Executive Licensing Panel - minutes

Centre 0344 (Hewitt Fertility Centre, Knutsford) Progress update further to renewal inspection report

Friday, 30 June 2017

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Juliet Tizzard (Chair) Anna Coundley Anna Quinn	Director of Strategy & Corporate Affairs Information Access and Policy Manager Scientific Policy 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. Background

1.1. The Hewitt Fertility Centre, Knutsford is located in Cheshire. The centre has been licensed by the HFEA since July 2015. The centre currently holds a treatment and storage licence and provides a full range of fertility services.

1.2. The Executive Licensing Panel considered the centre's application to renew the treatment and storage licence at its meeting on 19 May 2017, noting that at the time of the inspection there were two critical, three major and three other areas of non-compliance identified. The panel noted in particular the two critical areas of non-compliance relating to staffing levels and the submission of data to the HFEA. The panel noted that the Person Responsible (PR) had committed to fully implementing the recommendations.

1.3. The panel had concerns about the unresolved critical areas of non-compliance and the number of major areas of non-compliance.

1.4. The panel therefore decided to defer its decision on the renewal of the centre's licence until after 2 June 2017, given to the number of actions due by this date.

2. Consideration of application

2.1. The panel considered the papers, which included an executive update, inspection report and licensing minutes up to the last licence renewal.

2.2. The panel noted that the Executive had confirmed that actions, due by 2 June 2017, have been implemented within the timescales provided. The panel noted that further action is still required regarding medicine management; this is being addressed by the PR and a follow up audit of controlled drug administration is due by 2 September 2017.

2.3. The panel noted the inspectorate's recommendation to renew the centre's treatment and storage licence for a period of four years without additional conditions.

2.4. The panel noted the inspectorate's recommendation that due to the licence expiring on 20 July 2017, that a Special Direction to the PR under Section 24 (5A)(b) of the HF&E Act 1990 (as amended) might need to be issued, to permit the continuation of the centre's treatment and storage licence, to allow time for the administrative process of licence renewal to be completed within the usual timeframe.

3. Decision

3.1. The panel considered the update from the inspectorate and was pleased to see that the critical and major areas of non-compliance had been addressed within the prescribed timescales.

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

3.3. The panel endorsed the inspectorate's recommendation to issue Special Directions to the PR under Section 24 (5A)(b) of the HF&E Act 1990 (as amended) to permit the continuation of the centre's treatment and storage licence during the period of administration for the licence renewal. These Directions will come into force on 20 July 2017.

4. Chair's signature

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

Signature

Name

Juliet Tizzard

Date

11 July 2017

Executive Licensing Panel
30 June 2017

Centre number	0344
Centre name	Hewitt Fertility Centre, Knutsford
Person Responsible	Andrew Drakeley

Update to renewal inspection report

1. The renewal inspection report for Hewitt Fertility Centre, Knutsford was considered by the Executive Licensing Panel on 19 May 2017.

2. The panel had concerns about the unresolved critical areas of non-compliance and the number of major areas of non-compliance. The panel decided to defer its decision on the renewal of the centre's licence until after 2 June 2017, given to the number of actions due by this date.

3. Annex 1 provides an update on the implementation of these recommendations.

4. The Executive can confirm that actions that were due by 2 June 2017 have been implemented within the timescales provided.

5. The centre's current licence is due to expire on 20 July 2017. If the ELP recommends the renewal of the centre's licence, the ELP may need to consider issuing Special Directions under Section 24 (5A) (b) of the HF&E Act 1990 (as amended) to permit the continuation of the centre's current treatment and storage activities if a renewed licence cannot be issued in time.

Louise Winstone
Inspector

Annex 1: Recommendations that required further action

Critical area of non-compliance

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
1. Staffing The inspection team consider that staffing levels are inadequate for the usual level of activity undertaken. SLC T12.	The PR should assess how many cycles of treatment can be safely accommodated, taking into account staffing levels, skills mix, equipment and premises. A copy of the assessment should be submitted to the centre's inspector when responding to this report. The PR should ensure that workload is maintained within the safe limits determined in this assessment. When responding to this report, the PR should also provide the centre's inspector with a timeline of when the new nursing and laboratory staff posts are expected to be filled.	The outgoing PR can confirm that the cap that was put in place with regards to the numer of staff being required has been in place since the PR notified the HFEA (see email 09 February 2017 12:48) and the Trust Board have decided to limit Knutsford activity to 500 collections per annum. Additoinal staff are to be recruited including a doctor who is to provide full time clinical cover. the incoming PR can provide an update of this recuitment at the HFEA's request.	The executive acknowledges the PR's response and will remain in regular contact with the PR until the recruitment of staff has been completed. Further action is required. **Progress update:** A review of the service provided at Knutsford was presented to the Liverpool Women's NHS Foundation Trust Board in April 2017 and a summary of this review has been submitted to the centre's inspector. The decision was to maintain Knutsford as a fully functional IVF unit, with an anticipated activity limit of 500 egg collections. There are currently additional posts out

