Licence Committee - minutes

Centre 0185 (CARE Manchester)
Renewal Licence

Thursday, 12 July 2018

HFEA, 10 Spring Gardens, London, SW1A 2BU

Committee members	Andy Greenfield (Chair) Ruth Wilde Kate Brian	
Members of the Executive	Dee Knoyle Richard Chamberlain Catherine Burwood	Committee Secretary Temporary Committee Clerk (Observer) Senior Governance Manager (Observer)
Legal Adviser	Graham Miles	Blake Morgan LLP
Specialist Adviser		
Observers		

Declarations of interest:

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

The committee had before it:

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

The following papers were considered by the committee:

- Renewal Inspection Report
- Renewal Application Form
- Email from the PR confirming application for embryo testing
- Submissions relating to an Adverse Incident
- Previous licensing minutes up to the last licence renewal:
  - Licence Committee - 10 November 2016 - Executive update
  - Executive Licensing Panel - 4 November 2016 - Variation of premises
  - Licence Committee - 8 September 2016 - Executive update
  - Licence Committee - 14 July 2016 - Interim inspection report
  - Executive Licensing Panel - 20 May 2016 - Variation change of Person Responsible
  - Executive Licensing Panel - 6 May 2016 - Variation of premises
  - Executive Licensing Panel - 21 March 2016 - Variation change of Licence Holder
  - Executive Licensing Panel - 30 May 2014 - Renewal inspection report

1. Background

1.1. CARE Manchester, centre 0185, is located in Manchester and is part of the CARE Fertility Group. The centre has held a licence with the HFEA since 1999 and provides a full range of fertility services including embryo testing.

1.2. The current licence was varied to reflect the following changes:

- Premises - further variation
- Premises
- Person Responsible (PR)
- Licence Holder (LH)

Interim Inspection

1.3. Following an interim inspection in March 2016, significant issues came to light relating to the centre's legal parenthood consent practices since the introduction of changes in this area in 2009. Immediately after this inspection, the Person Responsible (PR) resigned and a new PR was appointed by the Executive Licensing Panel at its meeting held on 20 May 2016.

1.4. The report of the interim inspection was considered by the Licence Committee in July 2016 and the Executive provided an update to the committee in September 2016 and November 2016. The PR had provided evidence that she had fully implemented the recommended actions, which assured the Executive that no further actions were required. The Licence Committee endorsed the Executive's recommendation for the continuation of the centre's licence with no additional conditions.

Renewal Inspection

1.5. The Executive carried out the renewal inspection of the centre on 17 and 18 April 2018.

1.6. During the renewal inspection, the Executive undertook a detailed review of an incident, which was reported after the interim inspection and occurred prior to the appointment of the current PR.

1.7. The Executive has now submitted the report of the renewal inspection for consideration by the Licence Committee.

2. Consideration of application

Renewal Inspection

Application

2.1. The committee noted that the centre had submitted an application for the renewal of the treatment (including embryo testing) and storage licence.

2.2. The committee noted that the application contains the supporting information required by General Direction 0008 and that the appropriate fee has been paid.

Inspection Process

2.3. The committee noted that in the 12 months to 28 February 2018, the centre provided 1430 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a large centre.

2.4. The committee noted that for IVF and ICSI, HFEA-held register data for the period 1 December 2016 to 30 November 2017 showed the centre's success rates were in line with national averages.

2.5. The committee noted that for the year 2017 the centre reported 19 cycles of partner insemination with two clinical pregnancies. This represented a clinical pregnancy rate that was consistent with the national average.

2.6. The committee noted that from 1 December 2016 to 30 November 2017, the centre's multiple pregnancy rate for all IVF, ICSI and FET (frozen embryos transfer) cycles for all age groups was 5%. This means that the centre's multiple live birth rate is significantly lower than the 10% maximum multiple live birth rate target for this period.

2.7. The committee noted that the renewal inspection took place on 17 and 18 April 2018. The renewal inspection report covers the performance of the centre since the last inspection, the findings from the renewal inspection visit and communications received from the centre. The committee noted that at the time of the renewal inspection there were a number of areas of practice that required improvement, including four major and two 'other' areas of non-compliance. The committee noted that since the inspection visit the PR has committed to fully implementing all of the following recommendations within the prescribed timescales:

Major areas of non-compliance:

- The PR should ensure that the time of administration for controlled drugs is recorded accurately and legibly.
- The PR should ensure that the centre's quality management system (QMS) is compliant with all relevant requirements and that auditing processes are effective in identifying and implementing appropriate corrective actions in response to audit findings.
- The PR should ensure that all consents are accurately completed and that the patient's intentions are clear.
- The PR should ensure that all licensed treatment activity is reported to the Authority within the timeframe required by General Direction 0005.

