Human Fertilisation and Embryology Authority

Minutes of the Executive Licensing Panel

Meeting held at HFEA, Finsbury Tower, 103-105 Bunhill Row, London, EC1Y 8HF on
22 May 2015

Minutes – item no. 2

Centre 0329 (Wales Fertility Institute – Neath) – Renewal Inspection Report

Members of the Panel:	Juliet Tizzard Director of Strategy & Corporate Affairs (Chair) Joanne Anton Policy Manager Paula Robinson Head of Business Planning
Members of the Executive in attendance:	Sam Hartley Head of Governance & Licensing Dee Knoyle Committee Secretary

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 the 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 the 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 the publication of Authority and committee papers

Consideration of application

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

2. The panel noted that this is a treatment (including embryo testing) and storage centre which provides a full range of fertility services. The panel noted that in relation to activity levels this is a small centre.

3. The panel noted that the centre has been licensed by the HFEA since August 2013. The initial licence was granted for a period of two years and is due to expire on 31 July 2015.

4. The panel noted that in the 12 months to 31 December 2014, the centre provided 443 cycles of treatment (excluding partner intrauterine insemination).

5. For IVF and ICSI, HFEA-held register data for the period October 2013 to September 2014 showed the centre's success rates were in line with national averages with the following exception:
    - success rates following IVF treatment in women under 38 years old were lower than average at a statistically significant level.

6. The panel noted that in 2013, the centre reported four cycles of partner insemination with no pregnancies. This was consistent with the national average.

7. The panel noted that in 2014, the centre reported 44 cycles of partner insemination with one pregnancy. Statistical analysis of the sector IUI data for 2014 has not yet been carried out and therefore it is not known if this will be consistent with the national average.

8. Between October 2013 and September 2014, the centre's multiple pregnancy rate for all IVF, ICSI and frozen embryo transfer (FET) cycles for all age groups was 18%. This represented performance that was not likely to be statistically different from the 10% maximum multiple live birth rate target for this period.

9. The panel noted that at the time of the inspection on 24 and 25 February 2015, the Inspectorate identified three major and six other areas of non-compliance. In particular the panel noted the non-compliances relating to consent and patient records. The panel noted that since the inspection the Person Responsible (PR) has implemented some of the recommendations and committed to implementing the outstanding recommendations.

10. The panel noted that the Inspectorate recommends the renewal of the centre's treatment (including embryo testing) and storage licence for a period of four years without additional conditions.

Decision

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

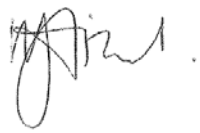
12. The panel was satisfied that the qualifications and character of the PR are such as is required for the supervision of licensed activities, and the PR has discharged their duty under section 17 of the HFE Act 1990 (as amended).

13. The panel noted that the premises to be licensed are suitable for the conduct of the licensed activities.

14. The panel noted that record keeping issues were identified and some corrective actions were implemented. However, the panel urged the PR to develop a more rigorous approach to record keeping and endorsed the Inspectorate's recommendation that the PR should perform a further review to identify the causes of the poor record keeping issues noted on inspection. The panel noted that a summary report of the findings of the review, including corrective actions and the timescale for implementation of the corrective actions was due to be submitted to the Inspectorate by 25 May 2015 and an audit must be submitted by 25 August 2015 to provide assurance that corrective actions have been effective.

15. The panel endorsed the Inspectorate's recommendation to renew the centre's treatment (including embryo testing) and storage licence for a period of four years without additional conditions.

Signed: Date: 3 June2015



Juliet Tizzard (Chair)

Inspection Report

Purpose of the Inspection Report

This is a report of an inspection, carried out to assess whether this centre complies with essential requirements in providing safe and high quality care to patients and donors. The inspection was scheduled (rather than unannounced) and the report provides information on the centre's application for a renewal of its existing licence. Licences are usually granted for a period of four years. The Authority's Executive Licensing Panel (ELP) uses the application and this report to decide whether to grant a new licence and, if so, whether any additional conditions should be applied to the licence.

Date of inspection: 24 and 25 February 2015

Purpose of inspection: Renewal of a licence to carry out treatment (including embryo testing) and storage

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

Inspectors: Sara Parlett (lead), Janet Kirkland, Louise Winstone, Neil McComb, Tarek Hussain and Margaret Gilmore (observing)

Date of Executive Licensing Panel: 22 May 2015

Centre name	Wales Fertility Institute - Neath
Centre number	0329
Licence number	L/0329/1/c
Centre address	Neath Port Talbot Hospital, Baglan Way, Port Talbot, SA12 7BX
Person Responsible	Professor Adnan Bunkheila
Licence Holder	Mr Hamish Laing
Date licence issued	1 August 2013
Licence expiry date	31 July 2015
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:
Wales Fertility Institute – Neath is situated in Port Talbot and has been licensed by the HFEA since August 2013 when an initial treatment (including embryo testing) and storage licence was granted for a period of two years. This inspection represents the first visit to the centre since it was initially licensed. The inspection team is satisfied that the activities carried out at the centre are necessary or desirable in order to provide licensed treatment services.

