Human Fertilisation and Embryology Authority

Minutes of the Executive Licensing Panel

Meeting held at
Finsbury Tower, 103-105 Bunhill Row, London, EC1Y 8HF
on
13 February 2015

Minutes – item no. 1

Centre 0197 (Salisbury Fertility Centre) – Renewal Inspection Report

Members of the Panel:	Juliet Tizzard **Director of Strategy & Corporate Affairs (Chair)** Matthew Watts **Regulatory Policy Manager** Rachel Hopkins **Head of Human Resources**
Observing:	
Committee Secretary:	Trent Fisher

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:

- HFEA protocol for the conduct of meetings of the Executive Licensing Panel
- 8th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- decision trees for granting and renewing licences and considering requests to vary a licence (including the PGD decision tree)
- guidance for members of the Authority and committees on the handling of conflicts of interest approved by the Authority on 21 January 2009
- guidance on periods for which new or renewed licences should be granted
- standing orders and instrument of delegation
- indicative sanctions guidance
- HFEA Direction 0008 (where relevant) and any other relevant directions issued by the Authority
- guide to Licensing
- compliance and enforcement policy
- policy on the publication of Authority and committee papers

Consideration of Application

1. The Panel considered the papers, which included a completed application form, Licence Renewal Report and licensing minutes for the past three years.

2. The Panel noted that Salisbury Fertility Centre was located in Salisbury and provided treatment and storage services.

3. The Panel noted that this centre had been licensed by the HFEA since 2002.

4. The Panel noted that in the 12 months to 31 October 2014, the centre provided 492 cycles of treatment (excluding partner intrauterine insemination).

5. The Panel noted that for IVF and ICSI, HFEA-held register data for the period 1 July 2013 and 30 June 2014 show that the centre's success rates were in line with national averages.

6. The Panel noted that in 2013 the centre performed 55 cycles of partner insemination with five pregnancies. This equates to a 10% clinical pregnancy rate which is consistent with the national average.

7. The Panel notes that between 1 July 2013 and 30 June 2014, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 23%. This represented performance that was not likely to be statistically different from the 10% maximum multiple live birth rate target for this period.

8. The panel noted that an inspection was carried out at the centre on from 25 to 26 November 2014

9. The Panel noted that at the time of inspection there were 10 areas requiring action including two critical, three major and five 'other' areas of non-compliance.

10. The Panel noted that the two critical areas of non-compliance had been escalated from a major non-compliance as these were reoccurring from the renewal inspection in January 2011 and the interim inspection held in March 2013.

11. The Panel noted that the Inspectorate had recommended that this application was granted.

Decision

12. The Panel was concerned about the recurring non-compliances relating to validation of critical equipment and critical processes.

13. The Panel noted that the centre was requested to provide a list of critical equipment acquired in the last two years and all critical processes, including the date of validation or the planned date by when validation is to be completed. The Panel also noted that the list was requested to be provided to the HFEA by the time the inspection report was considered, although this was not explicitly referenced in the report.

14. The Panel was also concerned about the non-compliances relating to legal parenthood and donor sperm screening.

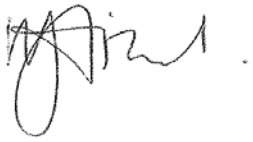
15. The Panel noted that there are a number of recommendations relating to major and 'other' non-compliances which require action by 25 February 2015. Given that that date is

very near and given the need for clarity about whether the centre had submitted the list information relating to the critical non-compliances, the Panel agreed to adjourn its decision to renew the centre's licence to the Executive Licensing Panel meeting on 13 March 2015.

16. The Panel asked the Inspectorate to provide information to satisfy them that the recommendations to be completed by the 25 February 2015 have been implemented.

17. The Panel also requests the Inspectorate to provide a list of the all critical processes and critical equipment acquired in the last two years including date of validation or the planned date by when validation is to be completed.

Signed: Date: 16 February 2015
Juliet Tizzard (Chair)



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: 25/26 November 2014

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: Andrew Leonard (Lead), Louise Winstone, Gill Walsh, Cathy Hodgson and Rebecca Loveys.