			to advert across all staff groups. The executive and the PR are assured that there is an adequate balance between staffing and activity. No further action is required.
2. Obligations and reporting requirements 38% (46/121) of the IVF and 67% (8/12) of the DI treatments reviewed at inspection had not been reported to the HFEA. 38% (38/73) of the IVF and 25% (1/4) of the DI treatments reviewed at inspection had been reported to the HFEA outside the period required by General Direction 0005. 268 IVF and 8 DI fewer treatments are recorded on the HFEA register for this centre than are recorded on the centre's own patient records system. This is largely because treatments have	The PR should review procedures for submitting licensed treatment data to the HFEA to ensure that it is accurate and is provided within the timeframes specified in Directions. When responding to this report, the PR should provide a plan of action to address the issues identified at this inspection regarding the miss-registration of treatment information. Where treatments at the centre have been recorded as having taken place at centre 0007, action should be taken to ensure the records of both centres accurately reflect the licenced activity they have undertaken.	The outgoing PR can confirm that the incoming PR will meet with the relevant discipline heads for both centre 0007 and 0344 to review the process of form submissions, meeting timeframes and staff involved and will provide an update summary by the 2nd June 2017. Issues regarding form submissions via third party systems have already been identified and errors have been corrected however a full review will take place to ensure that this does not happen again.	The executive acknowledges the PR's response and awaits the summary of the review of the submission of licensed treatment data by 2 June 2017. Further action is required. **Progress update:** The PR has provided an update summary and has confirmed that all historical discrepancies have now been cleared. The centre has put measures in place to improve the accuracy and timeliness of data submission. No further action is required.

been submitted by centre 0007. General Direction 0005; SLC T9(e), T41.	The procedures used to submit licensed treatment data should be reviewed to identify and address the reasons for non-reporting and delayed submissions (NB. this must include review and acting upon error reports which would have identified the reporting across two centres issue at a much earlier stage). A summary of this review should be submitted to the centre's inspector by 2 June 2017.		

Major area of non compliance

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

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
3. Medicines Management On inspection, the following issues were noted: • in two out of four patient records reviewed, the amount of a controlled drug recorded as having been administered in the controlled drugs register was different from that recorded in the patient's records; • the centre has not conducted a recent quarterly audit of controlled drugs in line with Trust policy;	The PR should ensure that medicines management practices at the centre are compliant with legal requirements and professional best practice. The PR should conduct a review of the centre's controlled drugs procedures and this should include staff training requirements. A summary report of the review, including corrective actions taken, should be sent to the centre's inspector by 2 June 2017. Within three months of having implemented corrective	The outgoing PR can confirm that the incoming PR will meet with the clinical staff to review the process of dispensing medicines and provide a full summary and action plan by the 2nd June 2017. A 3 month review has been added to the audit schedule and a summary report will be sent to the centre's inspector by 2nd September. The incoming PR will then commission the revised processes, the location of the drugs cabinet and staff training. The incoming PR will then provide an update of the timeframes these actions will then be implemented. The workforce	The executive acknowledges the PR's response and awaits the summary of the review by 2 June 2017, the follow up audit of controlled drug administration by 2 September 2017 and confirmation of staff training. Further action is required. **Progress update:** The PR has provided a summary and action plan including evidence of staff training. A follow up audit of controlled drug administration is due by 2 September 2017. The location of the controlled drugs cabinet is currently

• nursing staff routinely dispense 'top up' medicines to patients for self-administration. Staff could not provide assurance of training in dispensing medicines nor is there an SOP to direct this process; • the controlled drugs cabinet is not fixed onto an external wall. SLC T2; The Misuse of Drugs (Safe Custody) Regulations 1973; NMC (2010) Standards for Medicines Management.	actions, the centre should audit the recording of controlled drug administration in patient records to ensure actions taken are effective and ensure ongoing compliance with regulatory requirements and practice guidance. A summary report of the audit should be sent to the centre's inspector by 2 September 2017. The PR should commission a review of dispensing practice and management of medicines by a registered pharmacist including an assessment of the controlled drugs cabinet. The PR should advise the centre's inspector of the timescale for achieving this. Following this review, the PR should provide details of how and when staff are to receive training in the dispensing of medicines to take away.	review and recruitment of staff will enable staff to have the time required to submit the relevant forms within the required timeframes.	under investigation and will be followed up by the centre's inspector. Further action is required.
4. Quality management system	The PR should review the centre's audit programme to	The outgoing PR can confirm that the audit programme is to	The executive acknowledges the PR's response and awaits