'Other' areas that require improvement:

- The PR should ensure that documentation of witnessing checks is completed at the time the procedure takes place.
- The PR should ensure that patient/partner consents to disclosure of identifying information to researchers are accurately recorded on the HFEA register.

Adverse Incident

2.8. The committee noted that since the time of the interim inspection in March 2016, the PR reported a serious incident relating to donor gametes used, contravening the conditions placed on their use by the donor at the time of donation. At the request of the donor concerned, the committee agreed to receive and consider documents relating to this incident, including submissions from the donor, the Executive and the PR. The committee noted that the adverse incident in question had not been referred to the committee for consideration at the meetings in September or November 2016 because the incident investigation was still in progress at those times.

2.9. The committee noted that the centre and the CARE corporate clinical governance team advised the HFEA as soon as they became aware of the incident. The committee also noted that the HFEA Executive was kept informed of the centre's investigations, root cause analysis and the actions taken to ensure that an incident of this nature would not recur.

2.10. The committee noted that the HFEA's Clinical Governance Lead undertook a detailed review of the centre's donor recruitment pathway and the processes now in place to ensure donor gametes are only used in accordance with any restrictions on their use requested by the donor. The inspectorate concluded that the centre's procedures for reporting adverse incidents and management of donor consents are now compliant with HFEA requirements and that the centre reports all adverse incidents (including serious adverse events and reactions) to the HFEA. The centre also investigates all adverse incidents that occur.

2.11. The committee also noted that the centre has a new management team, including the PR, Medical Director, Clinic Director, Donation Lead and Quality Manager, compared to the time at which the incident occurred.

2.12. The committee noted the centre's expression of regret and acknowledgment of the significant impact of this incident on the donor. The committee expressed its empathy for the donor concerned and also noted that the CARE Group has contacted the donor and offered support in accordance with HFEA guidance.

Management Review

2.13. The committee noted that due to the centre's recent licensing history and significant failings with regard to consent to legal parenthood, identified following the interim inspection in March 2016, the Executive held a management review meeting on 14 May 2018, in accordance with the HFEA Compliance and Enforcement Policy, to evaluate the centre's performance. At this meeting, the Executive considered the findings of this inspection, the centre's licensing history and the PR's engagement with the HFEA. The considerations of the management review, alongside guidance from the HFEA Guidelines for Licensing regarding length of licence, informed the Executive's recommendation on the length of licence to be offered.

2.14. The Executive noted the high level of engagement from the PR, which was positive, in addition to the improvements in the centre's practices and procedures. The Executive also acknowledged the recent sustained levels of improved performance, which it recognised and encouraged.

2.15. However, due to the centre's licensing history, the Executive decided that the Licence Committee should consider the application for the renewal of the centre's licence.

Recommendations

2.16. The committee noted that some improvement is required for the centre to reflect suitable practices. The centre has a Quality Management System (QMS) and the PR is encouraged to ensure that it is used to best effect to monitor and improve the quality of the service provided.

Licence

2.17. The committee noted that the Executive is mindful that this centre has received high levels of involvement from the HFEA and serious consideration was given to recommending a shorter length of licence than four years. However, on balance, the Executive believed that this would not reflect the hard work undertaken by the team at this centre to address the non compliances.

2.18. The committee noted the Executive's recommendation to renew the centre's treatment (including embryo testing) and storage licence for a period of four years, without additional conditions, subject to the continued engagement and commitment of the PR to fully implement the recommendations made in the renewal inspection report within the prescribed timescales. The centre's performance will continue to be monitored by the inspectorate. The committee gave careful consideration to this recommendation. In doing so, the committee had regard to the factors relevant to the length of a licence, as set out in the HFEA Guidance on Licensing.

3. Decision

3.1. The committee had regard to its decision tree, the HFEA Compliance and Enforcement Policy and HFEA Guidance on licensing.

Administrative Requirements

Supporting Information under General Direction 0008

Application

3.2. The committee was satisfied that the application was submitted in the form required and contained all the supporting information required by General Direction 0008. Furthermore, it was satisfied that the appropriate fees had been paid.

Proposed Person responsible (PR) – Dr Sue Montgomery

3.3. The committee noted that the proposed PR, Dr Sue Montgomery is willing to assume the responsibility of the role of PR.

3.4. The committee was satisfied that the proposed PR possesses the required qualifications and experience and that the character of the proposed PR is such as is required for supervision of the licensed activities. It was further satisfied that the proposed PR will discharge her duties under section 17 of the HFE Act 1990 (as amended). The committee noted that the inspectorate was satisfied that the proposed PR had satisfactorily completed the PR entry programme. The committee agreed to the appointment of the proposed PR.

