Executive Licensing Panel - minutes

Centre 0153 (Homerton Fertility Centre)

Renewal Inspection Report

Thursday, 12 July 2018

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Caylin Joski-Jethi (Chair) Niamh Marren Kathleen Sarsfield Watson	Head of Intelligence Regulatory Policy Manager Communications Manager
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers		

Declarations of interest

- Members of the panel declared that they had no conflicts of interest in relation to this item.

The panel had before it:

- 8th edition of the HFEA Code of Practice
- Standard licensing and approvals pack for committee members.

1. Consideration of application

1.1. The panel considered the papers, which included a completed application form, inspection report and licensing minutes for the last three years.

1.2. The panel noted that Homerton Fertility Centre has held a treatment and storage licence with the HFEA since 1995 and provides a full range of fertility services.

1.3. The panel noted that, in the 12 months to 31 January 2018, the centre has provided 1269 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a large sized centre.

1.4. The panel noted that HFEA held register data, between November 2016 and October 2017, shows the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 14%. This represents performance that is not likely to be statistically different from the 10% multiple live birth rate target.

1.5. The panel noted that for IVF and ICSI, HFEA held register data, for the period November 2016 to October 2017, shows the centre's success rates are in line with the national average, with the exception of IVF treatments involving fresh embryos in women under 38 years old which are lower than average at a statistically significant level.

1.6. The panel noted that in 2017, the centre reported 74 cycles of partner insemination with 10 pregnancies. This represents a clinical pregnancy rate of 13%, which is in line with the national average.

1.7. An inspection was carried out at the centre on the 6 and 7 March 2018.

1.8. The panel noted that at the time of the inspection, there were eight major areas of non-compliance regarding pregnancy success rates, witnessing, medicines management, imports and exports, traceability, the Quality Management System (QMS), consent to storage and CE marking. There were also eight 'other' non-compliances concerning pre-operative assessment and the surgical pathway, equipment and materials, staff, disclosure of information, held on HFEA register for use in research, screening of patients, record keeping and documentation and obligations and reporting requirements. The panel noted that since the inspection, the Person Responsible (PR) had fully implemented the recommendation with regards to CE markings.

1.9. The panel noted that the PR had given a commitment to fully implementing the outstanding major areas of non-compliance regarding pregnancy success rates, witnessing, medicines management, imports and exports, traceability, and the QMS alongside the 'other' areas of non-compliance concerning pre-operative assessment and the surgical pathway, equipment and materials, staff, disclosure of information, held on HFEA register for use in research, screening of patients, record keeping and documentation and obligations and reporting requirements.

1.10. The inspection team noted the success rates for IVF treatments involving fresh embryos in women under 38 years are below the national average and this was identified as an area of concern at the previous inspection. The PR has previously investigated the low success rates and believes it due to the centre treating a higher than normal proportion of patients with poor prognosis. In September 2015 the centre moved to an elective frozen embryo transfer policy (as opposed to fresh embryo transfer in the same cycle of treatment) for patients who responded well to ovarian stimulation. The PR provided information on inspection that currently approximately one third of women under the age of 38 undergo elective frozen embryo transfer and that there is a good clinical pregnancy rate for this group of patients.

1.11. The panel noted that, as fresh embryo transfer is still indicated for some patients, the PR is urged to monitor and continue to strive to improve success rates for those patients. The PR has taken

steps to introduce changes to improve success rates overall and specifically in this group of patients and has reiterated his commitment to keeping these success rates under review. The inspection team commended the centre on lowering their multiple pregnancy rate and, in so doing, reduce the single biggest risk of infertility treatment.

1.12. The panel noted that, due to the number of non-compliances and recurrences of some non-compliances, a Management Review Meeting was held on 2 May 2018 in accordance with the HFEA's Compliance and Enforcement Policy to consider whether there are any serious or urgent risks to patients and the safety of gametes and embryos. Significant improvement is required for the centre to reflect suitable practices and the PR is encouraged to review the centre's QMS to ensure that it can be used to best effect to monitor and improve the services provided to patients.

1.13. A further Management Review Meeting was held on 7 June 2018 to consider the PR's responses to addressing the non-compliances and implementing the recommendations made in the licence renewal inspection report. The inspection team referred to HFEA's Guidance on Licensing and considered the balance of evidence concerning the centre's non-compliances identified on inspection.

1.14. The panel noted the inspectorate's recommendation to renew the centre's treatment and storage licence for a period of three years, with an announced interim inspection to be undertaken within the first year to ensure that the recommendations made in this report have been effectively implemented. The centre's inspector will continue to monitor the centre's performance and the implementation of this report's recommendations within the required timescales.

2. Decision

2.1. The panel was pleased to see the reduction in the centre's multiple pregnancy rate since the last inspection. However, the panel expressed concern regarding the number and extent of non-compliances identified at the renewal inspection, impacting on the high quality of care and safety of patients.

2.2. The panel decided to adjourn renewal of the centre's licence, requesting the matter to be referred to the Licensing Committee for consideration. The panel noted that further updates on pregnancy success rates, witnessing, medicines management, imports and exports, traceability, the QMS, consent to storage, pre-operative assessment and the surgical pathway, multiple births, equipment and materials, staff, disclosure of information held on the HFEA register, for use in research and record keeping and documentation are due for receipt by 6 July 2018, requesting the inspector to provide the Licensing Committee with progress on these non-compliances.

2.3. The panel agreed to issue Special Directions under Section 24 (5A)(b) of the HF&E Act 1990 (as amended), to permit the continuation of licensed activity upon expiry of the centre's current licence, to allow time for the renewal to be considered by the Licence Committee and for the administration of the outcome of their consideration to be completed within the usual timeframe. These Special Directions would come into force on 1 September 2018 and would remain in force until any new licence comes into effect, or to 30 November 2018, whichever is sooner.

3. Chair's signature

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

Signature

Name

Caylin Joski-Jethi

Date

16 July 2018

Inspection Report

Purpose of the Inspection Report

This is a report of an inspection, carried out to assess whether this centre complies with essential requirements in providing safe and high quality care to patients and donors. The inspection was scheduled (rather than unannounced) and the report provides information on the centre's application for a renewal of its existing licence. Licences are usually granted for a period of four years. The Authority's Executive Licensing Panel (ELP) uses the application and this report to decide whether to grant a new licence and, if so, whether any additional conditions should be applied to the licence.