The centre offers a full range of licensed treatments to NHS funded patients and provided 443 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 December 2014. In relation to activity levels this is a small centre.

Other licensed activities of the centre include storage of gametes and embryos.

The initial licence granted to the centre had an additional condition attached: “use of embryos for the purpose of training persons in embryo biopsy, embryo storage or other embryological techniques is not to be undertaken by this centre until it provides further information on the training techniques and methods to be used”.

This condition was added because the Licence Committee (LC) was not entirely satisfied that the information provided was sufficient to allow them to reach a decision on whether the use of embryos for training was necessary and should be licensed as an activity. The LC stressed that there was no censure or criticism of the centre implied by the imposition of this condition. Subsequent to this decision being made, legal advice was sought on whether it is necessary for a LC to see evidence of whether the use of embryos for training is necessary before a decision can be made to grant a licence for this activity. Legal advice concluded that it is not. A committee agreed to remove the additional condition in January 2014.

An application to vary the centre’s licence to reflect a change of Licence Holder (LH) from Mr Pushpinder Mangat to Mr Hamish Laing was granted by an ELP in November 2014.

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period October 2013 – September 2014 show the centre's success rates are in line with national averages with the following exception:

- success rates following IVF treatment in women under 38 years old are lower than average at a statistically significant level.

Refer to section 3 of this report for details.

In 2013, the centre reported four cycles of partner insemination with no pregnancies. This is consistent with the national average.

In 2014, the centre reported 44 cycles of partner insemination with one pregnancy. Statistical analysis of the sector IUI data for 2014 has not yet been carried out and so it is not known if this will be consistent with the national average.

Multiple births[2]

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

Between October 2013 and September 2014, 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 for this period.

[1]The data in the Register may be subject to change as errors are notified to us by clinics, or picked up through our quality management systems. 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%.

Summary for licensing decision

Taking into account the essential requirements set out in the Human Fertilisation and Embryology (HF&E) Act 1990 (as amended), the HF&E Act 2008 and the HFEA Code of Practice (CoP), the inspection team considers that it has sufficient information to conclude that:

- the application has been submitted in the form required;
- the application has designated an individual to act as the Person Responsible (PR);
- the PR's qualifications and experience comply with section 16 (2) (c) of the HF&E Act 1990 (as amended);
- the PR has discharged his duty under section 17 of the HF&E Act 1990 (as amended);
- the premises (including those of relevant third parties) are suitable;
- the centre's practices are suitable;
- the application contains the supporting information required by Directions 0008, in application for renewal of their licence;
- the centre has submitted an application fee to the HFEA in accordance with requirements.

The ELP is asked to note that at the time of the inspection there were a number of areas of practice that required improvement, including three major and six 'other' areas of non-compliance.

The PR has provided evidence that the following recommendations have been implemented:

'Other' areas that requires improvement:

- the PR should ensure that the disposal of sperm not needed for treatment is witnessed.
- the PR should ensure that screening results for each sperm donor are provided and reviewed to assess whether the results meet UK screening requirements prior to importing sperm for use in treatment.
- the PR should ensure that the centrifuge used during sperm preparation is recorded to allow for full equipment traceability.

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

Major areas of non compliance:

- the PR should ensure that the centre's procedures for accurate patient record keeping are compliant with all relevant regulatory requirements and guidance.
- the PR should establish compliant third party agreements (TPAs) with its diagnostic laboratory and the courier used to transport gametes and embryos.
- the PR should review the centre's consenting procedures to ensure that fully informed and effective consent is freely given by patients and donors.

'Other' areas that requires improvement:

- the PR should review the location of the centre's low oxygen alarm taking into consideration potential health and safety risks.
- the PR should ensure that the centre submits accurate information to the Authority regarding consent to disclosure to researchers.

- the PR should ensure that all licenced treatment activity is reported to the Authority within the timeframe required by Directions 0005

Recommendation to the Executive Licensing Panel

The centre has no critical areas of concern but does have three major areas of concern.

The inspection team notes that the success rates are consistent with the national average with one exception and their multiple clinical pregnancy rates meet the target.

Some improvement is required in order for the centre to demonstrate suitability of their practices. The centre has a quality management system (QMS) in place and the PR is encouraged to use the QMS to best effect to monitor and improve the service provided.

The inspection team recommends the renewal of the centre's treatment and storage (including embryo testing) licence for a period of four years without additional conditions subject to the recommendations made in this report being implemented within the prescribed timescales.

Section 2: Inspection findings

This section details what the centre does well and which areas need to be improved to meet essential requirements. We break this down in to four areas covering all the activities of a licensed centre:

1. The protection of the patient, and children born following treatment at this centre
2. The experience of patients at this centre
3. The protection of gametes (sperm and eggs) and embryos at this centre
4. How this centre looks after important information

1. Protection of the patient and children born following treatment

Witnessing and assuring patient and donor identification

What the centre does well

Witnessing (Guidance note 18)
The centre's procedures for double checking the identification of gametes and embryos and the patient or donor to whom they relate are broadly compliant with HFEA requirements. This ensures that patients receive treatment using the correct gametes or embryos.

