Executive Licensing Panel - minutes

Centre 0301 (London Women's Clinic, Wales)

Interim Inspection Report

Friday, 17 November 2017

HFEA, 10 Spring Gardens, London SW1A 2BN

Panel members	Juliet Tizzard (Chair) Anna Quinn Helen Crutcher	Director of Strategy and Corporate Affairs Scientific Policy Manager Risk and Business Planning Manager
Members of the Executive	Dee Knoyle Erin Barton	Secretary Policy Manager (Observer)
External adviser		
Observers		

Declarations of interest

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

The panel had before it:

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

1. Consideration of application

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

1.2. The panel noted that London Women's Clinic, Wales is located in Cardiff. The centre has held a licence with the HFEA since 2008 and provides a full range of fertility services.

1.3. The panel noted that the inspection took place on 22 August 2017.

1.4. The panel noted that in the 12 months to 31 July 2017, the centre provided 769 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a medium-sized centre.

1.5. The panel noted that for the period May 2016 to April 2017, HFEA-held register data for IVF and ICSI, showed the centre's success rates were in line with national averages.

1.6. The panel noted that in 2016 the centre reported 18 cycles of partner insemination with one pregnancy. This is in line with the national average.

1.7. The panel noted the progress made by the centre in meeting the HFEA multiple birth rate targets. Between May 2016 and April 2017, the centre's multiple pregnancy rate for all IVF, ICSI and FET (frozen embryo transfer) cycles for all age groups was 11%. This represents performance that is not likely to be statistically different from the 10% maximum multiple live birth rate target for this period.

1.8. The panel noted that at the time of the interim inspection on 22 August 2017, one major and three other areas of non-compliance were identified. The panel noted that since the inspection the Person Responsible (PR) has addressed all of the other areas of non-compliances. The panel also noted that there were two outstanding actions required to fully address the major area of non-compliance related to the storage of gametes and embryos, one of which requires the PR to provide the inspectorate with updates on progress and the other is to undertake a review, including legal advice by 22 November 2017.

1.9. The panel noted that the inspectorate recommends the continuation of the centre's treatment and storage licence.

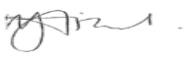
2. Decision

2.1. The panel was satisfied that the centre was fit to have its treatment and storage licence continued.

3. Chair's signature

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

Signature



Name

Juliet Tizzard

Date

27 November 2017

Interim Licensing Report

Centre name: London Women's Clinic, Wales
Centre number: 0301
Date licence issued: 01/03/2016
Licence expiry date: 28/02/2020
Additional conditions applied to this licence: None
Date of inspection: 22/08/2017
Inspectors: Janet Kirkland MacHattie, Lesley Brown.
Date of Executive Licensing Panel: 03/11/2017

Purpose of the report

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

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

This is a report of an 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 2015-2017 the focus of an interim inspection is:

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

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

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

Summary for the Executive Licensing Panel

The inspection team recommends the continuation of the centre's licence. In particular we note the progress made by the centre in meeting the HFEA multiple birth rate targets.

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

The PR has since the inspection event confirmed that she has complied with the following recommendations:

'Major' areas of non-compliance:

- the PR should ensure that there is effective consent for all gametes and embryos in storage.

'Other' areas of practice that require improvement:

- the PR should ensure that patients and donors are asked about recent travel history with regards to the risk from Ebola virus, prior to planning a treatment cycle, and that patient information regarding the risks is up to date and relevant;

- the PR should ensure that sharps boxes used at the centre are clearly labelled with the date of assembly and date of closure. The PR should also ensure that clinical waste is labelled in accordance with the centre's own infection control policy;

- the PR should review the system of stock control at the centre to ensure that all equipment used in treatment services is within its expiry date and is fit for use.

Information about the centre

The London Women's Clinic, Wales is located in Cardiff and has held a licence with the HFEA since 2008.

The centre provides a full range of fertility services.

The centre provided 769 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 July 2017. 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 important indicators of a centre's ability to provide high quality patient care and to meet the requirements of the law.

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period May 2016-April 2017 show the centre's success rates are in line with national averages.

In 2016 the centre reported 18 cycles of partner insemination with one pregnancy. This is in line with the national average.

Multiple births[2]

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

Between May 2016 and April 2017, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 11%: this represents performance that is not likely to be statistically different from the 10% multiple live birth rate target.

Witnessing

Good witnessing processes are vital to ensure there are no mismatches of gametes or embryos and that identification errors do not occur.

The inspection team was not able to observe any laboratory activities during the inspection but was able to discuss witnessing with staff and to review the centre's most recent witnessing audit. These activities indicated that witnessing procedures are compliant with HFEA requirements.