Although there is a comprehensive QMS, the centre's audit programme needs to be reviewed because: i) a recent quarterly audit of controlled drugs, in line with Trust policy, has not been undertaken. ii) audits that have identified and documented non-conformances do not consistently record corrective actions and the implementation of those actions. SLC T36. The centre does not have written SOPs for: i) the dispensing of top-up medication by nurses. ii) submitting data to the HFEA. iii) the legal parenthood SOP does not clearly define HFEA legal parenthood consent requirements. SLC T33b.	ensure that it is compliant in the range of audits performed, the methodology used and the documentation of corrective and preventative actions and their implementation. The PR should provide the centre's inspector with a copy of the review and an action plan for the implementation of this recommendation by 2 June 2017. The PR should provide copies of the audits and SOPs identified in this report as non-compliant by 2 June 2017.	be reviewed by the quality team and corrective and preventative actions put in place to meet the requriements of SLC T36. A copy of the review and copies of the audits and SOPs will be sent to the centre's inspector by the incoming PR by 2nd June 2017.	the review of the audit programme by 2 June 2017 and copies of the outstanding audits and SOPs by 2 June 2017. Further action is required. **Progress update:** The PR has provided evidence that the audit program has been reviewed. The audits and SOPs identified as outstanding have been submitted. No further action is required.

5. Equipment and materials On the day of inspection, the centre was unable to provide documented evidence of the validation of the heated stages used in the embryology laboratory and the Gilson pipettes used for culture dish preparation. SLC T24. 1ml and 25ml pipettes used for culture dish preparation are not CE marked. SLC T30.	The PR should ensure that all critical equipment is appropriately validated and that validation is documented. A timeframe for the validation of the Gilson pipettes and the heated stages should be provided when responding to this report. It is expected that validation of these items will be complete by 2 June 2017. A timeframe for the introduction of CE marked 1ml and 25ml pipettes should be provided when responding to this report.	The outgoing PR can confirm that that the validation of critical equipment and relevant documentation will be completed in accordance with SLC T24 by the 2nd June 2017. The outgoing PR can confirm that CE marked serological pipettes will be sourced and introduced to the embryology laboratory by 1 July 2017.	The executive acknowledges the PR's response and awaits confirmation that the equipment identified has been validated by 2 June 2017 and that CE marked serological pipettes are in use by 1 July 2017. Further action is required. **Progress update:** The PR has provided evidence that the items identified have now been validated and has provided the purchase order for CE marked pipettes. No further action is required.

Other areas of practice that requires improvement

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
6. Safety and suitability of premises and facilities Safety signage was not displayed in the gas store area. SLC T17.	The PR should ensure that compressed gas hazard signage is in place where medical gasses are stored and provide confirmation of this to the centre's inspector when responding to this report.	The outgoing PR can confirm that the appropriate hazard signage has been requested and will be in place as a matter of urgency. The incoming PR will confirm to the Centre's inspector when this has been completed.	The executive acknowledges the PR's response and awaits confirmation that gas hazard signage is in place. Further action is required. **Progress update:** The PR has provided evidence that signage for stored compressed gas hazard warning has been ordered. No further action is required.
7. Traceability A traceability record of centrifuges used in the processing of sperm for use in treatment is not kept. SLC T99.	The PR should ensure that all equipment (notably the centrifuges used to process sperm for use in treatment) and materials which may influence the quality and safety of gametes and embryos are traceable.	The outgoing PR can confirm that a record of which centrifuge is used during sperm preparations was introduced shortly after the inspection team highlighted this non-conformance. An audit of these records will be performed and the report sent	The executive acknowledges the PR's response and awaits a summary of the audit by 2 June 2017. Further action is required. **Progress update:** The PR has provided evidence that traceability of

	When responding to this report, the PR should provide confirmation that this information is being recorded to ensure traceability. An audit should subsequently be performed to ensure the actions taken are effective. A summary of this audit should be provided to the centre's inspector by 2 June 2017.	to the Centre's inspector by 2nd June 2017.	centrifuges is now recorded and has provided the audit report. No further action is required.
8. Consent When discussing the process for obtaining consent to legal parenthood, it was noted that couples are asked to provide consent at the same appointment as they receive implications counselling. It could be considered that couples do not have sufficient time to reflect before providing consent. Guidance note 5.8.	The PR should review the process for seeking consent to legal parenthood to ensure couples have sufficient time to reflect or seek further information before providing consent. A summary of this review and an action plan should be provided to the centre's inspector by 2 June 2017.	The outgoing PR can confirm that the relevant discipline heads will meet to review the process of taking legal parenthood consent. A summary of which will be provided to the Centre's inspector by 2nd June 2017.	The executive acknowledges the PR's response and awaits the summary of the review by 2 June 2017. Further action is required. **Progress update:** The PR has provided a summary of the review of the process for seeking consent to legal parenthood and has made acceptable changes. The modified legal parenthood SOP has been submitted. No further action is required.

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: 1 and 2 March 2017

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: Louise Winstone (lead), Lesley Brown and Shanaz Pasha; Chris Hall and Joel McChesney (register team)

Date of Executive Licensing Panel: 19 May 2017

Centre name	Hewitt Fertility Centre, Knutsford
Centre number	0344
Licence number	L/0344/1/b
Centre address	Knutsford Business Park, 4 The Pavillions, Mobberley Road, Cheshire, Knutsford, WA16 8ZR, United Kingdom
Person Responsible	Andrew Drakeley
Licence Holder	Kathryn Thomson
Date licence issued	21 July 2015
Licence expiry date	20 July 2017
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:

Hewitt Fertility Centre, Knutsford has held a Treatment and Storage licence with the HFEA since July 2015. This initial licence was granted for two years without additional conditions which is standard for a new centre.

