

The centre's procedures for taking consent to disclosure to researchers are broadly compliant with HFEA requirements.

What the centre could do better

Four discrepancies were found in 28 patient/partner disclosure consents completed pre April 2015 and the related consent data submitted for inclusion on the register (CH(10)05 and General Directions 0005). Therefore the centre's procedures have failed to ensure that the HFEA holds an accurate record of consents to disclosure, although the errors would not lead to a risk that the HFEA may release patient identifying information to researchers without consent. See recommendation 13.

[1] Revised consent to disclosure forms were issued in April 2015

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). This ensures that the centre has respect for the special status of the embryo when conducting licensed activities.

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

What the centre could do better

Nothing identified at this inspection.

Screening of patients
Storage of gametes and embryos

What the centre does well

Screening of patients (Guidance note 17)
The centre's procedures for screening patients are compliant with HFEA requirements. It is important that gamete providers are appropriately screened to minimise the risks of cross infection during treatment, processing and storage of gametes and/or embryos.

Storage of gametes and embryos (Guidance note 17)
The centre's procedures for storing gametes and embryos are compliant with HFEA requirements. These measures ensure that gametes and embryos are stored appropriately to maintain their quality and safety. Furthermore, the centre only stores gametes and embryos in accordance with the consent of the gamete providers. The storage of gametes and embryos is an important service offered by fertility clinics, as it can enable patients to preserve their fertility prior to undergoing other medical treatment such as radiotherapy. The storage of embryos not required for immediate use also means that women can undergo further fertility treatment without further invasive procedures being performed.

What the centre could do better

Nothing identified at this inspection.

Use of embryos for training staff (Guidance note 22)
What the centre does well **Use of embryos for training staff (Guidance note 22)** The centre's procedures for using embryos for training staff are partially compliant with HFEA requirements.
What the centre could do better During a review of records it was found that embryos from one patient had been used for training staff in embryological techniques but the patients had not provided written consent for this (HF&E Act 1990 (as amended) schedule 3, 2 (1ba) and SLC T94). See recommendation 1.

4. Information management

Record keeping
Obligations and reporting requirements

What the centre does well

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

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

The centre's procedures for submitting information, about licensed activities to the Authority are partially compliant with HFEA requirements

What the centre could do better

The HFEA register information team found evidence of problems with the timeliness and accuracy of the centre's submission of data to the Register: 2% (2/97) of the IVF and 12% (2/18) of the DI treatments reviewed at inspection had not been reported to the HFEA (General Directions 0005 and SLC T41). 94% (89/97) of the IVF and 89% (16/18) of the DI treatments reviewed at inspection had been reported to the HFEA outside the period required by General Directions 0005 (General Directions 0005, SLC T41 and T9e). See recommendation 9.

Section 3: Monitoring of the centre's performance

Following the interim inspection in 2013, recommendations for improvement were made in relation to one area of major non-compliance and three 'other' areas of non-compliance.

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

On-going monitoring of centre success rates

In the last year, the centre has not received any alerts in relation to centre success rates.

Areas of practice requiring action

The section sets out matters which the Inspection Team considers may constitute areas of non compliance. These have been classified into critical, major and others. Each area of non-compliance is referenced to the relevant sections of the Acts, Regulations, Standard Licence Conditions, 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
1. **Use of embryos for training staff** Embryos from one patient had been used for training staff in embryological techniques but the patients had not provided written consent for this (HF&E Act 1990 (as amended) schedule 3, 2 (1ba) and SLC T94).	The PR should undertake an audit of patient records to identify whether the inspection observations represent a systemic failure or a rare occurrence. A summary report of the review findings including corrective actions and the timescale for their implementation should be submitted to the HFEA by 5 November 2015. The PR should provide monthly updates to the HFEA on progress in implementing	We have audited all documents relating to the validation and/or introduction of new methodologies and can confirm that no other embryos have been used for training purposes. Consequently, the case identified represents a single isolated case. The results of this audit will be forwarded to the HFEA. Our centre will contact the gamete providers in this single case to inform them and to offer counselling.	The PR is taking appropriate action regarding this issue. It is expected that the gamete providers will be informed of the use of their embryos at the earliest opportunity and that PR should inform the HFEA when this has happened. Further action required.

	corrective actions. Where it is confirmed that embryos have been used in training without the consent of both gamete providers, the PR should ensure that the gamete providers are informed and offered an opportunity to receive counselling. The HFEA should be advised of the number of patients affected and be provided with confirmation that the individuals have been contacted. Within three months of the implementation of corrective actions, the centre should conduct an audit of consent to use of embryos in training and a summary report of the findings of the audit should be provided to the HFEA.		