What the centre could do better

It was noted on the first day of inspection that the centre does not witness the disposal of sperm not needed for treatment (SLC T71 and CoP Guidance 18.4). This non-compliance was resolved by the second day of inspection and the centre's witnessing procedure has been revised (recommendation 4).

Donor selection criteria and laboratory tests

Screening of donors prior to procuring, processing gametes and embryos
Payments for donors
Donor assisted conception

What the centre does well

Screening of donors (Guidance note 11)
The centre does not recruit donors; therefore this area of practice is not relevant to this inspection.

Payments for donors (Guidance note 13; Directions 0001)
The centre does not recruit donors; therefore this area of practice is not relevant to this inspection.

Donor assisted conception (Guidance note 20)

A donor-conceived person is entitled to know details of their donor and any donor-conceived genetic siblings they may have. Parents of a donor-conceived child are able to access information on their child's donor (and about any donor-conceived genetic siblings) from the HFEA or the clinic where they received treatment.

Therefore it is important that centres use donated gametes or embryos from identifiable donors. The centre's procedures are compliant with HFEA requirements to ensure the donor conceived will be able to receive this information.

What the centre could do better

Nothing identified at this inspection.

Suitable premises and suitable practices

Safety and suitability of premises and facilities
Laboratory accreditation
Infection control
Medicines management
Pre-operative assessment and the surgical pathway
Multiple births
Procuring gametes and embryos
Transport and distribution of gametes and embryos
Receipt of gametes and embryos
Imports and exports
Traceability
Quality management system
Third party agreements
Transports and satellite agreements
Equipment and materials
Process validation
Adverse incidents

What the centre does well

Safety and suitability of premises and facilities (Guidance note 25)
The centre's premises are suitable. This is important to ensure that all licensed activities are conducted in a suitable environment that is fit for purpose.

The centre has procedures in place that are broadly compliant with requirements to ensure that risks are taken into account to ensure patients and staff are in safe surroundings that prevent harm.

The premises of the centre's laboratories conducting tests that impact on the quality and safety of gametes and embryos (relevant third parties) are suitable.

The centre is compliant with HFEA requirements to process gametes and embryos in an environment of appropriate air quality.

Laboratory accreditation (Guidance note 25)
The centre's third party laboratories which undertake the diagnosis and investigation of patients, patients' partners or donors, or their gametes, embryos or any material removed

from them, are compliant with HFEA requirements for accreditation by CPA (UK) Ltd or another body accrediting to an equivalent standard. This is important to assure the quality of the services provided.

Infection control
The centre has systems in place to manage and monitor the prevention and control of infection that are compliant with guidance.

Medicines management
The centre has arrangements in place for obtaining, recording, handling, using, keeping, dispensing, administering and disposing of medicines that are broadly compliant with guidance.

Pre-operative assessment and the surgical pathway
The centre has policies and procedures in place that are compliant with professional body guidelines for pre-operative assessment and management of the surgical pathway. This is important to ensure that all patients are safely assessed and cared for pre, peri and post operatively.

The centre is planning to offer surgical sperm collection at the centre. The inspection team was assured that the intended surgical pathway and staff competence have been suitably assessed.

Multiple births (Guidance note 7; Directions 0003)
The centre's procedures are compliant with HFEA multiple births minimisation strategy requirements for keeping a summary log of cases in which multiple embryos have been transferred and conducting regular audits and evaluations of the progress and effectiveness of the strategy. The single biggest risk of fertility treatment is a multiple pregnancy.

Procurement of gametes and embryos (Guidance note 15)
The centre's procedures are broadly compliant with HFEA requirements to:

- document the justification for the use of the patient's gametes (or embryos created with their gametes) in treatment, based on the patient's medical history and therapeutic indications;
- where the sperm is procured at home, the centre keeps a record of this in the gamete provider's records.

Transport and distribution of gametes and embryos (Guidance note 15; Directions 0009)
The centre's procedures for the transport, distribution and recall of gametes and embryos are compliant with HFEA requirements. This is important to ensure that all gametes/embryos sent to other licensed centres within or outside the UK are:

- packaged and transported in a manner that minimises the risk of contamination and preserves the characteristics and biological functions of the gametes or embryos;
- shipped in a container that is designed for the transport of biological materials and that maintains the safety and quality of the gametes or embryos;
- appropriately labelled with the transport conditions, including temperature and time limit being specified;
- the container/package is secure and ensures that the gametes or embryos are

maintained in the specified conditions. All containers and packages are validated as fit for purpose.

Receipt of gametes and embryos (Guidance note 15)
The centre's procedures for the receipt of gametes and embryos are compliant with HFEA requirements. This is important to ensure that the centre only accepts gametes and embryos from other centres if the gametes and embryos are appropriately labelled and are provided with enough information to permit the gametes and embryos be stored or used in treatment in a way that does not compromise their quality and safety.

Imports and exports (Guidance note 16; Directions 0006)
The centre's procedures for import and export of gametes and embryos are broadly compliant with HFEA requirements.