Date of inspection: 6 and 7 March 2018

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: Shanaz Pasha (lead), Karen Conyers, Kathryn Mangold and Mhairi West (observer). Clare Ettinghausen (observer). Register team: Chris Hall, Zakia Ezzouyar, Finnian Bamber (observer).

Date of Executive Licensing Panel: 6 July 2018

Centre name	Homerton Fertility Centre
Centre number	0153
Licence number	L/0153/15/a
Centre address	Homerton University Hospital NHS Trust, Homerton Row, London, E9 6SR, United Kingdom
Person Responsible	Mr Anil Gudi
Licence Holder	Miss Tracey Fletcher
Date licence issued	1 September 2014
Licence expiry date	31 August 2018
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:

The Homerton Fertility Centre has held a Treatment and Storage licence with the HFEA since 1995 and provides a full range of fertility services.

The centre provided 1269 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 January 2018. In relation to activity levels this is a large centre.

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

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period November 2016 to October 2017 show the centre's success rates are in line with national averages with the following exceptions:

- IVF treatments involving fresh embryos in women under 38 years old are lower than average at a statistically significant level (see recommendation 1).

In 2017, the centre reported 74 cycles of partner insemination with 10 pregnancies. This represents a clinical pregnancy rate of 13%, which is in line with the national average.

Multiple births[2]

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

Between November 2016 to October 2017 the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 14%. This represents performance that is not likely to be statistically different from the 10% multiple live birth rate target.

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

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

Summary for licensing decision – pre review of draft by PR

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, standard licence condition (SLCs) and the HFEA Code of Practice (CoP), the inspection team considers that it has sufficient information to conclude that:

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

The ELP is asked to note that at the time of the inspection there were a number of areas of practice that required improvement, including eight major and eight 'other' areas of non-compliances. Since the inspection visit, the PR has provided assurance that actions have been taken to implement the following recommendation:

Major areas of non-compliance:

- The PR should ensure that CE marked medical devices are used where possible.

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

Major areas of non-compliance:

- The PR should seek to improve the pregnancy success rates for IVF treatments involving fresh embryos in women under 38 years old.
- The PR should ensure that witnessing checks are documented.
- The PR should ensure compliance with the Trust's protocols and best practices guidelines for safe handling of controlled drugs.
- The PR should review the centre's procedures for import and export of gametes and/or embryos to compliance with General Direction 0006 before gametes and/or embryos are imported or exported.
- The PR should establish documented procedures to ensure that all gametes and embryos and critical equipment are traceable from procurement, to patient treatment or disposal. The PR should ensure that all containers used in the course of procurement, possessing, use and storage of gametes are labelled with the patient's full name and a further identifier.
- The PR should ensure that the centre's QMS and auditing processes are effective
- The PR should ensure that there is consent in place for all gametes and embryos that are in storage.

'Other' areas that requires improvement:

- The PR should review practices related to the sign in processes before induction of anaesthesia

- The PR should ensure that a clear explanation of the reasons for transferring more than one embryo is documented in the patient records.
- The PR should ensure that the validation of all equipment is documented and that processes for monitoring of critical equipment are effective.
- The PR should ensure that assessments of competence in obtaining consent to storage for oncology patients are undertaken and documented.
- 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 ensure with immediate effect that patients and their partners are assessed for possible past or present Ebola virus exposure or infection
- The PR should ensure that the centre maintain a record of by whom, the patient/partner has been reliably identified.
- The PR should ensure that all licensed treatment activity is reported to the Authority within the timeframe required by General Direction 0005

Recommendation to the Executive Licensing Panel

The centre has eight major areas of concern.

The inspection team notes the success rates for IVF treatments involving fresh embryos in women under 38 years are below the national average. Success rates in this group of women was identified as an area of concern at the previous inspection. The PR has previously investigated the low success rates and believes it due to the centre treating a higher than normal proportion of patients with poor prognosis. In September 2015 the centre moved to an elective frozen embryo transfer policy (as opposed to fresh embryo transfer in the same cycle of treatment) for patients who responded well to ovarian stimulation. The PR provided information on inspection that currently approximately one third of women under the age of 38 undergo elective frozen embryo transfer and that there is a good clinical pregnancy rate for this group of patients. However, as fresh embryo transfer is still indicated for some patients, the PR is urged to monitor and continue to strive to improve success rates for those patients. The PR has taken steps to introduce changes to improve success rates overall and specifically in this group of patients and has reiterated his commitment to keeping these success rates under review; see recommendation 1. The inspection team commends the centre on lowering their multiple pregnancy rate and, in so doing, reduce the single biggest risk of infertility treatment.

Due to the number of non compliances and recurrences of some non compliances, a Management Review Meeting was held on 2 May 2018 in accordance with the HFEA's Compliance and Enforcement Policy to consider whether there are any serious or urgent risks to patients and the safety of gametes and embryos. Significant improvement is required for the centre to reflect suitable practices. The PR is encouraged to review the centre's QMS to ensure that it can be used to best effect to monitor and improve the services provided to patients. A management review meeting was held on 7 June 2018 to consider the PR's responses to addressing the non-compliances and implementing the recommendations made in the licence renewal inspection report. The inspection team has referred to HFEA's Guidance on Licensing and considered the balance of evidence concerning the centre's non-compliances identified on inspection. The inspection team recommends the renewal of the centre's Treatment and Storage licence for a period of three years, with an announced interim inspection to be undertaken within the first year to ensure that the recommendations made in this report have been effectively implemented.

The centre's inspector will continue to monitor the centre's performance and the implementation of this report's recommendations within the required 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)** It is important that patients receive treatment using the correct gametes or embryos. The centre's procedures for double checking the identification of gametes and embryos and the patient to whom they relate are partially compliant with HFEA requirements.
What the centre could do better During an audit of records, the inspection team noted that one missing signature which was a check of dishes at the time of egg collection. SLCT71; see recommendation 2. The inspection team were concerned because this is a critical witnessing step and therefore there is no evidence of the check having taken place. The documentation of the witness checking of the man producing sperm samples for freezing is not consistently documented. The inspection team noted that the member of staff who performs the procedure, records the patient's passport or ID number but does not sign to confirm that check. SLC T71; see recommendation 2. The centre does not witness or record the discard of sperm after completion of treatment. SLC T71, SLC T99; see recommendation 2.

