Executive Licensing Panel - minutes

Centre 0196 (Jessop Fertility) Renewal

Friday, 29 July 2016

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Paula Robinson (Chair) Joanne Anton Anjeli Kara	Head of Business Planning Head of Regulatory Policy Regulatory Policy Manager
Members of the Executive	Dee Knoyle Ian Brown	Secretary Head of Corporate Governance
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 Jessop Fertility, centre 0196, is located in Sheffield. The centre provides a full range of fertility services. In relation to activity levels this is a large centre.

1.3. The panel noted that the centre has held a licence with the HFEA since 2001.

1.4. The panel noted that in the 12 months to 29 February 2016, the centre provided 1023 cycles of treatment (excluding partner intrauterine insemination).

1.5. The panel noted that for IVF and ICSI, HFEA-held register data for the year ending November 2015 showed the centre's success rates were in line with national averages, with the following exception:

- clinical pregnancy rates following IVF in patients aged 16-37 years were below average at a statistically significant level. However, this was due to a failure in the computer system for submitting data to the HFEA, in November 2015 - a technical fault which has since been resolved. Therefore, this apparent outcome is not an accurate reflection of the centre's true clinical pregnancy rates.

1.6. The panel noted that in 2015, the centre reported 273 cycles of partner insemination with 40 clinical pregnancies. This equates to a 15% clinical pregnancy rate which is likely to be in line with national averages.

1.7. Between December 2014 and November 2015 the centre's multiple pregnancy rate for all IVF, ICSI and frozen embryo transfer (FET) cycles for all age groups was 11%. This means that the centre's multiple live birth rate is likely to be consistent with the 10% maximum multiple live birth rate target for this period.

1.8. The panel noted that at the time of the renewal inspection on 19 and 20 April 2016, three major and two other areas of non-compliance were identified. The panel noted that since the inspection the Person Responsible (PR) has implemented some of the recommendations and has committed to implementing all of the outstanding recommendations.

1.9. The panel noted that some improvement is required in order for the centre to demonstrate the suitability of their practices.

1.10. The panel noted that the centre has a Quality Management System in place and the PR is encouraged to use it to best effect to monitor and improve the service provided.

1.11. The panel noted that the inspectorate recommends the renewal of the centre's treatment and storage licence for a period of four years without additional conditions subject to the recommendations made in this 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 their duty under section 17 of the HFE Act 1990 (as amended).

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

3. Chair's signature

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

Signature

Name

Paula Robinson

Date

2 August 2016

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: 19 and 20 April 2016

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

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

Inspectors: Susan Jolliffe (Lead), Vicki Lamb, Shanaz Pasha, Neil McComb.

Date of Executive Licensing Panel: 29 July 2016

Centre name	Jessop Fertility
Centre number	0196
Licence number	L/0196/8/a
Centre address	Sheffield Teaching Hospitals NHS Foundation Trust, Jessop Wing, Tree Root Walk, Sheffield, S10 2SF.
Person Responsible	Rachel Cutting
Licence Holder	Sheffield Teaching NHS Trust
Date licence issued	1 October 2012
Licence expiry date	30 September 2016
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:

Jessop Fertility has held a Treatment and Storage licence with the HFEA since 2001.

The centre provides a full range of fertility services to self funded and National Health Service (NHS) patients.

The centre provided 1023 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 29 February 2016. In relation to activity levels this is a large centre.

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

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the year ending November 2015 show the centre's success rates are in line with national averages, with the exception of clinical pregnancy rates following IVF in patients aged 16-37 years which appear to be below average at a statistically significant level; this is not an accurate reflection of the centres clinical pregnancy rates, which appear to be good. The below average outcome was caused by a failure of the electronic data exchange in November 2015, which has since been resolved.

In 2015 the centre reported 273 cycles of partner insemination with 40 clinical pregnancies. This equates to a 15% clinical pregnancy rate. The centre's success rate for partner insemination is likely to be in line with national averages.