Consent: To the storage of cryopreserved material

The storage of gametes and embryos is an important service offered by fertility clinics. It enables patients to undergo further fertility treatment without additional invasive procedures and to preserve their fertility prior to undergoing other medical treatment such as

[1]The data in the Register may be subject to change as errors are notified to us by clinics, or picked up through our quality management systems. Centre success rates are considered statistically different from the national averages, and multiple pregnancy rates are considered statistically different from the 10% multiple live birth rate target, when $p \leq 0.002$.

[2]The HFEA use a conversion factor of 1.27 to convert the 10% multiple live birth rate (MLBR) target to a multiple pregnancy rate (MPR) target of 13%.

radiotherapy. It is important that the centre has measures in place to ensure that gametes and embryos are stored in accordance with the consent of the gamete providers.

On inspection, reports of audits of all stored gametes and embryos and of the accuracy of storage logs and consent records were reviewed. The 'bring-forward' system was discussed with staff and storage records were reviewed. These activities indicate that the centre's processes for storing gametes and embryos in line with the consent of the gamete providers are not fully effective. The centre did not have written effective consent for the storage of cryopreserved embryos for two sets of patients, in both instances consent to storage expired in March 2017. In addition, one set of gametes were being stored beyond the statutory storage period, without the required written opinion from a medical practitioner to confirm that the storage period can be extended (recommendation 1).

Storage where consent had expired was noted as a non-compliance at the previous inspection in 2015. The inspection team was satisfied on this inspection event that the 'bring forward' system is effective in instigating contact with patients, but patients have not been responding to communications from the centre or attending for scheduled appointments to discuss their consent to storage.

Staffing

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

Members of the centre team present on the day of the inspection assured the inspection team that there were adequate numbers of staff for the level of activity at the centre. Staff in the laboratory said that they were able to carry out their activities without distraction and were available to carry out witnessing activities when required.

The inspection team considered that staffing levels in the clinic appeared suitable for the activities being carried out.

Quality Management System (QMS)

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

The effectiveness of the centre's QMS was assessed by reviewing the reports of the following audits: witnessing, consent to storage, medicines management and infection control. A review of the QMS performed by the centre in 2016 was also submitted to the inspection team immediately following the inspection.

The centre's procedures for auditing and acting on the findings of audits are compliant with requirements.

We also considered whether the clinic's processes for implementing learning are effective. If a clinic is to achieve continuous improvement and encourage a learning culture then it is important that they act to review their practices when guidance is issued by the HFEA or

other bodies. The clinic's procedures for acting on guidance from the HFEA were evaluated with reference to the following:

- the use of CE marked medical devices;
- the use of the most recently issued HFEA consent form versions;
- HFEA Clinic Focus articles regarding the risks from Zika and Ebola viruses.

The centre is broadly effective in implementing guidance from the HFEA as the centre team does not ensure that all patients and donors are asked about recent travel history with regards to the risks from Ebola virus, prior to planning a treatment cycle, or that patient information regarding the risks is up to date and relevant (recommendation 2).

Medicines management

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

During the inspection, the clinic's processes for medicines management and the safe storage, disposal and administration of medicines were reviewed and were found to be compliant with guidance.

Prescription of intralipid 'off label'

Intralipid is an intravenous nutritional supplement sometimes prescribed to facilitate IVF treatment in a particular subset of women. This centre does not prescribe intralipid therapy therefore requirements related to its use were not relevant at this inspection.

Infection Control

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

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

- sharps bins waiting to be collected were not labelled with date of assembly and date of closure (recommendation 3);
- bags containing clinical waste were not labelled (recommendation 3);
- syringes on the emergency trolley were out of date (recommendation 4).

Equipment and Materials

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

The CE mark status of the following medical devices was reviewed in the course of the inspection: media, flush solution, vitrification kits, sperm preparation kits, and laboratory plasticware. We found the centre to be compliant with HFEA requirements to use CE marked medical devices wherever possible.

Patient experience

During the inspection, there were no patients available to speak with the inspectors about their experiences at the centre. The inspection team did however discuss with members of

centre staff their method of collecting patient feedback and what actions would be taken if the feedback identified any concerns. The centre team has introduced a new feedback questionnaire which the lead inspector found to be comprehensive. Patient feedback received by the centre was reviewed by the lead inspector and the majority of the patients were satisfied with their treatment at the centre.
On the basis of this feedback and observations made in the course of the inspection, it was possible to assess that the centre:

- has respect for the privacy and confidentiality of patients in the clinic;
- provides a clean and well organised environment for patient treatment;
- has staff who are supportive and professional.

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

Information submitted by the centre in their self-assessment questionnaire, the pre-inspection assessment and observations during the visit to the centre, indicate that the centre is compliant with HFEA requirements, with the exception of areas detailed elsewhere in the report.

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in 2015 recommendations for improvement were made in relation to one critical, six major and two 'other' areas of non-compliance.