▶ **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 currently does not recruit, assess or screen donors therefore this area of practice was not reviewed at this inspection. The PR has confirmed that he will provide information to the centre's inspector should the commence donor recruitment activities.

Payments for donors (Guidance note 13; General Direction 0001)
The centre currently does not recruit donors, therefore this area of practice was not reviewed at this inspection.

Donor assisted conception (Guidance note 20)
It is important that centres use donated gametes or embryos from identifiable donors and keep records of donor characteristics. This is because patients using donated gametes and embryos in treatment and the parents of donor-conceived children, are able to access non identifying information regarding the donor from the clinic. Furthermore, donor-conceived persons are entitled to know non-identifying details about their donor and any donor-conceived genetic siblings they may have at the age of 16 years, and donor identifying information at 18 years.

The centre's procedures are compliant with HFEA requirements which ensure the donor-conceived and their parents will be able to receive all required donor-related information.

What the centre could do better
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 so that patients and staff are in safe surroundings that prevent harm.

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

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

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

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

Prescription of intralipid 'off label'
Intralipid is an intravenous nutritional supplement sometimes prescribed to facilitate IVF treatment in a particular subset of women. This centre does not prescribe intralipid therapy therefore requirements related to its use were not relevant at this inspection.

Pre-operative assessment and the surgical pathway (Guidance Note 25)
It is important to ensure that all patients are safely assessed and cared for pre, peri and post operatively. The centre has policies and procedures in place that are broadly compliant with professional body guidelines for pre-operative assessment and management of the surgical pathway.

Multiple births (Guidance note 7; General Direction 0003)
The single biggest risk of fertility treatment is a multiple pregnancy. The centre's procedures are broadly 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 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 they are appropriately labelled and are accompanied by enough information to permit them to be stored or used in treatment in a way that does not compromise their quality and safety.

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

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

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

Quality management system (QMS) (Guidance note 23)
The centre has a QMS that is partially 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 transport and satellite arrangements.

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

The centre is broadly 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
Medicines management (Guidance Note 25)
During the inspection, it was observed that a member of theatre staff removed a controlled drug from the controlled drug cupboard and drew this up into a syringe without checking it with a second qualified member of staff. This is contrary to best practice guidelines and the Trust's own controlled drugs policy.
Management of controlled drugs was an area of improvement identified at the last inspection. SLC T2 and Safer Management of Controlled Drugs. A guide to good practice in secondary care (England) (2007); see recommendation 3.

Pre-operative assessment and the surgical pathway (Guidance Note 25)
Observation of the patient "sign-in" process in theatre for one patient highlighted that members of staff had not followed Trust policy i.e. a nurse and operating department practitioner had undertaken the patient check rather than a nurse/operating department practitioner and the anaesthetist. SLC T2; see recommendation 9.

Multiple births (Guidance note 7; General Direction 0003)
In one set of patient records reviewed; the patient met eSET criteria but had undergone double embryo transfer but there was not a clear explanation of the reasons for transferring more than one embryo. General Direction 0003; see recommendation 10.

Imports and exports (Guidance note 16; General Direction 0006)
The centre could not provide evidence that they had complied with all the requirements of General Direction 0006 (Schedule 4, 1e) for one of two gamete import/export cases reviewed during the inspection. General Direction 0006; see recommendation 4.

Traceability (Guidance note 19)
Embryos that have been donated for use in training were recorded in the trainee's log but the patient's lab sheet indicated that the embryos had been discarded; SLC T99; see recommendation 5.

The centre does not record the discard of sperm after completion of treatment.
SLC T99; see recommendation 5.

One of five items currently in use in the laboratory was not correctly documented in the centre's traceability records. SLC T99; see recommendation 5.

No record is kept for traceability purposes of the transport incubator used during an egg collection. SLC T99; see recommendation 5.

The centre uses unlabelled dishes during the egg collection in main theatres. On the day of inspection, several unlabelled dishes were set out in the workstation. SLC T101; see recommendation 5.

The lids of dishes used for procedures are labelled with the patient's full name, date of birth and a further identifier, but the base of the dishes are only labelled with the patient's surname and further identifier only, not the patient's full name. SLC T101; see recommendation 5.

Quality management system (QMS) (Guidance note 23)
The centre own audit of stored donor samples had identified missing documents and screening results, however the findings had not prompted actions to investigate this further, and corrective actions had not been documented or implemented. SLC T36; see recommendation 6.

A trust audit of controlled drugs in theatre 3 had identified non-conformances but the centre did not have information or evidence relating to the implementation of the corrective actions. SLC T36; see recommendation 6.

A number of non-compliances identified at previous inspections have also been identified on this inspection. However, these areas for improvement were not identified by the centres own audits. SLC T32; see recommendation 6.

The centre's audit of witnessing practice did not include an evaluation of electronic witnessing system alerts. SLC T36; see recommendation 6.

Equipment and materials (Guidance note 26)
The centre is using a 5 well culture dish that is CE marked as an in vitro diagnostic device but the dish is being used as a medical device. SLC T30; see recommendation 7.

The validation of the centre's Embryoscope and transport incubator has not been documented. Centre staff described the validation that had been undertaken but this had not been documented. SLC T24; see recommendation 11.

Although laboratory equipment is subject to routine monitoring to ensure that the critical parameters are maintained within acceptable limits, the acceptable ranges documented on the record sheet do not match those that are used in practice. Centre staff undertake regular temperature mapping but the lab record sheets are not updated with these temperature ranges. Therefore, a number of apparently 'out of range' values had been recorded with no corrective actions, but none were necessary as the value was considered to be acceptable. SLC T24; see recommendation 11.

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.

