HFEA Executive Licensing Panel Meeting

24 January 2014

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

Minutes – Item 1

Centre 0301 – (London Women's Clinic, Wales) – Interim Treatment & Storage (including Embryo Testing) Inspection Report

Members of the Panel:	**Committee Secretary:**
Juliet Tizzard – Interim Director of Strategy (Chair)	Dee Knoyle
Paula Robinson – Head of Business Planning	**Observing:**
David Moysen – Head of IT	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 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 an inspection report, an executive update and licensing minutes for the past three years.

2. The Panel noted that this is a medium-sized centre, licensed by the HFEA since 2008, and providing a full range of licensed treatments.

3. The Panel noted that the centre is currently on a four-year licence, due to expire on 29 February 2016.

4. The Panel noted that the inspection took place on 13 November 2013.

5. The Panel noted that from September 2012 to June 2013, HFEA-held register data show the centre's success rates in terms of clinical pregnancy rates are in line with national averages.

6. The Panel noted that for the year 2012, the centre reported five cycles of partner insemination with no pregnancies; this is consistent with the national average.

7. The Panel noted that the first IVF/ICSI cycles were performed at the centre in September 2012 and the number of cycles performed in this month was too few to be analysed in respect of the 15% maximum live birth rate target in force from April 2011 to October 2012. However risk tool analysis demonstrates that the centre is being effective in managing the 10% maximum live birth rate target introduced in October 2012.

8. The Panel noted that at the time of the inspection, one major and three other areas of non-compliance were identified. The Panel noted that since the inspection the PR has informed the Inspectorate of the centre's commitment to implement the recommendations.

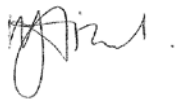
9. The Panel acknowledged the positive comments made by patients in relation to their experience of the centre.

10. The Panel noted that the Inspectorate recommends the continuation of the centre's licence.

Decision

11. The Panel had regard to its decision tree and was satisfied that the centre was fit to have its Treatment (including embryo testing) and Storage licence continued.

12. The Panel approved the Inspectorate's recommendation to continue the centre's licence with no additional conditions.



Signed: Date: 4 February 2014

Juliet Tizzard (Chair)

Executive Update for Executive Licensing Panel
24 January 2014

Centre number	0301
Centre name	London Women's Clinic, Wales
Person Responsible	Dr Hemlata Thackare

Update on recommendation made in interim inspection report

Background

1. The report of the interim inspection at London Women's Clinic, Wales is being considered by this Executive Licensing Panel.

2. At the time of the inspection there were recommendations for improvement in relation to one major and three 'other' areas of non-compliance. In response to the inspection report, the Person Responsible (PR) indicated that she did not intend to implement the following recommendation:

   The PR should ensure that only CE marked consumables are used, where suitable alternatives are available.

   Consequently, the Executive recommended the following:

   It is a Standard Licence Condition that CE marked consumables are used, where available. The ELP is asked to require that the PR complies with the conditions attached to the centre's licence. If the centre does not comply, the Executive will implement the HFEA's Compliance and Enforcement Policy.

3. Upon review of the final report, the PR has provided a further response:

   "Having reviewed the situation regarding point 4, although we feel that the current consumables and equipment are adequately suitable for our processes, we will follow the HFEA instructions and use CE marked products where available as soon as the current stock needs to be replaced."

4. The lead inspector acknowledges the PR's response. The PR should inform the centre's inspector when CE marked products have been introduced (if suitable) and by 13 February 2014 at the latest.

Sara Parlett
Inspector

Doc name: Executive Update, centre 030

TRIM reference: 2014/001319

Interim Licensing Report

Centre name: London Women's Clinic, Wales
Centre number: 0301
Date licence issued: 29/02/2012
Licence expiry date: 29/02/2016
Additional conditions applied to this licence: None
Date of inspection: 13/11/2013
Inspectors: Mrs Sara Parlett (Lead), Parvez Qureshi and Eileen Graham (observer)
Date of Executive Licensing Panel: 24/01/2014

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 (SLCs).

This is a report of an unannounced 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 2012-14 the focus of an interim inspection is:

- **Quality of service**: the quality of service provided by a centre, including its success rates and performance in reducing multiple births – the biggest single risk of IVF.
- **Patient experience**: it is considered crucial that the experiences of service users feed into any evaluation of a centre's performance.

