HFEA Executive Licensing Panel Meeting

10 January 2014

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

Minutes – Item 2

Centre 0105 – (London Women's Clinic) – Renewal Treatment (including embryo testing) & Storage Inspection Report

Members of the Panel:	**Committee Secretary:**
Juliet Tizzard – Interim Director of Strategy (Chair)	Dee Knoyle
Ian Peacock – Analyst Programmer	**Observing:**
Matthew Watts – Regulatory Policy Manager	Sam Hartley – Head of Governance and Licensing

Declarations of Interest: members of the Panel declared that they had no conflicts of interest in relation to this item.

The Panel also had before it:

- HFEA Protocol for the Conduct of Meetings of Executive Licensing Panel
- 8th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- Decision trees for granting and renewing licences and considering requests to vary a licence (including the PGD decision tree)
- Guidance for members of Authority and Committees on the handling of conflicts of interest approved by the Authority on 21 January 2009
- Guidance on periods for which new or renewed licences should be granted
- Standing Orders and Instrument of Delegation
- Indicative Sanctions Guidance
- HFEA Direction 0008 (where relevant), and any other relevant Directions issued by the Authority
- Guide to Licensing
- Compliance and Enforcement Policy
- Policy on Publication of Authority and Committee Papers

Consideration of Application

1. The Panel considered the papers, which included a completed application form, inspection report and licensing minutes for the past three years.

2. The Panel noted that this is a treatment (including embryo testing) and storage centre which provides a full range of licensed treatments including embryo testing and an egg share programme. The Panel noted that in relation to activity levels this is a large centre.

3. The Panel noted that the centre has been licensed by the HFEA since 1992 and is on a five-year licence due to expire on 28 February 2014.

4. The Panel noted that in the 12 months to 31 August 2013 the centre provided 2055 cycles of treatment (excluding partner intrauterine insemination).

5. The Panel noted that for IVF and ICSI, HFEA-held register data for the period 1 July 2012 to 30 June 2013 show the centre's clinical pregnancy rates for IVF, ICSI, FET and DI are in line with national averages.

6. The Panel noted that in 2012, the centre reported 91 cycles of partner insemination with 13 pregnancies. This equates to a 14% clinical pregnancy rate which is comparable to the national average.

7. Between 1 April 2010 and 31 March 2011, the centre's multiple live birth rate for all IVF, ICSI and FET cycles for all age groups was 23%. This represented performance that was not statistically different from the 20% maximum multiple live birth rate target for this period.

8. Between 1 April 2011 and 30 September 2012, the centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 20%. This represented performance that was not likely to be statistically different from the 15% maximum multiple live birth rate target for this period.

9. The Panel noted the fact that a report on regulatory issues was considered by the Licence Committee on 28 March 2013. The Panel also noted the concerns raised have since been addressed by the centre and are being monitored by the Inspectorate.

10. The Panel noted that at the time of the inspection on 8 and 9 October 2013, the Inspectorate observed two major and 18 other areas of non-compliance. The Panel noted in particular the non-compliances in relation to data submission, donor screening, staffing levels, witnessing and the presentation of success rates on the centre's website. The Panel noted that some positive feedback had been received from patients, but also the complaints, in particular those relating to privacy and dignity. The Panel noted that since the inspection, the PR has provided evidence that some of the recommendations have been fully implemented. The Panel noted the PR's commitment to implement the outstanding recommendations within the prescribed timescales.

11. The Panel noted the Inspectorate's recommendation that some improvement is required in order for the centre to reflect good practice and demonstrate the quality and safety of the service it provides.

12. The Panel noted the Inspectorate recommends the renewal of the centre's Treatment (including embryo testing) and Storage licence for a period of four years without additional conditions, subject to compliance with the recommendations made in this report being implemented within the prescribed timescales.

Decision

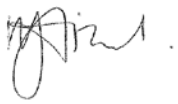
13. The Panel had regard to its decision tree. It was satisfied that the appropriate application and fee had been submitted and that the application contained the supporting information required by General Directions 0008.

14. The Panel was satisfied that the qualifications and character of the PR are such as is required for the supervision of licenced activities, and that she has discharged her duty under section 17 of the HF&E Act 1990 (as amended).

15. The Panel noted that the premises to be licensed are suitable for the conduct of the licensed activities.

16. The Panel urged the centre to work hard to fully address all the recommendations made in this renewal inspection report within the prescribed timescales.

17. The Panel endorsed the Inspectorate's recommendation to renew the centre's Treatment (including embryo testing) and Storage licence for four years, without additional conditions.



Signed: Date: 23 January 2014

Juliet Tizzard (Chair)

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: 8 & 9 October 2013
Purpose of inspection: Renewal of a licence to carry out 'Treatment (including embryo testing) and Storage'

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

Inspectors: Lisa Beaumont (Lead), Janet Kirkland-MacHattie, Andrew Leonard and Chris O'Toole. Audit: Cathy Hodgson and Barbara Lewis.

Date of Executive Licensing Panel: 10 January 2014

Centre name	London Women's Clinic
Centre number	0105
Licence number	L/0105/18/e
Centre address	113-115, Harley Street, London, W1G 6AP, UK
Person Responsible	Mrs Tourandokht Arian-Schad
Licence Holder	Dr Kamal Ahuja
Date licence issued	01/03/2009
Licence expiry date	28/02/2014
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:

The London Women's Clinic (LWC) has held a licence with the HFEA since 1992 and provides a full range of fertility services including embryo testing and an egg share programme. LWC is a private independent centre and part of a nationwide group of four centres.

The centre provided 2055 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31/08/2013. In relation to activity levels this is a large centre.

The centre's current licence was last renewed on 1 March 2009 and has no additional conditions. An application to vary the centre's licence to change the Person Responsible (PR) was considered and approved by an ELP in August 2010.

Since this last inspection, a number of regulatory issues have arisen regarding:

- welfare of the child assessments;
- use of donor sperm in ICSI;
- data submissions to HFEA.

A report relating to these issues was considered by a Licence Committee on 28 March 2013 and recommendations made in the report were followed up in the course of the renewal inspection.