Staff (Guidance note 2)

The centre is broadly compliant with HFEA requirements to have suitably qualified and competent staff, in sufficient number**,** to carry out the licensed activities and associated services. The centre has an organisational chart which clearly defines accountability and reporting relationships.

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

What the centre could do better

Staff (Guidance note 2)

Some laboratory staff are involved in taking consent to storage for oncology patients but they had not undergone any specific training or assessment of their competence in this area of practice. However, it is acknowledged that the member of staff designated for obtaining consent from oncology patients is very experienced and hence this non-compliance has been cited as an 'other'. SLC T15a; see recommendation 12.

Welfare of the child and safeguarding

What the centre does well

Welfare of the child (Guidance note 8)

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

Safeguarding (Guidance Note 25)

The centre's procedures are compliant with safeguarding guidance. This ensures that the centre's patients and staff are protected from harm where possible.

What the centre could do better

Nothing identified at this inspection.

Embryo testing

Preimplantation genetic screening

Embryo testing and sex selection

What the centre does well

Preimplantation genetic screening (Guidance note 9);
Embryo testing and sex selection (Guidance note 10)
The centre does not undertake pre-implantation genetic screening, embryo testing and sex selection therefore this area of practice was not relevant to this inspection.

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

2. The experience of patients

Patient feedback

What the centre does well

During the inspection visit the inspector spoke to two patients who provided feedback on their experiences. The centre's most recent patient survey responses were also reviewed. Feedback was generally positive, with nine of the individuals providing written feedback giving compliments about the care 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;
- provides a clean and well organised environment for patient treatment;
- has staff who are supportive and professional;
- gives patients sufficient, accessible information to enable them to make informed decisions;
- maintains an effective system for responding to patient phone calls.

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) 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 and sperm sharing arrangements (Guidance note 12; General Direction 0001)

The centre does not currently undertake egg and sperm sharing arrangements therefore this area of practice was not relevant to this inspection.

Surrogacy (Guidance note 14)
The centre does not currently undertake treatments that require a surrogate therefore this area of practice was not relevant to this inspection.

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 are compliant with HFEA requirements. This ensures that the centre gives prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions.

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

Consent and disclosure of information, held on the HFEA Register, for use in research

What the centre does well

Consent (Guidance note 5;6)
The centre's procedures for obtaining consent are compliant with HFEA requirements with the exception noted under staffing in this report. This ensures that patients and donors have provided all relevant consents before carrying out any licensed activity.

Legal parenthood (Guidance note 6)
Where a couple to be treated with donated gametes or embryos is not married or in a civil partnership, both the woman and her partner must give written consent in order for the partner to become the legal parent of any child born. If this consent is not documented properly or if proper information is not provided or counselling offered prior to both parties giving consent, there may be doubt about the effectiveness of the consent and in some cases it may be necessary for a patient couple to obtain a court declaration to establish legal parenthood.

To provide assurance of the continued compliance and effectiveness of the centre's legal parenthood consenting procedures, the inspection team discussed these procedures with staff and reviewed the results of recent legal parenthood consenting audits. Six sets of records where treatment with donor sperm had recently been provided in circumstances where consent to legal parenthood was required were also audited by the inspection team. These activities enabled the inspection team to conclude that the processes used to collect legal parenthood consent at this centre are compliant with HFEA requirements.

Disclosure of information, held on the HFEA Register, for use in research (General Direction 0005)
It 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.

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

What the centre could do better

Disclosure of information, held on the HFEA Register, for use in research (General Direction 0005)
Seven discrepancies were found between the 23 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. CH(10)05 and General Direction 0005; see recommendation 13.

3. The protection of gametes and embryos

Respect for the special status of the embryo

What the centre does well

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

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

What the centre could do better

Nothing identified at this inspection.

Screening of patients and Storage of gametes and embryos

What the centre does well

Screening of patients (Guidance note 17)

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

Storage of gametes and embryos (Guidance note 17)

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

Screening of patients (Guidance note 17)

Centre staff make no consideration of possible past or present Ebola virus exposure or infection when assessing patients and their partners for treatment.

The likelihood of past or present Ebola exposure or infection is considered extremely unlikely, hence this non compliance being listed as an 'other'. SLC T50d; see recommendation 14.

Storage of gametes and embryos (Guidance note 17)
On the day of the inspection the centre did not have effective consent for the storage of cryopreserved sperm for one gentleman and embryos for one couple. Schedule 3, 8(1) HF&E Act 1990 (as amended); see recommendation 8.

A review of seven sets of patient records showed one case in which there was a period of lapsed storage consent between the expiry of the original storage consent and the signing of storage extension consent, with completion of the MPS form outside the required period. The Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009. SLC T79; see recommendation 8.

Use of embryos for training staff

What the centre does well

Use of embryos for training staff (Guidance note 22)
The centre's procedures for using embryos for training staff are compliant with HFEA requirements with the exception noted under traceability in this report.

Embryos are only used for the purpose of training staff in those activities expressly authorised by the Authority.

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

4. Information management

Record keeping and Obligations and reporting requirements

What the centre does well

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

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

The HFEA register audit team found some evidence of problems with the timeliness and accuracy of the centre's submission of data to the Register.

What the centre could do better

Record keeping and document control (Guidance note 31)
The centre does not maintain a record of how, and by whom, each patient/partner has been reliably identified. SLC T46b, see recommendation 15.

Obligations and reporting requirements (Guidance note 32; General Direction 0005)
Whilst all 130 IVF and 68 DI treatments reviewed at inspection had been reported to the HFEA 6% (8/130) of IVF and 26% 18/68) of DI treatments had been reported to the HFEA outside the period required by General Direction 0005.

A small number of minor data entry errors and omissions only were identified. SLC T41 and General Direction 0005; see recommendation 16.

Section 3: Monitoring of the centre's performance

Following the interim inspection in 2016, recommendations for improvement were made in relation to 3 areas of major non compliance and 4 'other' areas of non compliance.

The PR provided information and evidence that all of the recommendations were fully implemented within the prescribed timescales. However, some areas of improvement that have been noted at previous inspections have recurred and therefore identified at the recent licence renewal inspection, see recommendation 10.