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

This report has enabled the inspection team to form a conclusion on the continuation of the centre's licence.

The inspection team recommends the continuation of the centre's licence. In particular we note the positive comments made by patients in relation to their experiences.

The ELP is asked to note that the report makes recommendations for improvement in relation to one major area of non-compliance and three 'other' areas of non-compliance. Since the inspection, the Person Responsible (PR) has given a commitment to implement the following recommendations within the specified timescales:

'Major' areas of non compliance:

- The PR should ensure gametes and embryos are stored within their consented storage period.

'Other' areas of practice that require improvement:

- The PR should take appropriate actions to ensure that the centre submits accurate information to the Register regarding consent to disclosure to researchers.
- The PR should consider further the risks of not labelling the containers used during egg collection.

The PR has indicated that she does not intend to implement the following recommendation:

'Other' areas of practice that require improvement:

- The PR should ensure that only CE marked consumables are used, where suitable alternatives are available.

It is a Standard Licence Condition that CE marked consumables are used, where available. The ELP is asked to require that the PR complies with the conditions attached to the centre's licence. If the centre does not comply, the Executive will implement the HFEA's Compliance and Enforcement Policy.

Information about the centre

The London Women's Clinic, Wales is located in Cardiff and has held a licence with the HFEA since 2008, initially for intrauterine insemination, donor insemination and storage of sperm.

In August 2012, an ELP approved the following variations to the centre's licence:

- To change its name from London Women's Clinic, Cardiff to London Women's Clinic, Wales;
- To change the licence type from Treatment (insemination using partner/donor sperm) and Storage to a Treatment and Storage licence;
- To re-locate to new premises.

The first IVF/ICSI cycles were performed at the centre in September 2012.

Further, in April 2013, an ELP approved the variation of the centre's licence to include embryo testing.

The centre therefore now provides a full range of fertility services and provided 591 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 30 September 2013. In relation to activity levels this is a medium sized centre.

Details of Inspection findings

Quality of Service

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

Outcomes[1]

HFEA held register data from September 2012 to June 2013 show the centre's success rates in terms of clinical pregnancy rates are in line with national averages.

For the year 2012 the centre reported five cycles of partner insemination with no pregnancies. This is consistent with the national average.

Multiple births[2]

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

[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.

[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.

The first IVF/ICSI cycles were performed at the centre in September 2012 and the number of cycles performed in this month was too few to be analysed in respect of the 15% live birth rate target in force from April 2011 to October 2012.

Risk tool analysis demonstrates that the centre is being effective in managing the 10% live birth rate target introduced in October 2012.

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: embryo transfer. All of the embryo transfer procedures observed were witnessed in accordance with HFEA requirements using an electronic witnessing system.

The inspection team was able to review witnessing records that were present in five sets of patient notes and concluded that records of witnessing are accurately maintained.

Consent: Disclosure to researchers

A patient providing informed consent is one of the most important principles in healthcare. Since 1 October 2009, the HFEA has been able to release patient-identifying information held by the HFEA to researchers if patients give their permission. Patients are asked to give their consent to the disclosure of this information and this is recorded in their records and the HFEA is notified of their decision through the electronic data interface (EDI) system. It is important that the reporting through EDI is accurate so that patient information is not disclosed without consent.

The records of consent to disclosure to researchers given by 19 patients were reviewed in the course of the inspection. The consents were completed and reported to the HFEA accurately in 16 cases. In three cases, the documented consent decision indicated that consent to disclosure had been given by the patients, but the HFEA register indicated that consent had not been given. See recommendation 2.

Consent: To the storage of cryopreserved material

A review of the centre's database indicated that gametes and embryos currently in store are being stored within their consented storage period with the exceptions detailed below. The storage periods for three sets of embryos recorded on the centre's database were cross checked against the consent given by the gamete providers. In the three sets of records checked, the material was being stored in accordance with those consenting decisions.

Sperm for two patients and embryos for five patients are currently being stored beyond their consented storage period. The consent for this material expired between April and October 2013.