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
2. **Medicines management** Medicines supplied to self-funding patients are not labelled with the name of the patient and in some cases an information sheet for the medicine is not supplied (SLC T2).	The PR should ensure that medicines supplied to patients are always labelled with the name of the patient and are accompanied by the manufacturer's drug information sheet or a facsimile of it. The PR should provide assurance that this is being done when responding to this report.	This issue has already been resolved. Now all medications are properly labelled with name of the patient and date of birth and the hospital number and the drug manufacturer information sheets are also provided.	The inspector is satisfied that appropriate action has been taken and this issue is now resolved. No further action.
3. **Transport and distribution of gametes and embryos** When gametes/embryos are transported from this centre the transport conditions do not specify the temperature and time limits or the date and time	The PR should take immediate action to ensure that the temperature and time limits of shipping containers are specified, that individuals using the containers understand the significance of	An updated version of our Third Party Agreement (containing these extra demands) with our courier has already been created and sent. We are awaiting the acceptance and return of this	The third party agreement, which includes the required points, has been sent to the HFEA. The PR is taking appropriate action regarding this issue.

of the start of transportation (SLC T107). Additionally, the shipper is not secured prior to release to the courier (SLC T108).	these limits in maintaining the viability of gametes/embryos and that the shipper is secured before release to the courier. The inspector should be advised of the measures taken to ensure that this happens when responding to this report. Within six months (or longer if gamete/embryo transfer is infrequent) the centre should conduct an audit of gamete/embryo transport to ensure that temperature and time limits are not being exceeded and a summary report of the findings of the audit should be provided to the centre's inspector.	agreement. As requested, within 6 months, we will conduct an audit to examine if time limits and temperature for gamete/embryo transport are within the specified values.	Further action required.
4. **Imports and exports** One sample of sperm has been exported and one set of embryos has been imported under General Directions 0006 when the requirements for import/export under General Directions 0006 were not met. The requirements of General Directions 0006 were not met	Before any further import or export of gametes or embryos, the PR should review the centre's procedures to ensure compliance with the requirements of General Directions 0006. Confirmation that this action will be taken should be given when	The centre has reviewed the Standard Operating Procedures for the export (DRM\QMS\Current SOPs\Embryology\SOP Emb 026 Transfer frozen material out of JCUH) and import (DRM\QMS\Current SOPs\Embryology\SOP Emb 027 Receipt of frozen	In addition to the comments made by the PR in this report, the PR has confirmed in separate correspondence that he has contacted the patients concerned and the embryos will not be used in contravention of SLC T54. The patients intend to return the embryos to the country of

because the sperm was exported with the intention of providing treatment with anonymous donor eggs, and the embryos had been created using anonymous donor eggs. The imported embryos have not yet been used for treatment (General Directions 0006).	responding to this report. The PR should note that use of the imported embryos would be in contravention of SLC T54. In responding to this report the PR should confirm that the embryos will not be used pending the outcome of the review described below. The PR should review the documentation relating to all gametes and/or embryos imported. The HFEA should be provided with a report documenting the status of each import in terms of compliance with General Directions 0006; whether the gametes or embryos have been used in treatment, and; where treatment has been provided, the outcome of that treatment in terms of live birth, ongoing pregnancy and/or creation of frozen embryos. This report should be provided by 5 November 2015. On receipt of the information the HFEA Executive will liaise with the PR to determine a	material into the JCUH) of gametes and embryos.	origin. The PR is taking appropriate action regarding this issue. Further action required.

