Executive Licensing Panel - minutes

Centre 0278 (Wrightington Wigan & Leigh Hewitt Fertility Partnership) Renewal Inspection Report

Friday, 11 March 2016

HFEA, Finsbury Tower, 103-105 Bunhill Row, London, EC1Y 8HF

Panel members	Juliet Tizzard (Chair) Ian Peacock Jessica Watkin	Director of Strategy & Corporate Affairs Analyst Programmer Policy Manager
Members of the Executive	Dee Knoyle	Secretary
External adviser		
Observers		

Declarations of interest

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

The panel had before it:

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

1. Consideration of application

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

1.2. The panel noted that this is a treatment (insemination using partner sperm) centre which provides basic fertility services. The panel noted that the centre also provides satellite IVF services to the Hewitt Fertility Centre, Liverpool (centre 0007), the Hewitt Fertility Centre, Knutsford (centre 0344) and CARE Manchester (centre 0185). Patients who require IVF are treated at the centre up to the point of egg collection and then referred to either centre 0007, 0344 or 0185 for completion of their treatment.

1.3. The panel noted that the centre has been licensed by the HFEA since 2007.

1.4. The panel noted that in 2014, the centre reported 196 cycles of partner insemination with 15 pregnancies. This equated to an 8% clinical pregnancy rate which was consistent with the national average.

1.5. The panel noted that at the time of the inspection on 5 January 2016, six major and one other areas of non-compliance were identified. The panel noted that since the inspection the Person Responsible (PR) has implemented one of the recommendations and has committed to implementing all of the outstanding recommendations.

1.6. The panel noted the inspectorate's recommendation that where areas of practice that require attention relate to satellite activities, the PR should liaise with the PR of the primary centres to ensure that these recommendations are effectively implemented. The PRs for the primary centres have been asked to provide evidence or commitment to fully implement these recommendations.

1.7. The panel noted that some improvement is required in order for the centre to demonstrate suitability of their practices. The centre has a Quality Management System in place and the PR is encouraged to use it to best effect to monitor and improve the service provided.

1.8. The panel noted that the inspectorate recommends the renewal of the centre's treatment (insemination using partner sperm) licence for a period of four years without additional conditions, subject to the recommendations made in this report being implemented within the prescribed timescales.

2. Decision

2.1. The panel had regard to its decision tree. It was satisfied that the appropriate application and fee had been submitted and that the application contained the supporting information required by General Directions 0008.

2.2. The panel was satisfied that the qualifications and character of the PR are such as is required for the supervision of licensed activities and the PR has discharged their duty under section 17 of the HFE Act 1990 (as amended).

2.3. The panel noted that the premises to be licensed are suitable for the conduct of the licensed activities.

2.4. The panel endorsed the inspectorate's recommendation to renew the centre's treatment (insemination using partner sperm) licence for a period of four years without additional conditions. The panel urged the centre to fully implement all of the outstanding recommendations within the prescribed timescales.

3. Chair's signature

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

Signature

Name

Juliet Tizzard

Date

18 March 2016

Inspection Report

Purpose of the Inspection Report

This is a report of an inspection, carried out to assess whether this centre complies with essential requirements in providing safe and high quality care to patients. 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: 5 January 2016

Purpose of inspection: Renewal of a licence to carry out Treatment (Insemination using partner sperm)

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), Susan Jolliffe

Date of Executive Licensing Panel: 11 March 2016

Centre name	Wrightington Wigan & Leigh Hewitt Fertility Partnership
Centre number	0278
Licence number	L/0278/3/b
Centre address	Wrightington Hospital, Hall Lane, Appley Bridge, Wigan, Lancashire, WN6 9EP, UK
Person Responsible	Mr Phillip Harris
Licence Holder	A new application has been received.
Date licence issued	1 July 2012
Licence expiry date	30 June 2016
Additional conditions applied to this licence	None

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Section 1: Summary report

Brief description of the centre and its licensing history:

The Wrightington Wigan & Leigh Hewitt Fertility Partnership has held a Treatment (Insemination using partner sperm) licence with the HFEA since 2007 and provides basic fertility services to NHS and self funding patients.