The centre provides a full range of licensed fertility treatments (excluding embryo testing), to NHS and self-funded patients. This inspection for licence renewal was the first visit to the centre since a licence was granted.

The centre provided 601 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 28 February 2017. In relation to activity levels this is a medium sized centre.

Shortly after the inspection, the centre applied to vary their licence to reflect a change of Person Responsible (PR). This change was planned and the proposed new PR was present at this inspection. On 24 March 2017, the centre's licence was varied and the PR is now confirmed as Mr Andrew Drakeley. The PR comments and commitment to implementing the recommendations made in this report were prepared by the previous PR in consultation with the new PR.

The clinic operates as a sister clinic to the Hewitt Fertility Centre in Liverpool (centre 0007).

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period December 2015 - November 2016 show the centre's success rates are in line with national averages.

The centre is yet to submit their 2016 data for partner insemination due to technical difficulties with submitting data via the HFEA 'Clinic Portal'. This is currently being investigated.

Multiple births[2]

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

Between December 2015 – November 2016, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 6%: 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

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

- the application has been submitted in the form required;
- the application has designated an individual to act as the Person Responsible (PR);
- the PR's qualifications and experience comply with section 16 (2) (c) of the HF&E Act 1990 (as amended);
- the previous PR has discharged her duty under section 17 of the HF&E Act 1990 (as amended) and the new PR has committed to discharge 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 their licence;
- the centre has submitted an application fee to the HFEA in accordance with requirements.

The ELP is asked to note that at the time of the inspection there were a number of areas of practice that required improvement including two critical, three major and three other areas of non compliance. The PR has given a commitment to fully implementing the following recommendations:

Critical areas of non compliance:

- **The PR should ensure that the staffing levels are appropriate for the activities being undertaken.**
- **The PR should review procedures for submitting licensed treatment data to the HFEA to ensure that it is accurate and is provided within the timeframes specified in Directions.**

Major areas of non compliance:

- The PR should ensure that medicines management practices at the centre are compliant with legal requirements and professional best practice.
- The PR should ensure that the centre's quality management system (QMS), notably the audits performed and the standard operating procedures (SOPs), is reviewed so that it can effectively guide, monitor and improve the services provided.
- The PR should ensure that all critical equipment is validated and that only CE marked medical devices are used.

Other areas that require improvement:

- The PR should ensure that compressed gas hazard signage is in place where medical gasses are stored.
- The PR should ensure that traceability data is recorded regarding which centrifuge is used to process sperm for use in treatment.
- The PR should review the process for seeking consent to legal parenthood to ensure couples have sufficient time to reflect or seek further information before providing consent.

Recommendation to the Executive Licensing Panel

The centre has two critical and three major areas of concern. The inspection team also notes that the success rates are consistent with the national average and their multiple clinical pregnancy/live birth rates meet the target.

Significant improvement is required in order for the centre to demonstrate the suitability of their practices. Such was the concern raised regarding staffing both before and after this inspection, the centre has been the subject of two management reviews. The executive has referred to the HFEA 'Guidance on Licensing'. Where there is a history that indicates a likelihood of or previous failure to implement recommendations for improvement, and where there are concerns relating to the quality of service, a shorter licence than the standard four years may be considered. Where there are concerns regarding performance or safety, the imposition of a sanction by way of an additional condition may be considered. The executive considered whether a shorter licence length is warranted, however concluded that, whilst the areas of concern identified at this inspection are significant, there is currently no indication that the recommendations made will not be implemented in full and in a timely manner. The executive also considers that it would be disproportionate to recommend that an additional condition be applied regarding staffing or the capping of activity levels at this point as the centre has imposed a voluntary restriction on activity to ensure safe patient care commensurate with the staff complement currently available.

The inspector will continue to closely monitor the centre's performance. Failure to implement the recommendations relating to the critical areas of non compliance within the prescribed timescales may result in the submission of a further report to the ELP with the recommendation that regulatory action be taken in accordance with the Authority's Compliance and Enforcement Policy.

The executive recommends the renewal of the centre's treatment and storage licence for a period of four years without additional conditions subject to the recommendations made in this report being implemented within the prescribed timescales. However, given that this inspection was the first since the licence was granted and also the first opportunity to observe the clinic in operation and; given the number of areas of concern identified, the inspection team recommends an interim inspection be conducted within 12 months of this licence coming into force to facilitate greater support to the centre and to monitor progress.

Section 2: Inspection findings

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

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

1. Protection of the patient and children born following treatment

Witnessing and assuring patient and donor identification

What the centre does well

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

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

Donor selection criteria and laboratory tests

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

What the centre does well

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

Payments for donors (Guidance note 13; General 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 broadly suitable. This is important to ensure that all licensed activities are conducted in a suitable environment that is fit for purpose.