Date of Executive Licensing Panel: 13 February 2015

Centre name	Salisbury Fertility Centre
Centre number	0197
Licence number	L/0197/9/b
Centre address	Salisbury District Hospital, Odstock Road, Salisbury, Wiltshire, SP2 8BJ, UK
Person Responsible	Mr Shaun Fountain
Licence Holder	Dr Lydia Brown
Date licence issued	01/05/2011
Licence expiry date	30/04/2015
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:

The Salisbury Fertility Centre (SFC) is located in Salisbury District Hospital, Odstock Road, Salisbury, and has held a licence with the HFEA since 2002. The centre provides a full range of fertility services and completed 492 treatment cycles (excluding partner intrauterine insemination) in the twelve months to 31 October 2014. In relation to activity levels this is a small centre**.** The centre is applying to renew the Treatment and Storage licence.

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period 1 July 2013 – 30 June 2014 show the centre's success rates are in line with national averages.

In 2013, the centre reported 55 cycles of partner insemination with five pregnancies. This equates to a 10% clinical pregnancy rate which is consistent with the national average.

Multiple births[2]

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

Between 1 July 2013 – 30 June 2014, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 23%: this represented performance that is not likely to be statistically different from the 10% multiple live birth rate target for this period.

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) though the continued non-compliance related to process validation, and the re-occurrence of non-compliance related to the validation of new equipment are noted;
- the premises (including those of relevant third parties) are suitable;
- the centre's practices are suitable;
- the activities to be authorised by the licence are necessary or desirable for the purpose of providing treatment services;

[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 system. 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%.

- 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 two critical, three major and five 'other' areas of non-compliance which have resulted in the following recommendations:

Critical areas of non compliance:

- **The PR must ensure all critical equipment is validated.**
- **The PR must ensure all critical processes are validated.**

Major areas of non compliance:

- The PR must review the centre's procedure for releasing for treatment imported donated sperm and ensure it includes a robust review, for each donor, of the potential need for additional screening tests. The PR should also ensure an equivalent review is included in the centre's gamete donor recruitment process.
- The PR must ensure that the activities and processes authorised by the licence and other associated activities, are audited against compliance with the regulatory requirements and the centre's own approved protocols.
- The PR must ensure that CE marked materials and consumables are used wherever they are available.

'Other' areas that requires improvement:

- The PR should take action to ensure that records are kept of the cleaning and disinfection of the laboratory and all relevant equipment.
- The PR must formally document in a SOP the centre's process for collecting consent to legal parenthood from patients using donated sperm or embryos.
- The PR must put in place a complaints process which protects patient confidentiality and consent.
- The PR must ensure that appropriate information is provided to patients in a timely manner prior to obtaining their consent.

The PR has committed in his response to the report to take corrective actions to implement all these recommendations within the timeframes specified in the report.

Recommendation to the Executive Licensing Panel

The centre has two critical areas of non-compliance and three major of areas of concern.

Some improvement is required in order for the centre to reflect suitable practices. The centre has a quality management system (QMS) in place. The PR is encouraged to continue to use it to best effect to monitor and improve the service provided. The inspector will continue to monitor the centre's performance.

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 partly compliant with HFEA requirements. It is important that donors are appropriately screened to minimise the risks of cross infection during treatment, processing and storage of gametes and/or embryos.

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

Donor assisted conception (Guidance note 20)
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 register 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

Screening of donors (Guidance note 11)
In one case in which donated sperm was used, the donor had not been screened for sickle cell disease even though he was from an at-risk population. This donor was not recruited by the centre however the centre's procedures did not identify that the additional screening test had been omitted (SLC T52; see recommendation 3).

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, with one minor exception. 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 has no satellite/transport facilities.

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

Laboratory accreditation (Guidance note 25)
The centre's laboratories and/or third party laboratories which undertake the diagnosis and investigation of patients, patients' partners or donors, or their gametes, embryos or

any material removed from them, are compliant with HFEA requirements 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 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 single biggest risk of fertility treatment is a multiple pregnancy. The centre's procedures are compliant with HFEA multiple births minimisation strategy requirements for keeping a summary log of cases in which multiple embryos have been transferred and conducting regular audits and evaluations of the progress and effectiveness of the strategy.