Activities of the centre:

Type of treatment	Number of treatment cycles during:
	01 Sep 2012 - 31 Aug 2013
In vitro fertilisation (IVF)	366
Intracytoplasmic sperm injection (ICSI)	352
Frozen embryo transfer (FET)	246
Donor insemination (DI)	913
Egg share provider (sharer)	38
Egg share recipient	38
Egg donation (non egg share)	102
	Calendar Year 2012
Partner insemination	91

Other licensable activities	
Storage of eggs	✓
Storage of sperm	✓
Storage of embryos	✓
Research (if applicable)	N/A

Outcomes [1]

For IVF and ICSI, HFEA held register data for the period 1 July 2012 to 30 June 2013 show the centre's clinical pregnancy rates for IVF, ICSI, FET and DI are in line with national averages.

In 2012, the centre reported 91 cycles of partner insemination with 13 pregnancies. This equates to a 14% clinical pregnancy rate which is comparable to the national average.

Multiple births[2]

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

Between 1 April 2010 and 31 March 2011, the centre's multiple live birth rate for all IVF, ICSI and FET cycles for all age groups was 23%. This represented performance that was statistically no greater than the 20% multiple live birth rate target for this period.

Between 1 April 2011 and 30 September 2012, the centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 20%. This represented performance that was not likely to be statistically different from the 15% multiple live birth rate target for this period.

[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. The HFEA considers differences in a centre's success rates and multiple pregnancy rates from the national averages are only statistically significant if they occur at a significance level of $P \leq 0.002$.

[2]The HFEA use a conversion factor of 1.27 to convert the multiple live birth rate (MLBR) target to a multiple clinical pregnancy rate (MCPR) target. The 2010/11 MLBR target of 20% is calculated as equivalent to a MCPR of 25%: the 2011/12 MLBR target of 15% is calculated as equivalent to a 19% MCPR.

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 PR is suitable and has discharged her duty under section 17 of the HF&E Act 1990 (as amended)
- the premises are suitable
- the practices are suitable
- the centre has submitted appropriately completed documentation in accordance with General Direction 0008, in application for renewal of their licence and
- 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 major and 18 'other' areas of non-compliance or poor practice.

Since the inspection visit, the PR has provided evidence that the following recommendations have been fully implemented:

Major areas of non compliance

- written agreements should be in place prior to licensed activity taking place, setting out the satellite centre's responsibility for taking consent

'Other' areas of non-compliance or poor practice that require improvement:

- an assessment should be undertaken of laboratory staff to ensure that the workload is managed and maintained within safe limits
- quality indicators for embryo biopsy procedures should be established
- all donors and patients should be screened in accordance with current professional guidance
- medicines should be dispensed safely in line with professional guidance and
- there should be a documented process to ensure all near miss adverse incidents are reported to the HFEA.

The PR has provided evidence that the following recommendations have been implemented in part and has committed to complete their implementation within the required timescales:

Major areas of non compliance:

- embryos and gametes should not be stored beyond their consented storage period

'Other' areas of non-compliance or poor practice that require improvement:

- all staff should complete all mandatory training
- a summary log should be maintained where more than one embryo is transferred to a woman who meets the criteria for elective single embryo transfer (eSET)

- checks should be undertaken to ensure that screening tests are carried out by laboratories that are CPA (UK) Ltd accredited (or equivalent), and where non accredited suppliers are used, action is taken to ensure compliance
- witnessing checks should be completed and documented in patient notes at the time samples are placed into storage, and audits should be undertaken of electronic witnessing non conformances
- all tubes used during the procurement and processing of gametes and embryos should be labelled or the PR should consider the risks of not labelling the tubes and document a risk assessment with appropriate risk control measures
- the following audits of procedures and processes should be undertaken:
    - confidentiality and privacy
    - stored sperm storage consents and location
    - embryo biopsy procedures and
    - data submissions to the HFEA.
- all licenced treatment activity should be reported to the Authority and within the timeframe required
- patient / partner disclosure consents should be reported accurately to the HFEA
- all staff should undertake safeguarding training and a risk assessment should be conducted to assess appropriate levels of training for all staff and
- blood samples for screening of individuals providing gametes for treatment of a partner should be obtained within three months of the gametes first being provided and be rescreened within two years if patients return for further treatment within that time..

The PR has provided a response confirming her commitment to implement the following recommendations:

'Other' areas of non-compliance or poor practice that require improvement:

- the processing of gametes should occur in an environment of at least Grade C air quality, with background of at least Grade D air quality
- the clinical environment should meet infection and prevention control requirements and staff should be formally trained in infection prevention and control (IPC) practices and
- the centre's website www.londoneggbank.com should meet the requirements of Chair's Letter CH (11)02.

Implementation of these recommendations will be subject to on-going monitoring by the centre's inspector.

Recommendation to the Executive Licensing Panel

Some improvement is required in order for the centre to reflect good practice and demonstrate the quality and safety of the service it provides.

The inspection team is satisfied that activities carried out at the centre are necessary or desirable in order to provide licensed treatment services.

The inspection team recommends the renewal of the centre's 'Treatment (including embryo testing) and Storage' licence for a period of four years without additional conditions subject to compliance with 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 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 (Guidance note 18)

What the centre does well.

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

What the centre could do better.

Witnessed checks of identifiers and the storage location are performed during the placement of embryos into the storage dewars for cryopreservation however these checks are not documented in the patient records. (SLC T71).

When mismatches occur within the electronic witnessing system, an explanation of the non-conformance is logged by the operator on the system. No subsequent audit of these electronic witnessing non-conformances is performed however to identify trends which may highlight training needs or system design/defect issues. (SLC T36).

See recommendation 9

Patient and donor selection criteria and laboratory tests

What the centre does well.

Screening of patients and donors (Guidance notes 11 and 5)

The centre's procedures for screening patients and donors are broadly compliant with HFEA requirements, minor exceptions being discussed below. 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.

Payments for donors (Guidance note 13)

Payments to donors are fully in line with the requirements of the HFEA. 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)
People born as a result of donation are entitled to request and receive their donor's name and last known address, once they reach the age of 18. Therefore it is important that centres use donated gametes or embryos from identifiable donors. The centre is fully in line with the requirements of the HFEA to ensure the donor conceived will be able to receive this information.

What the centre could do better.

Patient and donor screening
Donors of gametes and embryos are not screened in accordance with current guidance produced by the relevant professional bodies; e.g. screening for gonorrhoea is not undertaken. (CoP Guidance 11.21).

See recommendation 7

Blood samples for screening of partners or donors are not obtained within the three months before the gametes are first provided, or within 24 months of subsequent treatment cycles (SLC T51).