On-going monitoring of centre success rates

In 2016, the centre was asked to review procedures for the provision of IVF treatment with fresh embryos in women under 38 years. The PR responded to the request and during discussions at the time of the inspection, provided a commitment to keep success rates in this group of patients under review.

Areas of practice requiring action

The section sets out matters which the Inspection Team considers may constitute areas of non compliance. These have been classified into critical, major and others. Each area of non compliance is referenced to the relevant sections of the Acts, Regulations, Standard Licence Conditions, General Directions or the Code of Practice, and the recommended improvement actions required are given, as well as the timescales in which these improvements should be carried out.

Critical area of non compliance

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

A critical area of non compliance is identified in the report by a statement that an area of practice is not compliant with requirements.

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

Major area of non compliance

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

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

A major area of non compliance is identified in the report by a statement that an area of practice is partly compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
1. Pregnancy success rates The centre's success rates for IVF treatments involving fresh embryos in women under 38 years old are lower than the national average at a statistically significant level. Success rates in this group of women was identified as an area of concern at the previous inspection. SLC T2.	The PR should seek to improve the pregnancy success rates for IVF treatments involving fresh embryos in women under 38 years old. The PR should commission an independent review of all clinical and laboratory practices and procedures that can have an impact on the pregnancy success rates for IVF treatments involving fresh embryos in women under 38 years.	We freeze a significant proportion of embryos of our under 38 years and the frozen embryo sucsses rates are higher than the national average We will be planning an external review on all clinical and laboratory practices and procedures that will have an impact on syucess rates and will aim to have one in July 2018. A full summary and actions will be provided to the HFEA after the review before the 6th	The Executive acknowledge the PR's commitment to implementing this recommendation. The executive awaits a summary report of the detailed action plan by 6 July 2016 and a summary report of the independent review by 6 January 2018.

	The review should include an action plan for addressing the success rates, a schedule for implementation and review of any corrective actions identified. The PR should provide the centres' inspector with a plan for commissioning an independent review by 6 July 2018. A summary of the independent review and action plan for the implementation of any recommendations to address the success rates should be provided to the centre's inspector by 6 January 2019.	of January 2016 and will review and implement the recommendations We have already contacted 2 senior specialists to arrange a date for a review	
2. Witnessing During an audit of records the inspection team noted that one missing signature which was a check of dishes at the time of egg collection	The PR should ensure that witnessing checks are documented. The PR should provide the centres' inspector with a plan as to how he will address the	1. The nurse on duty at Egg Collection performs patient identity check and the dish check at the same time. Then she signs in two places on the lab sheet, but in this	The Executive acknowledge the PR's commitment to addressing this area of non-compliance. The executive await a summary report of the detailed risk assessment by 6 July 2018 and a

The documentation of the witness checking of the man producing sperm samples for freezing is not consistently documented. The inspection team noted that the member of staff who performs the procedure records the patient's passport or ID number but does not sign to confirm that check. The centre does not witness or record the discard of sperm after completion of treatment. SLC T71 and SLC T99.	non-compliances noted on inspection when responding to the report. The PR should undertake a risk assessment of the procedures where a witness step was not documented and for the records of sperm freezing since the time of the last inspection to evaluate whether there has been any potential mismatches of gametes or embryos. The PR should also consider if a further review of records of treatments is indicated to consider whether there is additional missing documentation of witnessing steps. A summary report of the findings of the risk assessment should be provided to the centre's inspector by 6 July 2018 Soon after the inspection, centre staff informed the centre's inspector that lab sheets used for sperm freezing had been reviewed and updated so that the documentation of the	occasion forgot to sign in one place- the dish check. In addition each EC is performed with only one dish and the embryologist remove the dish and leave the theatre. A second embryologist then go for the next EC and start the whole precess from the start. The embryologists are now given instructions to check the lab sheet for all signatures before leaving the theatre. An audit will be done on witnessing signatures after 3 months 2. Sperm freezing is done by one embryologist who see the patient for collection of sample, obtaining consents and then the actual freezing procedure. There are two lab sheets involved in this procedure, Semen Collection and Analysis worksheet, and Semen Freezing Record. There is a box on the second form for the embryologist to sign, but not on the first one. Patient signs on the first form, and although we can	summary report of the audit by 6 October 2018.

	witnessing of the identity of the man providing sperm for freezing is now much clearer. Within three months the PR should audit the effectiveness of these changes to the lab sheets. A summary report of this audit should be provided to the centre's inspector by 6 October 2018.	identify the embryologist who witnessed the signature (from the second form) there was no signature box on the first form. We have now added a box for the embryologist to sign next to the patient signature on the form (LF96) 3. We now 'discard' all the sperm tubes on RI witnessing and we will audit this practice after 3-month period. We will send a risk assesment by 6th July and a completed audit by 6th October 2018	
3. Medicines Management During the inspection, it was observed that a member of theatre staff removed a controlled drug from the controlled drug cupboard and drew this up into a syringe without checking it with a second qualified member of staff. This is contrary to best practice guidelines and the Trust's own controlled drugs policy.	The PR should ensure compliance with the Trust's protocols and best practices guidelines for safe handling of controlled drugs. The PR should review processes, practices, staff training and medicines management updates in relation to the safe handling of controlled drugs in theatre. A summary of the findings of the review including corrective actions and the timescales for implementation	We have informed the directorate and the consultant incharge has been contacted . A review summary with action plan will be available as requested by 06-07-18 . We will ensure that an audit of controlled drugs by 6th October 2016	The Executive acknowledge the PR's commitment to addressing this non-compliance. The executive await a summary report of the review by 6 July 2018 and a summary report of the audit by 6 October 2018.