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

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

Transport and distribution of gametes and embryos (Guidance note 15; General Direction 0009)
The centre's procedures for the transport, distribution and recall of gametes and embryos are partly 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. These procedures are important as they ensure that the centre only accepts gametes and embryos from other centres if the gametes and embryos are

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

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

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

- to identify and locate gametes and embryos during any step from procurement to use for human application or disposal;
- to identify the donor and recipient of 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 partly 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 does not have any satellite or transport centres.

Equipment and materials (Guidance note 26)
The centre uses equipment and materials that are partly compliant with HFEA requirements. All of the equipment and most of the 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 has documented procedures for the operation of critical equipment and procedures to follow if equipment malfunctions.

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 and has investigated them appropriately. Reporting and investigation of adverse incidents is important to ensure that centres share the lessons learned from incidents and continuously improve the services it offers.

What the centre could do better

Safety and suitability of premises and facilities (Guidance note 25)
Laboratory cleaning is not consistently documented in the records maintained by the centre, though the laboratory appeared clean at the time of the inspection (SLC T26; see recommendation 6).

Quality management system (QMS) (Guidance note 23)
The centre has not audited the activities and processes authorised by the licence and other associated activities, against compliance with the regulatory requirements and their own approved protocols, in the last two years (SLC T36; see recommendation 4).

The centre does not have a SOP documenting the process by which patient consent to legal parenthood is collected before treating a woman with donor sperm or embryos (SLC T33b; see recommendation 7).

Equipment and materials (Guidance note 26) and Transport and distribution of gametes and embryos (Guidance note 15; General Direction 0009)
The following items of laboratory plasticware used by the centre are not CE marked: 1ml, 5ml and 10ml volumetric pipettes; 5ml and 14ml test tubes (SLC T30; see recommendation 5).

The centre is non-compliant with HFEA requirements to validate all critical equipment. The following critical equipment has not been validated: the primovision timelapse video system; some of the cryostorage dewars; the laser used for assisted hatching. These pieces of equipment have all been recently acquired. It was also unclear whether dewars used for the transport of frozen gametes and embryos are validated (SLC T24; see recommendation 1).

Process validation (Guidance note 15)
The centre is non-compliant with HFEA requirements to validate all critical processes (SLC T72; see recommendation 2). Process validation ensures that all processes are effective and do not render the gametes or embryos clinically ineffective or harmful to the recipient.

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 certificate number T/1094/7).

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, before treatment, the welfare of any child who may be born as a result of treatment and of any other child who may be affected by the birth, are broadly 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

Welfare of the child (Guidance note 8)
In one of the five patient records reviewed, the final page of a WoC assessment form was not present, thus evidence that a review of the WoC assessment had been made before treatment was unavailable (SLC T56). The inspection team considered that this was probably due to the final page of the WoC assessment form being lost (SLC T47, see recommendation 8) rather than that the assessment had not been completed, since the centre's audit of the records of 64 patients treated in the year to 31 August 2014, showed that all the records reviewed contained appropriate WoC assessments.

Embryo testing

Preimplantation genetic screening
Embryo testing and sex selection

What the centre does well

Preimplantation genetic screening (Guidance note 9); Embryo testing and sex selection (Guidance note 10)
The centre does not undertake embryo testing.

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

2. The experience of patients

Patient feedback

What the centre does well

During the inspection visit, no patients wished to provide feedback to the inspectors. Twenty patients have however provided feedback directly to the HFEA in the time since the last inspection. Feedback was very positive with 18 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 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.
- Responds effectively to patient feedback.

What the centre could do better

Nothing identified at this inspection.

Treating patients fairly

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

What the centre does well

Treating patients fairly (Guidance note 29)

The centre's procedures are compliant with the HF&E Act 1990 (as amended) and 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 consents to licensed treatment activities and/or legal parenthood.