Activities

3.5. The committee was satisfied with the suitability of the activities applied for.

Premises – 108 -112 Daisy Bank Road, Victoria Park, Manchester, M14 5QH

3.6. The committee was satisfied that the premises and facilities are suitable for the conduct of the licensed activity applied for.

3.7. The committee was satisfied that the third-party premises are also suitable.

Licence

3.8. The committee noted the level of engagement and progress made by the new PR, mindful of the serious concerns raised, and carefully considered the duration of licence it should offer with reference to the 'Guidance on licensing'. Carefully weighing all factors in the balance, the committee agreed that a four-year licence, with no additional conditions, subject to the implementation of the recommendations, including the completion of audits to the inspectorate's satisfaction, as outlined in the renewal inspection report, was appropriate.

3.9. The committee noted that the Executive would continue to monitor the centre's performance and implementation of the recommendations made in the renewal inspection report.

4. Chair's signature

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

Signature

Name

Andy Greenfield

Date

31 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 Licence Committee 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: 17 and 18 April 2018

Purpose of inspection: Renewal of a licence to carry out treatment (including embryo testing) and storage

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

Inspectors: Karen Conyers (lead), Susan Jolliffe, Vicki Lamb, Paula Nolan, Chris Hall, Zakia Ezzouyar and Janet Anderson-Pearce (observer)

Date of Licence Committee: 12 July 2018

Centre name	CARE Manchester
Centre number	0185
Licence number	L/0185/10/d
Centre address	108 -112, Daisy Bank Road, Victoria Park, Manchester, M14 5QH, United Kingdom
Person Responsible	Dr Sue Montgomery
Licence Holder	CARE Fertility Group Limited
Date licence issued	1 October 2014
Licence expiry date	30 September 2018
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:

CARE Manchester is located in Manchester and is part of the CARE Fertility group. The centre has held a licence with the HFEA since 1999. The current licence was varied to reflect the following changes: Licence Holder (LH) in March 2016, Person Responsible (PR) and premises in May 2016, and a further variation of premises in November 2016. The centre provides a full range of fertility services including embryo testing. Other licensed activities of the centre include storage of gametes and embryos.

The centre provided 1430 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 28 February 2018. In relation to activity levels this is a large centre.

Following the interim inspection in March 2016, significant issues came to light relating to the centre's legal parenthood consent practices since the introduction of changes in this area in 2009. These are discussed in the 'Legal parenthood' section in the report. Immediately after this inspection the PR resigned and a new PR, who remains the current PR, was appointed in May 2016. The findings of the interim inspection were considered by the Licence Committee in July 2016, as well as two progress updates in September 2016 and November 2016. The executive was assured that the PR had provided evidence that she had fully implemented the recommended actions, and the Licence Committee agreed with the executive's recommendation to continue the centre's licence. The Licence Committee did not consider it should impose any conditions on the centre's licence and no further actions were required.

During the inspection reported on here the executive undertook a detailed review of an incident reported after the interim inspection in March 2016. This is discussed in the 'Adverse incidents' section in the report. The executive notes the events occurred prior to the appointment of the current PR.

Given the centre's recent licensing history and significant failings with regard to consent to legal parenthood identified following the interim inspection in March 2016, the executive considered that a management review, to evaluate the centre's performance, should be held in accordance with the HFEA Compliance and Enforcement Policy. The meeting was held on 14 May 2018. Consideration was given to the findings of this inspection, the centre's licensing history, and the PR's engagement with the HFEA in order to inform a recommendation on the length of licence to be offered.

The executive noted the high and positive level of engagement by the PR, in addition to the improvements noted in the centre's practices and procedures. The executive considers this should be acknowledged and the recent sustained levels of improved performance be recognised and encouraged. Due to the centre's licensing history, the executive considers that the application for the renewal of the centre's licence should be considered by a Licence Committee of the HFEA rather than the Executive Licensing Panel.

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period 1 December 2016 to 30 November 2017 show the centre's success rates are in line with national averages

For the year 2017 the centre reported 19 cycles of partner insemination with two clinical pregnancies. This represents a clinical pregnancy rate which is consistent with the national average.

Multiple births[2]

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

For the period from 1 December 2016 to 30 November 2017, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 5%. This means that the centre's multiple live birth rate is significantly lower than the 10% multiple live birth rate target.

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

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

Summary for licensing decision

Taking into account the essential requirements set out in the Human Fertilisation and Embryology (HF&E) Act 1990 (as amended), the HF&E Act 2008, Standard Licence Conditions (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 PR;
- the PR's qualifications and experience comply with section 16(2)(c) of the HF&E Act 1990 (as amended);
- the PR has discharged her duty under section 17 of the HF&E Act 1990 (as amended);
- the premises (including those of relevant third parties) are suitable;
- the centre's practices are suitable;
- the application contains the supporting information required by General Direction 0008, in application for renewal of 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 four major and two 'other' areas of non-compliance.