Multiple births[2]

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

Between December 2014 and November 2015 the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 11%. This means that the centre's multiple live birth rate is likely to be consistent with the 10% multiple live birth rate target.

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

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

Summary for licensing decision

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

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

Since the inspection, the PR has provided evidence that the following recommendations have been implemented:

Major areas of non compliance:

- The PR should ensure compliance with medicines management regulations.
- The PR should ensure that there is consent in place for all gametes in store.

'Other' areas that require improvement:

- The PR should ensure that all critical equipment where gametes are stored, have the appropriate alarm system in place to identify malfunction.

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

Major areas of non compliance:

- The PR should ensure that the laboratory which undertakes diagnostic semen analysis is accredited by Clinical Pathology Accreditation UK (CPA) or equivalent, or provide evidence to support a status equivalent to accreditation.

'Other' areas that require improvement:

- The PR should review procedures and take appropriate corrective actions to 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 centre has no critical areas of concern but does have three major areas of concern. The inspection team notes that the success rates are consistent with or above the national average, with one exception. The centre's multiple clinical pregnancy rate is likely to meet the live birth rate target.

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

The inspection team recommends the renewal of the centre's Treatment and Storage licence for a period of four years without additional conditions subject to the recommendations made in this report being implemented within the prescribed timescales.

Section 2: Inspection findings

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

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

1. Protection of the patient and children born following treatment

Witnessing and assuring patient and donor identification

What the centre does well

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

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

Donor selection criteria and laboratory tests

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

What the centre does well

Screening of donors (Guidance note 11)
The centre's procedures for screening donors are compliant with HFEA requirements. It is important that donors are appropriately screened to minimise the risks of cross infection during treatment, processing and storage of gametes and 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)
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 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 process 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 partially 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 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;
- if sperm is procured at home, the centre keeps a record of this in the gamete provider's records.

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

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

Receipt of gametes and embryos (Guidance note15)
The centre's procedures for the receipt of gametes and embryos are compliant with HFEA requirements. This is important to ensure that the centre only accepts gametes and embryos from other centres if 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 Direction 0006)
The centre's procedures for import and export of gametes and embryos are compliant with HFEA requirements.

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

- to identify and locate gametes and embryos during any step from procurement to use for human application or disposal;
- to identify the donor and recipient of 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 compliant with HFEA requirements. The establishment and use of a QMS is important to ensure continuous improvement in the quality of treatments and services.

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

Transport and satellite agreements (Guidance note 24; General Direction 0010)
The centre no longer has any transport or satellite centres.

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

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

What the centre could do better

Laboratory accreditation (Guidance note 25)
The laboratory the centre uses to undertake diagnostic semen analysis is not accredited by CPA (UK) Ltd or another body accrediting to an equivalent standard. Centre staff informed the inspection team that the laboratory staff are working towards International Organisation for Standardization (ISO) 15189 – Medical Laboratory Accreditation. The inspection team reviewed the information available to achieve equivalence, and noted there are a number of SOPs outstanding (SLC T21, recommendation 1).

Medicines management
The centre does not consistently record the disposal of any unused portion of a controlled drug in the controlled drugs register. In an audit of the drug register, three recent entries showed a part ampoule was given, which was recorded accurately in the three patient records, but the controlled drug register did not have a record of the remainder of the ampoule being disposed of.

The inspection team is confident from talking to staff and observing practice that this is a record keeping issue, and the system for witnessing the disposal of any unused controlled drug is performed correctly.

An audit of five patient's theatre records undertaken by the inspection team identified that signatures and dates were bracketed for several medicines prescribed, rather than signing and documenting the date prescribed for each drug individually, in accordance with the centre's own operating procedures.

In one set of patient theatre records the date the controlled drug was administered did not match the entry in the controlled drugs register.

(Misuse of Drugs Regulation 2001, schedule 27. Safer management of controlled drugs – a guide to good practice 4.16.1.2, recommendation 2).