Traceability (Guidance note 19)
The centre's procedures are broadly compliant with HFEA traceability requirements. These requirements are important to ensure that the centre has the ability:

- to identify and locate gametes and embryos during any step from procurement to use for human application or disposal:
- to identify the donor and recipient of particular gametes or embryos;
- to identify any person who has carried out any activity in relation to particular gametes or embryos; and
- to identify and locate all relevant data relating to products and materials coming into contact with particular gametes or embryos and which can affect their quality or safety.

Quality management system (QMS) (Guidance note 23)
The centre has a QMS in place that is compliant with HFEA requirements. The establishment and use of a QMS is important to ensure continuous improvement in the quality of treatments and services.

Third party agreements (Guidance note 24)
The centre's TPAs are partially compliant with HFEA requirements.

Transport and satellite agreements (Guidance note 24; Directions 0010)
The centre does not have transport or satellite centres, therefore this area of practice is not relevant to this inspection.

Equipment and materials (Guidance note 26)
The centre uses equipment and materials that are compliant with HFEA requirements. All of the equipment and materials used in licensed activity are designated for the purpose and are appropriately maintained in order to minimise any hazard to patients and/or staff.

The centre is compliant with HFEA requirements to validate critical equipment.

The centre has documented procedures for the operation of critical equipment and procedures to follow if equipment malfunctions.

Process validation (Guidance note 15)
The centre's procedures are compliant with HFEA requirements to validate critical processes. This ensures that these processes are effective and do not render the gametes or embryos clinically ineffective or harmful to the recipient.

Adverse incidents (Guidance note 27)
The centre's procedures for reporting adverse incidents are compliant with HFEA requirements. The centre reports all adverse incidents (including serious adverse events and reactions) to the HFEA. The centre investigates all adverse incidents that have occurred. Reporting and investigation of adverse incidents is important to ensure that centres share the lessons learned from incidents and continuously improve the services it offers.

What the centre could do better

Safety and suitability of premises and facilities (Guidance note 25)
Cleaning of the premises is performed by hospital cleaners, however additional cleaning is also performed by the centre's nursing staff. The record of weekly cleaning by the nurses was reviewed but had not been completed for 13 days. The lead nurse confirmed this hadn't been performed because the nursing team did not have time that week. It was also noted that the post operative area was slightly cluttered and untidy. However, the centre was visibly clean, no infection control issues were noted and the PR stated that he is satisfied with the nursing staff complement. The inspection team does not consider it necessary to make a formal recommendation in this report but requests that the PR reviews this area of practice.

The centre has a low oxygen alarm for monitoring oxygen levels in the cryostore. However, the alarm panel is situated within the cryostore room. In the event of the alarm being activated, staff cannot check the panel to ascertain the cause of the alarm without entering the room, which is a potential health and safety risk. A recent engineer's report received by the centre has also recommended that the panel should be mounted on a wall outside of the cryostore (CoP Guidance 25.17) (recommendation 5).

Medicines management
The records of drugs dispensed and administered to three patients at egg collection were reviewed. In one case, there was a discrepancy between the amount of a drug that was recorded as administered in the patient records and that documented in the controlled drugs book. This was discussed in detail with the lead nurse and a member of the theatre team. On further inspection of the controlled drugs book, the inspection team noted the documentation of the amount of the medication which had been witnessed as being discarded and it was considered that this was a record keeping error only (recommendation 1).

Procurement of gametes and embryos (Guidance note 15)
Refer to the record keeping section of this report and recommendation 1.

Imports and exports (Guidance note 16; Directions 0006)
The centre imports gametes for use in donor treatment. Directions 0006 set out the requirements under which a centre may import gametes. The centre provided written confirmation to demonstrate compliance with these requirements with one exception: only a generic statement of donor screening performed has been provided by the sperm bank. Screening results for each specific donor are not provided and so it is unclear how the centre can be fully assured that the screening results meet the UK requirements in each case (Directions 0006 and T110e) (recommendation 6).

Traceability (Guidance note 19)
Equipment traceability is not complete as the centrifuge used during sperm preparation is not recorded (SLC T99) (recommendation 7).

Third party agreements (Guidance note 24)
The centre's TPA with one of its diagnostic laboratories is in the process of being established (SLC T111) (recommendation 2).

When patients request transport of their gametes/embryos from the centre, they are directed to make their own arrangements with a courier firm. The centre does not consider this transport arrangement to be their responsibility and therefore does not have a TPA with the courier firm. However, Directions 0009 only authorise the keeping, of gametes/embryos in the course of carriage, on behalf of a person to whom a licence applies. The inspection team considers that the centre is responsible for gametes and embryos while they are in the course of carriage between licensed centres and that third party arrangements are required to ensure the quality and safety of gametes/embryos during the course of the carriage (SLC T111) (recommendation 2).

Staff engaged in licensed activity
Person Responsible (PR)
Staff

What the centre does well

Person Responsible (Guidance note 1)
The PR has academic qualifications in the field of medicine and has more than two years of practical experience which is directly relevant to the activity to be authorised by the licence. The PR has successfully completed the HFEA PR Entry Programme (PREP number T/1236/81).

Staff (Guidance note 2)
The centre is compliant with HFEA requirements to have suitably qualified and competent staff to carry out the licensed activities and associated services. The centre has an organisational chart which clearly defines accountability and reporting relationships.