The centre also provides satellite in vitro fertilisation (IVF) services to The Hewitt Fertility Centre, Liverpool (centre 0007), The Hewitt Fertility Centre, Knutsford (centre 0344) and CARE Manchester (centre 0185). Patients who require IVF are treated at the centre up to the point of egg collection and then referred to either centre 0007, 0344 or 0185 for completion of their treatment.

The centre's current licence was varied in March 2015 to reflect a change of premises and to change the centre name from The Assisted Conception Unit at Leigh Infirmary to The Wrightington Wigan & Leigh Hewitt Fertility Partnership.

Following the resignation of the Licence Holder (LH), an application to vary the licence to reflect a change of LH has been received and will be considered by ELP in due course.

Pregnancy outcomes
In 2014, the centre reported 196 cycles of partner insemination with 15 pregnancies. This equates to an 8% clinical pregnancy rate which is consistent with the national average.

Summary for licensing decision

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

- the application has been submitted in the form required;
- the application has designated an individual to act as the Person Responsible (PR);
- the PR's qualifications and experience comply with section 16 (2) (c) of the HF&E Act 1990 (as amended);
- the PR has discharged his duty under section 17 of the HF&E Act 1990 (as amended);
- 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 recommendations for improvement were made in relation to six major areas of non compliance and one 'other' area of practice.

Since the inspection visit, the following recommendation has been implemented:

Major areas of non compliance:

- The PR should ensure that all critical procedures are validated.

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

Major areas of non compliance:

- The PR should ensure that witnessing checks carried out at critical points of the clinical and laboratory process are documented.
- The PR should ensure that standard operating procedures (SOPs) and audits are in place for all activities authorised by the centre's licence and other activities carried out in the course of providing treatment services.
- In liaison with the PRs for the primary centres, the PR should ensure that audits are conducted of the satellite service provided to patients and that the appropriate satellite agreements in place.
- The PR should ensure that CE marked medical devices are used wherever possible.
- The PR should ensure that staff are trained and competent in taking consent.

'Other' areas that require improvement:

- The PR should ensure that the centre's procedures for accurate patient record keeping and document control are compliant with all relevant regulatory requirements and guidance.

Where areas of practice that require attention relate to satellite activities, it is recommended that the PR should liaise with the PR of the primary centres to ensure that these recommendations are effectively implemented. The PRs for the primary centres have been asked to provide evidence or commitment to fully implement these recommendations.

Recommendation to the Executive Licensing Panel

The centre has no critical areas of concern but does have six major areas of non compliance.

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

The inspection team recommends the renewal of the centre's treatment (Insemination using partner sperm) licence for a period of four years without additional conditions subject to the recommendations made in this report being implemented within the prescribed timescales.

Section 2: Inspection findings

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

1. The protection of the patient, and children born following treatment at this centre
2. The experience of patients at this centre
3. The protection of gametes (sperm) 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)
Good witnessing processes are vital in ensuring there are no mismatches of gametes and that identification errors do not occur. The centre's procedures for double checking the identification of gametes and the patient to whom they relate are partially compliant with HFEA requirements.

What the centre could do better
During a review of five sets of patient records, in one record, a second witness step for the identification of the gametes prior to insemination was not recorded (SLC T102 and T71). The patient identification check prior to insemination, although performed, was not documented (SLC T100 (a)).

See recommendation 1.

Donor selection criteria and laboratory tests

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

What the centre does well

The centre does not recruit donors or provide treatment with donor gametes therefore this area of practice is not applicable to this inspection.

What the centre could do better
Not applicable to this inspection.

Suitable premises and suitable practices
Safety and suitability of premises and facilities
Laboratory accreditation
Infection control
Medicines management
Pre-operative assessment and the surgical pathway
Multiple births
Procuring gametes and embryos
Transport and distribution of gametes and embryos
Receipt of gametes and embryos
Imports and exports
Traceability
Quality management system
Third party agreements
Transports and satellite agreements
Equipment and materials
Process validation
Adverse incidents

What the centre does well

Safety and suitability of premises and facilities (Guidance note 25)
The centre's premises are suitable. This is important to ensure that all licensed activities are conducted in a suitable environment that is fit for purpose.