SLC T2, Safer Management of Controlled Drugs A guide to good practice in secondary care (England) (2007).	should be provided to the centre's inspector 6 July 2018. Within three months, the centre should carry out an audit of controlled drugs practices to ensure that the proposed corrective actions have been effective in ensuring compliance. A summary report of the findings of the audit should be provided to the centre's inspector by 6 October 2018.		
4. Imports and Exports The centre could not provide evidence that they had complied with all the requirements of General Direction 0006 (Schedule 4, 1e) for one of two gamete import/export cases reviewed. General Direction 0006 This was an area for improvement identified at the previous licence renewal inspection.	The PR should review the centre's procedures for import and export of gametes and/or embryos to ensure that evidence required, demonstrating compliance with General Direction 0006 is obtained before gametes and/or embryos are imported or exported. A summary of the review and any changes implemented as a result should be provided to the centre's inspector by 6 July 2018.	Consent forms CN57 (for sperm) and CN58 (for embryos) have been amended to include the requirement of General Direction 0006 (Schedule 4, 1e)- stating that the law governing the use of gametes and/or embryos and the parentage of any resulting child may not be the same in the country in which the receiving centre is situated as it is in the United Kingdom.	The Executive acknowledge the PR's response and actions taken to amend two consent forms. The PR however has not provided a commitment to reviewing all import and export processes, as recommended. This area of practice was a concern at previous inspections. The PR should undertake a detailed review of all import and export activities and not just the areas noted on

	The PR should audit the records relating to imports and exports of gametes or embryos six months after the implementation of corrective actions against compliance with General Direction 0006 and forward a summary of the audit to the centre's inspector by 6 January 2019.		inspection, to ensure that the centre's processes are robust. The executive await a summary report of the review by 6 July 2018
5. Traceability A number of issues were noted in relation to traceability practices: • Embryos that have been donated for use in training were recorded in the trainee's log but the patient's lab sheet indicated that the embryos had been discarded. No record is kept for traceability purposes of the transport incubator used during an egg collection. • The centre uses unlabelled dishes during the egg collection in main	The PR should establish documented procedures to ensure that all gametes and embryos and critical equipment used are traceable from procurement, to patient treatment or disposal. The PR should provide the centres' inspector with a plan as to how he will address the individual issues relevant to this non compliances noted on inspection. The PR should provide a summary of the review and action plan, with time scales for implementation, to the centre's inspector by 6 July 2018.	1. The practice has been changed to identify the eggs/embryos used for training on the lab sheet. The letter 'P' (Practice) next to the egg/embryo now denotes that it is used for training. The SOP is changed accordingly 2. A small incubator has been installed in the EC theatre outside the Flow Cabinet. All the new/empty dishes for ECs are kept in this incubator. Only one dish is taken out at a time from the incubator to the flow cabinet for the EC procedure.	The Executive acknowledge the PR's commitment to addressing this area of non-compliance and the actions taken. The PR however has not addressed the issue related to the traceability of the transport incubator used during egg collection. Th PR should provide confirmation of action taken to address this by 6 July 2018. As this area of non-compliance was identified at the previous inspections. The Executive recommends that the PR undertakes regular audits of this practice to ensure that corrective actions

theatres. On the day of inspection, several unlabelled dishes were set out in the workstation. • The lids of dishes used for procedures are labelled with the patient's full name, date of birth and a further identifier, but the base of the dishes are only labelled with the patient's surname and further identifier only, not the patient's full name SLC T99 and SLC T101. This was an area for improvement identified at the interim and renewal inspections.	The PR should ensure that all containers used in the course of procurement, possessing, use and storage of gametes are labelled with the patient's full name and a further identifier. While it is acknowledged that only one egg collection takes place at a time, the PR should consider the risks of not labelling all containers used during egg collection. The centre's inspector should be informed of any actions taken to mitigate the risks of misidentification as a result of the practices noted in this non-compliance by 6 July 2018	The SOP is updated with the new practice 3. The practice has been changed- the base of the dish is also written with the full name and the unit number. The SOP is updated with the new practice.	have been effective. A summary report of the initial audit(s) should be sent to the centre's inspector by 6 October 2018.
6. QMS The centre own audit of stored donor samples had identified missing documents and screening information, however the findings had not prompted action and review on inspection showed that corrective actions had not	The PR should ensure that the centre's QMS and auditing processes are effective. The PR should review the findings of audits performed since the last inspection to ensure that any corrective	1. The known sperm donor audit has identified some missing blood and screening test after the last sperm donation and after the quarantine period in the sperm freezing pack. These patients' original notes have been requested from	The Executive acknowledge the PR's response to addressing this area of non-compliance and the actions taken. The Executive await summary reports for the following:

been documented or implemented. A trust audit of controlled drugs in theatre 3 had identified non-conformances but the centre did not have information or evidence relating to the implementation of the corrective actions. A number of non-compliances identified at previous inspections have also been identified on this inspection. However, these areas for improvement were not identified by the centres own audits. The centre's audit of witnessing practice did not include an evaluation of electronic witnessing system alerts. SLC T32 and SLC T36.	actions have been identified and fully implemented. Confirmation that this action has been taken should be provided to the centre's inspector by 6 September 2018. The PR should ensure that the centres QMS and auditing processes are effective in identifying non conformances and developing corrective actions that will address the issues identified and improve processes and practices. The PR should conduct an audit of the centre's electronic witnessing system alerts since the time of the last inspection to assess whether any alerts may have resulted in an actual mismatch of gametes or embryos, or any identification errors. The PR should review the centre's processes to ensure that electronic witnessing system alerts are assessed regularly and update staff training and competency in	offsite storage and missing results have been recorded. From January 2018, the Unit has ceased the practice of sperm freezing for known donors. 2. RI witnessing system is in place to prevent any incidents in the workstations, but the alerts were not evaluated or audited. We have decided to include this as an annual audit in future. As requested by the inspection team we are currently performing a 3-month audit on the RI witnessing alerts and this will be submitted by July 6th.	• Review of all audit findings since the last inspection to ensure that corrective actions identified have been implemented. • Review of auditing processes. • Review of all electronic witnessing system alerts since the time of the last inspection. • Review staff training and competency in relation to actions to be taken when a witnessing alert has been issued.

