# Executive Licensing Panel - minutes

## Centre 0329 (Wales Fertility Institute Neath) Interim Inspection Report

Thursday, 6 April 2017

HFEA, 10 Spring Gardens, London SW1A 2BU

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| Panel members | Juliet Tizzard (Chair)<br>Ian Peacock<br>Joanne Anton | Director of Strategy & Corporate Affairs<br>Systems Manager<br>Head of Regulatory Policy |
| Members of the Executive | Bernice Ash<br>Siobhain Kelly | Secretary<br>Senior Governance Manager |
| External adviser | | |
| Observers | Anna Quinn | Scientific Policy Manager |

## 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 noted that Wales Fertility Institute Neath is located near Port Talbot. The centre has held a licence with the HFEA since August 2013. The centre currently holds a Treatment (including embryo testing) and Storage licence and forms part of a two-site service with Wales Fertility Institute, Cardiff which enables patients to access services local to their area of residence. The centre provides a full range of fertility services.

**1.2.** The panel noted that in the 12 months to 30 November 2016, the centre provided 407 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a small centre.

**1.3.** The panel noted that other licensed activities include the storage of gametes and embryos.

**1.4.** The panel noted that the inspection took place on 24 January 2017.

**1.5.** The panel noted that at the time of the interim inspection the centre had two major areas of non-compliance regarding medicines management and legal parenthood. The panel noted that PR had already implemented two of the recommendations and had given a commitment to implementing those that remained.

**1.6.** The panel noted that the inspectorate recommends the continuation of the centre's licence. In particular, the inspection team noted the commitment of all staff to provide a quality service and regulatory compliance.

## 2. Decision

**2.1.** The panel noted the non-compliances and the PR's commitment to addressing these.

**2.2.** The panel was satisfied that the centre was fit to have its 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**

18 April 2017

# Interim Licensing Report

**Centre name:** Wales Fertility Institute - Neath
**Centre number:** 0329
**Date licence issued:** 1 August 2015
**Licence expiry date:** 31 July 2019
**Additional conditions applied to this licence:** None
**Date of inspection:** 24 January 2017
**Inspectors:** Polly Todd (Lead), Sara Parlett
**Date of Executive Licensing Panel:** 7 April 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, the inspection team notes the commitment of all staff to provide a quality service and regulatory compliance.

The ELP is asked to note that recommendations for improvement are made in relation to two major areas of non-compliance as follows:

'Major' areas of non-compliance:

- The PR should ensure compliance with medicines management regulations and best practice guidance.
- The PR should seek legal advice regarding the anomaly found in the legal parenthood consent form identified in this report, and consider what actions are to be taken in light of this advice. The PR should also ensure that the centre's legal parenthood consent and audit processes are effective and robust.

The PR has fully implemented the following recommendation, and where required, and by the dates specified, the PR will provide a summary of audits conducted to ensure the corrective actions taken are affective:

'Major' areas of non-compliance:

- The PR should ensure compliance with medicines management regulations and best practice guidance.

The PR's initial response to the legal parenthood recommendation was deemed, in part, to be unsatisfactory to the Executive. Therefore, in line with the HFEA Compliance Directorate standard operating procedure (SOP) for post inspection actions, a management review was held on 8 March 2017 to discuss the PR's response to the report. The Executive was concerned that the PR had not given a commitment to implementing all aspects of the recommendation, and had not given an indication of his actions following the legal advice taken regarding the consenting anomaly. Based on the PR's response to this report, the Executive were not sufficiently assured that the PR would fully implement the recommendation and felt it was appropriate and proportionate to discuss this with the PR and invite him to submit a further response to the report. This he did on 13 March 2017 and has now provided a commitment to fully implement the following recommendation within the agreed timescales:

'Major' areas of non-compliance:

- The PR should seek legal advice regarding the anomaly found on the legal parenthood consent form identified in this report, and consider what actions are to be taken in light of this advice.

## Information about the centre

Wales Fertility Institute - Neath is located in Port Talbot and has held a licence with the HFEA since August 2013. The centre forms part of a two-site service with Wales Fertility Institute - Cardiff which enables patients to access services local to their area of residence.

The centre provides a full range of fertility services.

In the 12 months to 30 November 2016 the centre provided 407 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a small centre.

Other licensed activities include the storage of gametes and embryos.

The ELP granted a variation of the current licence to change the Person Responsible (PR) in September 2016.

## 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 October 2015 to September 2016 show the centre's success rates are in line with national averages.

In 2015, the centre reported 28 cycles of partner insemination with three pregnancies. This is in line with the national average.

#### Multiple births[2]

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

Between October 2015 and September 2016, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 18%: 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 following laboratory activities were observed in the course of the inspection: embryo transfer. The procedure observed was witnessed using an electronic witnessing system in accordance with HFEA requirements.

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[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%.

The centre's audit of witnessing was also reviewed. 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 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 effective.

### Staffing

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

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

### 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 centre has recently implemented a new QMS which they are piloting as part of a Trust wide initiative. Early indications suggest that this system will facilitate more effective quality management activities and can be used across the Welsh Fertility Institute sites at Neath and Cardiff to ensure consistent quality management procedures and processes.