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

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

- care is taken when selecting egg providers donating for benefits in kind

- egg providers are fully assessed and medically suitable, and
- the benefit offered is the most suitable for the egg provider and recipient(s) (where relevant).

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

Complaints (Guidance note 28)
The centre's procedures are broadly 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

Complaints (Guidance note 28)
Complainants must address written complaints to the local hospital trust Customer Services team, who are not subject to the centre's licence. Patients cannot make a formal written complaint to a person from the centre. A letter of complaint could be taken to imply that the complainant consents to the disclosure of their identifying information, but the inspection team were concerned that such consent may not be freely given, since patients are not provided with the option to complain to a person operating under the auspices of the HFEA licence. The inspection team notes CoP Guidance 28.4 which recommends 'The centre should nominate a member of staff to act as complaints officer' and that such a complaints officer is subject to the centre's licence (see recommendation 9).

Information

What the centre does well

Information (Guidance note 4; Chair's Letter CH(11)02)
The centre's procedures for providing information to patients and / or donors are broadly 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
The centre does not provide information to patients about legal parenthood options, consent to disclosure and WoC assessment, prior to the consent forms and the WoC assessment form being given to patients. Patients take these documents away to complete them and they are reviewed at the next consultation. This puts the centre at risk of failing to provide effective information to patients regarding the important content of these forms. The inspection team notes that information on these matters may be

provided verbally to patients but also that information must be given to patients regarding consent to disclosure before consent is provided (CoP Guidance 5.27), on welfare of the child assessment before treatment is offered (CoP Guidance 4.2) and on legal parenthood options before treatment is provided (SLC T60 and 61; see recommendation 10).

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.

The partners of women treated with donated gametes or embryos, where the couple are neither married nor in a civil partnership, must give their consent in order to become the legal parent of any child born. If this consent is not properly taken, it can have serious consequences, such as the partner having to adopt any child born in order to become the legal parent. 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. On this inspection we reviewed the centre's audit and found that it had been performed according to the method specified by the HFEA and that actions had been taken, if necessary, in response to the audit findings.

Disclosure of information, held on the HFEA Register, for use in research (General Direction 0005)
The Register is a rich source of information about assisted reproductive technologies (ART) which can be used by researchers to improve knowledge about the health of patients undergoing ART and those born following ART treatment. The HFEA is permitted to disclose non-identifying information to researchers but patient-identifying information can only be provided with the consent of the patients. Therefore, it is important that patients are asked to provide their consent and that their wishes are accurately recorded and passed on to the HFEA. The centre's procedures for doing this ensure that the HFEA holds an accurate record of consents to disclosure to researchers, so that patient-identifying information is only released to researchers with the consent of the patient.

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

3. The protection of gametes and embryos

Respect for the special status of the embryo

What the centre does well

The centre's procedures are compliant with the requirements of the HF&E Act 1990 (as amended). 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 the gametes and embryos are stored appropriately to maintain their quality and safety. Furthermore, the centre only stores gametes and embryos in accordance with the consent of the gamete providers. The storage of gametes and embryos is an important service offered by fertility clinics, as it can enable patients to preserve their fertility prior to undergoing other medical treatment such as radiotherapy. The storage of embryos not required for immediate use also means that women can undergo further fertility treatment without further invasive procedures being performed.

What the centre could do better

Nothing identified at this inspection.

Use of embryos for training staff (Guidance note 22)
What the centre does well 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. The centre may soon commence using embryos in biopsy training as it is seeking to develop an embryo testing service and is also a training centre for embryologists. This new training activity is included in the patient information related to the use of embryos in training.
What the centre could do better No non-compliances were identified at this inspection.

4. Information management

Record keeping
Obligations and reporting requirements

What the centre does well

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

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

The HFEA Register audit team found no evidence of problems with the timeliness and accuracy of the centre's submission of data to the Register.

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

Section 3: Monitoring of the centre's performance

Following the interim inspection in March 2013, recommendations for improvement were made in relation to no areas of critical non-compliance, two areas of major non-compliance and no areas of 'other' non-compliance.