	using the electronic witnessing system in relation to actions to be taken when an alert has been issued. A summary report of the audits and review including corrective actions, and the timescales for their implementation, should be provided to the centre's inspector by 6 September 2018.		
7. CE marking The centre is using a 5 well culture dish that is CE marked as an in vitro diagnostic device but the dish is being used as a medical device. SLC T30.	The PR should ensure that CE marked medical devices are used where possible. We would not recommend precipitous changes that might impact on the quality of treatment, however, the PR should ensure that appropriately CE marked medical devices are used. The PR should ensure compliance with this requirement by 6 July 2018.	The 5-well dish has been changed to a new product that can be used as a medical device- CE mark with the number.	The PR Acknowledge the PR's commitment to implementing the recommendation. No further action is required.
8. Consent to storage On the day of the inspection the centre did not have	The PR should ensure that there is consent in place for	1. Sperm storage:The man had been in contact with us and he was meant to come	The Executive acknowledge the PR's response and

effective consent for the storage of cryopreserved sperm for one gentleman and embryos for one couple. Schedule 3, 8(1) HF&E Act 1990 (as amended) Soon after the inspection, centre staff informed the centre's inspector that the embryos had been discarded. A review of seven sets of patient records showed one case in which there was a period of lapsed storage consent between the expiry of the original storage consent and the signing of storage extension consent, with completion of the MPS form outside the required period. The Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009 and SLC T79.	all gametes and embryos that are in storage. The PR is reminded of guidance issued by the HFEA in CH (03)03 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. The PR should ensure storage is only extended beyond the statutory storage period when there is compliance with the 2009 storage regulations, both in relation to patient consent and evidence of either premature infertility or of likely premature infertility in the future. In any cases where there has been a failure to comply with the 2009 storage regulations, the PR should seek independent legal advice on how to proceed, including whether affected patients	and sign the form before the expiry date. Then he was in the hospital and could not come on the day and it was delayed. Now the consent has been signed. 2. Embryo storage: We discard gametes and embryos on the day after the completion of the full year. This set of embryos expires on 3/11/2019 but the women gave the withdrawal of storage consent on 27/2/17. The partner did not gave consent, so we left it for one years cooling period. We meant to discard them on 27/2/18 but actually discarded on 6/3/18, on the day of inspection when it was detected by the inspection team. 3. Lapsed storage consent between forms and MPS form: This had happened in the previous centre in 2014 and we received the samples in 2016. At the time of receipt the storage consents were in place and the cancer survivor	actions taken to achieve compliance.

	ought to be informed. Proposed actions in response to this advice should be forwarded to the HFEA for review prior to any action being taken. The outcome of this investigation, including the centre's intended actions and the timescales for their implementation should be submitted to the centre's inspector by 6 July 2018.	need this sperm for treatment, we cannot discard. Now we have discussed this with the legal department in the hospital. A decision is made not to accept samples in future from other centres if there is any gap in the storage consent, even if they have current consent in place. The SOP has been amended for receiving samples from other centres. We have asked our legal team . One of the cases came to us with valid consent. The extension of storage was done by another centre and the legal team looks at direction from the HFEA since , the patient is a cancer survivor .	

Other areas of practice that requires improvement

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

An 'other' area of non compliance is identified in the report by a statement that an area of practice is 'broadly' compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
9. Pre-operative Assessment and the Surgical Pathway Observation of the patient "sign-in" process in theatre for one patient highlighted that members of staff had not followed Trust policy i.e a nurse and operating department practitioner had undertaken the patient check rather than a nurse/operating department practitioner and the anaesthetist. SLC T2.	The PR should review practices related to the sign in processes before induction of anaesthesia. A summary of the findings of the review including corrective actions and the timescales for implementation should be provided to the centre's inspector by 6 July 2018 .	We have informed the directorate and the consultant incharge has been contacted . A review summary with action plan will be available as requested by 06-07-18 . We will ensure that an audit of controlled drugs by 6th October 2016 We plan to review practices related to the signing processes before induction	The Executive acknowledge the PR's commitment to addressing this recommendation and await a summary report of the review by 6 July 2018.
10. Multiple Births In one set of patient records reviewed; the patient met eSET criteria but had undergone double embryo transfer. However, there was not a clear explanation of the	The PR should ensure that a clear explanation of the reasons for transferring more than one embryo is documented in the patient records.	We will conduct a training workshop for all the relevant staff about SET policy . Any deviations will be explained in detail and noted	The Executive acknowledge the PR's commitment to addressing this recommendation and await a summary report of the review by 6 July 2018.

reasons for transferring more than one embryo in the patient records. General Direction 0003	The PR should review practices related to the recording of reasons for deviations from the multiple birth minimisation strategy. A summary of the findings of the review including corrective actions and the timescales for implementation should be provided to the centre's inspector by 6 July 2018.	This will be iuncluded in our Multiple pregnancy and SET audit . We plan to send a changed protocol and the training course by the 6th of JUly 2018	
11. Equipment and Materials The validation of the centre's Embryoscope and transport incubator has not been documented. Although laboratory equipment is subject to routine monitoring to ensure that the critical parameters are maintained within acceptable limits, the acceptable ranges documented on the record sheet are not accurate. Centre staff undertake regular temperature mapping but the lab record sheets are not	The PR should ensure that the validation of all equipment is documented and that processes for monitoring of critical equipment are effective. The PR should provide a list of all critical equipment including the date of validation or the planned date by which validation is expected to be complete. The list should be provided to the centre's inspector when responding to this report The PR should ensure that validations will be completed	1. All the essencial laboratory equipment except the transport incubators were validated. The EmbryoScope is currently under validation. The reports for the abobe will be submitted by 6th July. 2. Acceptable temperature ranges in the 'start up form' have been changed so that the set temperature values are not outside this range. The set temperatures are decided by temperature mapping of varies surfaces and the culture media inside the dish.	The Executive acknowledge the PR's response to this area of non-compliance. The PR has not provided a list of all critical equipment as requested and is reminded to do so. The Executive await a sample of validation documents by 6 September 2018 A summary report of the review of the centres equipment monitoring processes by 6 September 2018 is awaited.

