

# Executive Licensing Panel - minutes

## Centre 0075 (London Women's Clinic, Darlington) Interim Inspection Report

Monday, 21 March 2016

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

Panel members	Juliet Tizzard (Chair) David Moysen Ian Peacock	Director of Strategy & Corporate Affairs Head of IT Analyst Programmer
Members of the Executive	Dee Knoyle Ian Brown	Secretary Head of Corporate Governance
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.

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## 1. Consideration of application

- 1.1. The panel noted that London Women's Clinic, Darlington, centre 0075, has held a licence with the HFEA since 1992. The centre provides a full range of fertility services
- 1.2. The panel noted that the centre's licence is due to expire on 31 March 2018.
- 1.3. The panel noted that the inspection took place on 26 November 2015.
- 1.4. The panel noted that in the 12 months to 31 October 2015, the centre provided 420 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a small centre.
- 1.5. The panel noted that for IVF and ICSI, HFEA-held register data for the year ending July 2015 showed the centre's success rates were in line with national averages.
- 1.6. The panel noted that in 2014, the centre reported eight cycles of partner insemination with no pregnancies. This was consistent with the national average.
- 1.7. Between August 2014 and July 2015, the centre's multiple pregnancy rate for all IVF, ICSI and frozen embryo transfer (FET) cycles for all age groups was 10%. This means that the centre's multiple live birth rate is likely to be consistent with the 10% maximum multiple live birth rate target.
- 1.8. The panel noted that in March 2015, the Licence Committee renewed the centre's licence and expressed deep concern regarding the number and seriousness of the areas of non-compliance noted on the renewal inspection, especially those in relation to staff training and patient safety. However, the committee noted the engagement of the Person Responsible (PR) with the executive and agreed to renew the centre's licence for a period of three years instead of the usual four and the committee strongly endorsed the executive's proposal to undertake a targeted inspection within nine months of the licence renewal.
- 1.9. The panel noted that the interim inspection was carried out eight months after the centre's licence was renewed. This interim inspection was an announced visit, rather than a standard unannounced interim inspection, to allow for a full review of the effectiveness of the implementation of the recommendations from the renewal inspection in November 2014.
- 1.10. The panel noted that at the time of this interim inspection on 26 November 2015, one critical, three major and one other areas of non-compliance were identified. The panel noted that the inspectorate was concerned to note a repeat of three non-compliances from the previous inspection, especially with respect to medicines management. The panel noted that since the inspection the PR has provided evidence that all of the recommendations have been implemented. It is expected that the PR will audit the areas which required improvement regularly to ensure that progress is maintained.
- 1.11. The panel noted that the PR will provide an update or summary of audits conducted by the dates specified, to ensure that the corrective actions taken are effective. The executive will monitor the centre's progress closely and, if there are concerns, will perform an additional focussed inspection before the next scheduled visit at the end of 2017.
- 1.12. The panel noted that the inspectorate recommends the continuation of the centre's treatment and storage licence without additional conditions.

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## 2. Decision

- 2.1.** The panel was concerned that despite the fact that the interim inspection was an announced, targeted inspection, there were still a number of non-compliances identified that had also been an issue at the renewal inspection, in particular those relating to medicines management and consent. However, the panel noted that since the interim inspection, the centre has addressed all of the non-compliances. The panel stressed that it expects to see these improvements sustained and that the inspector see evidence of this at the next inspection.
- 2.2.** The panel had regard to its decision tree and was satisfied that the centre was fit to have its treatment and storage licence continued.

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## 3. Chair's signature

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

### Signature



### Name

Juliet Tizzard

### Date

30 March 2016

# Interim Licensing Report



**Centre name:** London Women's Clinic, Darlington  
**Centre number:** 0075  
**Date licence issued:** 1 April 2015  
**Licence expiry date:** 31 March 2018  
**Additional conditions applied to this licence:** None  
**Date of inspection:** 26 November 2015  
**Inspectors:** Sara Parlett (Lead), Gill Walsh, Polly Todd  
**Date of Executive Licensing Panel:** 21 March 2016

## Purpose of the report

The Human Fertilisation and Embryology Authority (HFEA) is the UK's independent regulator of the fertility sector. The HFEA licenses centres providing in vitro fertilisation (IVF) and other fertility treatments and those carrying out human embryo research.

Licensed centres usually receive a licence to operate for up to four years and must, by law, be inspected every two years. The full inspection prior to a licence being granted or renewed assesses a centre's compliance with the law and the HFEA's Code of Practice (CoP) and Standard Licence Conditions (SLC).