The centre has access to a nominated registered medical practitioner and scientist, within the UK, to advise on and oversee medical and scientific activities respectively.

What the centre could do better

Staff (Guidance note 2)
The centre is not currently at its full staff complement: the senior embryologist is currently on maternity leave and the consultant embryologist is covering this post. The consultant embryologist works between this centre and the sister clinic, Wales Fertility Institute – Cardiff (centre 0049) where he is also PR. Centre staff confirmed that there are contingency arrangements in place to manage this short term staff shortage and that embryologists from centre 0049 or locum embryologists can be deployed when necessary.

The inspection team was assured of the suitability of these arrangements but requests that the PR keeps staffing arrangements under review to ensure that workload does not

exceed that which can safely be accommodated.

Welfare of the child and safeguarding

What the centre does well

Welfare of the child (Guidance note 8)
The centre's procedures to ensure that the centre takes into account the welfare of any child who may be born as a result of the licensed treatment, and of any other child who may be affected by that birth before treatment is provided are compliant with HFEA requirements.

Safeguarding
The centre's procedures are compliant with safeguarding guidance. This ensures that the centre's patients and staff are protected from harm where possible.

What the centre could do better

Nothing identified at this inspection.

Embryo testing

Preimplantation genetic screening
Embryo testing and sex selection

What the centre does well

Preimplantation genetic screening (Guidance note 9); Embryo testing and sex selection (Guidance note 10)
Embryo testing has not been performed at the centre since it was initially licensed. It was explained that the Welsh commissioning group that funds this service requires patients to have the full treatment cycle in one of two centres in London. The commissioning group will be reviewing this policy in 2015/2016.

This area was assessed by the executive in 2012 and because no activity has taken place and no changes have been made, it was not reviewed again on this inspection. Confirmation was received that staff competence has been maintained in this area.

What the centre could do better

Nothing identified at this inspection.

2. The experience of patients

Patient feedback

What the centre does well

During the inspection visit no patients were available to speak to an inspector to provide feedback on their experiences. However, 39 patients provided feedback directly to the HFEA in the time since the centre was licensed. Feedback was very positive with 26 of the individuals commenting that they have compliments about the care that they received, particularly the caring and friendly staff.

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 patients sufficient, accessible and up-to-date information to enable them to make informed decisions;
- provides patients with satisfactory facilities for their care.

What the centre could do better

Nothing identified at this inspection.

Treating patients fairly

Counselling
Egg sharing arrangements
Surrogacy
Complaints
Confidentiality and privacy

What the centre does well

Treating patients fairly (Guidance note 29)
The centre's procedures are compliant with requirements to ensure that prospective and current patients and donors are treated fairly and that all licensed activities are conducted in a non-discriminatory way.

Counselling (Guidance note 3)
The centre's counselling procedures are broadly compliant with HFEA requirements. This is important to ensure that counselling support is offered to patients and donors providing relevant consent.

Egg sharing arrangements (Guidance note 12; Directions 0001)
The centre does not provide treatment involving egg sharing; therefore this area of practice is not relevant to this inspection.

Surrogacy (Guidance note 14)
The centre is in the early stages of providing treatment for its first two surrogacy cases. The patient records were reviewed and discussions were held with the counsellor and PR. It was considered that the centre's planned procedures for treatment involving

surrogacy are compliant with HFEA requirements. This is important to protect the surrogate and any children born as a result of the treatment.

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

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

What the centre could do better

Counselling (Guidance note 3)
The inspection team was satisfied that counselling is offered to patients and donors. However, this offer is not always clearly documented in the patient notes. Refer to the record keeping section of this report and recommendation 1.

Information

What the centre does well

Information (Guidance note 4; CH(11)02)
The centre's procedures for providing information to patients are broadly compliant with HFEA requirements. This ensures that the centre gives prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions.

What the centre could do better

Information (Guidance note 4; CH(11)02)
The inspection team was satisfied that appropriate information is given to patients. However, this is not always clearly documented in the patient notes. Refer to the record keeping section of this report and recommendation 1.

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

What the centre does well

Consent (Guidance note 5;6)
The centre's procedures for obtaining consent are partially compliant with HFEA requirements. This ensures that patients and donors have provided all relevant consents before carrying out any licensed activity.

Disclosure of information, held on the HFEA Register, for use in research (Directions 0005)
The centre's procedures for taking consent to disclosure to researchers are broadly

compliant with HFEA requirements.

This is important to ensure that the HFEA holds an accurate record of patients' consent, so that it only releases the patients identifying information, to researchers, with their consent. Information can be used by researchers to improve the knowledge about the health of patients undergoing treatment and those born following treatment.