	proportionate recommendation about the subsequent use of such gametes and or embryos. The PR should review all processes relating to export and import, to ensure compliance with General Directions 0006. A summary report of the findings of that review including any corrective actions identified and the timescale for their implementation should be provided by 5 November 2015. Six months after the implementation of any corrective actions the PR should audit the effectiveness of these actions in ensuring compliance: a summary of the audit should be provided by 5 May 2016.		
5. **Traceability** The sperm gradient medium had a 'first use' date that was in the future so it was not possible to know when this	The PR should take immediate action to ensure that all relevant data about anything coming into contact with gametes or embryos is	Traceability: A Standard Operating Procedure for traceability already exists (DRM\QMS\Current SOPs\Embryology\SOP Emb	In addition to the comments made by the PR in this report, the PR has sent the traceability SOP to the HFEA. The inspector is satisfied that

medium had first been used or for which patients (SLC T99). At egg collection not all containers (dishes, vials, ampoules, tubes etc) used during the procurement of eggs are labelled with the patient's/donor's full name and a further identifier (SLC T101)	traceable. The HFEA should be advised of the measures taken to ensure that this happens when responding to this report. Within three months of the implementation of corrective actions the centre should conduct an audit of traceability and a summary report of the findings of the audit should be provided to the centre's inspector. Whilst the PR has previously provided information of the actions taken to mitigate the risks of misidentification at egg collection, the practice has since changed. The PR should provide the HFEA with a summary report of the current actions taken to mitigate the risks of misidentification as a result of this practice when responding to this report.	030 Consumable and Media Use and Traceability). This includes all media and consumables that come into contact with gametes and embryos. At the time of the inspection, all the batches of media and the consumables that were currently in use had been logged although, as correctly identified by the inspector, the month of opening one batch of medium was incorrect. An audit of traceability will be undertaken within three months. Egg Collection: The practice to mitigate the risks of misidentification at egg collection (as agreed with the HFEA from their inspection in May 2013) has not essentially changed. As suggested by the HFEA at the inspection in August this year, we have now introduced a witnessing step to ensure the removal of flasks, tubes and dishes (DRM\QMS\Current Forms\Embryology\FRM Emb 021 Witness form IVF).	this non-compliance appears to be due to human error and not due to a systematic failure. The PR has provided a summary report of the current actions taken to mitigate the risks of misidentification at egg collection. The inspector considers that appropriate action has been taken. Further action required

6. **Third party agreements** The centre occasionally undertakes procurement of sperm and/or eggs in the main theatres of the hospital but there is no third party agreement in place (SLC T111).	The PR should establish a third party agreement with the main theatres of the hospital that includes all the activities that are performed by the main theatres of the hospital that may influence the quality and safety of gametes and embryos. This third party agreement should be established and a copy sent to the centre's inspector by 5 November 2015.	The creation of this Third Party Agreement with theatres in the hospital is in preparation and will be sent to the HFEA by 5 Nov 2015.	The PR is taking appropriate action regarding this issue. Further action required.
7. **Equipment and materials** The incubators are not subject to continuous monitoring and external alarm systems to alert staff to malfunctions outside normal working hours (SLC T24).	The PR should establish a system of appropriate monitoring and alarms to ensure that the critical parameters are maintained within acceptable limits at all times in the centre's incubators. The PR should provide information on how this will be achieved when responding to this report. The system should be in place by 5 November 2015 and the PR should inform the centre's inspector when this has been done.	In accordance with T24, the incubators have continuous appropriate monitoring in the form of temperature and gas levels by internal alarms. Although T24 does not specify the requirement for external alarm auto-dial systems (in comparison to the clear regulations for liquid nitrogen dewars), we will be installing external auto-dial alarms for temperature and gas in the next month.	The inspector is satisfied that appropriate action is being taken and looks forward to hearing from the PR when the work is finished. Further action required.

8. **Adverse incidents** During discussions with the PR the inspection team discovered that a letter had been sent to the wrong patient in the past year. This had not been reported to the HFEA as an adverse incident as the PR and staff were not aware that a breach of confidentiality of this nature constituted an adverse incident reportable to the HFEA. This incident had not therefore been investigated and followed up (SLC T118).	The PR should review the centre's procedures for adverse incident reporting. Additionally, the PR should review all adverse incidents that have occurred since the interim inspection in 2013 and establish whether incidents have been reported to the HFEA appropriately. A summary report of this review including corrective actions and the timescale for their implementation should be submitted to the HFEA by 5 November 2015. The PR should provide monthly updates to the HFEA on progress in implementing corrective actions. Within six months of the implementation of corrective actions, the centre should conduct an audit of adverse incidents reported to the HFEA against adverse incidents and events reported on the centre's own incident database and a summary report of the findings of the	Since the inspection we developed a further SOP and it is attached. We will make sure similar incidents are reported to the HFEA in the future.	The inspector is satisfied that appropriate action is being taken and looks forward to receiving the summary report and audits in due course. Further action required.