This is a report of an announced interim inspection together with our assessment of the centre's performance based on other information. We do this at the mid-point of the licence period. For 2015-2017 the focus of an interim inspection is:

- **Quality of care:** the quality of care provided by a centre is defined by positive healthcare outcomes and a positive patient experience delivered via safe and effective care.
- **Patient safety:** patient safety is a fundamental and essential attribute to quality healthcare: without safety there cannot be high quality. Improving safety is an ethical imperative for healthcare providers, and the individuals who deliver that care.
- **Patient experience:** understanding what matters to patients and improving the patient experience is crucial in delivering high quality care.

We also take into account the centre's own assessment of its service; the progress made in implementing the actions identified at the last inspection; and our on-going monitoring of the centre's performance.

The report represents a mid-term evaluation of a centre's performance based on the above. The aim is to provide the Authority's Executive Licensing Panel (ELP) with information on which to make a decision about the continuation of the licence.

## Summary for the Executive Licensing Panel

The ELP is asked to note that there are recommendations for improvement in relation to one critical, three major and one 'other' areas of non compliance or poor practice.

In responding to the report the PR has provided evidence that the following recommendations have been implemented:

### **'Critical' areas of non compliance:**

- **The PR should ensure that a suitably trained and competent controlled drugs accountable officer (CDAO) is appointed.**

**The PR should review practices relating to the management of medicines, including safe and secure transport, to ensure compliance with legislation and best practice guidance.**

### **'Major' areas of non compliance:**

- The PR should ensure that audits are effective and should review barriers to implementing learning from guidance or recommendations provided by the HFEA and other sources.
- The PR should ensure that patient consent is recorded clearly and accurately.
- The PR should ensure that all standard operating procedures (SOPs) accurately describe the procedures used at the centre.

### **'Other' areas of practice that require improvement:**

- The PR should ensure that all notices fixed to walls in clinical areas are 'wipe clean' and that clinical areas are cleaned thoroughly to ensure compliance with infection control best practice guidance.

Where required and by the dates specified, the PR will provide an update or summary of audits conducted to ensure that the corrective actions taken are effective.

### **Recommendation to ELP**

The inspection team was concerned to note a repeat of three non-compliances from the previous inspection, especially with respect to medicines management.

The inspection team recommends the continuation of the centre's licence without additional conditions. It is expected that the PR will audit the areas which required improvement regularly to ensure that progress is maintained. The executive will monitor the centre's progress closely and if there are concerns, will perform an additional focussed inspection before the next scheduled visit at the end of 2017.

## Information about the centre

London Women's Clinic, Darlington has held a licence with the HFEA since 1992 and provides a full range of fertility services.

The centre provided 420 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 October 2015. In relation to activity levels this is a small centre.

This interim inspection was carried out eight months after the centre's licence was renewed. The licence committee (LC) in March 2015 that renewed the centre's licence expressed deep concern regarding the number and seriousness of the areas of non compliance noted on inspection, especially those in relation to staff training and patient safety. The committee noted the engagement of the PR with the executive and agreed to renew the centre's licence for a period of three years but strongly endorsed the executive's proposal to undertake a targeted inspection within nine months of the licence renewal.

This inspection was an announced visit, rather than a standard unannounced interim inspection, to allow for a full review of the effectiveness of the implementation of the recommendations from the renewal inspection in November 2014.

## Details of Inspection findings

### Quality of Service

Each interim inspection focuses on the following themes: they are important indicators of a centre's ability to provide high quality patient care and to meet the requirements of the law.

### Pregnancy outcomes<sup>1</sup>

For IVF and ICSI, HFEA held register data for the year ending July 2015 show the centre's success rates are in line with national averages.

In 2014, the centre reported eight cycles of partner insemination with no pregnancies. This is consistent with the national average.

### Multiple births<sup>2</sup>

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

Between August 2014 and July 2015 the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 10%. This means that the centre's multiple live birth rate is likely to be consistent with the 10% multiple live birth rate target.

### Witnessing

Good witnessing processes are vital in ensuring there are no mismatches of gametes or embryos and that identification errors do not occur. The following laboratory activity was observed in the course of the inspection: preparation for embryo transfer. The procedure

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<sup>1</sup>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  $p \leq 0.002$ .

<sup>2</sup>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%.

was witnessed using an electronic witnessing system in accordance with HFEA requirements.