See recommendation 19

Laboratory Tests
The centre does not check to ensure that patient blood test results are from laboratories which have suitable accreditation from CPA (UK) Ltd or another body certifying to an equivalent standard. The centre is not proactive in checking for CPA (or equivalent) accreditation and taking appropriate corrective actions. These observations indicate there is a risk that patients might be treated on the basis of diagnostic test data from laboratories which are not certified by CPA or equivalent. (SLC T21)

See recommendation 8

Good clinical practice

What the centre does well.

Multiple births (Guidance note 7)
The single biggest risk of fertility treatment is a multiple pregnancy.

The progress in reducing the clinical multiple pregnancy rates suggests that the centre is being proactive and effective in adapting their strategy to meet the HFEA's multiple birth rate target.

Process Validation (Guidance note 15)
The centre has fully validated all critical processing procedures to ensure that these procedures are effective and do not render the gametes or embryos clinically ineffective or harmful to the recipient.

Traceability (Guidance note 19)
The centre's procedures are broadly compliant with HFEA requirements to ensure it has the ability -
(a) to identify and locate gametes and embryos during any step from procurement to use for human application or disposal,
(b) identify the donor and recipient of particular gametes or embryos,
(c) to identify any person who has carried out any activity in relation to particular gametes or embryos, and
(d) 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 (Guidance note 23)
The centre has a quality management system in place that is broadly compliant with HFEA requirements. The centre uses its quality management system to ensure optimum outcomes and improve the quality and safety of the treatment and services it provides to patients.

Third party agreements (Guidance note 24)
The centre has agreements in place which cover the:
(a) procurement, testing or processing of gametes or embryos on behalf of the licensed centre, and the
(b) supply of any goods or services (including distribution services) to the licensed centre which may affect the quality or safety of gametes or embryos.

Equipment and materials (Guidance note 26)
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.

Safe and suitable premises and facilities (Guidance note 25)
All licenced activities are conducted in a broadly suitable environment that is fit for purpose. Risks are taken into account to ensure patients and staff are in safe surroundings that prevent harm.

Infection control
The centre is broadly compliant in having appropriate systems in place to manage and monitor the prevention and control of infection, and provides care in an environment that is broadly compliant with HFEA requirements.

Adverse incidents (Guidance note 27)
The centre reports all adverse incidents (including serious adverse events and reactions) to the HFEA. The centre has investigated all of the adverse incidents that have occurred and has shared the lessons learned in order to continuously improve the services it offers.

Medicines management
The centre is broadly compliant in ensuring appropriate arrangements are in place for obtaining, recording, handling, using, keeping, dispensing, administering and disposing of

the medicines required for the purposes of licensed activity, with one exception noted below.

Pre-operative assessment and the surgical pathway
The centre has appropriate policies and procedures in place, in line with professional guidelines, to ensure all patients are safely assessed and cared for pre, peri and post operatively. There are appropriate procedures in place when discharging patients and staff are trained to manage clinical emergencies.

What the centre could do better.

Multiple births
The centre does not keep a summary log of cases in which multiple embryos have been transferred to a patient who meets the criteria for single embryo transfer. (General Direction 0003).

See recommendation 5

Quality management system
Audits of confidentiality and privacy, stored sperm storage consents and location, and embryo biopsy procedures have not been undertaken and/or documented within the last two years. (SLC T36).

See recommendation 13

Traceability
At egg collection, tubes used to collect follicular fluid are not labelled with the patient's full name and a further unique identifier or a uniquely identifying donor code. (SLC T101.

See recommendation 10

Safe and suitable premises and facilities
Air quality in the critical work area in the andrology laboratory was compliant, however recent air quality testing data indicated that the background environment in the andrology laboratory does not comply with at least Grade D air quality. (SLC T20).

See recommendation 11

Embryos are processed in an environment of at least Grade C air quality, as confirmed by annual air quality checks performed when the air flow cabinets are serviced. The centre also documents weekly counts of 0.5 μm diameter particles in the air flow cabinets but counts of 5 μm diameter particles are not documented even though they are performed. It is suggested that these 5 μm diameter particle counts are documented as evidence to confirm air quality is maintained at Grade C or better on a weekly basis.

Infection control
On inspection it was noted that there was no evidence that any staff had undergone any formal training for infection prevention and control (IPC), however the inspection team

were informed that the link nurse is due to go on an IPC study day soon. (SLC T15)

See recommendation 17

In some areas the clinical environment is not appropriate to ensure it can be maintained in an optimum state so as to prevent and control infection. There is carpet on the scan room floor and basins in clinical areas do not have 'hands-free' taps. These issues were also raised during a previous external infection control inspection, commissioned by the centre in November 2012. The inspection team were told that a planned refurbishment starting in the next few months would address some of these concerns, however no documented evidence was provided to support this. (SLC T2).

See recommendation 17

Adverse incidents:
On inspection it was found that the centre had not reported a recent 'near miss' incident to the HFEA. This 'near miss' has now been reported and the centre has been requested to forward to the HFEA any investigation findings and actions. The centre does not have documented procedures for reporting such 'near misses' to the HFEA. (General Direction 0011).

See recommendation 12

Medicines management
It is current practice for the centre's nurses when on call outside normal working hours, to administer medicines from their own homes to patients, under certain circumstances. (SLC T2)

See recommendation 16

Staff engaged in licensed activity

What the centre does well.

Person Responsible (Guidance note 1)
The PR has a key role to play in implementing the requirements of the HF&E Act 1990 (as amended) and is the person under whose supervision the licensed activities are authorised. The PR has the primary (legal) responsibility under Section 17 of the HF&E Act 1990 (as amended) to secure:

- that suitable practices are used in undertaking the licensed activities;
- that other persons working under the licence are suitable and;
- that the conditions of the licence are complied with.

The PR has academic qualifications in the field of nursing 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 no.

T/1171/8).

Staff (Guidance Note 2)
The centre is broadly compliant in having suitably qualified and competent staff to carry out all of the licensed activities and associated services, with some minor exceptions discussed below.

What the centre could do better.

Staff:
Laboratory staff reported that they have little input into treatment planning or staff scheduling, such that the Scientific Inspector considered there to be a risk that treatment activity could be inappropriately matched to laboratory staffing level. (SLC T12).

See recommendation 3

Some embryology staff have not completed all the modules required for their mandatory training. (SLC T12 and T15).