The centre has procedures in place that are compliant with requirements to ensure that risks are taken into account so that patients and staff are in safe surroundings that prevent harm.

The centre is compliant with HFEA requirements to processes 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 CPA (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 and this area of regulation is therefore not relevant to this inspection.

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

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

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

Transport and distribution of gametes and embryos (Guidance note 15; General 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 note 15)
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 broadly 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 operate any transport or satellite IVF services therefore this regulatory area is not relevant to this inspection.

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

Safety and suitability of premises and facilities (Guidance note 25)
Safety signage was not displayed in the gas store area.

SLC T17; see recommendation 6.

Medicines Management (Guidance Note 25)
On inspection, the following issues were noted:

- In two out of four patient records reviewed, the amount of a controlled drug recorded as having been administered in the controlled drugs register was different from that recorded in the patient's records.
- Nursing staff routinely dispense 'top up' medicines to patients for self-administration. Nursing and Midwifery Council (NMC) guidance states that this is an extension to a nurse's role and should only be performed following appropriate training and in accordance with an approved SOP. Staff could not provide assurance of training in dispensing medicines nor is there an SOP to direct this process.
- The controlled drugs cabinet is not fixed onto an external wall. The clinic were unable to provide any assurances that the wall that the cabinet was affixed to met regulations.

SLC T2; The Misuse of Drugs (Safe Custody) Regulations 1973; NMC (2010) Standards for Medicines Management.

See recommendation 3.

Traceability (Guidance note 19)
The centre uses two centrifuges during the sperm preparation process that are used interchangeably. The centrifuge used in each case is not recorded and is therefore not traceable.

SLC T99; see recommendation 7.

Quality management system (QMS) (Guidance note 23)
The following was noted regarding the centre's audits:

- a quarterly audit of controlled drugs, as required by Trust policy, has not been conducted;
- audits that have identified and documented non-conformances do not consistently record corrective actions and the implementation of those actions. For example, the welfare of the child audit identified non-conformances, however the audit report provided did not show what the corrective actions were and whether these had been implemented.

SLC T36; see recommendation 4.

The following was noted regarding the centre's SOPs:
There is no written SOP for:

- the dispensing of top-up medicines by nurses;
- submitting data to the HFEA and;
- the legal parenthood SOP does not clearly define HFEA legal parenthood consent requirements.

SLC T33; see recommendation 4.

Equipment and materials (Guidance note 26)
The centre was unable to provide documented evidence of the validation of the heated stages used in the embryology laboratory and the Gilson pipettes used for culture dish preparation.

1ml and 25ml pipettes used for culture dish preparation are not CE marked.

SLC T24; see recommendation 5.

Staff engaged in licensed activity
Person Responsible (PR)
Staff

What the centre does well

Person Responsible (Guidance note 1)
The PR has complied with HFEA requirements.

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 partially 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)
Prior to the inspection visit, the PR contacted the centre's inspector to inform the HFEA of a staffing shortage at this centre. The PR reported that the centre currently has high levels of staff sickness, maternity leave and only has medical cover on Mondays, Wednesdays and Fridays. This has an additional impact as staff numbers are already limited.

In accordance with the HFEA Compliance and Enforcement Policy, a management review meeting was held on 10 February 2017. It was considered that inadequate staffing levels may pose a risk to the safety and care of patients. The safety and well-being of staff may also be affected if staff are unable to take breaks and days off. It was agreed that in the first instance, the centre's inspector would communicate with the PR regarding actions to be taken to mitigate any immediate risks by 'capping' activity to ensure it is commensurate with the number and experience of staff available to safely deliver care. The PR provided assurance regarding interim measures to ensure the safety of patients already in treatment and steps to ensure treatment numbers are aligned to safe staffing levels, including securing temporary staff cover from the centre's sister clinic, Hewitt Fertility Centre, Liverpool. The PR was also asked to ensure that the HFEA was kept informed of progress with discussions between the centre and the Trust regarding safe staffing levels. The PR was later able to confirm that new posts for nursing and laboratory staff have now been approved by the Trust but have yet to be finalised.

Given the concerns previously raised by the PR and the potential risks identified, inspectors spoke at length with staff in all departments at this inspection. All staff reported that they were over stretched and were unable to take time off. In the laboratory, there is only one full time HCPC registered Clinical Scientist who is required to work beyond contracted hours as non–HCPC registered embryologists require clinical supervision. Nurses are often required to work 15-18 hour days.

The inspection team acknowledge that the centre has not reported any incidents relating to poor staffing nor has there been any negative feedback or complaints from patients. Staff considered that patient safety was not being compromised and showed commitment to providing a good standard of care. The inspection team consider however that this level of 'good will' support from staff is unsustainable as the high workload could further contribute to the already high levels of staff sickness and pose an increased risk to patients and staff wellbeing. Temporary measures to provide cover from sister clinic centre 0007 are unsustainable as that centre is also experiencing staffing issues. The inspection team are therefore concerned that staffing levels are inadequate for the usual level of activity undertaken.