### **Consent: To the storage of cryopreserved material**

The storage of gametes and embryos is an important service offered by fertility clinics. It enables patients to undergo further fertility treatment without additional invasive procedures and to preserve their fertility prior to undergoing other medical treatment such as radiotherapy. It is important that the centre has measures in place to ensure that gametes and embryos are stored in accordance with the consent of the gamete providers.

On inspection, reports of audits of stored gametes and embryos, the accuracy of storage logs and consent records were reviewed and the 'bring-forward' system was discussed with staff. These activities indicate that the centre's processes for storing gametes and embryos in line with the consent of the gamete providers are effective.

### **Staffing**

Having the right numbers of staff, competent to carry out highly technical work in a non-pressured environment is important in infertility services.

Following the concerns relating to staffing at the last inspection, this area was reviewed in detail. The inspection team considered that staffing levels in the clinic are currently suitable for the activities being carried out.

### **Quality Management System (QMS)**

It is important that centres audit all of their practices at least every two years to ensure they are delivering the expected quality of service, that staff are following prescribed SOPs and that the centre's processes meet the HFEA's regulatory requirements. It is also important that these audits are robust and that any necessary changes that are identified are made, as this supports continuous improvement.

The effectiveness of the centre's QMS was assessed by reviewing the reports of the following audits: witnessing; storage of gametes and embryos; consent and infection control.

It is noted that the centre's consent and infection control audits failed to identify non compliance with requirements, as noted later in this report. On this basis it is concluded that the centre's procedures for auditing are broadly compliant with requirements (recommendation 2).

The inspectors also considered whether the clinic's processes for implementing learning are effective. If a clinic is to achieve continuous improvement and encourage a learning culture then it is important that they act to review their practices when guidance is issued by the HFEA or other bodies. The clinic's procedures for acting on guidance from the HFEA were evaluated with reference to the following:

- the use of CE marked medical devices;
- the centre's processes for obtaining consent to legal parenthood;
- the content of the centre's website;
- the use of the most recently issued HFEA consent form versions;

- HFEA clinic focus articles regarding screening requirements and medicines management.

A recommendation has been made relating to medicines management (recommendation 1) and three recommendations from the last inspection have not been fully implemented (refer to page 7 of this report). In consideration of this it can be concluded that some improvement is required for the centre to have a fully effective learning culture (recommendation 2).

### **Medicines management**

It is important that clinics follow best practice for medicines management both to protect patients and ensure that medicines are stored, administered and disposed of in the correct way.

During the inspection, the clinic's processes for medicines management and the safe storage, disposal and administration of medicines were reviewed and were not compliant with requirements because:

- the PR stated that a CDAO application was made to the CQC soon after the inspection in 2014. However, on this inspection centre staff were not aware of this and no CDAO is in place;
- the centre has recently changed its supplier of medicines. The current supplier employs a different practice for the transport and delivery of controlled drugs to the centre which does not provide adequate tracking or assurance of continuous safe custody. It is noted that centre staff have raised this with the supplier as a concern;
- the cabinet in which medicines are being stored is a lockable office cabinet which does not meet relevant British Standards requirements for the safe storage of medicines;
- a review of the controlled drug book on inspection found that a record of the full name, form and strength of controlled drug is not documented in all instances.

The centre has also not conducted a comprehensive audit of its management of controlled drugs within the last two years.

See recommendation 1.

### **Infection Control**

It is important that clinics have suitable arrangements in place so that patients experience care in a clean environment and to prevent patients and staff acquiring infections.

During the inspection, the inspectors reviewed infection control practices and found them to be broadly compliant with guidance because:

- some notices fixed to walls in clinical areas were not 'wipe clean';
- individual patient bays in the recovery area have sliding doors – the grooves in which these doors run had collected dirt and debris.

See recommendation 5.

## Equipment and Materials

It is important that products (known as medical devices) that come into contact with gametes and/or embryos are approved for the provision of fertility treatment, to ensure the safety of gametes, embryos and patients. The approval of such products is denoted by the issue of a 'CE mark'.

The CE mark status of all consumables and reagents were reviewed in the course of the inspection. The centre is compliant with HFEA requirements to use CE marked medical devices wherever possible.

## Patient experience

During the inspection, two patients were available to speak with the inspectors about their experiences at the centre. Three patients provided feedback directly to the HFEA in the time since the last inspection. Feedback was positive with two giving compliments about the care received.

The centre's own patient satisfaction survey results were reviewed and were very positive.