See recommendation 4

Welfare of the child (Guidance note 8)

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

What the centre could do better.
Nothing noted at time of inspection

Safeguarding

What the centre does well.
The centre's procedures for safeguarding are broadly compliant with requirements. The centre is committed to protecting patients and staff from harm and procedures are in place to enable concerns to be escalated to the appropriate authority, where issues are raised about the possible or actual abuse or neglect of any persons attending the centre.

What the centre could do better.
It was noted on inspection that there was no evidence of any member of staff having undertaken level 1 or above, safeguarding training. (SLC T15).

See recommendation 18

Embryo testing

What the centre does well.

Embryo testing (Guidance notes 9 and 10)

The centre's procedures for performing embryo testing are broadly compliant with HFEA requirements ensuring that:

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

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

What the centre could do better

Embryo Testing

The inspection team noted that there is no documented procedure for embryo biopsy and quality indicators have not been established for embryo biopsy. (SLCs T33 and T35).

See recommendation 6

2. The experience of patients

Patient feedback

What the centre does well.

During the inspection visit the inspector(s) spoke to two patients who provided feedback on their experiences. A further 26 patients also provided feedback directly to the HFEA in the time since the last inspection. Six of the individuals providing written feedback to the HFEA commented 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:

- provides patients with satisfactory facilities for their care.

What the centre could do better.

Several patients commented in their direct feedback to the HFEA, and within complaints to the centre on the need to improve: communication, the quality of the information provided to them concerning treatment, privacy and dignity, and the continuity of care.

Treating patients fairly

What the centre does well.

Counselling (Guidance note 3)
The centre's counselling procedures are compliant with HFEA requirements, ensuring that counselling support is available to patients before and during the consenting process and treatment.

Gamete sharing arrangements (Guidance note 12)
The centre's procedures for egg sharing arrangements are compliant with HFEA requirements to ensure that:
(a) care is taken when selecting egg and sperm providers donating for benefits in kind
(b) egg and sperm providers are fully assessed and medically suitable, and
(c) the benefit offered is the most suitable for the egg or sperm provider and recipient(s) (where relevant).

Surrogacy (Guidance note 14)
The centre's procedures for treatment involving surrogacy are compliant with HFEA requirements. Patients providing gametes in surrogacy arrangements are screened as donors in order to safeguard the health of the surrogate.

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

Treating patients fairly (Guidance note 29)
The centre treats prospective and current patients and donors fairly, and ensures that all licensed activities are conducted in a non-discriminatory way.

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

What the centre could do better

Confidentiality and privacy:
A confidentiality and privacy audit has not been undertaken within the last two years to assess compliance with approved protocols, regulatory requirements and quality indicators. (SLC T36).

The inspection team and a patient noted the lack of confidentiality and privacy at the reception desk. (SLC T43).

See recommendation 13

Information

What the centre does well.

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.

Provision of a costed treatment plans (Guidance note 4)
The centre provides an individual costed treatment plan to all of its patients. This ensures that patients know the full cost of their proposed treatment before deciding on whether to proceed or not.

What the centre could do better.

The inspection team considers that the London Women's Clinic website is compliant with Chief Executive's Letter 10(05)) and Chair's Letter 11(02), however there are concerns that the website for the London Egg Bank (www.londoneggbank.com), owned and run by LWC, shows misleading success rate information for users of donated eggs, non compliant with Chair's Letter 11(02).

For example, live birth rates are not provided. Instead a 60% clinical pregnancy rate (CPR) is quoted, derived from treatment data between January 2013 and August 2013, but it is not indicated whether this CPR is per treatment cycle started or per embryo transfer and no age-stratified data is available.

See recommendation 20

Consent

What the centre does well.

Good consenting practices ensure that patients and donors have provided all relevant consents before carrying out any licensed activity. The centre's procedures for obtaining consent are partially compliant with HFEA requirements.

Disclosure of information, held on the HFEA Register, for use in research

The Register started operating in August 1991 and is a rich source of information about assisted reproductive technologies (ART), its outcomes and the factors that contribute to the birth of a baby following treatment. This information can be used by researchers and, in certain circumstances, linked to other health registers to improve the knowledge about the health of patients undergoing ART and those born following ART treatment. Whereas the HFEA is permitted to disclose non-identifying information to researchers it can only provide identifying information with the consent of patients. Therefore, it is important that patients are asked to give their consent and that their wishes are accurately recorded and passed on to the HFEA.

The centre's procedures for reporting consent to disclosure decisions to the HFEA are broadly effective in ensuring that the HFEA holds an accurate record of the patients consent, so that it only releases the patients identifying information, to researchers, with their consent.

What the centre could do better.

The centre has two satellite providers who obtain consent. The centre does not have written agreements in place documenting the satellite providers' responsibilities around taking consent. (General Direction 0010).

See recommendation 1

On the day of the inspection, the centre did not have written effective consent for the storage of cryopreserved gametes for one patient and cryopreserved embryos for six patients. (Schedule 3, 8(1) and (2) HF&E Act 1990 (as amended)).

See recommendation 2

Review of the bring-forward system indicated that when patients extend sperm storage consent by only one year, there is a risk that the bring-forward system fails to warn the centre appropriately about the next expiry of consent. This was seen to have occurred for one gamete sample. (CoP Guidance 17.18).

See recommendation 2

It was noted that the sperm storage log was inaccurate in that some samples noted in the log as being in storage but beyond the storage consent expiry date had actually already been allowed to perish. (CoP Guidance 17.8)

See recommendation 2

One discrepancy was found between completed patient/partner disclosure consents in patient files and the related consent data submitted for inclusion on the HFEA register. (Chair's Letter CH (10)05 and supplementary guidance and General Direction 0007).

See recommendation 15

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). This ensures that the centre has respect for the special status of the embryo when conducting licensed activities.

- 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.
- 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 noted at time of inspection.

Storage of gametes and embryos

What the centre does well.

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.

The centre's procedures for storing gametes and embryos are broadly 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.

What the centre could do better.

The results of the monthly rolling physical and consent audits of stored sperm samples have not been documented. (SLC T36).

Please see the 'consent' section of this report and recommendation 14.

Distribution and / or receipt of gametes and embryos

What the centre does well.

The centre's procedures for distributing and / or receiving gametes and embryos are compliant with HFEA requirements. This ensures that all gametes / embryos sent to other licensed centres within or outside the UK are appropriately labelled and relevant

information is sent to the other centre to ensure the continued quality and safety of the gametes and embryos. The centre only accepts gametes and embryos from other centres if the gametes and embryos are appropriately labelled and has enough information to permit the gametes and embryos be stored or used in a way that does not comprise their quality and safety.