What the centre could do better

Consent (Guidance note 5;6)
During a review of patient notes and in discussion with staff, the following two issues were noted:

- centre staff request that patients consent to gamete/embryo storage for the time period for which NHS funding is available. People giving consent should be free to choose how long to consent to the storage of their gametes and/or embryos for, within what is permitted by regulations. The HFEA advises that storage consent should not be restricted to tie in with payment or funding terms. Guidance on this will be issued to the sector on 1 April with updates to the CoP;

- for consent to the use of embryos in training staff, in addition to completing the HFEA consent form, patients are asked to complete the centre's own consent form. This local consent form is then deemed by the centre to supersede consent collected on the HFEA form. Staff explained that prior to use of embryos for training, they therefore only check the consenting decision recorded on the local consent form. In one set of notes reviewed on inspection, the patients had not consented to the use of embryos on the HFEA consent forms, but had given consent on the local consent form. Both sets of consents had been completed on the same day and therefore it was not clear to the inspection team which had been completed first. Directions 0007 requires that consent is recorded on the appropriate HFEA consent form. Although it is acknowledged that some centres do use local consent forms in addition, the inspection team considers that all related documented consent decisions should be consistent. The inspection team is also concerned that this suggests information given to patients before completing the HFEA treatment forms was not sufficient to allow them to give fully informed consent (SLCs T57 and T58).

See recommendation 3.

Legal parenthood
The partners of women treated with donated gametes or embryos where the couple are neither married nor in a civil partnership must give their consent if they wish to become the legal parent of any child born. If this consent is not documented or if the requirements to provide information or offer counselling are not met, it can have serious consequences, such as the partner having to adopt any child born in order to become the legal parent. In February 2014, the HFEA asked all centres to audit their procedures for giving patients an opportunity to consent to legal parenthood to ensure they are suitable, to report the findings of the audit to the HFEA and to respond to those findings. The centre submitted its audit in May 2014; it had been performed according to the method specified by the HFEA and no issues were identified.

However, three sets of notes were reviewed on inspection of patients who have had

treatment with donor sperm since the centre's legal parenthood audit was performed in 2014. One couple had three cycles of DI in 2014 and were successful on the third cycle. However, the female's consent to her partner being the legal parent was not completed until after the first cycle. The consent checklist in the notes recorded this as being completed before the first cycle (SLC T61). It is acknowledged that patients may decline to give consent to parenthood and the absence of a consent does not necessarily indicate a failure to provide the opportunity to give consent but on the basis of information in the patient's records, if the first cycle had been successful then this could have left the legal parenthood of a child born the subject of dispute (recommendation 3).

Disclosure of information, held on the HFEA Register, for use in research (Directions 0005)

Four discrepancies were found in the course of a review of 29 completed patient/partner disclosure consents in patient records and the related consent data submitted for inclusion on the register (Directions 0005) (recommendation 8).

3. The protection of gametes and embryos

Respect for the special status of the embryo

What the centre does well

The centre's procedures are compliant with the requirements of the HF&E Act 1990 (as amended). This ensures that the centre has respect for the special status of the embryo when conducting licensed activities.

- licensed activities only take place on licensed premises;
- only permitted embryos are used in the provision of treatment services;
- embryos are not selected for use in treatment for social reasons;
- embryos are not created by embryo splitting;
- embryos are only created where there is a specific reason to do so which is in connection with the provision of treatment services for a particular woman; and
- embryos are only stored if those embryos were created for a woman receiving treatment services or from whom a third party agreement applies.

What the centre could do better

Nothing identified at this inspection.

Screening of patients
Storage of gametes and embryos

What the centre does well

Screening of patients (Guidance note 17)
The centre's procedures for screening patients are compliant with HFEA requirements.

It is important that gamete providers are appropriately screened to minimise the risks of cross infection during treatment, processing and storage of gametes and embryos.

Storage of gametes and embryos (Guidance note 17)
The centre's procedures for storing gametes and embryos are compliant with HFEA requirements. These measures ensure that the gametes and embryos are stored appropriately to maintain their quality and safety. Furthermore, the centre only stores gametes and embryos in accordance with the consent of the gamete providers. The storage of gametes and embryos is an important service offered by fertility clinics, as it can enable patients to preserve their fertility prior to undergoing other medical treatment such as radiotherapy. The storage of embryos not required for immediate use also means that women can undergo further fertility treatment without further invasive procedures being performed.

What the centre could do better

Nothing noted on this inspection.

Use of embryos for training staff (Guidance note 22)
What the centre does well **Use of embryos for training staff (Guidance note 22)** The centre's procedures for using embryos for training staff are broadly compliant with HFEA requirements. Embryos are only used for the purpose of training staff in those activities expressly authorised by the Authority.
What the centre could do better Refer to the consent section of this report and recommendation 3.

4. Information management

Record keeping
Obligations and reporting requirements

What the centre does well

Record keeping and document control (Guidance note 31)
The centre's procedures for keeping records are partially compliant with HFEA requirements to ensure that accurate medical records are maintained. Good medical records are essential for the continuity of the patient's care.

Obligations and reporting requirements (Guidance note 32; Directions 0005)
The centre's procedures for submitting information, about licensed activities to the Authority are broadly compliant with HFEA requirements. This is important to ensure the HFEA can supply accurate information to a donor-conceived person and their parents or donors.

What the centre could do better

Record keeping and document control (Guidance note 31)
The patient records reviewed on inspection had loosely and poorly filed documents within the notes. This could result in documents being lost or misfiled (SLC T47).