A second management review was held on 27 March 2017 to discuss the findings of this inspection. It was agreed that the PR had taken steps to mitigate immediate risks and that the Trust has in principle agreed the additional posts. However, given that it will take some time to recruit into these posts, the management review team agreed that should activity levels rise once more it would pose a risk to patients and staff. Steps must therefore be taken by the centre to ensure that activity remains commensurate with the number and experience of staff currently available.

SLC T12; SLC T2; see recommendation 1.

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)
Embryo testing is not provided at this centre.

What the centre could do better
Not applicable.

2. The experience of patients

Patient feedback

What the centre does well
During the inspection, the inspectors reviewed the centres own patient satisfaction surveys and spoke to two patient couples who provided feedback on their experiences at the centre. One patient also provided feedback directly to the HFEA in the time since the last inspection.

Based on this feedback and observations made during 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 currently does not undertake egg sharing arrangements.

Surrogacy (Guidance note 14)
Treatment requiring a surrogate is not provided at this centre.

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 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 broadly compliant with HFEA requirements. This ensures that patients and donors have provided all relevant consents before carrying out any licensed activity.

Legal parenthood (Guidance note 6)
Where a couple to be treated with donated gametes or embryos 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 its effectiveness and, in some cases, it may be necessary for a patient couple to obtain a court declaration to establish legal parenthood.

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.

On this inspection, we reviewed the centre's legal parenthood audit and found that it had been performed according to the method specified by the HFEA.

To provide further assurance of the effectiveness of the centre's procedures, the inspection team discussed the process used for obtaining effective consent to legal parenthood and reviewed five sets of records where treatment with donor sperm had recently been provided in circumstances where consent to legal parenthood was required. Effective consent to legal parenthood with a prior offer of counselling was seen to be in place before treatment in all cases. In summary, the inspection team considers the processes used to obtain consent to legal parenthood at this centre to be compliant with HFEA requirements, however, see recommendation 8.

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

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

What the centre could do better

Consent (Guidance note 5;6)
When discussing the process for obtaining consent to legal parenthood, it was noted that couples are asked to provide consent at the same appointment as they receive implications counselling. It could be considered that couples do not have sufficient time to reflect before providing consent.

Guidance note 5.8; see recommendation 8.

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
Storage of gametes and embryos

What the centre does well

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

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

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

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

4. Information management

Record keeping
Obligations and reporting requirements

What the centre does well

Record keeping and document control (Guidance note 31)
The centre's procedures for keeping records are compliant with HFEA requirements to ensure that accurate medical records are maintained. 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. To allow 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 and allow donors to find out about the outcome of their donation.

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

What the centre could do better

Obligations and reporting requirements (Guidance note 32; General Direction 0005)
During this inspection members of the HFEA register team conducted an audit of patient records against data submitted to the HFEA. It was noted that 38% (46/121) of the IVF and 67% (8/12) of the Donor Insemination (DI) treatments reviewed had not been reported to the HFEA.

38% (38/73) of the IVF and 25% (1/4) of the DI treatments reviewed during the inspection had been reported to the HFEA outside the period required by General Direction 0005.

During this audit a significant discrepancy was noted in that 268 IVF and 8 DI fewer treatments cycles are recorded on the HFEA register for this centre than were recorded on the centre's own patient records system. By way of explanation, the registry team were informed that during a period when the centre was unable to submit data to the HFEA, some data had been submitted via the centre's sister clinic, centre 0007. A sample check of the HFEA register indicated this to be the case for many of the apparently unreported treatments, although not in all instances.

The effect of this action is that the treatments reported would appear on the HFEA register as having been conducted at centre 0007, not centre 0344. The implications of this finding impact on both centres and the HFEA in the following ways:

- The efficacy of the HFEA Risk Based Assessment Tool (RBAT) is compromised. RBAT is used to monitor centre's performance, treatment cycles attributed to one clinic but reported as having been conducted at another will not accurately reflect the performance of either centre.

- Choose a fertility clinic (CaFC) published data is drawn from the number and type of treatment cycles reported to the HFEA by each centre. Where treatment cycles are attributed to the wrong centre this will distort the CaFC data.
- HFEA fees are payable according to the number and type of treatment cycles performed as per treatment data submitted to the HFEA register, therefore centre 0007 will have fees generated for treatment the centre did not provide. It is however acknowledged that both centres are part of the same Trust.

The registry team were assured that the supplier of the centre's own patient records system had indicated an ability to transfer the correct data from the associated centre electronically.

General Direction 0005; SLC T9(e), T41; see recommendation 2.

Section 3: Monitoring of the centre's performance

Following the initial licence inspection in 2015, recommendations for improvement were made in relation to one area of major non compliance and two 'other' areas of practice. The PR provided evidence that all recommendations were fully implemented within the timescales.