A storage review has recently been performed and the centre's intended actions with respect to this stored material have been identified. The circumstances of each case were discussed on inspection and the reasons for keeping the material in storage past the consented period were explained. The centre has a bring forward system in place to

manage stored material at the end of the consented period. However, in these seven cases, the centre considers further attempts to communicate with the patients are required before taking necessary action. See recommendation 1.

Staffing

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

Staffing levels observed in the course of the on-site inspection appeared to be suitable for the activities being carried out: patients were seen promptly on arrival; the atmosphere in the clinic appeared calm at all times; staff in the laboratory were able to carry out their activities without distraction and were available to carry out witnessing activities when required.

Patient experience

During the inspection visit we spoke to four patients who provided feedback on their experiences and observed interactions between centre staff and patients. A further three patients also provided feedback directly to the HFEA in the time since the last inspection. Feedback was positive with two of the individuals providing written feedback to the HFEA commenting that they have compliments about the care that they received. The patients interviewed also provided positive feedback on their experiences.

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

- has respect for the privacy and confidentiality of patients in the clinic;
- gives 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.

The centre conducts patient satisfaction surveys on a quarterly basis and the most recent survey results from October 2013 were provided on inspection. Positive feedback was received. The PR considered that the frequency of these centre questionnaires may have discouraged patients from also completing the HFEA patient survey.

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 the information submitted by the centre in their self assessment questionnaire and from observations during the visit to the centre, the inspection team identified the following non-compliances:

- At egg collection, not all containers used during the procurement of eggs are labelled with the patient's/donor's full name and a further unique identifier or a uniquely identifying donor code. The laboratory manager confirmed that a check of theatre and

laboratory critical work areas between each egg collection is made to mitigate any risk, but this check is not recorded. See recommendation 3.

- Egg collection tubes and dishes are not CE marked. However, the laboratory manager provided assurance to the inspection team of their suitability and confirmed that CE marked alternatives had been sourced and would be used once new stock was required (expected January 2014). Serological pipettes used in the laboratory are also not CE marked. It is the inspection team's understanding that CE marked equivalents are available. See recommendation 4.

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in 2011 recommendations for improvement were made in relation to eight major areas of non-compliance and six 'other' areas of non-compliance.

The PR provided information and evidence that all of the recommendations have been fully implemented.

Following the centre's application for a variation of its licence in 2012 (change of licence type and re-location to new premises) a desk based assessment was performed and recommendations for improvement were made in relation to two areas of practice. The PR provided information and evidence that both recommendations were fully implemented prior to commencing licensed activities.

Following the centre's application to vary its licence to include embryo testing in 2013, a desk based assessment was performed and recommendations were made in relation to two major and one 'other' areas of non-compliance. The PR provided information and evidence that all of the recommendations have been fully implemented.

On-going monitoring of centre success rates

No risk tool alerts have been received by the centre in relation to success rates or multiple pregnancy rates in the last twelve months.

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.

The centre is compliant with register submission related requirements.

Annex 1

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’ 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 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
None noted.			

‘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
- 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
1. Sperm for two patients and embryos for five patients are currently being stored beyond their consented storage period (Schedule 3, 8(1) and 8(2) HF&E Act 1990 (as amended)). A storage review has recently been performed and the centre’s intended actions with respect to this stored material have been identified. The circumstances of each case were discussed on inspection and the reasons for keeping the material in storage past the consented period were explained. The centre has a	The PR should provide the centre’s inspector with an update on the centre’s intended actions with respect to the material in storage beyond its consented period and the anticipated timescale for their implementation by the time the PR responds to this report. The PR should provide monthly updates to the centre’s inspector on progress in implementing the proposed actions. The centre has a bring forward system in place but in these seven cases the centre considers further attempts to communicate with the patients are required before taking the necessary action. The inspection team acknowledges the importance	The bring forward system is currently being reviewed. Of the seven patients currently having sperm/embryos in storage beyond consented storage, we have now disposed of sperm/embryos for five patients. One patient has renewed consent for storage and the situation regarding one patient remains unresolved. We are aware that patient wants to keep embryos in storage but has not yet completed consent to	The lead inspector acknowledges the PR’s response and this will be subject to on-going monitoring.

bring forward procedure in place to manage stored material at the end of the consented period.	of ensuring the patients' wishes are sought. However, it is recommended that the bring forward system is reviewed, with the aim of ensuring sufficient notice is given to patients to ensure that gametes and embryos are not stored beyond the consented period. A summary report of the findings of the review including corrective actions and the timescale for their implementation should be submitted to the centre's inspector by 13 February 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 centre's inspector.	extend storage.	