A number of templates are used to record information in the patient notes. In the records reviewed, these were not always fully completed; for example the checklist for the initial consultation with the patient which includes details of the patient information given and records the offer of counselling. Being able to demonstrate that all relevant information has been provided to each patient and that counselling has been offered is critically important to the consent process. The medical history of the patients was also not clearly documented in all patient notes reviewed.

In one set of notes, a female patient was recorded as being single, although she was having treatment with a partner. In another set of notes, a heterosexual couple was recorded as being in a civil partnership. It is acknowledged that this information was recorded by the patients themselves, but the importance of checking such information, which is critical for legal parenthood considerations, was discussed with centre staff.

The PR is aware of the issues with the patient records and explained that this was partly due to the centre's intention when initially licensed to use an electronic patient notes system. However, the introduction of this has taken much longer than anticipated. As a result of the delay, the PR explained they had recognised the need for corrective action and have performed a full review of patient record keeping. Corrective action has included drafting new detailed proformas that are currently being piloted.

See recommendation 1.

Obligations and reporting requirements (Guidance note 32; Directions 0005)
The HFEA register audit team found some evidence of problems with the timeliness and accuracy of the centre's submission of data to the HFEA's register of treatments.

Eleven percent (13/121) of the IVF and one of eight of the DI treatments reviewed at inspection had not been reported to the HFEA as required by Directions 0005.

A number of IVF and DI treatments reviewed at inspection had been reported to the HFEA outside the period required by Directions 0005. The centre informed the HFEA in October 2014 that were experiencing difficulty with submitting information through the HFEA's electronic data interface system which was outside their control and took some time to resolve. These issues account for a significant number, but not all, of these late reported cycles (recommendation 9).

Section 3: Monitoring of the centre's performance

Following the initial new premises inspection in 2014, recommendations for improvement were made in relation to five areas of major non-compliance and three 'other' areas of non-compliance.

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

On-going monitoring of centre success rates

In the last year the centre has received one risk tool alert relating to pregnancy rates in IVF patients in <38. This alert was issued in September 2014 and may be due to missing outcome forms (see the information management section of this report and recommendation 9). Success rates will continue to be monitored closely by the executive.

Areas of practice requiring action

The section sets out matters which the Inspection Team considers may constitute areas of non compliance. These have been classified into critical, major and others. Each area of non-compliance is referenced to the relevant sections of the Acts, Regulations, Standard Licence Conditions, Directions or the Code of Practice, and the recommended improvement actions required are given, as well as the timescales in which these improvements should be carried out.

Critical area of non compliance

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
None			

Major area of non compliance

A major area of non compliance is a non critical area of non compliance:

- which poses an indirect risk to the safety of a patient, donor, embryo or to a child who may be born as a result of treatment services
- which indicates a major shortcoming from the statutory requirements;
- which indicates a failure of the Person Responsible to carry out his/her legal duties
- a combination of several "other" areas of non-compliance, none of which on their own may be major but which together may represent a major area of non-compliance.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
1. **Record keeping** The patient records reviewed on inspection had loosely and poorly filed documents within the notes. A number of templates are used to record information in the patient notes. In the records reviewed, some were not fully completed and others had inaccuracies. The records of drugs dispensed and administered to three patients at egg collection were reviewed. In one case, there was a discrepancy between the amount of a drug	The PR should ensure that the centre's procedures for accurate patient record keeping are compliant with all relevant regulatory requirements and guidance. It is acknowledged that record keeping issues have already been identified and some corrective actions implemented. However, the PR should perform a further review to identify the causes of the poor record keeping issues noted on inspection. A summary report of the findings of the review, including corrective actions and the timescale for implementation	`WFI are in the process of implementing an electronic patient record in the form of a fertility based IT system - Meditex. The implementation plan for the electronic patient record is in its final stages. The training schedule and implementation date have been agreed with the system integrators. The issue raised by the inspection team has been noted and the relevant audit added to the Centre's annual audit plan. Cascading of information has	The executive acknowledges the PR's response and his commitment to fully implementing this recommendation. The centre has confirmed that a summary report of the findings of the review will be submitted by 25 May 2015. Further action is required.

that was recorded as administered in the patient records and that documented in the controlled drugs book. SLC T47.	of the corrective actions should be submitted to the centre's inspector by 25 May 2015. Three months after the implementation of corrective actions, the centre should perform an audit to ensure that these corrective actions have been effective. This audit should be submitted by 25 August 2015.	been provided to all WFI staff.	
2. **TPAs** The centre's TPA with one of its diagnostic laboratories is in the process of being established. The centre does not have a TPA with its courier company. SLC T111 and Directions 0009.	The PR should establish compliant TPAs with its diagnostic laboratory and the courier used to transport gametes and embryos. Copies of these TPAs should be provided to the centre's inspector by 25 May 2015.	Third party agreements have been implemented with all of our Health Board diagnostic laboratory services. Following research and investigation of courier transport companies a third party agreement has been issued with an appropriate courier company. Signed copies of the third party agreements will be provided to the Centre's inspector by date advised.	The executive acknowledges the PR's response and his commitment to fully implementing this recommendation. Further action is required.
3. **Consent** During a review of patient notes and in discussion with staff, the following issues were	The PR should review the centre's consenting procedures to ensure that fully informed and effective consent	All WFI staff have been provided with the required information regarding the gamete/embryo storage	The executive was unclear about the PR's response regarding the use of embryos in training staff. A discussion