Since the inspection visit the PR has given a commitment to fully implementing all of the following recommendations in the prescribed timescales:

Major areas of non-compliance:

- The PR should ensure that the time of administration for controlled drugs is recorded accurately and legibly.
- The PR should ensure that the centre's quality management system (QMS) is compliant with all relevant requirements and that auditing processes are effective in identifying and implementing appropriate corrective actions in response to audit findings.
- The PR should ensure that all consents are accurately completed and that the patient's intentions are clear.
- The PR should ensure that all licensed treatment activity is reported to the Authority within the timeframe required by General Direction 0005.

'Other' area that requires improvement:

- The PR should ensure that documentation of witnessing checks is completed at the time the procedure takes place.
- The PR should ensure that patient/partner consents to disclosure of identifying information to researchers are accurately recorded on the HFEA register.

Recommendation to the Licence Committee

The centre has no critical areas of concern but does have four major areas of concern.

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

inspection team commends the centre on achieving a low multiple pregnancy rate and, in so doing, reduce the single biggest risk of infertility treatment.

Some improvement is required for the centre to reflect suitable practices. The centre has a QMS and the PR is encouraged to use it to best effect to monitor and improve the service provided.

The executive considers that there is sufficient information available to recommend renewal of the centre's licence and has referred to the HFEA Guidelines for Licensing regarding length of licence. In overall consideration of all information to hand and the evidence of the commitment and engagement of the PR, the inspection team considers that it is appropriate to recommend the renewal of the centre's treatment (including embryo testing) and storage licence for a period of four years without additional conditions.

The executive is mindful that this centre has received high levels of involvement from the HFEA. The executive gave serious consideration to recommending a shorter licence length period but, on balance, believe this would not reflect the hard work undertaken by the team at this centre. At the same time, it is finely balanced and we invite the Licence Committee to weigh up this assessment in the light of the evidence in this report.

The recommendation is subject to the continued engagement and commitment of the PR to fully implement the recommendations made in this report within the prescribed timescales. 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 or donor to whom they relate are broadly compliant with HFEA requirements.

What the centre could do better

Witnessing (Guidance note 18)
In one of five records reviewed the signature of the person witnessing the insemination was not recorded (see recommendation 5, SLC T71).

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

What the centre does well

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

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

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

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

What the centre could do better
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 premises of the centre's satellite/transport facilities and laboratories conducting tests that impact on the quality and safety of gametes and/or embryos (relevant third parties) are suitable.

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

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

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

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

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

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

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

The process for administering and monitoring patients during intralipid infusion was reviewed and considered to be suitable.

Written information provided to patients offered intralipid therapy is compliant with guidance.

Pre-operative assessment and the surgical pathway (Guidance Note 25)
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 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 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 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 has systems in place to manage satellite activities that are compliant with HFEA requirements. This is important to ensure that activities performed by satellite clinics on behalf of the licensed centre are suitable and meet the HFEA requirements.

Equipment and materials (Guidance note 26)
The centre uses equipment and materials that are compliant with HFEA requirements. All of the equipment and materials used in licensed activity are designated for the purpose and are appropriately maintained in order to minimise any hazard to patients and/or staff.

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

Process validation (Guidance note 15)
The centre's procedures are 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)
Reporting and investigation of adverse incidents is important to ensure that licensed centres share the lessons learned from incidents and continuously improve the services it offers. This area of practice was a focus at this inspection.

Since the time of the interim inspection in March 2016, the PR reported a serious incident relating to donor gametes used contravening the conditions placed on their use by the donor at the time of donation. The centre and the CARE corporate clinical governance team (as the donor service covered all clinics in the CARE group) advised us as soon as they became aware of the incident; kept the HFEA informed of its investigations, its root cause analysis and the actions taken to ensure that an incident of this nature could not recur. The CARE group has contacted those involved and has offered support in accordance with HFEA guidance. The executive has been in regular contact with the centre to ensure the appropriate balance between sensitivity and candour in this situation has been achieved.

The HFEA's Clinical Governance Lead undertook a detailed review of the centre's donor recruitment pathway and the processes now in place to ensure donor gametes are only used in accordance with any restrictions on their use requested by the donor.

From this review the inspection team was able to conclude that the centre's procedures for reporting adverse incidents and management of donor consents are compliant with HFEA requirements and that the centre reports all adverse incidents (including serious

adverse events and reactions) to the HFEA. The centre investigates all adverse incidents that have occurred.

What the centre could do better

Medicines management (Guidance Note 25)
The following issues were noted with the centre's controlled drugs register (see recommendation 1):

- In two out of five patient records audited by the inspection team, the time that the controlled drug was administered was not legible in the controlled drug register.
- In one out of five records audited, the time the controlled drug was administered was documented in the controlled drug register, but was different to the time shown in the patient's record.