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

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

Laboratory accreditation (Guidance note 25)
The centre's laboratories and third party laboratories which undertake the diagnosis and investigation of patients, patients' partners, or their gametes, are compliant with HFEA requirements for accreditation by CPA (UK) Ltd or another body accrediting to an equivalent standard. This is important to assure the quality of the services provided.

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

Medicines management
The centre has systems in place for the safe storage, disposal and administration of medicines that are compliant with guidance.

Pre-operative assessment and the surgical pathway
The centre does not perform surgical procedures as part of its licensed activities therefore this area of practice is not applicable to this inspection.

Multiple births (Guidance note 7; General Direction 0003)
The centre provides insemination with partner sperm treatment only and is therefore not subject to the requirements of General Direction 0003 regarding the number of embryos transferred.

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

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

Transport and distribution of gametes (Guidance note 15; General Direction 0009)
The centre does not transport or distribute gametes therefore this area of practice is not applicable to this inspection.

Receipt of gametes (Guidance note 15)
The centre does not receive distributed gametes or embryos from other centres; therefore this area of practice is not applicable to this inspection.

Imports and exports (Guidance note 16; General Direction 0006)
The centre does not import or export gametes or embryos therefore this area of practice is not applicable to this inspection.

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

Quality management system (QMS) (Guidance note 23)
The centre has a QMS in place 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 is a satellite IVF provider to the three primary centres identified earlier in this report. It is important to ensure that activities performed by satellite clinics on behalf of the licensed primary centres are suitable and meet HFEA requirements. The primary centres to which centre 0278 is a satellite have agreements in place that are partially compliant with HFEA requirements.

Equipment and materials (Guidance note 26)
The centre uses equipment and materials that are partially 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 partially compliant with HFEA requirements to validate critical processes. This ensures that these processes are effective and do not render the gametes 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 has not experienced any adverse incidents. The inspection team was confident after discussion with the PR that any adverse incidents would be reported. 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

QMS (Guidance note 23)
The QMS was considered by the inspection team to be non-compliant in several areas:

- the centre does not have a quality manager or recognised quality lead to ensure that the QMS is maintained effectively (CoP 23.3(a));
- the SOP for pre treatment advice is still in draft form (SLC T33b);
- whilst staff were able to clearly describe the processes used for screening patients and their partners, the centre does not have an SOP in place for this activity (SLC T33b);
- the SOP for the management of a needle stick injury is marked for review by May 2014 but this has not been done (SLC T34);
- the centre does not have an SOP to ensure that all patient records are kept for a minimum of 30 years (SLC T33b, T48);
- the centre does not have an SOP for the process of obtaining consent to legal parenthood (SLC T33b).

The centre has not audited the following activities: infection control, record keeping or confidentiality within the last two years (SLC T36).

See recommendation 2.

Transport and satellite agreements (Guidance note 24; General Direction 0010)
The satellite agreements were considered by the inspection team to be non-compliant because:

- there was no evidence that the three primary centres have audited the satellite service to ensure that the service is compliant with HFEA requirements (CoP 24.1, 3a, c and 6);
- the satellite agreement in place with CARE Manchester (0185) has not been

reviewed since 2009 (SLC T114(c));
- the satellite agreement in place with The Hewitt Fertility Centre (0007 and 0344) was not sufficient in scope to fulfil the requirements of General Direction 0010.

See recommendation 3.

Equipment and materials (Guidance note 26)
The following medical devices used by the centre are not CE marked: 5 ml and 10 ml tubes used to prepare sperm for treatment (SLC T30).

See recommendation 4.

Process validation (Guidance note 15)
At the time of the inspection the 'swim-up' procedure used for processing sperm for treatment had not been validated (SLC T72).

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 academic qualifications in the field of medicine and has more than two years of practical experience which is directly relevant to the activity to be authorised by the licence. The PR has successfully completed the HFEA PR Entry Programme (PREP number T/1125/7).

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)
In one of five sets of patient records reviewed, the patient had completed a consent to legal parenthood form but was not receiving treatment using donated gametes or embryos. The inspection team was concerned that this may indicate that staff seeking these consents are not all trained and competent in the correct use of these consent forms (SLC T12 and T15 (a, d)). See recommendation 6).