Equipment and materials (Guidance note 26)
All the dewars in which cryo preserved gametes and embryos are stored have a malfunction alarm fitted with the exception of one. This was a dewar containing donor sperm. Following discussion with the PR it was established that several dewar alarms had been sent away for repair together, resulting in a temporary shortfall of one alarm. The PR had assessed the risk of a dewar not being connected to an alarm and had taken the decision to not alarm the donor sperm dewar as she considered that if the dewar failed then further donor samples could be obtained. The PR stated that the repaired

alarms were due back the following week, at which point the donor sperm dewar would be connected (SLC T24, recommendation 4).

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 biological sciences and has more than two years of practical experience which is directly relevant to the activity to be authorised by the licence. The PR has successfully completed the HFEA PR Entry Programme (PREP number T/1172/8).

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 The centre does not perform embryo testing and therefore this area of practice is not applicable to this inspection.
What the centre could do better Not applicable to this inspection.

2. The experience of patients

Patient feedback

What the centre does well

During the inspection visit the inspectors spoke to five patients who provided positive feedback on their experiences. One patient provided feedback directly to the HFEA in the time since the last inspection. Feedback was positive, with all of the individuals 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 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.

The centre's own patient satisfaction survey results were reviewed by the inspection team, the findings were overall very positive. The results of these surveys are carefully considered by the centre and demonstrates a learning culture at the centre.

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's procedures for egg sharing arrangements are compliant with HFEA requirements. This is important to ensure that:

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

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

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

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

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

Information

What the centre does well

Information (Guidance note 4; Chair's Letter CH (11)02)
The centre's procedures for providing information to patients and donors are compliant. 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
Legal Parenthood, and
Disclosure of information, held on the HFEA Register, for use in research

What the centre does well

Consent (Guidance note 5)

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 are not married or in a civil partnership, both the woman and her partner must give written consent in order for the partner to become the legal parent of any child born. If this consent is not documented properly or if proper information is not provided or counselling offered prior to both parties giving consent, there may be doubt about the effectiveness of the consent and in some cases it may be necessary for a patient couple to obtain a court declaration to establish legal parenthood. In February 2014, the HFEA asked all centres to audit their practices in this area to ensure they are suitable, to report the findings of the audit to the HFEA and to respond to those findings. The centre provided evidence that their audit was comprehensive and that their procedures for obtaining consent to parenthood are robust.

To provide assurance of the effectiveness of the centre's procedures, the inspection team reviewed four sets of patient notes, where treatment with donor sperm had recently been provided in circumstances where consent to legal parenthood is required. The centre's procedures are compliant with legal parenthood requirements.

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

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

What the centre could do better

Disclosure of information, held on the HFEA Register, for use in research (General Direction 0005)
Five discrepancies were found between 17 completed patient/partner disclosure consents on patient files, and the related consent data submitted for inclusion on the Register.

Therefore, the centre's procedures have failed to ensure that the HFEA holds an accurate record of consents to disclosure. This failing leads to a risk that the HFEA may release patient identifying information, to researchers, without consent in these five cases (CH (10) and General Directions 0005 recommendation 5).

3. The protection of gametes and embryos

Respect for the special status of the embryo

What the centre does well

The centre's procedures are compliant with the requirements of the HF&E Act 1990 (as amended). 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 embryos.

Storage of gametes and embryos (Guidance note 17)

The centre's procedures for storing gametes and embryos are partially 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

Storage of gametes and embryos (Guidance note 17)

The centre has one sample stored without the appropriate consent. This is a sperm sample that was stored eight years ago. On discovering the consent was not in place the PR reported this as an incident, and has taken action to try and contact the patient, without

success, the PR has investigated the incident and a corrective and preventive action plan was implemented. This was an isolated case and the general management of storage and the bring forward system is robust (HF&E Act as amended Schedule 3 paragraph 8 (1), recommendation 3).

Use of embryos for training staff (Guidance note 22)

What the centre does well

Use of embryos for training staff (Guidance note 22)
The centre's procedures for using embryos for training staff are compliant with HFEA requirements. Embryos are only used for the purpose of training staff in those activities expressly authorised by the Authority.