Quality management system (QMS) (Guidance note 23)
The following issues were noted with the centre's QMS (see recommendation 2, SLC T36):

- The centre has not audited the following critical activity: consent to treatment.
- Non-compliances or corrective actions have not been fully documented in several audits, for example: counselling, egg and sperm donation, welfare of the child, witnessing, EDI submission.
- The centre's audit of surrogacy treatments completed on 9 April 2018 showed that in six of the ten cases audited, the required blood borne virus screening had not been completed at the time of donation. In all six cases retrospective screening had been performed and the patients were not at risk. The donation coordinators assured the inspection team that the issues identified would have been discussed with the host surrogate, however this was not documented in the audit report. These six treatment cycles were carried out using embryos created prior to April 2017 and it is acknowledged that screening practices were reviewed and revised in April 2017. The inspection team noted that for the other four cases, treatment had been carried out after April 2017 and no non-compliances were identified.

The centre's recent audit of all treatment cycles and of all electronic witnessing system mismatches in 2017 identified a number of non-compliances ranging in significance. The inspection team noted that the PR had reviewed the audit findings and concluded that there were no concerns that any mismatches had occurred, and that staff were to be reminded to ensure documentation of witnessing checks. The inspection team considered that this was not an appropriate corrective action given that similar findings had been noted in the previous annual audit and similar recurrence of non-compliances was noted in recent monthly audits. Immediately after the inspection, the PR undertook a root cause analysis of the witnessing audit findings and provided this to the centre's inspector. The root cause analysis was comprehensive and identified specific changes and improvements to practice. The PR also confirmed that she had reviewed all cases in detail and was assured that no actual mismatches of gametes or embryos had taken place. Furthermore, the PR confirmed that she would re-audit this area of practice again in two months. Therefore, no further recommendations are being made in relation to the audit of witnessing.

Staff engaged in licensed activity

Person Responsible (PR)
Staff

What the centre does well

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

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 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's procedures for performing embryo testing are compliant with HFEA

requirements. This ensures that:

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

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

What the centre could do better

Nothing identified at this inspection.

2. The experience of patients

Patient feedback

What the centre does well

During the inspection visit the inspectors spoke to three patients who provided positive feedback on their experiences at the centre. The centre's patient survey responses were also reviewed during the inspection. Between April 2016 and March 2018, the centre had received 162 compliments and 10 negative comments. The inspection team noted that there were no trends or themes in the negative feedback, and that these comments had been followed up by centre staff to try to resolve the specific issues raised.

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.

What the centre could do better

Nothing identified at this inspection.

Treating patients fairly

Counselling
Egg sharing arrangements
Surrogacy
Complaints
Confidentiality and privacy

What the centre does well

Treating patients fairly (Guidance note 29)

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

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

Counselling (Guidance note 3)

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

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

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

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

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

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

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

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

Information

What the centre does well

Information (Guidance note 4; Chair's Letter CH(11)02)
The centre's procedures for providing information to patients and/or donors are compliant with HFEA requirements. This ensures that the centre gives prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions.

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

Consent
Legal parenthood
Consent to disclosure of information, held on the HFEA Register, for use in research

What the centre does well

Consent (Guidance note 5;6)
It is important that patients and donors have provided all relevant consents before carrying out any licensed activity. The centre's procedures for obtaining consent are partially compliant with HFEA requirements.

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.

In February 2014, the HFEA asked all centres to audit their practices in this area to ensure they are suitable, to report the findings of the audit to the HFEA and to respond to those findings. The centre sent the report of the audit to the HFEA within the required timeframe. The audit showed that four couples were affected by legal parenthood consent anomalies. The PR confirmed that actions had been taken in response to the audit findings.

As part of the HFEA's ongoing activities relating to 'legal parenthood', in October 2015 all PRs were asked to confirm that specific actions had been undertaken; that there are effective methods for assessing the on-going competence of staff to take this consent; and that effective audit procedures are in place to ensure on-going compliance with consent taking requirements. The PR responded to this communication and provided the required reassurances to the satisfaction of the executive.

At the interim inspection in March 2016, we reviewed the centre's audit and found that it had not been performed according to the method specified by the HFEA, and that appropriate actions had not been taken in response to the audit findings. The executive undertook a second focused inspection, also in March 2016, and the centre's legal parenthood consent practices were reviewed in detail. As a result of these activities, the centre was required to re-audit all treatments since 6 April 2009, when new requirements for consent to legal parenthood were introduced. Several anomalies in consent to legal parenthood were identified in this re-audit, and as a result, further recommendations were made by the executive.