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

- has respect for the privacy and confidentiality of patients in the clinic;
- provides a clean and well organised environment for patient treatment;
- has staff who are supportive and professional;
- gives prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions;
- maintains an effective system for responding to patient phone calls.

## Monitoring of the centre's performance

In addition to commenting on evidence gathered on the inspection it is important to report on the centre's performance since the granting of the licence based on other evidence available to us.

## Compliance with HFEA standard licence conditions

From a review of patient records during the visit to the centre, the inspection team identified the following non-compliances:

- in several sets of records the patient's unique identifier (for example: NHS number) had not been recorded on the HFEA consent forms;
- in one set of records the consent decisions of a patient were not clear in relation to disclosure of identifying information. The patient had ticked 'yes' to disclosure to her GP but had also ticked 'not to anyone (other than in a medical emergency)'. Letters containing identifying information had been sent to the GP and it is unclear to the inspection team if this disclosure was made with the consent of the patient;
- HFEA consent forms require patients to sign and date a declaration on each page to confirm they have read the page and fully agree with the consent and information given. In one set of records the page declaration on one page of a male treatment (MT) consent form had been signed and dated by the patient, but the date recorded was partly the date of signing and partly the patient's birth year.

See recommendation 3.

## **Compliance with recommendations made at the time of the last inspection**

Following the renewal inspection in November 2014, recommendations for improvement were made in relation to four critical, eight major and three 'other' areas of non compliance.

This inspection focussed on the effective implementation of the recommendations from the renewal inspection. The PR provided evidence that most of the recommendations had been fully implemented prior to the inspection visit and further evidence was provided on inspection to demonstrate continuing compliance, with the exceptions noted below:

- the PR should ensure that procedures for the management of medicines are compliant with all relevant regulatory requirements and guidance (recommendation 1);
- the PR should ensure that all centre SOPs accurately describe the procedures used at the centre. Two SOPs were reviewed on inspection: the centre's 'safe handling of controlled drugs' referred to the nurse manager as the CDAO which is incorrect. The centre's procedure for managing needle stick injuries still references staff referral to a hospital in London, rather than locally, which was noted at the last inspection (recommendation 4);
- the PR should ensure that patients' consent decisions are recorded clearly and accurately (recommendation 3).

## **On-going monitoring of centre success rates**

No risk tool alerts related to success rates have been issued since January 2014.

## **Provision of information to the HFEA**

Clinics are required by law to provide information to the HFEA about all licensed fertility treatments they carry out. This information is held in the HFEA Register.

The clinic is compliant with requirements to submit information to the HFEA.

## **Legal parenthood**

Where a couple to be treated with donated gametes or embryos are not married or in a civil partnership, both the woman and her partner must give written consent in order for the partner to become the legal parent of any child born. If this consent is not documented properly or if proper information is not provided or counselling offered prior to both parties giving consent, there may be doubt about the effectiveness of the consent and in some cases it may be necessary for a patient couple to obtain a court declaration to establish legal parenthood. In February 2014, the HFEA asked all centres to audit their practices in this area to ensure they are suitable, to report the findings of the audit to the HFEA and to respond to those findings. The centre provided the report of the audit to the HFEA within the required timeframe and took appropriate action with respect to the issues identified by the audit.

Evidence has been provided by the centre that their audit was comprehensive and that their current procedures for obtaining consent to parenthood are robust.

To provide assurance of the effectiveness of the centre's procedures, the inspection team reviewed five sets of patient notes, where treatment with donor sperm had recently been provided. Consent to legal parenthood had been appropriately obtained in all cases, with the exception of incomplete unique patient identifiers recorded on seven consent forms (recommendation 3).

## Areas of practice that require the attention of the Person Responsible

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, 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 areas 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 child who may be born as a result of treatment services. 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	Inspection team's response to the PR's statement
<p><b>1. Medicines management</b></p> <p>The centre does not have a CDAO.</p> <p>('Controlled Drugs (Supervision of management and use) Regulations 2013').</p> <p>Safe custody of controlled drugs from supplier to centre cannot be assured.</p>	<p>The PR should ensure compliance with medicines management regulations and best practice guidance.</p> <p>The PR should ensure that a suitably trained and competent CDAO is appointed. The PR's actions in this regard should be summarised when responding to this report.</p> <p>It is recognised that controlled</p>	<p>As discussed at the inspection meeting there is no requirement for a CDAO. The CQC has responded. "I can confirm that the London Women's Clinic is currently exempt from appointing a Controlled Drugs Accountable Officer (CDAO). As discussed, this is linked to exemptions under The Health and Social Care Act 2008 registration regulations negating the need</p>	<p>The inspection team would have welcomed this discussion about the CDAO at the time of inspection, however confirmation from the CQC that the centre is exempt from this requirement was only provided when responding to this report.</p> <p>Evidence has been provided that procedures have been changed to ensure safe custody of controlled drugs to the centre.</p>