What the centre could do better.
Nothing noted at time of inspection.

Use of embryos for training staff (Guidance note 22)

What the centre does well.
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.

The centre uses embryos to train staff in the following activities:

- Embryo biopsy
- Blastocyst biopsy
- Cryopreservation and thawing techniques
- Vitrification
- Assisted hatching
    - Mechanical
    - Chemical
    - Laser
- Embryo handling and manipulation
- Assessment of embryos

All of these activities have been authorised by the Authority.

What the centre could do better.
Nothing noted at time of inspection.

4. Information management

Record keeping and submitting information to the HFEA

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)
The HFEA has a legal responsibility to maintain a register containing information about all licensed activities including information on donors and on any children conceived as a result of their donation. In order to maintain this register, clinics are required by law to provide information to the HFEA about all licensed fertility treatments they carry out. The primary purpose for keeping this information is to allow the donor conceived and their parents to access information about the donor and about any donor-conceived genetic siblings.

The centre's procedures for submitting information about licensed activities to the Authority, are broadly compliant with HFEA requirements to ensure the HFEA can supply accurate information to a donor-conceived person and their parents.

What the centre could do better.

Reporting Requirements
An audit of patient notes against data held on the HFEA register showed that 37% (48/130) of the IVF and 41% (96/234) of the DI treatments reviewed at inspection had been reported to the HFEA outside the period required. (SLC T9 (e), SLC T41 and General Direction 0005). The inspection team considered that there may be insufficient staffing resource to ensure data is submitted within the required timeframes.

The data submission for IUI success rates for the period January to December 2012 was also reported to the HFEA outside the period required. (SLC T9 (e), SLC T41 and General Direction 0005).

No audits of register submissions, including internal processes of how the data is transferred onto IDEAS, have been undertaken in the last two years. (SLC T36).

See recommendation 14

Section 3: Monitoring of the centre's performance

Following the interim inspection in 2011, recommendations for improvement were made in relation to two areas of major non-compliance and three 'other' areas of non-compliance.

The PR provided information and evidence that corrective actions to implement all the recommendations were completed within acceptable timescales.

Risk based assessment tool (RBAT) alerts

In the last 12 months the centre has been issued with three performance alerts:

- November 2012 - pregnancy rate per fresh cycle, stimulated, IVF, using patient's eggs and 38 years plus. The centre undertook 24 cycles between August 2011 and July 2012 resulting in four pregnancies (17% CPR)
- August 2013 and October 2013 - donors treatments reported to the HFEA with missing outcomes.

The centre responded to these alerts as requested.

Regulatory concerns - Report to Licence Committee held on 28 March 2013

Concerns relating to the following three areas of practice at LWC were investigated by the HFEA:

- the assessment of the welfare of the child (WOC);
- the use of donor sperm in ICSI and
- information held in relation to the outcomes of treatment cycles involving the use of gametes donated by sperm donors recruited by LWC.

The findings of the investigation were considered by a Licence Committee who recommended that:

- the centre should review its procedures for recording information about treatment cycles involving the use of donated gametes to ensure that the information is accurate and that the information held on the HFEA register matches the information held at LWC and report of the findings of the review including details of any planned changes in practice and the timescales for implementation of changes;
- the centre should provide information about measures taken to review their andrology laboratory protocols and bring them in line with those recommended by the World Health Organisation and the Association of Biomedical Andrologists and
- the Executive should ensure that monitoring such as spot checking donor information and getting monthly data from the centre is undertaken.

The centre has been subject to on-going monitoring, and the following actions have been taken in response to the recommendations above:

- The PR provided a report of an in-depth review of procedures for recording information about treatment cycles involving the use of donated gametes, to ensure that the information is accurate and that the information held on the HFEA register

matches the information held at LWC. The Executive was reassured that all the required actions have been taken.

- The PR has implemented the recommendations made by the independent review of the centre's ICSI processes and procedures. The centre's ICSI procedures and practices were reviewed in some detail in the course of the inspection and were found to be compliant. Ten sets of notes were reviewed and in all cases ICSI was only used where there was an appropriate reason to do so. The inspection team were reassured that actions have been taken as recommended by the external reviewer.
- The HFEA's information team report that the centre's responses to enquiries about donor treatments are in line with the HFEA reporting requirements.

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, 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
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. The centre has two satellite providers who obtain consent from patients. The centre does not have written agreements in place that document their responsibilities around taking consent and as the HFEA has not been provided with a copy of any agreement these providers, they are not included on the HFEA Choose a Fertility Clinic Website (CaFC). (General Direction 0010).	The PR should establish written agreements, compliant with General Direction 0010, with all satellite providers to ensure that they have effective systems in place for obtaining consent. Copies of the agreements should be provided to the HFEA by 9 December 2013. The PR should investigate how the services were established without proper consideration being given to the regulatory requirements. A summary report of the findings of the investigation should be provided to the HFEA, including any corrective actions by 16 December 2013.	The PR established written agreements with both satallite centres which include effective systems for obtaining consent. This was completed prior to the commencement of the arrangement. 1st of March 2013 and 11th of February 2013 However, these were not submitted to the HFEA. This information was submitted to the HFEA immediately following inspection. (16/10/2013) and are included with this report.	11 December 2013 The centre has submitted evidence that written agreements are in place for the two satellite providers, along with a consent audit for each provider, demonstrating compliance. No further action is required.