The executive considered that the PR had failed to discharge his duty under section 17 of the HF&E Act 1990 (as amended), because he provided assurance in October 2015 as to the robustness of the centre's 2014 audit of consent to legal parenthood, whereas there was no foundation to do so. Further to this, anomalies identified in the 2014 audit were not acted upon in accordance with HFEA guidance. Following these findings at the interim inspection, the PR of the centre resigned, and a new PR was appointed in May 2016.

That new, and current, PR confirmed her commitment to implementing the recommendations from the findings of the interim inspection. In addition, in July 2016 the PR agreed to voluntarily suspend treatments with donor sperm until such time that changes to processes and practices relating to consent to legal parenthood could be implemented and staff training and competency assessments could be completed.

In September 2016, the executive agreed that the centre could resume treatments with donor sperm, or embryos created with donor sperm, and a period of monitoring was undertaken by the executive. The PR audited the consent to legal parenthood for all treatments and provided monthly reports to the executive for a period of six months. During this time, no anomalies in consent to legal parenthood were noted, and the

executive was satisfied that no further actions were considered necessary.

The PR and CARE group have supported the couples affected by anomalies in consent to legal parenthood and a number of couples have sought declarations of legal parenthood through the courts.

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

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

What the centre could do better

Consent (Guidance note 5;6)
During an audit of records the following issues were identified (recommendation 3, Schedule 3 of the HF&E Act 1990 (as amended) and SLC T57):

- In one set of records the patient had signed all the consent forms with printed initials which were different to the signature that was provided by the patient on their photographic identity document. There was nothing to explain why these were different or to confirm that they were from the same person.
- In one set of records the patient/donor had ticked 'No' to the question whether they consent to their embryos being stored but had also completed the option for storage for 10 years. This was the same in all three consent forms (WT, WD and MT) in that set of records and raises doubt over the patient's consent intentions. The inspection team noted that no embryos were available to be stored for that couple or for the recipient.

Disclosure of information, held on the HFEA Register, for use in research (General Direction 0005)
Three discrepancies were found between 23 completed patient/partner and donor disclosure consents on patient files and the related consent data submitted for inclusion on the register (see recommendation 6, CH(10)05 and General Direction 0005). Therefore, the centre's procedures have failed to ensure that the HFEA holds an accurate record of consents to disclosure. The inspection team notes that in one case this failing

means there is a risk that the HFEA may release patient identifying information, to researchers without consent, and in the other two cases the consent wishes of the patient may not be able to be followed.

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 15)

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

What the centre does well

Use of embryos for training staff (Guidance note 22) The centre's procedures for using embryos for training staff are compliant with HFEA requirements. Embryos are only used for the purpose of training staff in those activities expressly authorised by the Authority.
What the centre could do better Nothing identified at this inspection.

4. Information management

Record keeping 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 compliant with HFEA requirements to ensure that accurate medical records are maintained. Good medical records are essential for the continuity of the patient's care.

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

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

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

Obligations and reporting requirements (Guidance note 32; General Direction 0005)
The audit team found that 4% (5/135) of the IVF and 12% 6/50) of the DI treatments reviewed at inspection had not been reported to the HFEA (see recommendation 4, General Direction 0005 and SLC T41).

The following issues with the timeliness and accuracy of the centre's submission of data to the Register were also noted:

- at the time of inspection there were a number of donor registration issues awaiting resolution.
- a small number of simple input errors were identified via our review of source documentation.
- our pre-inspection review of data submission error reports identified a potential process issue with data being submitted out of sequence.

Section 3: Monitoring of the centre's performance

Following the interim inspection in 2016, recommendations for improvement were made in relation two critical, two major and one 'other' area of non-compliance or poor practice.

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

On-going monitoring of centre success rates

The centre has not been sent any alerts regarding 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 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 on this inspection.			

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. Medicines management In two out of five patient records audited by the inspection team, the time that the controlled drug was administered was not legible in the controlled drug register. In one out of five records audited, the time the controlled drug was administered was documented in the controlled drug register, but was different to the time shown in the patient's record. Safer Management of	The PR should ensure that the time of administration for controlled drugs is recorded accurately and legibly. The PR should ensure that staff prescribing and administering controlled drugs are aware of the record keeping requirements for controlled drugs. A summary report of the actions taken in response to this non-compliance, including any corrective actions with timescales for implementation,	Action was taken immediately after inspection to raise awareness of these issues with the individuals responsible for documenting the time of administration of the controlled drugs - summary report provided. An audit wil be completed and provided as recommended.	The executive acknowledges the PR's response and her commitment to fully implementing this recommendation. The PR has provided a report of the review of the centre's processes in this area of practice, and a summary of the actions to be taken to address this finding. The audit of practice due by 18 October 2018 is awaited.