<p>(Home Office 2013 Guidance for the safe custody of controlled drugs and drug precursors in transit).</p> <p>The cabinet in which medicines are being stored does not meet relevant British Standards (BS 2881-1989).</p> <p>A record of the full name, form and strength of controlled drug is not documented in the controlled drug book in some instances (NMC 'Standards for medicines management' Standard 26 sections 31-36).</p> <p>The centre has not conducted a comprehensive audit of its management of controlled drugs (SLC T36).</p> <p><b>Medicines management was an issue at the centre's previous inspection.</b></p>	<p>drug orders and their safe custody remain the responsibility of the supplier until the recipient acknowledges receipt. The PR should ensure that the centre's supplier complies with relevant regulations or seek an alternative supplier. The PR should provide the centre's inspector with an update with regard to assuring full traceability and safe custody in transit to the point of delivery and receipt when responding to this report.</p> <p>The PR should conduct a review of the centre's medicine management procedures and this should include staff training requirements. The findings of the review including corrective actions and timescales for implementation of the corrective actions should be submitted to the centre's inspector by 26 February 2016.</p> <p>Three months after the</p>	<p>for the clinic to be registered with the Care Quality Commission (CQC)." The CQC email is attached.</p> <p>The PR can ensure that the centres supplier has committed to deliver the controlled drugs delivery directly to the clinic premises for signature by clinic staff. This ensures traceability directly to the clinic rather than to the hospital. email from the delivery service is attached.</p> <p>A new medicines cabinet compliant with BS 2881-1989 has been delivered, installed and is in use.</p> <p>A comprehensive audit of the clinics management of the controlled drugs has been carried out. Internal audits will be carried out weekly and any non conformances managed via the incident management SOP.</p> <p>All these audits will be</p>	<p>A summary report of a detailed review of the centre's medicines management procedures has been provided.</p> <p>This recommendation has been implemented in full. No further action is required beyond the PR providing a report of the follow up audit to the HFEA in May 2016 to demonstrate continuing compliance.</p>
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	implementation of corrective actions, the centre should perform an audit to ensure that these corrective actions have been effective. This audit should be submitted by 26 May 2016.	provided to the inspector on the 26th of February 2016.	
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▶ **‘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 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;
- which can comprise 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	Inspection team’s response to the PR’s statement
<p><b>2. Quality Management System</b></p> <p>The centre’s own audit practices failed to identify significant areas of non compliance or poor practice identified during this inspection and described in the body of the report.</p> <p>The centre has not fully implemented guidance issued by the HFEA in Clinic Focus July 2015 or all recommendations from its previous inspection.</p> <p>SLC T32.</p>	<p>The PR should conduct a review of the centre’s quality management and audit process to ensure that audits are performed against regulatory requirements and corrective actions are documented and reviewed for effectiveness. The outcome of the review and an action plan with timescales for the implementation of any changes should be provided to the centre’s inspector by 26 February 2016.</p> <p>The PR should review the process for disseminating information within the team to</p>	<p>A review of the Quality Management System relating to the issues identified has been carried out.</p> <p>We will continue to review all QMS issues at our monthly meeting along with the newly implemented system for corrective actions. This was discussed at the inspection meeting. NCD/Incidents and CAPA will continue to be discussed and logged as per our QMS.</p> <p>Disseminating information will continue to primarily be done via the monthly meetings. A</p>	<p>The PR has submitted the outcome of the centre’s review of its quality management system and the actions taken to ensure it is used to best effect to ensure compliance and drive continuous improvement at the centre.</p> <p>No further action is required.</p>