The effectiveness of the centre's QMS was assessed by reviewing the reports of the following audits: consent, legal parenthood, storage of gametes and embryos and witnessing. 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 centre's audits of patient consents;
- the centre's practices regarding additional screening requirements;

- the use of CE marked medical devices;
- the use of the most recently issued HFEA consent form versions;
- the centre's audit of legal parenthood consent;
- the HFEA reports of adverse incidents from 2010-2012 and 2013;
- HFEA Clinic Focus articles regarding storage period changes and multiple birth rates.

The centre has been effective in ensuring compliance with guidance issued by the HFEA.

### 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 partially compliant with guidance. The records of drugs dispensed and administered to five patients were reviewed. In one case, not only was there a discrepancy between the amount of a drug administered recorded in the patient record and in the controlled drugs register, but the amount of drug recorded in the controlled drugs register left 10 micrograms of drug unaccounted for (see recommendation 1).

### 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 compliant with guidance.

### Equipment and Materials

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

The CE mark status of the following medical devices, consumables and reagents were reviewed in the course of the inspection: follicular flush, culture media, vitrification kits and a sample of plasticware. The centre was found 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. Ten patients provided feedback directly to the HFEA in the time since the last inspection. Feedback was positive with nine of the individuals providing written feedback giving compliments about the care received.

Based on this feedback and observations made during the inspection, it was possible to assess that the centre:

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

## 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 fully compliant with HFEA requirements with the exceptions noted in this 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 three major and six 'other' areas of non-compliance.

The PR subsequently provided information and evidence that all 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 clinic is generally compliant with requirements to submit information to the HFEA. There are some late submissions of 'intention to treat' and pregnancy outcomes information. Discussions with the quality manager during the inspection confirmed that the centre was aware of these late submissions and had already implemented corrective actions to address this matter, therefore no recommendation has been made at this time.

### 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 the effectiveness of the consent and in some cases it may be necessary for a patient couple to obtain a court declaration to establish legal parenthood.

In February 2014, the HFEA asked all centres to audit their practices in this area to ensure they are suitable, to report the findings of the audit to the HFEA and to respond to those findings. The centre sent the report of the audit to the HFEA within the required timeframe. The audit showed that no couples were affected by legal parenthood consent anomalies.

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 at the time, responded to this communication and provided the required reassurances to the satisfaction of the Executive.

To provide further assurance of the effectiveness of the centre's procedures, the inspection team reviewed four sets of records where treatment with donor sperm had recently been provided. In two of the records the patients were married so legal parenthood consenting requirements do not apply. In the remaining two sets of records the couples were neither married nor in a civil partnership and therefore consent to legal parenthood was required. In one of these records the patient had put their date of birth in the date of signing section of the declaration page. The patient is currently pregnant.

The legal parenthood consents in these records had recently been audited by the centre but the audit had failed to identify this anomaly. This casts doubt on the validity and robustness of both the centre's legal parenthood consenting practice and the audit methodology used to review that practice.

In summary, the inspection team considers the processes used to collect and audit legal parenthood consent at this centre to be partially compliant with HFEA requirements (see recommendation 2).

**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 |
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| 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 |
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| **1. Medicines management**<br>In one case, not only was there a discrepancy between the amount of a drug administered recorded in the patient record and in the controlled drugs register, but the amount of drug recorded in the controlled drugs register left 10 micrograms of drug unaccounted for.<br><br>Discrepancies between patient records and the controlled drugs register were noted as a non-compliance at the renewal inspection in 2015.<br><br>SLC T2. | The PR should ensure compliance with medicines management regulations and best practice guidance.<br><br>Whilst it is acknowledged that the current PR was not the PR at the renewal inspection, he should investigate why this non-compliance has occurred again and should implement corrective actions so that medicines are managed in a manner compliant with regulatory requirements and practice guidance.<br><br>A summary report of the findings of the investigation, including staff training | Having looked at the both the controlled drugs record book and the patient notes it is clear that the patient record is completed first with the CD register completed afterward. The patient received 80 micrograms in total in two administrations of 50 and 30 and subsequently recorded in the CD log as 70 administered and 20 discarded. The error therefore is the amount recorded as being administered in the CD log not the patient drug admin chart. The reconciliation of total number of ampoules used has been found to be correct. | The Executive acknowledges the PR’s response and action taken in response to this recommendation.<br><br>No further action beyond submission of the audit due 24 July 2017. |