	Within three months of the establishment of the written agreements, the centre should conduct an audit of patient consents obtained by the satellite centres. A summary report of the findings of the audit should be provided to the HFEA.	A summary report of an audit of consents from both centres are included with this report.	
2. On the day of the inspection the centre did not have written effective consent for the storage of cryopreserved gametes for one patient and embryos for six patients. (HF&E Act 1990 (as amended), Schedule 3, 8(1)). The inspection team were also concerned with the accuracy of the sperm storage log. (CoP Guidance 17.8).	The PR should provide the HFEA with an update on the number of patients for whom gametes and embryos remain in store without effective consent by the time this report is considered by the ELP on 10 January 2014. A plan should at the same time be submitted to the HFEA documenting the centre's intended actions and the timescale for their implementation. The PR should provide monthly updates to the HFEA on progress in implementing those actions. The PR should review the bring-forward systems and procedures for auditing storage of cryopreserved material. Summary reports of the findings of both reviews including corrective actions and the timescale for their	At the time of this report there are two patients with embryos in storage that are without effective consent. These will be discarded or consent extended by the 2nd of January 2014. (As guided by the SOP). No patients have sperm in storage without effective consent. The bring forward system has been reveiwed and a copy of the SOP is included with this report. A summary of the changes has been provided.	11 December 2013 The centre has submitted a report outlining the centre's plan to address the ongoing storage of embryos without effective consent. The centre has submitted an audit of sperm in storage, undertaken in November 2013 and action was taken in relation to three samples being stored without effective consent; all sperm in storage now has effective consent. The centre has submitted a revised SOP to demonstrate that the bring forward system has been reviewed. The PR has taken appropriate

	implementation should be submitted to the HFEA by 9 January 2014. Within three months of the implementation of corrective actions, the centre should conduct an audit of consent to storage and a summary report of the findings of the audit should be provided to the HFEA. The PR is reminded of guidance issued by the HFEA in CH (03)02 (http://www.hfea.gov.uk/2721.html) in relation to the timely disposal of cryopreserved material where there is consent to do so and actions should there be a possibility of legal challenge to the disposal of cryopreserved material.	The sperm storage log has been updated and is accurate at the time of this report. A summary report if the audit of consents to storage witll be provided to the HFEA within 3 months of implimentation. (1st march 2014)	actions to implement the recommendation and committed to complete them within the specified timeframe. This will be reviewed by the Executive through the on-going monitoring system.

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
3. It was observed that the centre has not undertaken an assessment of staff resources and treatment activity to ensure that the workload is maintained within safe limits. (SLC T12)	The PR should assess how many cycles of treatment can be safely accommodated taking into account staffing levels, the skills mix and competence of staff, equipment and premises. A copy of the assessment should be submitted to the HFEA by 16 December 2013. The PR should ensure that the workload is maintained within the safe limits determined by this assessment.	The PR has undertaken an assessment of cycles of treatment taking into account staffing levels, skill mix and comptence of staff. A copy of the assessment will be provided by the 16th of December 2013.	16 December 2013 The centre has submitted evidence to demonstrate that an assessment of staff resources and treatment activity has been undertaken. No further action is required.
4. Some embryology staff have not completed all modules required for their mandatory training. (SLC T12 and T15).	The PR should provide the HFEA with a report documenting for each member of the laboratory staff, the mandatory training relevant to each staff member and the anticipated date for completion of the relevant training. This report should be submitted 9 December 2013. The PR should provide monthly updates to the HFEA thereafter, documenting progress in the	Members of the embryology team have completed part of the required mandatory training. A report/spreadsheet is provided with this report. Monthly updates of completion	11 December 2013 The centre has submitted a report detailing the completed and planned mandatory training for the embryology team. The Executive will review Its timely implementation through the on-going monitoring system.

	provision of all outstanding mandatory training until all training has been provided. It is recommended that the provision of training be prioritised on the basis of risk.	will be provided to the HFEA.	
5. The centre does not keep a summary log of cases in which multiple embryos have been transferred to a patient who meets the criteria for single embryo transfer. (General Direction 0003).	The PR should immediately establish a summary log of cases where multiple embryos have been transferred to a patient who meets the criteria for single embryo transfer. Confirmation of the establishment of the log should be provided to the HFEA by the 9 December 2013. Within three months of the establishment of the log, the PR should conduct an audit of the compliance of the documentation of cases where multiple embryos have been transferred to a patient who meets the criteria for single embryo transfer. A summary report of the audit findings including corrective actions and the timescale for their implementation should be submitted to the HFEA.	As part of the established embryology daily log a summary log of cases in which mulitple embryos have been transferred to a patient who meets the criteria for single embryo transfer has been established. A summary report of an audit of cases where multiple embryos have been transferred to a patient who meets the criteria for single embryo transfer within 3 months. (1st of March 2014)	11 December 2013 The inspection team acknowledges that a summary log has been established, and that the PR has committed to provide the Executive by 1 March 2014 with a report of an audit to assess compliant use of the summary log. The completion of this action will be reviewed by the Executive through the on-going monitoring system.

6. The inspection team noted that there is no documented process for embryo biopsy (SLC T33b) and quality indicators have not been established for embryo biopsy procedures. (SLC T35).	The PR is required to establish quality indicators relevant to biopsy procedures and to document a formal process for embryo biopsy. Evidence of the actions taken should be provided to the HFEA by 9 December 2013.	The PR has established quality indicators relevant to biopsy procedures and the formal process for embryo biopsy is documented in the laboratory manual. These are included with this report.	16 December 2013 The centre has submitted an amended Laboratory Manual which details the formal biopsy procedure, and quality indicators for embryo biopsy. No further action required.
7. Donors of gametes and embryos are not screened in accordance with current guidance produced by the relevant professional bodies. Screening for gonorrhoea is not undertaken. (CoP Guidance 11.21).	The PR is required to ensure that the gametes and embryos of all donors are screened in accordance with current professional best practice, to include the screening for gonorrhoea with immediate effect. The PR should provide evidence to the HFEA that practice has been changed appropriately by 9 December 2013.	The PR has ensured that gametes and embryos of all donors are screened in accordance with current best practice by including the screening for gonorrhea. A copy of the screening checklist (from the electronic test patient records) checklist is included with this report. A copy of the updated SOP is included with this report.	11 December 2013 The centre has provided the following evidence to demonstrate that screening for gonorrhoea is now in place: • an updated screening check list and • an updated SOP - 'Step by Step Matching Egg providers with Ovum Recipients'. No further action is required.
8. Some patient tests are not carried out by laboratories which have suitable accreditation, for example	The PR should immediately ensure that the accreditation of all laboratories is checked before accepting patient screening and	A process of checking the CPA website for confirmation of accrediation will be implimented. A member of staff will check	11 December 2013 The centre has submitted a 'Confirmation of Laboratory CPA