	<p>identify where there are barriers to the implementation of learning from guidance/recommendations provided by the HFEA and/or other sources.</p> <p>The PR should provide a summary of the review and detail of any actions taken in response, to the centre's inspector by 26 February 2016.</p>	<p>more robust documenting and circulating of minutes will be implemented.</p> <p>A summary of the review will be provided to the inspector by the requested date.</p>	
<p><b>3. Consent</b></p> <p>In several sets of records the patient's unique identifier had not been recorded on the HFEA consent forms.</p> <p>In one set of records the consent decisions of a patient were not clear in relation to disclosure of identifying information. Letters containing identifying information had been sent to the GP and it is unclear to the inspection team if this disclosure was made with the consent of the patient.</p>	<p>The PR should review the centre's process by which staff check consent forms after completion by the patients to ensure that documentation is complete, accurate and that consent decisions are clear. A summary report of the findings of the review including corrective actions and the timescale for implementation of corrective actions should be submitted to the centre's inspector by 26 February 2016.</p> <p>Three months after the implementation of corrective actions, the centre should</p>	<p>The PR has reviewed the process and has reminded all staff the importance of robust checking of all consent forms. All patients attend a review appointment, this will continue.</p> <p>The nursing team who take and check consent forms will attend further training in early February 2016.</p> <p>All patients are informed in a standard initial appointment letter that a copy of the consultation letter will be sent to the GP. Staff have been reminded that it is important</p>	<p>The PR has submitted the outcome of the centre's review of its consent procedures and the corrective actions taken.</p> <p>No further action is required beyond the PR providing a report of the follow up audit to the HFEA in May 2016 to demonstrate continuing compliance.</p> <p>The inspection team was concerned with the PR's response to the potential disclosure of identifying information to a patient's GP without consent. A letter</p>

<p>In one set of records the page declaration on a MT consent form had been signed and dated by the patient, but the date recorded was partly the date of signing and partly the patient's birth year.</p> <p><b>Consent non compliances were noted at the centre's previous inspection.</b></p>	<p>perform an audit to ensure that these corrective actions have been effective. This audit should be submitted by 26 May 2016.</p> <p>The PR should investigate the potential disclosure of identifying information without patient consent noted in the inspection report and provide a summary of the findings of this investigation at the time of responding to this report.</p>	<p>that the consent forms are clearly and accurately completed.</p> <p>The outcome of the internal audit will be provided to the inspector as required.</p>	<p>provided to the patient prior to consent to disclosure being obtained which informs them that identifying information will be released to the patient's GP appears wholly at odds with the general principles of consent.</p> <p>Further update 26 February 2016:</p> <p>Clarification and assurance was provided by the PR. A new double checking procedure has been introduced to ensure that identifying information is not released when clear consent is not in place.</p> <p>No further action is required.</p>
<p><b>4. Standard operating procedures (SOPs)</b> Two SOPs were reviewed on inspection and neither adequately described procedures at this centre.</p> <p>SLC T33b.</p> <p><b>This was an issue at the</b></p>	<p>The PR should review all centre SOPs to ensure that they accurately describe the local procedures to be followed at the centre.</p> <p>Confirmation that this has been completed and a list of all centre SOPs should be provided to the centre's</p>	<p>Both SOP's discussed at the time of inspection have been updated with the relevant addresses of partner agencies.</p> <p>A list of all SOP's was provided at the time of inspection. This will be resubmitted to the inspector on the 26th of February 2016.</p>	<p>The inspection team acknowledges the PR's response but reminds the PR that the recommendation was for all centre SOPs to be reviewed, not just the two sampled on inspection.</p> <p>Further update 26 February 2016:</p>

<p><b>previous inspection and assurance was provided that all SOPs had been reviewed, this has therefore been escalated to a major non compliance.</b></p>	<p>inspector by 26 February 2015.</p> <p>A sample of SOPs will then be randomly selected and requested for review.</p>		<p>The PR has confirmed that all centre SOPs have been reviewed and has submitted a list of all centre SOPs. A random selection of SOPs will be requested for review by the centre's inspector.</p>
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▶ **‘Other’ areas of practice that requires improvement**

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

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team’s response to the PR’s statement
<p><b>5. Infection control</b></p> <p>Some notices fixed to walls in clinical areas were not ‘wipe clean’.</p> <p>Individual patient bays in the recovery area have sliding doors – the grooves in which these doors run were dirty.</p> <p>Health and Social Care Act 2008; Code of Practice on the prevention and control of infections and related guidance.</p>	<p>The PR should ensure that all notices fixed to walls in clinical areas are ‘wipe clean’ and that clinical areas are cleaned thoroughly to ensure compliance with infection control best practice guidance.</p> <p>Confirmation that this has been addressed should be provided to the centre’s inspector when responding to this report.</p>	<p>All notices have been laminated and wipe clean.</p> <p>The hospital cleaning service has been contacted and asked to review their cleaning shedule and practice to meet the inspectors requirements.</p>	<p>The inspection team acknowledges the PR’s response.</p> <p>No further action is required.</p>

**Additional information from the Person Responsible**

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