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| Controlled Drugs in Perioperative Care (2006).<br><br>Misuse of Drugs Regulations (2001).<br><br>NMC (2010) Standards for Medicines Management. | requirements and other corrective actions, with timescales for implementation, should be provided to the centre's inspector by 24 April 2017.<br><br>Three months after the implementation of the corrective actions the PR should audit medicines management practices to ensure that the corrective actions implemented have been effective in achieving compliance with regulatory requirements and practice guidance.<br><br>The PR should provide a summary report of this audit to the centre's inspector. It is anticipated that this will be no later than 24 July 2017. | All nurses and anaesthetists involved in the administration of drugs during egg collection procedures will be reminded via email to ensure that not only must a correct record of administered drugs be maintained in the patient record but that this must be reconciled with records in the controlled drugs usage log. Audits will be performed in conjunction with the pharmacy department and results forwarded to the HFEA within the requested timescales | |
| 2. **Legal Parenthood**<br>In one patient record where consent to legal parenthood was required, the patient had written their date of birth instead of the date of signing on the declaration page. | The PR should seek legal advice regarding the anomaly found on the legal parenthood consent form identified in this report, and consider what actions are to be taken in light of this advice. | Initial contact has been made via the Head of Risk and Legal Services with ABMUs solicitors who have provided an initial opinion. Following discourse with the HFEA about this advice, further communication with the | The Executive acknowledges receipt of the legal advice taken by the centre. The Executive is concerned that the legal advice received by the PR may not have fully considered the implications of the consenting anomalies in |

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| These records had been subject to a legal parenthood audit by the centre which had failed to identify this anomaly.<br><br>Section 44(1) of Part 2 of the HF&E Act 2008. | The PR should also ensure that the centre's legal parenthood consent and audit processes are effective and robust.<br><br>The PR should provide the centre's inspector with a summary of the advice received and a plan of action to support the couple affected. This should be provided no later than 24 April 2017.<br><br>The PR is reminded that, especially in light of recent legal judgements, the centre has a duty of candour to inform the couple of this anomaly, and facilitate guidance and support during the process.<br><br>In light of the previous PR's assurances to the HFEA that the centre's legal parenthood processes were robust and appropriate, the current PR should also undertake a full investigation with root cause analysis, into why this consenting anomaly has occurred. The investigation | solicitors has been requested to ensure they fuilly understand the issues and potential problems consequent to the error on the consent form. Once this further advice has been received a formal plan of action can be formulated and will include informing the patient of the anomaly in the consent form; explaining the potential consequences of the anomaly; sharing the legal advice that WFI receive; suggesting that the patient seek their own legal opinion and generally supporting the patients through any particular process as necessary.<br><br>An investigation into why the anomaly was not discovered prior to treatment will be undertaken and advice sought as to the most effective measures to implement to prevent such an occurrence from being repeated. | line with the Munby judgements and will therefore have further discussions with the PR.<br><br>The PR has a duty of candour to inform the patients of this anomaly. The Executive are confident that the PR will fulfil this duty as he has done so in previous cases. The Executive will have further discussion with the PR to confirm his actions.<br><br>The Executive has made it clear that it is the responsibility of the PR to ensure that correct legal parenthood consents are in place and appropriately completed.<br><br>The Executive is not in a position to give legal advice to the PR.<br><br>The Executive is concerned that the PR has not made a commitment to review the legal parenthood auditing processes; conduct a full root cause analysis or a complete a full legal parenthood re-audit, |

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| | should include the corrective and preventative actions taken to limit the risk of this incident reoccurring and provide firm assurance that the centre's consenting processes are robust. A summary report of this investigation should be provided to the centre's inspector by 24 April 2017.<br><br>The PR should also review the legal parenthood audit processes and investigate why this anomaly was not identified when the records were recently audited by centre staff.<br><br>The PR should inform the centre's inspector of the outcome of the review, together with any corrective actions taken, when responding to this report.<br><br>The PR should then conduct a full re-audit of all records since the granting of the centre's initial licence in 2013, where patients have been treated with donated gametes or embryos (not married or in a | The above will provide the basis of the consent audit review which will aim to make the process more robust.<br><br>The ammended process will be sent to the HFEA along with the investigation as to why the anomoly was not discovered.<br><br>A full reaudit of all cases involving donor sperm will be undertaken by the quality manager and 2 members of the embryology team who will double witness that all forms have been completed properly.<br><br>Audits of the consenting process and also of the auditing of the process will be conducted to ensure corrective actions have been effective | and will be having further discussions with the PR to ensure these actions are completed.<br><br>Further action required.<br><br>**Update 14 March 2017:**<br>The Executive acknowledges the PR's additional response and confirmation of his commitment to fully implement this recommendation within the agreed timescales.<br><br>Further action required. |

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| | civil partnership), to ensure that the correct legal parenthood consents are in place.<br><br>The PR should inform the centre's inspector of the outcome of this audit. To ensure that a robust and thorough audit is undertaken it is anticipated that the PR will provide a summary report of the audit to the centre's inspector no later than 24 April 2017.<br><br>Three months after the implementation of the corrective actions the PR should review both the legal parenthood consenting and legal parenthood auditing processes to ensure that corrective actions implemented have been effective in ensuring regulatory compliance.<br><br>The PR should provide a summary report of this review to the centre's inspector by 24 July 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 |
|---|---|---|---|
| None | | | |

| Additional information from the Person Responsible |
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| Many thanks to the HFEA for such an efficient and useful visit. All WFI staff very much appreciate the collegiate approach that the HFEA take towards inspections and value the ongoing open and transparent discussions that we are able to hold with the inspectors. This affords staff the opportunity to engage directly with the regulator and gain from their experience in the sector. |