It was also noted that at the time of inspection there was no SOP to direct the process for

seeking consent to legal parenthood (SLC T33 (b), see recommendation 2.

Welfare of the child and safeguarding

What the centre does well

Welfare of the child (Guidance note 8)
The centre's procedures to ensure that the centre takes into account the welfare of any child who may be born as a result of the licensed treatment, and of any other child who may be affected by that birth before treatment is provided are compliant with HFEA requirements.

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

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

Embryo testing

Preimplantation genetic screening
Embryo testing and sex selection

What the centre does well

The centre does not create embryos or perform embryo testing and therefore this area of practice is not applicable to this inspection.

What the centre could do better
Not applicable to this inspection.

2. The experience of patients

Patient feedback

What the centre does well

During the inspection visit the inspectors spoke to three patients who provided feedback on their experiences. A further 12 patients also provided feedback directly to the HFEA in the time since the last inspection. Feedback was positive, with 11 of the individuals providing written feedback to the HFEA commenting that they have compliments about the care that they received.

On the basis of this feedback and observations made in the course of the inspection it was possible to assess that the centre:

- has respect for the privacy and confidentiality of patients in the clinic;
- gives patients sufficient, accessible and up-to-date information to enable them to make informed decisions;
- provides patients with satisfactory facilities for their care.

What the centre could do better

Nothing identified at this inspection.

Treating patients fairly

Counselling
Egg and sperm sharing arrangements
Surrogacy
Complaints
Confidentiality and privacy

What the centre does well

Treating patients fairly (Guidance note 29)
The centre's procedures are compliant with the HF&E Act 1990 (as amended) to ensure that staff members understand the requirements for a conscientious objection to providing a particular licensed activity governed by the Act.

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

Counselling (Guidance note 3)
The centre is not required to provide counselling for basic partner IUI services however, counselling is offered to all patients including those treated as part of satellite services. The centre's counselling procedures are compliant with HFEA requirements. This is important to ensure that counselling support is offered to patients and donors providing relevant consent and prior to consenting to legal parenthood.

Egg and sperm sharing arrangements (Guidance note 12; General Direction 0001)
The centre does not undertake egg and sperm sharing arrangements and therefore this

area of practice is not applicable to this inspection.

Surrogacy (Guidance note 14)
The centre does not provide surrogacy treatments and therefore this area of practice is not applicable to this inspection.

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

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

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

Information

What the centre does well

Information (Guidance note 4; Chair's Letter CH(11)02)
The centre's procedures for providing information to patients are compliant with HFEA requirements. This ensures that the centre gives prospective and current patients 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
Disclosure of information, held on the HFEA Register, for use in research

What the centre does well

Consent (Guidance note 5;6)
The centre's procedures for obtaining consent are compliant with HFEA requirements. This ensures that patients and donors have provided all relevant consents before carrying out any licensed activity. However, please see section 'Staff' and recommendation 6.

Disclosure of information, held on the HFEA Register, for use in research (General Direction 0005)
Consent to disclosure to researcher's requirements is not relevant to basic partner IUI services and therefore this area of practice is not relevant to this inspection.

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

3. The protection of gametes and embryos

Respect for the special status of the embryo

What the centre does well
The centre does not create embryos therefore this area of practice is not applicable to this inspection.

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 and processing of gametes.

Storage of gametes and embryos (Guidance note 17)
The centre does not store gametes and embryos therefore this area of practice is not applicable to this inspection.

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

Use of embryos for training staff (Guidance note 22)

What the centre does well

The centre does not use embryos for training staff therefore this area of practice is not applicable to this inspection.

What the centre could do better
Not applicable to 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 broadly compliant with HFEA requirements to ensure that accurate medical records are maintained. Good medical records are essential for the continuity of the patient's care.

Obligations and reporting requirements (Guidance note 32; General Direction 0005)
The centre provided an annual return for treatments undertaken in 2014 within the required timeframe (General Direction 0005). At the time of writing, the due date for submission of 2015 data had not been reached.

What the centre could do better

Record keeping and document control (Guidance note 31)
The centre's procedures for record keeping were considered to be non-compliant in the following areas:

- in five sets of patient records reviewed, the consent forms were not completed with the patient identification number on each page of the document. If separated it would not be possible to identify to whom the consent form related (SLC T37, General Directions 0012);
- two patient information sheets for medication had no document control; therefore it was difficult to provide assurance that this was the most current version, or when it had last been reviewed. Staff did however provide assurance that the information was correct (SLC T34).