On-going monitoring of centre success rates

No risk tool alerts have been issued to this clinic 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.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
1. Staffing The inspection team consider that staffing levels are inadequate for the usual level of activity undertaken. SLC T12.	The PR should assess how many cycles of treatment can be safely accommodated, taking into account staffing levels, skills mix, equipment and premises. A copy of the assessment should be submitted to the centre's inspector when responding to this report. The PR should ensure that workload is maintained within the safe limits determined in this assessment. When responding to this report, the PR should also	The outgoing PR can confirm that the cap that was put in place with regards to the numer of staff being required has been in place since the PR notified the HFEA (see email 09 February 2017 12:48) and the Trust Board have decided to limit Knutsford activity to 500 collections per annum. Additoinal staff are to be recruited including a doctor who is to provide full time clinical cover. the incoming PR can provide an update of	The executive acknowledges the PR's response and will remain in regular contact with the PR until the recruitment of staff has been completed. Further action is required.

	provide the centre's inspector with a timeline of when the new nursing and laboratory staff posts are expected to be filled.	this recuitment at the HFEA's request.	
2. Obligations and reporting requirements 38% (46/121) of the IVF and 67% (8/12) of the DI treatments reviewed at inspection had not been reported to the HFEA. 38% (38/73) of the IVF and 25% (1/4) of the DI treatments reviewed at inspection had been reported to the HFEA outside the period required by General Direction 0005. 268 IVF and 8 DI fewer treatments are recorded on the HFEA register for this centre than are recorded on the centre's own patient records system. This is largely because treatments have been submitted by centre 0007.	The PR should review procedures for submitting licensed treatment data to the HFEA to ensure that it is accurate and is provided within the timeframes specified in Directions. When responding to this report, the PR should provide a plan of action to address the issues identified at this inspection regarding the miss-registration of treatment information. Where treatments at the centre have been recorded as having taken place at centre 0007, action should be taken to ensure the records of both centres accurately reflect the licenced activity they have undertaken. The procedures used to submit licensed treatment data	The outgoing PR can confirm that the incoming PR will meet with the relevant discipline heads for both centre 0007 and 0344 to review the process of form submissions, meeting timeframes and staff involved and will provide an update summary by the 2nd June 2017. Issues regarding form submissions via third party systems have already been identified and errors have been corrected however a full review will take place to ensure that this does not happen again.	The executive acknowledges the PR's response and awaits the summary of the review of the submission of licensed treatment data by 2 June 2017. Further action is required.

General Direction 0005; SLC T9(e), T41.	should be reviewed to identify and address the reasons for non-reporting and delayed submissions (NB. this must include review and acting upon error reports which would have identified the reporting across two centres issue at a much earlier stage). A summary of this review should be submitted to the centre's inspector by 2 June 2017.		

Major area of non compliance

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

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
3. Medicines Management On inspection, the following issues were noted: • in two out of four patient records reviewed, the amount of a controlled drug recorded as having been administered in the controlled drugs register was different from that recorded in the patient's records; • the centre has not conducted a recent quarterly audit of controlled drugs in line with Trust policy; • nursing staff routinely dispense 'top up'	The PR should ensure that medicines management practices at the centre are compliant with legal requirements and professional best practice. The PR should conduct a review of the centre's controlled drugs procedures and this should include staff training requirements. A summary report of the review, including corrective actions taken, should be sent to the centre's inspector by 2 June 2017. Within three months of having implemented corrective actions, the centre should	The outgoing PR can confirm that the incoming PR will meet with the clinical staff to review the process of dispensing medicines and provide a full summary and action plan by the 2nd June 2017. A 3 month review has been added to the audit schedule and a summary report will be sent to the centre's inspector by 2nd September. The incoming PR will then commission the revised processes, the location of the drugs cabinet and staff training. The incoming PR will then provide an update of the timeframes these actions will then be implemented. The workforce review and recruitment of staff	The executive acknowledges the PR's response and awaits the summary of the review by 2 June 2017, the follow up audit of controlled drug administration by 2 September 2017 and confirmation of staff training. Further action is required.

medicines to patients for self-administration. Staff could not provide assurance of training in dispensing medicines nor is there an SOP to direct this process; • the controlled drugs cabinet is not fixed onto an external wall. SLC T2; The Misuse of Drugs (Safe Custody) Regulations 1973; NMC (2010) Standards for Medicines Management.	audit the recording of controlled drug administration in patient records to ensure actions taken are effective and ensure ongoing compliance with regulatory requirements and practice guidance. A summary report of the audit should be sent to the centre's inspector by 2 September 2017. The PR should commission a review of dispensing practice and management of medicines by a registered pharmacist including an assessment of the controlled drugs cabinet. The PR should advise the centre's inspector of the timescale for achieving this. Following this review, the PR should provide details of how and when staff are to receive training in the dispensing of medicines to take away.	will enable staff to have the time required to submit the relevant forms within the required timeframes.	
4. Quality management system	The PR should review the centre's audit programme to ensure that it is compliant in the range of audits performed,	The outgoing PR can confirm that the audit programme is to be reviewed by the quality team and corrective and	The executive acknowledges the PR's response and awaits the review of the audit programme by 2 June 2017