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

4. Information management

Record keeping
Obligations and reporting requirements

What the centre does well

Record keeping and document control (Guidance note 31)
The centre's procedures for keeping records are compliant with HFEA requirements to ensure that accurate medical records are maintained, with one exception detailed in the medicines management section of this report. Good medical records are essential for the continuity of the patient's care.

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

The HFEA register audit team was aware of technology issues that had caused problems with the timeliness of the centre's submission of data to the Register. Findings at the inspection indicate that the centre's procedures for submitting information about licensed activities are now compliant with HFEA requirements.

Due to the EDI issues faced by the centre causing the delays in submission it is felt to be unnecessary to make any recommendations regarding the timeliness of submissions.

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

Section 3: Monitoring of the centre's performance

Following the interim inspection in 2014, recommendations for improvement were made in relation to one major non-compliance and one 'other'.

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

- The laboratory the centre uses to undertake diagnostic semen analysis is not accredited by CPA (UK) Ltd or another body accrediting to an equivalent standard (recommendation 1).

On-going monitoring of centre success rates

There have been four risk tool alerts issued to the centre relating to poor pregnancy rates in patients less than 38 years receiving treatment with ICSI and IVF, the last one being in September 2015. The PR responded within the requested time, taking appropriate action to review practices.

In September 2015, it was found that although the HFEA risk based assessment tool (RBAT) was showing a problem with pregnancy rates this was actually due to a fault with the centre's electronic data interface (EDI) computer which meant that data for 240 treatments had not been transmitted to the HFEA correctly. This impacted on the centre's success rates as, without an early outcome of treatment being known, RBAT will record a negative outcome. Success rates reviewed on inspection showed the centres results to be within the national average. No further alerts have been issued.

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 Direction or the Code of Practice, and the recommended improvement actions required are given, as well as the timescales in which these improvements should be carried out.

Critical area of non compliance

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

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

Major area of non compliance

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

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
1. Laboratory Accreditation The laboratory the centre uses to undertake diagnostic semen analysis is not accredited by CPA (UK) Ltd or another body accrediting to an equivalent standard. The centre was unable to achieve equivalence due to a number of outstanding SOP'. Centre staff informed the inspection team that they are	The PR must ensure that diagnostic semen analysis is conducted by a suitably accredited laboratory or that evidence of equivalence can be demonstrated. The PR should inform the Lead Inspector when the outstanding SOPs have been developed or if ISO 15189 is awarded, no later than September 2016.	The Andrology department has made significant progress with the implementation of a quality management system. This has been supported by a seconded member of staff from ACU to drive the project forward. The outstanding SOPs are currently being written and will be in place by September. We will await further guidance from the HFEA regarding equivalence	The Executive acknowledges the PR's response, the work already completed and the clear commitment to fully implement this recommendation. Further guidance regarding equivalence has been sent to the PR as requested. Further action is required.

working towards ISO 15189. SLC T21. This was identified at the last inspection.			
2. Medicines management The centre does not consistently record the wastage of unused portions of controlled drugs accurately in the register. The centre does not consistently record the prescribing and date given for individual drugs; instead a number of drugs were bracketed as prescribed and given together. Misuse of Drugs Regulations, 2001 Schedule 27. SLC T2.	The PR should ensure compliance with medicines management regulations. The PR should undertake a review to identify the factors that have led to these non-compliances. A summary report of the review including corrective actions and the timescale for implementation of the corrective actions should be sent to the centre's inspector by 20 July 2016. Within three months of implementing changes, the centre should carry out an	Staff have undergone further training under the supervision of the senior sister to ensure there is consistent accurate recording of the unused portion of controlled drugs. A check of the controlled drug book was conducted by the PR 1 month post inspection. All logs were accurate and included the recording of all unused portions. During the HFEA inspection it was noted that the drug chart for egg collections used brackets to sign for a number of items prescribed for the process of egg collection. Advice was sought from a	The centre has submitted evidence to satisfy this recommendation, staff have been through a training programme, the audit of the controlled drug register is compliant. The centre has submitted copies of the revised transvaginal oocyte recovery procedure form, showing controlled drugs are to be signed for individually by a Doctor. No further action is required.