The PR subsequently provided information and evidence that all the recommendations were fully implemented within the required timescales.

Provision of information to the HFEA

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

The HFEA register team report that there are currently no significant data submission issues at this clinic. This conclusion is based on a review of the clinic's register submissions conducted on 4 August 2017.

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

Legal parenthood

Where a couple to be treated with donated gametes or embryos is not married or in a civil partnership, both the woman and her partner must give written consent in order for the partner to become the legal parent of any child born. If this consent is not documented properly or if proper information is not provided or counselling offered prior to both parties giving consent, there may be doubt about its effectiveness and, in some cases, it may be necessary for a patient couple to obtain a court declaration to establish legal parenthood.

In February 2014, the HFEA asked all centres to audit their practices in this area to ensure they are suitable, to report the findings of the audit to the HFEA and to respond to those findings. The centre sent the report of the audit to the HFEA within the required timeframe. The audit showed that three couples were affected by legal parenthood consent anomalies.

As the PR was not present on the day of the inspection the lead inspector arranged a telephone conversation with her to discuss the current situation regarding the three couples who were affected by anomalies in their consent to legal parenthood.

The PR informed the lead inspector that in the cases where anomalies were identified each partner had been sent a registered letter outlining the problems associated with their parenthood consent, its potential consequences, and the support available from the centre including free counselling and independent legal advice. Of the three couples identified one couple had proceeded to seek legal advice, an application had been made to the High Court for declaration of parenthood and that this had been granted. The PR has contacted the other two couples on two separate occasions but has not received a response.

At the inspection on 21 July 2015, we reviewed the centre's audit and found that it had been performed according to the method specified by the HFEA. Actions had been taken in response to the audit findings.

As part of the HFEA's ongoing activities relating to 'legal parenthood', in October 2015 all PRs were asked to confirm that specific actions had been undertaken; that there are effective methods for assessing the on-going competence of staff to take this consent; and that effective audit procedures are in place to ensure on-going compliance with consent taking requirements. The PR responded to this communication and provided the required reassurances to the satisfaction of the Executive.

As part of this interim inspection, to provide further assurance of the effectiveness of the centre's procedures, the inspection team reviewed three sets of records where treatment with donor sperm had recently been provided. Effective consent to legal parenthood with a prior offer of counselling was seen to be in place before treatment in all circumstances where consent to legal parenthood was required.

In summary, the inspection team considers the processes used to collect legal parenthood consent at this centre to be compliant with HFEA 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 areas of non compliance

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

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team's response to the PR's statement
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 child who may be born as a result of treatment services;
- which indicates a major shortcoming from the statutory requirements;
- which indicates a failure of the Person Responsible to carry out his/her legal duties;
- which can comprise a combination of several ‘other’ areas of non compliance, none of which on their own may be major but which together may represent a major area of non compliance.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team’s response to the PR’s statement
1. **Storage of gametes and embryos** On the day of the inspection the centre did not have written effective consent for the storage of cryopreserved gametes for one patient, nor cryopreserved embryos for two sets of patients. (Schedule 3, 8(1) and 8(2) HF&E Act). The gametes referred to above are being stored beyond the statutory storage period without the required written opinion from a medical practitioner to	The PR should establish an action plan for resolving the cases where gametes and embryos are being stored beyond the consented storage period. A copy of the plan should be provided to the HFEA with the PR’s response to this report. The plan should aim to resolve all the current issues by 22 November 2017. The PR should provide monthly updates to the HFEA on progress in implementing the proposed actions. The PR should conduct a review to identify reasons why material has continued to be stored without	Lab Manager has confirmed that two sets of cryopreserved embryos were discarded as the HFEA inspector agreed on the day that the centre had tried its best to contact patients for extending storage consent. Written effective consent from an oncology patient for one set of cryopreserved gametes for extended storage is not in place as yet. However patient has given verbal consent to extend storage and has assured us that he will complete the LGS consent form. The MPS was	The inspector acknowledges the PR’s response, and confirms that during the inspection the inspector was satisfied that the centre had followed their own procedures for contacting patients reaching the end of their consented storage period. The inspector also confirms that it was agreed that the gametes from an oncology patient remain in storage as the patient has indicated that he wants to continue to store the samples. The PR will provide updates