Controlled Drugs 2007 4.11.1.2.	should be provided to the centre's inspector when responding to this report. Within three months of the implementation of any changes to practices, the centre should conduct an audit of the controlled drug register and a summary report of the findings of the audit should be provided to the centre's inspector by 18 October 2018.		**Further action is required**.
2. QMS The following issues were noted with the centre's QMS • The centre has not audited the following critical activity in the last two years: consent to treatment. • Non-compliances or corrective actions have not been fully documented in several audits. • The centre's audit of surrogacy treatments completed on 9 April 2018 showed that in six of the ten cases audited, the required blood borne virus screening had not been completed at the time of	The PR should ensure that the centre's QMS is compliant with all relevant requirements and that auditing processes are effective in identifying and implementing appropriate corrective actions in response to audit findings. The PR should carry out an audit of consent and a summary report of the findings of the audit should be provided to the centre's inspector by 18 July 2018. The PR should review audit findings since the time of the	The clinic prospectively audits consent for every treatment cycle prior to the procedure. Three people - a clinician, an embryologist and a nurse – complete independent checks cross referencing the hard copy consent form in the patient's notes against an electronic audit tool known locally as the folliculogram. The checks are recorded on the electronic audit tool including the identity of the person completing the checks. The SOP for this process has been provided. The folliculogram provides a	The executive acknowledges the PR's response and her commitment to fully implementing this recommendation. The PR has provided the requested audit of consent to treatment and no anomalies were identified. The executive commends the centre on the systems in place such that three members of staff check consents prior to treatment so that any issues identified can be addressed. However, the executive notes

donation. In all six cases retrospective screening had been performed and the patients were not at risk. The donation coordinators assured the inspection team that the issues identified would have been discussed with the host surrogate, however this was not documented in the audit report. SLC T36.	last inspection in March 2016 to ensure that these are all clearly documented and reviewed, and have led to the implementation of appropriate corrective actions. A summary report of the findings of these reviews including corrective actions, with timescales for implementation, should be provided to the centre's inspector by 18 October 2018. The findings of the audit of surrogacy treatments are due to be presented to the CARE group 'donation meeting' in May where they will be discussed. A summary of the outcome of those discussions should be provided to the centre's inspector by 18 July 2018.	visual red flag to staff highlighting where corrective actions are required and what corrective action is needed. The red flag is removed when the corrective action is completed. To meet audit requirements, any errors identified are logged on the clinic's DATIX system. This ensures that trends can be identified and RCA completed if relevant. Any resulting preventative actions are documented on the clinic's governance action log (as is the case with all audits) which ensures that implementation of preventative actions is documented and monitored. Completing the audit prospectively ensures that any anomalies are addressed before treatment and the PR believes that this prospective audit meets the requirements of the standard licence condition. In consideration of the recommendation of this report however a retrospective audit of HFEA consent forms has been completed and a copy	that issues in the consent forms identified during this inspection had not been picked up by the centre through their current checking or auditing processes. Therefore, the PR and LH should consider how the centre's auditing processes can be made more robust and consistent with those already in place within the CARE group so as to ensure that the centre is able to audit its practices in accordance with SLC T36. In addition to the information provided in the response to this report, the PR has provided further details about the discussions with regard to the findings of the audit of surrogacy treatments held as part of the CARE group donation meeting. The audit findings were discussed at this meeting and corrective actions identified and implemented. The review of audit findings since the time of the last inspection due by 18 October 2018 is awaited.

		has been provided. With respect to the failure to include non conformities included in the body of the report in the section of the report identifying corrective and preventative action the review of audit findings will be completed and provided as requested. The Manchester surrogacy audit was presented and discussed at theGroup Donation team meeting on 3.5.18. The comments from the meeting minutes were: " Audit for Manchester discussed, feedback was good and Audit went well" . No further actions were reccomended.	**Further action is required**.
3. Consent During an audit of records the following issues were identified: • In one set of records the patient had signed all the consent forms with printed initials which were different to the signature that was	The PR should ensure that all consents are accurately completed and that the patient's intentions are clear. The PR should undertake a review of the centre's processes for completing and checking consent forms to	As an immediate action the SOP for completion of the folliculogram checks has been updated to stipulate that staff must check the signature on all consent forms against the photo ID provided in the notes (see appended SOP). Training will be provided to all staff re	The executive acknowledges the PR's response and her commitment to fully implementing this recommendation. The PR has provided a summary of the immediate actions taken to ensure that

provided by the patient on their photographic identity document. There was nothing to explain why these were different or to confirm that they were from the same person. • In one set of records the patient/donor had ticked 'No' to the question whether they consent to their embryos being stored but had also completed the option for storage for 10 years. This was the same in all three consent forms (WT, WD and MT) in that set of records and raises doubt over the patient's consent intentions. The inspection team noted that no embryos were available to be stored for that couple or for the recipient. Schedule 3 of the HF&E Act 1990 (as amended) and SLC T57.	address the reasons why these issues occurred. 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 18 July 2018. Within three months, the centre should carry out an audit of consent forms 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 18 October 2018.	the changes in the SOP. In addition an RCA will be carried out for the second case in order to understand any contributory factors and identify any corrective actions required. The RCA and subsequent re-audit will be provided in line with the requested schedule.	the identity of the patients is checked when consents are being completed. The review due by 18 July 2018 and audit of practice due by 18 October 2018 are awaited. **Further action is required**.