	audit of medicines management procedures to ensure that the corrective actions have been effective in ensuring compliance. A summary report of the audit should be sent to the centre's inspector by 20 October 2016	Senior Pharmacist in the Trust as to whether this is acceptable practice. The view of the Pharmacist was that this document is legally a Patient Specific Direction (PSD) rather than a prescription and therefore it was acceptable. However, after corresponding with the HFEA and further discussions with the senior clinical team the form has been changed to ensure all controlled drugs are signed for individually. The form was submitted to the HFEA for review on 7th July. The updated form has been re-issued and staff have been informed of the requirements.	
3. Consent to storage of gametes. The centre did not have effective consent in place for the storage of one sperm sample.	The PR should ensure that there is valid consent in place for all gametes in storage. The PR should seek legal advice and provide an	The sample has not been kept over the statutory storage period and the patient did sign in house consent for storage. Contact has been made with the patient through the referring doctor.	The centre has submitted evidence to satisfy this recommendation. No further action is required.

It is noted that the HFEA's assessment framework recommends classification of storage without consent as a critical non-compliance, but in consideration that the gametes of only one patient are being stored without consent and that there are specific issues that have made the centre reluctant to dispose of the sample; this has been classified as major. Schedule 3, 8(1) HF&E Act.	update on the proposed next steps by the time this report is considered by the Executive Licensing Panel. The PR is reminded of guidance issued by the HFEA in CH (03)03 (http://www.hfea.gov.uk/2687.html) in relation to the timely disposal of cryopreserved material where there is consent to do so and actions should there be a possibility of legal challenge to the disposal of cryopreserved material.	I can confirm that we received confirmation from the patient that he wished his sample to be thawed and allowed to perish last week. We have therefore carried out his wishes so the sample we found the day before our inspection without proper HFEA storage consent is no longer in storage	

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
4. Equipment The donor sperm dewar is not alarmed; the inspection team was assured this would be addressed in the week following the inspection. It is noted that the HFEA's assessment framework recommends classification of major for failure to alarm critical equipment, but in consideration that this had been identified, and the issue was being addressed at the time of inspection it was classified as an other. SLC T24	The centre should ensure that all critical equipment where gametes are stored, have the appropriate alarm system to identify malfunctions. The PR should provide an update on the action taken to resolve this non-compliance when responding to this report.	The donor sperm dewar is now alarmed and connected to the facility monitoring alarm system	The centre has submitted evidence to satisfy this recommendation. No further action is required.

5. Disclosure of information held on the HFEA Register, for use in research. In five of the 17 patient consent to disclosure forms reviewed, the patients had consented to contact research but the data submitted by the centre to the HFEA indicated that the patients had not. The Centre's designated HFEA Form Returnee has been provided with the relevant patient and partner numbers so that the form data can be reviewed and corrected. CH (10)05 and General Direction 0005	The PR should review procedures and take appropriate corrective actions to ensure that the disclosure consent information supplied to the Authority accurately reflects that given and recorded on disclosure consent forms. The PR should also correct the submissions that have been identified as being incorrect. These recommendations should be implemented by the time the inspection report is considered by a licensing committee and the inspector informed of the results of the review and actions taken. The PR should conduct an audit six months after implementing any corrective actions, to confirm that the actions have had the desired effect. A summary	The business manager will ensure a 6 month audit is conducted, reported to the PR and will provide further training to the data entry team	The Executive acknowledges the PR's response and commitment to fully implement this recommendation. Further action is required.

	of the audit should be provided to the Authority.		

Response from the Person Responsible to this inspection report
The team welcome the positive comments that reflect the many areas of compliance that are done well in the centre. Jessop Fertility would like to thank the HFEA team for a productive inspection and will work towards full compliance.