by CPA (UK) Ltd (or an equivalent standard). (SLC T21).	other diagnostic test results, to ensure the tests have been performed by appropriately accredited laboratories. The PR should advise the HFEA by 9 December 2013 of the actions taken to implement this recommendation. Three months after the actions are implemented; the PR should audit patient records to assess the compliance of test results within them with the laboratory accreditation requirements of SLC T21.	against the CPA website when results are received. An audit of compliance will be provided to the HFEA within 3 months. (1st March 2014)	Accreditation of Results' SOP. The PR has committed to provide the Executive by 1 March 2014 with a report of an audit to ensure the SOP is adhered to. The completion of this action will be reviewed by the Executive through the on-going monitoring system.
9. Witnessing checks performed when samples are placed in storage are not documented in the patient records. (SLC T71). Within the last two years there has been no audit of the electronic witnessing non-conformances. (SLC T36).	The PR should ensure that witnessing is completed and recorded at all critical points of the clinical and laboratory process, including the placing of samples into storage. The HFEA should be advised of the measures taken to ensure that this happens by 9 December 2013. Within three months of the implementation of corrective actions, the centre should audit the electronic witnessing system non	The PR has ensured that the witnessing processes include the placing of samples in storage. The ammended witnessing practice SOP is included with this report and an ammended witnessing record sheet. An audit of the electronic witnessing system (following the addition of the required witnessing step) will be provided	11 December 2013 The centre has submitted an amended witnessing SOP and witnessing record sheet. The PR has committed to provide the Executive by 9 April 2014 with a report of an audit of electronic witnessing non-conformances. The completion of this action will be reviewed by the Executive through the on-going monitoring system.

	conformances and provide a summary report of the findings of the audit to the HFEA by 9 April 2014.	to the HFEA by the 9 April 2014.	
10. At egg collection, tubes used to collect follicular fluid are not labelled with the patients / donor's full name and a further unique identifier or a uniquely identifying donor code. (SLC T101).	The PR should either ensure that all follicular fluid tubes are appropriately labelled or should consider the risks of not labelling the tubes and document a risk assessment with appropriate risk control measures. The HFEA should be advised of the measures taken to correct this non-compliance by 9 December 2013. Within three months of the implementation of corrective actions, the centre should audit their implementation and provide a summary report of the findings of the audit to the HFEA.	A risk assessment of the existing process identifying the risk control measures in place is included with this report. These risk control measures will be monitored and a summary audit report provided to the HFEA within 3 months. (1st March 2014)	18 December 2013 The centre has submitted a risk assessment of the existing process, identifying risk control measures currently in place. The PR has committed to provide the Executive by 1 March 2014 with a report of an audit to ensure risk control measures are consistently applied. The completion of this action will be reviewed by the Executive through the on-going monitoring system.
11. The processing of gametes in the andrology laboratory takes place in a background environment which fails to achieve Grade D air quality. (SLC T20).	The PR is required to ensure that the centre's activities, where required, are undertaken in air of the required quality, notably in the andrology laboratory. A plan to achieve this should be provided to the HFEA by 9 December 2013.	The andrology laboratory is part of the planned refurbishment of the whole of the laboratory and clinical areas. Evidence of compliant air quality throughout the centres laboratories and critical work	18 December 2013: The Executive acknowledges the centre's laboratories are being refurbished. The PR has also committed to provide evidence of the compliance of the

	Evidence of compliant air quality throughout the centre's laboratories and critical work areas should be provided by 9 April 2014.	areas will be provided as part of the changein premises requirement and to the HFEA by the 9th of April 2014. Application 2627 for change of pemises made 30/10/2013.	laboratory air quality within the required time frame. The Executive will review the delivery and quality of this evidence as part of the consideration of the centre's application to vary their licensed premises.
12. The centre failed to report a recent 'near miss' to the HFEA and does not have a documented procedure requiring such 'near misses' to be reported to the HFEA. (General Direction 0011)	The PR should develop an appropriate documented procedure to ensure all 'near misses' are reported to the HFEA within the required timeframes by 9 December 2013. The PR is required to undertake an internal investigation into the 'near miss', document findings and identify any actions required. The PR should inform the HFEA of the investigation findings by 9 December 2013.	The PR has further developed the SOP to ensure all 'near misses' are reported to the HFEA within the required time frames. The ammended SOP is included with this report. An internal investigation noted that the 'near miss' had been recognised, investigated and CAPA implimented at the time of the near miss. However, it was an oversight that it was not reported to the HFEA.	11 October 2013 The centre has submitted details of the near miss and subsequent investigation to the HFEA. 13 December 2013 The centre has submitted a revised SOP to ensure near misses are reported to the HFEA. No further action is required.
13. The centre has not conducted and/or documented audits within the last two years for: • confidentiality and privacy	The PR should ensure that all activities authorised by the licence and other activities carried out in the course of providing treatment services that do not require a licence, including:	The PR will provide the required audits by the 9 April 2014.	18 December 2013 The PR has committed to provide the Executive with the required audits by 9 April 2014. The completion of this action

• stored sperm storage consents and location • embryo biopsy procedures • electronic witnessing including mismatches and other non-conformances • data submissions to the HFEA (SLC T36). The inspection team and a patient noted the lack of confidentiality and privacy at the reception desk. (SLC T43)	• confidentiality and privacy • stored sperm storage consents and location • embryo biopsy procedures • electronic witnessing including mismatches and other non-conformances and • data submissions to the HFEA are audited against compliance with approved protocols, regulatory requirements and QIs. The PR is to provide the lead inspector with a copy of the audit findings by 9 April 2014.		will be reviewed by the Executive through the on-going monitoring system.
14. An audit of patient notes showed that 37% (48/130) of the IVF and 41% (96/234) of the DI treatments reviewed had been reported to the HFEA outside the period required. (SLC T9 (e), SLC T41, General Direction 0005). The data submission for IUI success rates for the	The PR must ensure that all licenced treatment activity is reported to the Authority within the timeframe required by General Direction 0005. The systems and processes used to submit licensed treatment data should be reviewed to identify reasons for late reporting of IVF and DI cycles. Corrective actions should be taken and reported to the HFEA by 9 December 2013.	The PR will ensure that all required data is submitted within the required timeframe. Individual members of staff have been allocated the responsibility for each form. This will be auditted weekly to ensure compliance. A summary report of these audits	18 December 2013 The PR has committed to implement this recommendation and to provide the Executive with audits of the centre's form submission by 9 April 2014. These audits will be reviewed by the Executive through the on-going monitoring system.