confirm that the storage period can be extended. With regards to the embryos in both instances consent to storage expired in March 2017. This was also identified as a non-compliance in the previous inspection report in 2015. The inspection team taking into account the circumstances described by the senior embryologist consider it proportionate to grade this non-compliance as major rather than critical. Human Fertilisation and Embryology (Statutory Storage Period for Gametes and Embryos) Regulations 2009, paragraph 3(3)(b), SLC T79.	written effective consent. A copy of this review along with identified corrective actions to prevent future occurrences should be submitted the centre's inspector by 22 November 2017. In cases where there has been a failure to comply with the 2009 storage regulations, the PR should seek independent legal advice on how to proceed. Proposed actions in response to this advice should be forwarded to the HFEA for review prior to any action being taken. The PR is reminded of guidance issued in Chairs letter (03) 03 (CH(03)03) in relation to the timely disposal of cryopreserved material where there is consent to do so and actions to take should there be a possibility of legal challenge to the disposal of cryopreserved material.	completed afer we received verbal instructions from the patient for continued storage. In this instance after discussion with the HFEA inspector, it was agreed that we cannot discard the gametes as they were stored for fertility preservation prior to chemotherapy and patient has indicated that he wants continue storage of the gametes. We will keep the HFEA updated of the progress made in this case. Lab Manager will review the identified corrective actions to prevent future occurrences and submit this to the centre inspector by 22.11.17.	regarding progress made in this case. Review, including legal advice as referred to in the recommendation, to be received by 22 November 2017.

‘Other’ areas of practice that requires improvement

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

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team’s response to the PR’s statement
2. **Ebola** Centre staff interviewed on the day of the inspection were unaware if patients or donors are asked about recent travel history prior to embarking on treatment, with reference to the risks from Ebola virus. Clinic focus April 2017, SLC T50(d) and T52(h).	The PR should ensure that all patients and donors are asked about recent travel history with regards to the risks of Ebola prior to planning a treatment cycle. The PR should review the centre's SOPs to ensure that recent travel history is taken into account when preparing patients and donors for treatment, and that the SOPs reflect current professional guidelines and guidance from the HFEA. The PR should ensure that patient information regarding risks from Ebola is up to date and reflects current professional guidelines and guidance from the HFEA.	HFEA Clinic focus of March 2016 and April 2017 both dealing with risks of Ebola . For your records, I confirm that the Clinic Focus of March 2016 was disseminated to the centre team via email on 03.03.2016 and April 2017 issue was discussed at our multi disciplinary meeting on 06.04.17 with minutes ciirculated to all staff. Travel history regarding travel to West African countries affected by Ebola has been sought but not formally documented. We have not treated any Ebola survivors. We have not treated any patients or donors who	The inspector acknowledges the PR’s response. No further action.

	The PR should ensure that communications from the HFEA such as clinic focus articles are disseminated to the centre team and are acted on where relevant. The PR should review the reason why information published in a clinic focus article was not acted on or disseminated to the centre team. The PR should consider in any cases where it is not clear that travel history was sought, and the risks of diseases such as Ebola were not assessed, whether there are any risks to patients and partners, donors and gametes and embryos in storage. The PR should confirm that she has addressed all aspects of this recommendation by 22 November 2017.	have travelled to Ebola affected areas. We will add recent travel history to our checklist when preparing donors and patients for treatment. Patient information regarding Ebola infection and fertility treatment is now displayed in reception and circulated to all patients currently preparing for treatment and all new appointments.	
3. **Infection control** Sharps boxes waiting for	The PR should ensure that sharps boxes are clearly labelled with the date of	All staff concerned were informed in a team meeting and by email of this point. The	The inspector acknowledges the PR's response.

collection were not labelled with the date of assembly and closure. Bags of clinical waste waiting for collection were not labelled in accordance with the centre's own infection control policy. SLC T2.	assembly and date of closure. The PR should ensure that clinical waste is labelled in accordance with the centre's own infection control policy. The PR should provide the centre's inspector of assurance that these actions have been implemented when responding to the inspection report.	infection control lead has assured me now that sharps boxes are clearly labelled with the date of assembly and date of closure. Clinical waste is now labelled prior to disposal	No further action.
4. **Infection control** On the day of the inspection, syringes in the emergency pack in the centre's procedure room were past their expiry date. SLC T2.	The PR should ensure that all equipment used in treatment services is within its expiry date and fit for use. The PR should with immediate effect consider whether any syringes past their expiry date have been used in patients' treatments. The PR should seek advice as to whether there has been any risk to patients if the syringes have been used. The PR should review the centre's system of stock control to ensure that all equipment in the centre is	Our stock control audit has shown that no syringes were used in patients treatment past their expiry date. We have found no evidence to suggest that single use pre-packaged sterile syringes lead to infection risk if used past their expiry date. Both, the Nurse Manager and IVF Lab Manager have confirmed that all stock and equipment in current use are in date. There is a system in place for either weekly or monthly stock take and it has been reviewed to ensure that	The inspector acknowledges the PR's response. A statement regarding the centre's system of stock control has been received in addition to a list of consumables used and their expiry dates. No further action.

	within the expiry date. The PR should provide the centre's inspector with a copy of this review when responding to the inspection report.	all stock held is within its expiry date.	

Additional information from the Person Responsible