The PR provided information and evidence that both of the recommendations were implemented within the prescribed timescales. Equipment validation was an issue at the last inspection and is so at this inspection, but this is due to a failure to validate newly acquired equipment effectively, as discussed elsewhere in this report (page 9), rather than to the PR not implementing the recommendations of the last inspection report.

On-going monitoring of centre success rates

The centre has not been sent any risk tool emails regarding its performance in terms of treatment success rates.

Areas of practice requiring action

The section sets out matters which the Inspection Team considers may constitute areas of non compliance. These have been classified into critical, major and others. Each area of non-compliance is referenced to the relevant sections of the Acts, Regulations, Standard Licence Conditions, General 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
1. The following critical equipment has not been validated: the primovision timelapse video system; some cryostorage dewars; the laser system used for assisted hatching. All these pieces of equipment have been recently acquired. It was also unclear whether the the transport dewar used for inter-centre movements of frozen gametes and embryos is validated (SLC T24).	The PR must ensure all critical pieces of equipment used by the centre are validated. The PR should provide a list of critical equipment acquired in the last two years including the date of validation or the planned date by which validation is expected to be complete. The list should be provided to the HFEA by the time the report is considered by a licensing committee. The PR should provide monthly updates to the HFEA on	We are putting together a list of all critical equipment including the primovision timelapse video system, cryostorage dewars and the laser system for assisted hatching. Validation will be complete by 25th May 2015 at the latest.	29 January 2015: The PR has committed to implement the recommendation within the required time limit. This non-compliance was also seen at the last renewal inspection. The implementation of each aspect of the recommendation will therefore be monitored closely by the Executive to ensure completion within the required time limit. Further actions are required.

This non-compliance has been escalated from a major to a critical non-compliance because equipment validation was a non-compliance at the interim inspection in March 2013.	progress in completing and revising validation documentation. It is expected that validation will be prioritised on the basis of risk and that validation will be complete by 25 May 2015. On completion of the validation programme the HFEA will ask for a sample of validation documents to be submitted for review.		
2. The centre is non-compliant with HFEA requirements to validate all critical processes (SLC T72). This non-compliance has been escalated from a major to a critical non-compliance because it was noted at the last renewal inspection in January 2011.	The PR must ensure all critical processes used by the centre are validated. The PR should provide a list of all critical processes including the date of validation or the planned date by which validation is expected to be complete. The list should be provided to the HFEA by the time the report is considered by a licensing committee. The PR should provide monthly updates to the HFEA on progress in completing validation. It is expected that validation will be prioritised on the basis of risk associated with the procedure and that	Validation of all critical processes which will be complete by 25th May 2015 at the latest.	29 January 2015: The PR has committed to implement the recommendation within the required time limit. This non-compliance was also seen at the last renewal inspection. The implementation of each aspect of the recommendation will therefore be monitored closely by the Executive to ensure completion within the required time limit. Further actions are required.

	validation will be complete by 25 May 2015. On completion of the validation programme the HFEA will ask for a sample of validation documents to be submitted for review.		

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
3. In one case reviewed in which donated sperm was used, the donor had not been screened for sickle cell disease even though he was from an at-risk population (SLC T52).	The PR should review the centre's procedure for releasing imported donated sperm for treatment and ensure it includes a review, for each donor, of the potential need for additional screening tests. The PR should also ensure an equivalent review is included in the centre's gamete donor recruitment process. The revised procedures should be provided to the HFEA by 25 February 2015. The PR should also audit all donors used by the centre in the last three years, to assess whether any other donors have been used in treatment even	We are reviewing our procedure for releasing imported donated sperm for treatment and will be implementing a review, for each donor, of the need for additional screening tests. The completed revised procedure will be provided to the HFEA by 25th February at the latest. We are currently auditing all donors used by us in the last 3 years to assess whether any other donors have been used in treatment who should have been screened for additional risks.	29 January 2015: The PR has committed to implement the recommendation within the required time limit and actions to do this have already commenced. The implementation of the recommendation will be monitored by the Executive to ensure completion within the required time limit. Further actions are required.