Although there is a comprehensive QMS, the centre's audit programme needs to be reviewed because: i) a recent quarterly audit of controlled drugs, in line with Trust policy, has not been undertaken. ii) audits that have identified and documented non-conformances do not consistently record corrective actions and the implementation of those actions. SLC T36. The centre does not have written SOPs for: i) the dispensing of top-up medication by nurses. ii) submitting data to the HFEA. iii) the legal parenthood SOP does not clearly define HFEA legal parenthood consent requirements. SLC T33b.	the methodology used and the documentation of corrective and preventative actions and their implementation. The PR should provide the centre's inspector with a copy of the review and an action plan for the implementation of this recommendation by 2 June 2017. The PR should provide copies of the audits and SOPs identified in this report as non-compliant by 2 June 2017.	preventative actions put in place to meet the requriements of SLC T36. A copy of the review and copies of the audits and SOPs will be sent to the centre's inspector by the incoming PR by 2nd June 2017.	and copies of the outstanding audits and SOPs by 2 June 2017. Further action is required.

5. Equipment and materials On the day of inspection, the centre was unable to provide documented evidence of the validation of the heated stages used in the embryology laboratory and the Gilson pipettes used for culture dish preparation. SLC T24. 1ml and 25ml pipettes used for culture dish preparation are not CE marked. SLC T30.	The PR should ensure that all critical equipment is appropriately validated and that validation is documented. A timeframe for the validation of the Gilson pipettes and the heated stages should be provided when responding to this report. It is expected that validation of these items will be complete by 2 June 2017. A timeframe for the introduction of CE marked 1ml and 25ml pipettes should be provided when responding to this report.	The outgoing PR can confirm that that the validation of critical equipment and relevant documentation will be completed in accordance with SLC T24 by the 2nd June 2017. The outgoing PR can confirm that CE marked serological pipettes will be sourced and introduced to the embryology laboratory by 1 July 2017.	The executive acknowledges the PR's response and awaits confirmation that the equipment identified has been validated by 2 June 2017 and that CE marked serological pipettes are in use by 1 July 2017. Further action is required.

Other areas of practice that requires improvement

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
6. Safety and suitability of premises and facilities Safety signage was not displayed in the gas store area. SLC T17.	The PR should ensure that compressed gas hazard signage is in place where medical gasses are stored and provide confirmation of this to the centre's inspector when responding to this report.	The outgoing PR can confirm that the appropriate hazard signage has been requested and will be in place as a matter of urgency. The incoming PR will confirm to the Centre's inspector when this has been completed.	The executive acknowledges the PR's response and awaits confirmation that gas hazard signage is in place. Further action is required.
7. Traceability A traceability record of centrifuges used in the processing of sperm for use in treatment is not kept. SLC T99.	The PR should ensure that all equipment (notably the centrifuges used to process sperm for use in treatment) and materials which may influence the quality and safety of gametes and embryos are traceable. When responding to this report, the PR should provide confirmation that this information is being recorded to ensure traceability. An audit should subsequently be performed to ensure the	The outgoing PR can confirm that a record of which centrifuge is used during sperm preparations was introduced shortly after the inspection team highlighted this non-conformance. An audit of these records will be performed and the report sent to the Centre's inspector by 2nd June 2017.	The executive acknowledges the PR's response and awaits a summary of the audit by 2 June 2017. Further action is required.

	actions taken are effective. A summary of this audit should be provided to the centre's inspector by 2 June 2017.		
8. Consent When discussing the process for obtaining consent to legal parenthood, it was noted that couples are asked to provide consent at the same appointment as they receive implications counselling. It could be considered that couples do not have sufficient time to reflect before providing consent. Guidance note 5.8.	The PR should review the process for seeking consent to legal parenthood to ensure couples have sufficient time to reflect or seek further information before providing consent. A summary of this review and an action plan should be provided to the centre's inspector by 2 June 2017.	The outgoing PR can confirm that the relevant discipline heads will meet to review the process of taking legal parenthood consent. A summary of which will be provided to the Centre's inspector by 2nd June 2017.	The executive acknowledges the PR's response and awaits the summary of the review by 2 June 2017. Further action is required.

Responses from the Person Responsible to this inspection report
The HFEA are aware that the outgoing PR (Karen Schnauffer) will hand over her responsibilities to the incoming PR (Andrew Drakeley) on the 13th April 2017 following the termination of her employment at the Hewitt Fertility Centre and the Liverpool Women's NHS Foundation Trust. The comments made in this report by the outgoing PR have been in response to reassurances made by the Liverpool Women's NHS Foundation Trust and by making the necessary arrangements for the non-conformances to be cleared as stated above. The PR would like to thank the HFEA for their constructive and encouraging advice during the inspection process, and also for all the help and support from the HFEA over the last few years during her position as PR for both Knutsford (0344) and Liverpool (0007) Hewitt Fertility Centres.