updated with these temperature ranges. Therefore, a number of apparently 'out of range' values had been recorded with no corrective actions, but none were necessary as the value was considered to be acceptable. SLC T24.	by 6 July. On completion the validations a sample of validation documents should be provided to the centre's inspector for review. The PR should review the centre's processes for equipment monitoring to ensure that the issues identified on inspection are addressed. A summary of the findings of the review including corrective actions and the timescales for implementation should be provided to the centre's inspector by 6 September 2018.		
12. Staff Some laboratory staff are involved in taking consent to storage for oncology patients but they had not undergone any specific training or assessment of their competence in this area of practice. However, it is acknowledged that the member of staff designated for obtaining consent from oncology patients is very	The PR should ensure that assessments of competence in obtaining consent to storage for oncology patients are undertaken and documented. A summary of the evidence of the relevant assessments should be sent to the centre's inspector by 6 July 2018.	Training on taking consent is covered during our Tuesday teaching sessions. The next one is being planned in June. Lab staff are competent assessed in all laboratory procedures, and the competency on taking consent will be added to the list.We plan a consenting workshop around oncology . Assessment form will be	The Executive acknowledge the PRs commitment to implementing the recommendation and await evidence of assessments by 6 July 2018.

experienced and hence this non-compliance has been cited as an 'other'. SLC T15a.		prepared and all lab staff will be assessed by July 6th.	
13. Disclosure of information, held on the HFEA Register, for use in research. Seven discrepancies were found between the 23 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. CH(10)05 and General Direction 0005. (NB. The Centre's designated HFEA Form Returnee has been provided with the	The PR should ensure that the disclosure consent information supplied to the Authority accurately reflects that given and recorded on disclosure consent forms. The PR should correct the submissions that have been identified as being incorrect and confirm that this has been completed when responding to this report. The PR should review the centre's procedures to ensure that the disclosure consent information supplied to the Authority accurately reflects that given and recorded on patient's consent forms. A summary of the findings of the review including corrective actions and the timescales for implementation should be provided to the	Introduction of dedicated clinic and staff where consents will be checked. Role of sending in registration forms will be transferred from nursing to dedicated admin team members. Time scales 1.Initial review of staffing levels to support change by - 01.06.18 2. list of forms to be corrected and resent to HFEA obtained from HFEA audit team on 15-04-18 3. All forms to be resent by Admin amanger or in her absense operation manager by 01-06-18 This will be added to the audit schedule and the	The Executive acknowledge the PR's commitment to addressing this non-compliance and the actions taken. The executive await: • A summary report of the review of the centre's disclosure consent information procedures by 6 July 2018. • A summary audit report by 6 October 2018.

relevant patient and partner numbers so that the form data can be reviewed and corrected).	centre's inspector by 6 July 2018. The PR should conduct an audit six month after implementing any corrective actions, to confirm that the actions have had the desired effect. A summary of the audit should be provided to the centres inspector by 6 January 2019.	summary would be provided by 6th of January 2019	
14. Screening of patients Centre staff make no consideration of possible past or present Ebola virus exposure or infection when assessing patients and their partners for treatment. The likelihood of past or present Ebola exposure or infection is considered extremely unlikely, hence this non compliance being listed as an 'other'. SLC T50d	The PR should ensure with immediate effect that patients and their partners are assessed for possible past or present Ebola virus exposure or infection. The PR should consider, with expert advice if necessary, if there is any risk to patients resulting from the past failure to perform Ebola assessment. If risk is present, appropriate risk control measures should be implemented. The PR should inform the centre's inspector of the actions taken to implement	History sheet(FO02) already amended on 16-04-18 to include assessment of ebola for patient and partner. We plan to complete an audit by 6th of October 2018 We have asked for advice from the Microbiology consultant about the past risk to any donors	The Executive acknowledge the PR's commitment to addressing this non-compliance and actions taken. The Executive await a summary report of the expert advice and a summary report of the audit by 6 October 2018.

	this recommendation when responding to this report. Three months after implementing corrective actions, the PR should audit their effectiveness. A summary report of this audit should be provided to the centre's inspector by 6 October 2018.		
15. Record keeping and documentation The centre does not document by whom, each patient/partner has been reliably identified. SLC T46b.	The PR should ensure that the centre maintain a record of by whom, the patient/partner has been reliably identified. The PR should undertake a review of the centre's processes for establishing the identity of patients. A summary of the findings of the review including corrective actions and the timescales for implementation should be provided to the centre's inspector by 6 July 2018 Within three months, the centre should carry out an audit of records to ensure that	History sheet(FO02) amended on 16-04-18 to include signature of clinician we will audit the process for establishing identity and send it to the HFEA by 6th July 2018	The Executive acknowledge the PRs commitment for addressing this non-compliance and the actions taken. The Executive awaits a summary report of the audit by 6 October 2018.

	the proposed corrective actions have been effective in ensuring compliance. A summary report of the findings of the audit should be provided to the centre's inspector by 6 October 2018.		
16. Obligations and reporting requirements Whilst all 130 IVF and 68 DI treatments reviewed at inspection had been reported to the HFEA 6% (8/130) of IVF and 26% 18/68) of DI treatments had been reported to the HFEA outside the period required by General Direction 0005. A small number of minor data entry errors and omissions only were identified General Direction 0005 and SLC T41.	The PR should ensure that all licensed treatment activity is reported to the Authority within the timeframe required by General Direction 0005. The PR should review the centre's procedures used to submit licensed treatment data to identify and address the reasons for delayed submissions A summary of the findings of the review including corrective actions and the timescales for implementation should be provided to the centre's inspector when responding to this report. The PR should conduct an audit six month after implementing any corrective actions, to confirm that the actions have had the desired effect. A summary of the audit	In 2016 the responsibility for sending forms was changed from one person sending all to departments being responsible. All areas had a deputy except donor inseminations . Unfortunately key staff were on long term sick and a few areas where identyfied as needing improvement. Corrective changes had already been put in place :- The laboratory team are now responsible for sending donor insemination treatment forms as of September 2017 .	The Executive acknowledge the PR's commitment to addressing this non-compliance and actions taken. The Executive await a summary report of the audit by 8 October 2018.

	should be provided to the centres inspector by 6 October 2018.		

Reponses from the Person Responsible to this inspection report
We aim to follow the recommendation by the HFEA and adhere to the time scales as suggested by the HFEA. We request for direction from the HFEA where sperm storage was extended in another rclinics and sperm was transferred with relevant consents . while we have change our protocols, the legal team is requesting guidance on the HFEA position ,since discarding sperm will have a significant impact on the persons future fertility .