‘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	Inspection team’s response to the PR’s statement
2. The records of consent to disclosure to researchers given by 19 patients were reviewed. In three cases, the documented consent decision indicated that consent to disclosure had been given by the patient, but the HFEA register indicated that consent had not been given. General Direction 0005.	The PR should correct the submissions that have been identified as being incorrect. The PR should audit procedures for submitting patients’ consent to disclosure to researchers to the HFEA. A summary report of the findings of the audit including corrective actions and the timescale for implementation of the corrective actions should be submitted to the centre’s inspector by 13 February 2014. Three months after the implementation of corrective actions the centre should audit a random sample of ten patient records to ensure that the consent to disclosure decisions taken from patients have been correctly transferred to the HFEA register. The records audited should have had this consent	The previous discrepancies have been corrected. It was noted that some staff were using patient and partner registration forms and not CD forms to record information on EDI. All staff were reminded at monthly audit meeting on 12.12.13 that only CD forms must be used to record the correct information. Further audits will be conducted in February and May 2014	The lead inspector acknowledges the PR’s response and this will be subject to on-going monitoring.

	completed within the previous three months. This audit should be submitted to the centre's inspector by 13 May 2014.		
3. At egg collection not all containers (dishes, vials, ampoules, tubes etc) used during the procurement of eggs are labelled with the patient's/donor's full name and a further identifier or a uniquely identifying donor code. SLC T101.	It is acknowledged that only one egg collection takes place at a time and that a check of theatre and laboratory critical work areas is made between each egg collection to mitigate any risk. However, the PR should consider whether the completion of this check should be recorded in the patient notes. The centre's inspector should be informed of any further actions taken to mitigate the risks of misidentification as a result of this practice by 13 February 2014.	Risk assessment carried out as attached. Risk will continue to be monitored. A record will be kept in patient notes confirming that hot block and trolley in theatre is empty of egg collection tubes before bringing in next patient.	The centre has submitted a risk assessment, but this does not document the risk of unlabelled tubes containing eggs in the *laboratory* critical working area. The PR is asked to re-assess the centre's practice and inform the centre's inspector of any further actions taken by 13 February 2014.
4. Egg collection tubes and dishes are not CE marked. However, the laboratory manager provided assurance to the inspection team of their suitability and confirmed that CE marked alternatives had been sourced and would be used once new stock was required (expected January 2014). Serological pipettes	The PR should ensure that wherever possible CE marked medical devices are used The PR should inform the centre's inspector when the use of CE marked egg collection tubes and dishes is implemented. The PR should review the CE marked volumetric pipettes that are commercially available. If these are	Reviewed the market as requested and the CE marked alternatives are not available for some of our processes; We have validated the relevant consumables and our treatment success rate will further validate this as well. We have never had an NCD or failure with the FDA regulated products	The HF&E Act 1990 was amended with effect from 5 July 2007 to bring The European Union Tissue and Cells Directive (EUTCD) into UK law. The EUTCD requires that CE marked medical devices must be used wherever possible. It should be noted that the HFEA makes no

used in the laboratory are also not CE marked. SLC T30.	considered to be a suitable alternative, the PR should ensure that these are used. The PR should inform the centre's inspector when these have been introduced (if suitable) and by 13 February 2014 at the latest.	we currently use.We have carried out risk assessment as the ones that have been recommended by the HFEA are markedly more expensive; Nonetheless further risk assessment will be carried out once again when the current stock needs to be replenished and we would be happy to change the products if the risk changes significantly or the CE marked products become available at competitive prices. We will also re-consider changing to CE marked products sooner if the HFEA are able to provide evidence that CE marked products are superior or safer than the FDA regulated products currently in use.	recommendations related to the use of specific products but the PR is reminded that compliance with this licence condition is not optional and/or related to cost. It is recommended that the PR reconsiders the decision not to use CE marked consumables. The centre's inspector should be informed of the outcome of this review by 23 January 2014.

Additional information from the Person Responsible
I have noted the audit dates and wil send compliance reports as requested