	audit should be provided to the HFEA.		
9. **Obligations and reporting requirements** 2% (2/97) of the IVF and 12% (2/18) of the DI treatments reviewed at inspection had not been reported to the HFEA (General Directions 0005 and SLC T41). 94% (89/97) of the IVF and 89% (16/18) of the DI treatments reviewed at inspection had been reported to the HFEA outside the period required by General Directions 0005 (General Directions 0005, SLC T41 and T9e).	The PR should review the centre's processes for reporting licensed treatment activity to the Authority in compliance with General Directions 0005. A summary report of the review, including corrective actions and the timescale for their implementation should be submitted to the centre's inspector by 5 November 2015. The PR should conduct an audit six months after implementing any corrective actions, to confirm that the actions have been effective in ensuring data submission in compliance with General Directions 0005. A summary of the audit should be provided to the centre's inspector.	This area is now well covered and we will be carrying out an audit after the current one. We will make sure that an audit is carried out every 6 months.	The inspector is satisfied that appropriate action is being taken and looks forward to receiving the summary report and audits in due course. Further action required.

Other areas of practice that requires improvement

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
10. **Safety and suitability of premises and facilities** The fire escape for the adjacent ward requires access through the centre. As the access doors are not secured this could pose a risk of inadvertent breach of confidentiality and/or a risk to privacy and dignity for the centre's patients, although the inspection team recognise that there is no evidence that this has occurred (SLC T17).	The PR should provide assurance that there is no risk of breach of confidentiality and/or a risk to privacy and dignity for the centre's patients when responding to this report.	Although this area is well covered in our unit, I do expect the inspection team to appreciate that we have new premises and also I do expect the draft report to be more precise. On the inspection day I did reassure the inspection team that securing the door is underway and now it is being done.	In addition to the comments made by the PR in this report, the PR has confirmed that there is no risk of breach of confidentiality and/or a risk to privacy and dignity for the centre's patients and has explained the reasons for this. No further action.
11. **Quality management system (QMS)** There is no SOP to direct staff in the case of equipment malfunction or failure (SLC T27 and T33b). Additionally, the centre has	The PR should establish an SOP to direct staff regarding action in the case of equipment malfunction or failure. A copy of the SOP should be provided to the centre's inspector by 5 November 2015.	Equipment malfunction: Each standard operating procedure for each piece of equipment now contains a paragraph stating the action required in the event of failure or malfunction. As an illustration of compliance, we enclose an	The PR has provided evidence that staff will be aware of the action to take in the case of equipment malfunction or failure. The PR has provided evidence of the establishment of quality

not established quality indicators or objectives relevant to administration activities (SLC T35).	The PR should establish quality indicators or objectives for administration activities. Documentation demonstrating the establishment of the quality indicators or objectives should be provided to the centre's inspector by 5 November 2015.	example of one such equipment SOP. Quality indicators for administration activities: attached.	indicators for administration activities. No further action.
12. **Equipment and materials** Some of the consumables in use currently are not CE marked. However, CE marked alternatives have already been identified where they are available and will be in use within the next six months (SLC T30). This non-compliance would normally be classed as 'major', but as centre staff had already taken steps to ensure compliance at the time of the inspection this non-compliance has been reclassified as 'other'.	The PR should update the centre's inspector as each CE marked consumable is brought into use. It is expected that all medical devices used by the centre will be CE marked by 5 February 2016.	The Centre agrees to this plan and timetable.	The PR is taking appropriate action regarding this issue. Further action required.
13. **Disclosure of information, held on the**	The PR should correct the submissions that have been	This important area is being rectified and in 6 months there	The submissions have been corrected.

HFEA Register, for use in research Four discrepancies were found in 28 patient/partner disclosure consents completed pre April 2015 and the related consent data submitted for inclusion on the register (CH(10)05 and General Directions 0005).	identified as being incorrect. These corrections should be completed by 5 November 2015. The PR should conduct an audit in six months' time to confirm that disclosure of information submissions are being reported correctly. A summary of the audit should be provided to the centre's inspector.	will be an audit which will be presented to the HFEA.	The PR is taking appropriate action regarding this issue. Further action required.

Reponses from the Person Responsible to this inspection report