4. Obligations and reporting requirements The audit team found that 4% (5/135) of the IVF and 12% 6/50) of the DI treatments reviewed at inspection had not been reported to the HFEA. The following issues with the timeliness and accuracy of the centre's submission of data to the Register were also noted: • At the time of inspection there were a number of donor registration issues awaiting resolution. • A small number of simple input errors were identified via our review of source documentation. • Our pre-inspection review of data submission error reports identified a potential process issue with data being submitted out of sequence. 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 outstanding donor registration issues should be resolved as quickly as possible. The PR should provide the centre's inspector with an update on progress with this action when responding to this report. The PR should review the centre's procedures used to submit licensed treatment data to identify and address the reasons for non-reporting, and validation errors caused by data being submitted out of sequence. 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 18 July 2018. Within three months, the centre should carry out an	The forms for EDI are automatically generated via our patient information system (CIS) when the corresponding data is inputted, without the need for staff to actually send the form. Cases where forms have been omitted will be due to data entry omissions on CIS where a member of staff was not aware that the field is required to generate a form. A report has been appended to show that 29/31 errors identified at inspection have been resolved and the appropraite correction forms sent. The remaining errors require IT assistance and will be resolved as quickly as possible. The PR will investigate the issues with data submission and provide a report, with an action plan within the requested timescale. A repeat audit will then be conducted within the required timescale.	The executive acknowledges the PR's response and her commitment to fully implementing this recommendation. The PR has provided confirmation that all but two of the issues identified during the inspection have been resolved, and that these remaining two errors will be addressed as quickly as possible. The review due by 18 July 2018 and audit of practice due by 18 October 2018 are awaited. **Further action is required**.

	audit of records 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 18 October 2018.		

Other areas of practice that require 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.

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
5. Witnessing In one of five records reviewed the signature of the person witnessing the insemination was not recorded. SLC T71. A similar issue in relation to documentation of witnessing was noted at the time of the renewal inspection. However, the inspection team considers that as this was found in one instance only this should remain classified as an 'other' non-compliance, in accordance with the HFEA's assessment framework.	The PR should ensure that documentation of witnessing checks is completed at the time the procedure takes place. The PR should take immediate action to ensure that witnessing is recorded at all critical points of the clinical and laboratory process. The inspector should be advised of the measures taken to ensure that this happens by 18 July 2018. Within three months of the implementation of any changes to the witnessing procedures, the centre should conduct an audit of witnessing	Following the inspection a full RCA of witnessing omissions was carried out and provided to the HFEA, including preventative actions (see appended witnessing RCA). An audit will be carried out to assess improvement within the required timescale.	The executive acknowledges the PR's response and her commitment to fully implementing this recommendation. The PR has provided the root cause analysis (RCA) and has confirmed that the preventative actions identified in that analysis have been implemented within the timescales. The audit of practice due by 18 October 2018 is awaited. **Further action is required**.

	and a summary report of the findings of the audit should be provided to the centre's inspector by 18 October 2018.		
6. Consent to disclosure to researchers Three discrepancies were found between 23 completed patient/partner and donor disclosure consents on patient files and the related consent data submitted for inclusion on the register. CH(10)05 and General Direction 0005	The PR should ensure that patient/partner consents to disclosure of identifying information to researchers are accurately recorded on the HFEA register. The PR should also correct the submissions that have been identified as being incorrect and confirm 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 centre's inspector by 18 July 2018.	The 3 discrepancies have been corrected on the HFEA register. An RCA will be carried out to investiagte any contributory factors and identify any preventative actions deemed necessary. The RCA report and subsequent re-audit will be carried out in line with the required time scale.	The executive acknowledges the PR's response and her commitment to fully implementing this recommendation. The PR has confirmed that the incorrect submissions have been corrected. The review due by 18 July 2018 and audit of practice due by 18 October 2018 are awaited. **Further action is required**.

	Within three months, the centre should carry out an audit of records 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 18 October 2018.		

Reponses from the Person Responsible to this inspection report
This report highlights some areas of practice for improvement, which we welcome and will address within the required timescales. As a clinic we have continued to strive for improvement under a new management team, as demonstrated by this inspection report. This has been achieved by the leadership and dedication of the senior team, who have all supported and implemented the changes to all staff. We look forward to further progress, for the benefit of all of our patients.