period January to December 2012 had also been reported to the HFEA outside the period required. (SLC T9(e), SLC T41 and General Direction 0005).	Within three months of this review, the centre should conduct an audit of data submission to the HFEA, to include the internal process of transferring the data onto IDEAS. A summary report of the findings of the audit should be provided to the HFEA by 9 April 2014.	will be provided to the HFEA by the 9th of April 2014.	
15. One discrepancy was found between completed patient/partner disclosure consents on patient files and the related consent data submitted for inclusion on the HFEA register. (Chair's Letter CH (10)05 and supplementary guidance and General Direction 0007).	The data submission identified as being incorrect should be corrected immediately. The PR is required to review systems and processes to ensure that going forward, the patient and partner disclosure consent information supplied to the HFEA accurately reflects that given and recorded on completed disclosure consent forms. A report of this review should be provided to the HFEA by 9 December 2013. An audit should be conducted three months after implementing any changes, to confirm that any changes made to systems and processes are having the desired effect. A report of this audit should be provided to the HFEA by 9 April	The PR has reviewed the systems and reminded staff of the need for accuracy. Weekly audits will be carried out to ensure the accuracy of submissions. A report of the outcome of these audits will be provided to the HFEA by the 9th of April 2014	11 October 2013 The HFEA's information team has confirmed that the data discrepancy has been corrected. The PR has also acted to implement this recommendation and committed to provide the Executive with a summary of the weekly audits of disclosure consent submission by 9 April 2014. This summary will be reviewed by the Executive through the on-going monitoring system.

	2014.		
16. It is current practice for the centre's nurses when on call outside normal working hours, to administer medicines from their own homes to patients, under certain circumstances. (SLC T2).	The PR must protect service users against the risks associated with the unsafe use and management of medicines, by ensuring appropriate arrangements are in place for the safe administration of medicines for the purposes of licensed activity. The PR is required to review immediately the administration arrangements for medicines outside of normal working hours. Actions taken to implement this recommendation should be advised to the HFEA by 9 December 2013. .	The PR has immediately reviewed the arrangements for for the delivery of medicines outside of working hours. Patients requiring medicines outside of working hours will be asked to attend the clinic and be met by a nurse and a member of the facilites team.	16 December 2013 The inspection team notes the action taken by the PR and considers that these revised arrangements implement this recommendation. No further action is required.
17. It was noted on inspection that there was no evidence that staff had undertaken any formal infection prevention and control (IPC) training. (SLC T15). In some areas, the clinical environment is not appropriate to ensure it can be maintained in an optimum state so as to prevent and control infection. There is carpet	The PR should ensure that staff are appropriately trained in the prevention and control of infection and that the clinical environment is suitable so as to be able to manage and maintain a clean environment. These recommendations should be implemented by 9 April 2013. Evidence of staff IPC training and the actions taken to secure the suitability of the premises (including area risk assessments) should be provided to the HFEA by this date.	The annual external infection control audit is sheduled for January 2014. This will be provided to the HFEA by the 9th of April 2014. An internal infection control audit has been completed and is included with this report. The carpet in the scan room will be replaced with more appropriate flooring and the 'hands free' taps will be fitted	16 December 2013 The centre has submitted evidence of an internal infection control audit. The PR has also committed to complete further actions to implement this recommendation within the required timeframe. The completion of these actions will be reviewed by the Executive through

on the scan room floor and basins in clinical areas do not have 'hands-free' taps. (SLC T2).		during the refurbishment 21st December 2013 to 13th of January 2014. An identified member of the nursing team will attend infection control training with the RCN on 24th and 25th of January 2014. Cascade training will follow.	the on-going monitoring system and also as part of the review of the centre's application to vary the licensed premises.
18. It was noted on inspection that there was no evidence of any member of staff having undertaken level 1, or above, safeguarding training. (SLCs T15).	The PR should implement suitable arrangements to ensure that those attending the centre are safeguarded against the risk of abuse, by ensuring that all staff have undertaken safeguarding training and know how to identify, report and respond appropriately to suspected or actual abuse. The PR should to undertake a risk assessment to identify those staff requiring safeguarding training, and at what level. The PR should provide evidence to the HFEA by 9 April 2014, to demonstrate that all staff have completed their safeguarding training to an appropriate level on the basis of the assessment.	The LWC counsellor has attended the City of Westminster training course on Safeguarding. (27/11/2013) This will be cascaded throught the organsation through training sessions, the nurses meeting and individual training sessions. During this time an assessment will be made on which staff (if any) require further training/ Members of the nursing team will access online Safguarding training. http://www.safeguarding.co.uk/index.aspx Evidence will be provided to the	16 December 2013 The centre has provided evidence that the counsellor has attended a Safeguarding training course. The PR has also committed to complete further actions to implement this recommendation within the required timeframe. The completion of these actions will be reviewed by the Executive through the on-going monitoring system

		HFEA by the 9th of April 2014.	
19. Blood samples for screening of individuals providing gametes for treatment of a partner are not obtained within the three months before the gametes are first provided or within 24 months of subsequent treatment cycles. (SLC T51).	The PR should take immediate action to ensure that individuals providing gametes for treatment of a partner are screened as required by T51 within three months of the gametes first being provided, and subsequently at a maximum interval of 24 months. This practice should be reflected within the SOP. The HFEA should be advised of the measures taken to ensure that this happens by 9 December 2013. Within three months of the implementation of any changes to procedures, the centre should conduct an audit of screening and its timing. A summary report of the audit findings should be provided to the HFEA by 9 April 2014.	The PR has taken immedate action to ensure that individuals providing gametes for partner treatment are screened at the appropriate time prior to treatment. This is reflected in the SOP. Patient information will be ammended to reflect the changes. An audit will be carried out and a summary report will be provided by 9th April 2014.	18 December 2013 The PR has submitted an amended screening SOP, as per the recommendation. The PR has also committed to modify patient information and provide the Executive by 9 April 2014, with a report of an audit of screening to ensure its compliance. The completion of this action will be reviewed by the Executive through the on-going monitoring system.
20. The centre's website www.londoneggbank.com was not compliant with Chair's Letter CH (11)02.	The PR should ensure that the centre's website satisfies the requirements of the Chair's Letter CH (11)02 by 9 January 2014.	The PR will ensure that the London Egg Banks website satisfies the requirement of the Chairs letter by the 9th of January 2014	18 December 2013 The PR has committed to implement this recommendation by 9 January 2014. This will be reviewed by the Executive through the on-going monitoring system.

Response from the Person Responsible to this inspection report
I would like to thank the inspection team for a thorough and professional inspection process.