See recommendation 7.

Section 3: Monitoring of the centre's performance

Following the interim inspection in 2014, no recommendations for improvement were made.

On-going monitoring of centre success rates

As this centre only provides partner IUI treatment, their success rates are not subject to on-going monitoring through the HFEA risk tool and the centre has not therefore been issued with any performance alerts.

Areas of practice requiring action

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

Critical area of non compliance

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

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

Major area of non compliance

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

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
1. Witnessing A review of five sets of patient records identified one record where a second witness check for the identification of the gametes prior to insemination was not recorded. The patient identification check prior to insemination, although performed, is not documented. SLC T71, SLC T100 (a).	The PR should ensure that witnessing checks carried out at critical points of the clinical and laboratory process are documented. The centre's witnessing sheet was amended on the day of the inspection to include the identification of the patient prior to insemination. In order to determine whether this corrective action is effective, the PR should conduct an audit of witnessing records within three months of this change having been implemented. A summary report of the audit should be submitted to the lead inspector	The documentation was altered on the day and the revised witnessing sheet seen by the inspection team. The audit of implementation is currently ongoingh to enable a summary report to be submitted by April as requested.	The inspector acknowledges the PR's response and awaits the summary report of the audit by 5 April 2016. Further action is required.

	by 5 April 2016.		
2. Quality management system The centre does not have a quality manager or recognised quality lead to ensure that the QMS is maintained effectively. CoP 23.3(a). The centre does not have a current SOP for: • pre treatment advice • screening of patients and their partners • management of a needle stick injury (review date of May 2014) • procedure to ensure that records are kept for at least 30 years. On inspection there was no SOP to direct the process for seeking consent to legal parenthood. This has subsequently been provided. SLC T33b.	The PR should take action to ensure that the QMS is effectively maintained by appointing a quality manager. The PR should inform the lead inspector how this will be addressed by 5 April 2016. The PR should ensure the appropriate SOPs are in place and authorised for release where indicated. Copies of the SOPs should be provided to the lead inspector by 5 April 2016. The PR should ensure that the outstanding audits identified in this report are completed within 3 months. A summary report of the audits including corrective actions and the timescale for their implementation should be submitted to the lead inspector by 5 April 2016.	A quality manager has been appointed. Job description is currently being updated to reflect the alteration ot roles. SOPs are being updated and will be submitted within the required timescale, the same applies to the audits not y et submitted. The confidentiality audit has already been submitted.	The inspector acknowledges the PR's response and awaits the SOPs and summary reports of the outstanding audits by 5 April 2016. Further action is required.

In the last two years the centre has not audited: • Infection Control • Record keeping • Confidentiality SLC T36.			
3. Satellite agreements The three primary centres have not audited the satellite service. The satellite agreement in place with CARE Manchester (0185) has not been reviewed since 2009. The satellite agreement in place with The Hewitt Fertility Centre (0007 and 0344) does not fulfil the scope of requirements of General Direction 0010.	The PR should work with the PRs of the primary centres to provide an action plan of how these recommendations are to be implemented and the timescale required. It is expected that these actions will have been completed by 5 July 2016. A summary of audits completed and a copy of any revised satellite agreements should be provided to the lead inspector by 5 July 2016.	We are working with the relevant PRs to update the Satellite agreements. LWH PR is providing support so that the audits can be undertaken and submitted by 5 July 2016, as requested. Response from the PR of centres 0007 and 0344: The PR of the primary centre (0007) can confirm that there is an audit schedule for the satellite service for Wrightington Wigan & Leigh Hewitt Fertility Centre. Response from the PR of centre 0185: It is planned that the PR of Manchester will visit Wrightington, Wigan and Leigh Hewitt Fertility partnership within the next 3 months to	The inspector acknowledges the PR's response and awaits the revised satellite agreements and the outcome of the audits by 5 July 2016. Further action is required.