	though they have not been screened for a condition which they are at risk of due to their origins, medical history or recent travel history. The results of this audit, including any corrective actions with timescales in response to adverse findings, should be provided to the HFEA by 25 February 2015. The PR should also review the centre's TPAs with donor recruiting centres, to ensure they specify the screening tests to be performed to maintain compliance with SLC T52. The results of this review, including any corrective actions with timescales, should be provided to the HFEA by 25 February 2015.		
4. The centre has not audited the activities and processes authorised by the licence and other associated activities, against compliance with the regulatory requirements and their own approved	The PR must ensure that the activities and processes authorised by the licence and other associated activities, are audited against compliance with the regulatory requirements and the centre's own approved protocols.	We are fully reviewing the last code of practice to identify activities and processes authorised by the licence against compliance with the regulatory requirements and our own approved protocols and will publish a revised audit	29 January 2015: The PR has committed to implement the recommendation within the required time limit and actions to do this have already commenced. The implementation of the

protocols, in the last two years (SLC T36).	A revised audit schedule to accomplish this by 25 May 2015 should be provided to the inspector by the time this report is considered by a licensing committee. The PR should provide monthly updates to the HFEA on progress in completing the audit schedule by 25 May 2015. On completion of the audit schedule the HFEA will ask for a sample of audit reports to be submitted for review.	schedule and report to you within the next 2 weeks to present to the licensing committee. The audit schedules will be completed by 25th May 2015	recommendation will be monitored by the Executive to ensure completion within the required time limit. Further actions are required.
5. The following items of laboratory plasticware used at the centre are not CE marked: 1ml, 5ml and 10ml volumetric pipettes; 5ml and 14ml test tubes (SLC T30).	The PR should ensure that CE marked materials are used wherever they are available. We would not recommend the implementation of precipitous changes that might impact on the quality of treatment. In consideration of this, the PR should provide the HFEA with a list of all laboratory plasticware used by the centre which is not currently CE marked, including the anticipated time by which a CE	We are reviewing all equipment used in the lab and will provide the HFEA with a list of plasticware which is currently not CE marked and the anticipated time by which CE marked is expected to be obtained or the action to be taken within the next year to ensure that all plasticware is CE marked by the 25th February 2015 by the latest.	29 January 2015: The PR has committed to implement the recommendation within the required time limit and actions to do this have already commenced. The implementation of the recommendation will be monitored by the Executive to ensure completion within the required time limit. Further actions are required.

	mark is expected to be obtained or the action that will be taken to ensure, within the next year, that all plasticware used in the centre is CE marked. The list should be submitted to the HFEA by 25 February 2015.		

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
6. Laboratory cleaning is not consistently documented in the records maintained by the centre. The laboratory appeared however to be clean at the time of the inspection (SLC T26).	The PR should take action to ensure that records are kept of the cleaning and disinfection of the laboratory and all relevant equipment. The PR should advise the HFEA of the actions taken to ensure this is done by the time this report is considered by a licensing committee: the PR should also provide a summary of actions taken to ensure that this non compliance does not recur by 25 February 2015.	We are instituting a cleaning record (in book form) to record all cleaning and disinfection of the laboratory and all relevant equipment. This will be ready within the next two weeks to present to the licensing committee.	29 January 2015: The PR has committed to implement the recommendation within the required time limit and actions to do this have already commenced. The implementation of the recommendation will be monitored by the Executive to ensure completion within the required time limit. Further actions are required.
7. The centre does not have a SOP to follow for collecting patient consent to legal parenthood before treating a woman with donor sperm or embryos (SLC T33b).	The PR should develop a SOP for the process of collecting consent to legal parenthood from patients using donated sperm or embryos. The PR should provide the SOP to the HFEA by 25 February 2015.	We are developing a SOP for the process of collecting consent to legal parenthood from patients using donated sperm or embryos. Because of the legal uncertainty about parenthood where donated embryos are used to treat single women we will not be offering embryo	29 January 2015: The PR has committed to implement the recommendation within the required time limit and actions to do this have already commenced. The PR has stated that the centre will not be offering donated embryos to single women for use in their