		carry out audits as required by the HFEA The satellite agreement with Wrightington, Wigan and Leigh will be reviewed within the next 3 months.	
4. CE marking The following medical devices used by the centre are not CE marked: 5 ml and 10 ml tubes used to prepare sperm for treatment. SLC T30.	The PR should ensure that CE marked medical devices are used wherever possible. We would not recommend the implementation of precipitous changes that might impact on the quality of treatment that is provided to patients. When responding to this report, the PR should confirm when the materials identified in this report will be either replaced with a suitable alternative, or the current products will obtain the appropriate certification. It is expected that suitable products will be in place by 5 July 2016.	Work ongoing to test alternative options regarding the tubes. Toxicity testing being undertaken. Currently still using stocks of the CE marked tubes. Changes to supplier will be made soon (probably to ELKA).	The inspector acknowledges the PR's response and commitment to ensuring that this recommendation is fully addressed. Further action is required.
5. Process validation The centre has not validated the following critical	The PR should ensure that all critical procurement and processing procedures are validated.	n/a	No further action is required.

procurement and processing procedures: sperm preparation for IUI treatment. SLC T72.	The inspection team was provided with a validation document for this procedure by the end of the inspection visit. **No further action is required.**		
6. Staff In one of five sets of patient records reviewed, the patient had a completed consent to legal parenthood form but the patient was not receiving treatment using donor gametes. The inspection team was concerned that this may indicate that staff taking these consents are not all trained and competent in the correct use of these consent forms. SLC T12, T15 a and d.	The PR should ensure that all relevant staff are trained and competent in taking consent including that which relates to legal parenthood. Where centre staff are seeking consent on behalf of the primary centres as part of the satellite service, in liaison with the PRs for the primary centres, the PR should review the consent process in place to ensure that staff are fully informed of the relevant consent requirements. A summary of this review including any corrective actions should be submitted to the lead inspector by 5 April 2016. Three months following the review, the PR should conduct an audit of patient records to ensure that the correct consent forms are being completed. A	Incorrect form destroyed. Support provided by matron at LWH to give additional training to the staff regarding consent forms. Audit will take place in a couple of months to ensure adequate implementation of corrective actions. Results will be submitted to lead inspector by 6 July 2016. Response from the PR of centres 0007 and 0344: The PR of the primary centre (0007) can confirm that week commencing 25th January the Hewitt Fertility Centre Liverpool Matron (Jane Mutch) attended Wrightington Wigan & Leigh Hewitt Fertility	The inspector acknowledges the PR's response and awaits the summary report of the follow up audit by 5 July 2016. A summary of the consent competency training report, including corrective actions has been submitted by the PR of centres 0007 and 0344. Further action is required.

	summary of the audit including any corrective actions and the timescale for their implementation should be submitted to the lead inspector by 5 July 2016.	Centre to perform consent competency training, she plans to repeat this. Response from the PR of centre 0185: The PR of CARE Manchester will liaise with the PR of Wrightington, Wigan and Leigh in order to seek reassurance that a process is in place to ensure correct consents are used.	

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
7. Record keeping and document control In five sets of patient records reviewed, the consent forms were not completed with the patient identification number on each page of the document. SLC T37, General Directions 0012. Two patient information sheets for medication had no document control. SLC T34.	The PR should ensure that the centre's procedures for accurate patient record keeping and document control are compliant with all relevant regulatory requirements and guidance. The PR should review the centre's process by which staff check consent forms after completion by the patients, to ensure that the documentation is complete. Corrective action should be implemented and the centre should perform an audit to ensure that these actions have been effective. A summary report of the audit including corrective actions and the timescale for their implementation should be submitted to the lead inspector by 5 July 2016. The PR should ensure there is an established document	Review of consent process being undertaken to ensure robust checks in place. An audit will be undertaken to ensure implementation. Audit to be submitted by 5 July 2016. Updated versions of the patient info sheets and document control procedure to be submitted by 5 April 2016.	The inspector acknowledges the PR's response and awaits the summary report of the audit by 5 July 2016 and the copy of the updated version of both the patient information leaflets and the document control procedure by 5 April 2016. Further action is required.

	control procedure in place; a copy of the updated version of both the patient information leaflets and the document control procedure should be submitted to the lead inspector by 5 April 2016.		

Reponses from the Person Responsible to this inspection report