		donation to single women. The SOP will be presented to the HFEA by 25th February 2015.	treatment. The inspection team recommend this course of action is reviewed by the PR's legal advisors for compliance with relevant equalities legislation before he considers its implementation. The implementation of the recommendation will be monitored by the Executive to ensure completion within the required time limit. Further actions are required.
8. In one of the five patient records reviewed, the final page of a WoC assessment form was not present and was presumed lost from the record (SLC T47).	Only one such record was found by the inspection team and the centre's audit of 64 patient records, treated in the year to 31 August 2014, showed that all contained complete WoC assessments. Therefore no recommendation is made regarding this non-compliance because it is likely to be an isolated event.		No actions were required.
9. Complainants must address written complaints to the local hospital trust Customer Services team, who are not subject to the	The PR should put in place a complaints process which protects patient confidentiality and consent. The complaints process should not force	We are looking at our complaints procedure and have temporarily appointed our Business Manager Paul Wylie as our Complaints/Customer	29 January 2015: The PR has implemented the recommendation within the required time limit by providing a complaints process within

centre's licence. Patients cannot make a formal written complaint to a person from the centre. A letter of complaint could be taken to imply that the complainant consents to the disclosure of their identifying information, but the inspection team were concerned that such consent may not be freely given, since patients are not provided with the option to complain to a person operating under the auspices of the HFEA licence. The inspection team notes CoP Guidance 28.4 which recommends 'The centre should nominate a member of staff to act as complaints officer' and that such a complaints officer is subject to the centre's licence.	patients to disclose their identifying information to unlicensed persons. The PR should document a plan to implement this recommendation and provide it to the HFEA by the time this report is considered by a licensing committee. The plan should be implemented by 25 February 2015 and the HFEA notified of the final actions.	Service Manager and will try to ensure that complaints are fully completed 'in house'. However, as an NHS establishment we also have a statutory duty under the NHS complaints procedure and, if patients are not happy with the outcome of our internal complaints process they have the right to go to the Hospital Customer Care department, if they choose and, if they are unhappy there, to go to the Complaints Ombudsman under Statutory Legislation. This is not negotiable	the centre, albeit the centre's complaints manager is only 'temporarily appointed'. The inspection team fully appreciate and respect the right of patients to make complaints outside of the centre. It is important however that patients can choose whether to make complaints to a licensed person, or to follow a complaints process outside of the centre. Patients should be informed regarding the impact of their choice of complaints process on the restrictions on the disclosure of their identifying information provided by the HF&E Act 1990 (as amended). The final implementation of the recommendation will be monitored by the Executive to ensure completion within the required time limit. Further actions are required.
10. The centre does not provide information to	The PR must ensure that all required information is	We are reviewing the mechanisms by which	29 January 2015: The PR has committed to implement the

patients about legal parenthood options, consent to disclosure and WoC assessment, prior to the consent forms and the WoC assessment form being given to patients. Patients take the forms away to complete them and the completed forms are reviewed at a subsequent consultation. This puts the centre at risk of failing to provide effective information to patients regarding the important content of these forms. The inspection team notes that information on these matters may be provided verbally but also that information must be given to patients regarding consent to disclosure before consent is provided (CoP Guidance 5.27), on welfare of the child assessment before treatment is offered (CoP Guidance 4.2) and on legal parenthood options before treatment is provided (SLC T60 and 61).	provided to patients within the timeframes specified in the HFEA CoP. The PR should review the mechanisms by which information, notably regarding legal parenthood options, consent to disclosure and WoC assessment, is given to patients to ensure all required information is provided in a timely manner. A summary of the review including the corrective actions taken should be submitted to the HFEA by 25 February 2015.	information, notably regarding legal parenthood options, consent to disclosure and WoC assessment, is given to patients to ensure that all required information is provided in a timely manner, before treatment is started. The summary of this review including corrective actions taken will be submitted to the HFEA by 25th February 2015.	recommendation within the required time limit and actions to do this have already commenced. The implementation of the recommendation will be monitored by the Executive to ensure completion within the required time limit. Further actions are required

Reponses from the Person Responsible to this inspection report