noted: • centre staff request that patients consent to gamete/embryo storage for the time period for which NHS funding is available; • a discrepancy was noted between patients' consent for the use of the embryos in staff training between the local centre consent form and the HFEA treatment consent forms; • in one set of notes reviewed the patient had three cycles of DI in 2014 and were successful on the third cycle. However, the female's consent to her partner being the legal parent was not completed until after the first cycle. The consent checklist in the notes recorded this as being completed before the first cycle occurred. SLCs T57, 58 and 61.	is freely given by patients and donors. This should specifically take into account the factors that led to the consent anomalies noted on inspection. A summary report of the findings of the review including corrective actions and the timescale for implementation of the corrective actions should be submitted to the centre's inspector by 27 April 2015. Three months after the implementation of corrective actions, the centre should perform an audit to ensure that these corrective actions have been effective. This audit should be submitted to the centre's inspector by 27 July 2015.	periods. The Centre will provide internal information regarding funding to all patients. Patient information has been reviewed and information regarding NHS funding is reiterated to all patients attending the WFI service. The discrepancy noted by the HFEA inspection team has been investigated. Subsequently, the Centre consent form specifies to the patient[s] that material that is donated for in house training is not used for research purposes but specifically for training WFI embryology staff. The HFEA consent form indicates that the patients do not consent to research of gametes/embryos and therefore the Centre feels that the use of the local Centre consent form is required for training purposes. Please see attached form. The DIUI patient notes were	with centre staff has since clarified matters for them and they have committed to fully implementing this recommendation. Due to this misunderstanding, an extension has been given for the review to be conducted and findings submitted to the executive by 25 May 2015. Further action is required. The non-compliance related to legal parenthood consent will be followed up by the executive with the centre where the first two DI cycles were performed.

		discussed with the inspection team at the time of the inspection. The previous 2 cycles were undertaken in another licenced Centre and therefore the legal parenthood forms were signed for the treatment cycle undertaken within our Centre	

Other areas of practice that requires improvement

Areas of practice that requires improvement is any area of practice, which cannot be classified as either a critical or major area of non compliance, but which indicates a departure from statutory requirements or good practice.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
4. **Witnessing** It was noted on the first day of inspection that the centre does not witness the disposal of sperm not needed for treatment. SLC T71 and CoP Guidance 18.4.	N/A	N/A	This non-compliance was resolved by the second day of inspection and the centre's witnessing procedure has been revised **No further action is required.**
5. **Health and safety** The centre has a low oxygen alarm for monitoring oxygen levels in the cryostore. However, the alarm panel is situated within the cryostore room. In the event of the alarm being activated, staff cannot check the panel to ascertain the cause of the alarm without entering the room, which is a potential health and safety risk. CoP Guidance 25.17.	The PR should review the location of the low oxygen alarm taking into consideration potential health and safety risks. The PR should advise the HFEA of the outcome of this review when responding to this report.	The supplying company has been contacted and a site visit arranged to cost the movement of the low oxygen monitoring panel to the exterior wall of the cryostore. The issue has been escalated onto the Health Board risk register following risk assessment and escalated to the WFI site manager.	The executive acknowledges the PR's response and his commitment to fully implementing this recommendation. The PR should provide an update to the centre's inspector by 25 May 2015.

6. **Import/Export** The centre imports gametes for use in donor treatment from an American sperm bank. Only a generic statement of donor screening performed has been provided by the sperm bank. Screening results for each specific donor are not provided and so it is unclear how the centre can be fully assured that the screening results meet the UK requirements in each case. Directions 0006 and SLC T111e.	The PR should ensure that, prospectively, screening results for each donor are provided and reviewed to assess whether the results meet UK screening requirements in each case. Confirmation of this should be provided when responding to this report.	The donor bank will supply copies of screening result - a copy of these will be retained by the Centre in the relevant donor's notes.	The executive acknowledges the PR's response. **No further action is required.**
7. **Traceability** Equipment traceability is not complete as the centrifuge used during sperm preparation is not recorded. SLC T99.	The PR should ensure that the centrifuge used during sperm preparation is recorded to allow for full equipment traceability. Evidence of this should be submitted to the centre's inspector by 25 May 2015.	Centre paperwork and SOP updated to record as requested.	The executive acknowledges the PR's response. **No further action is required.**
8. **Consent to disclosure** Four discrepancies were found in the course of the review of 29 completed patient/partner disclosure consents on patient files and the related consent	The PR should review systems and processes to ensure that the patient and partner disclosure consent information supplied to the Authority accurately reflects that given	CTD audit sample of notes added to Centre's audit plan - audit to be submitted to HFEA inspector by allocated ate. Cascadement of information to all staff regarding accurate	The executive acknowledges the PR's response and his commitment to fully implementing this recommendation.

data submitted for inclusion on the register. Directions 0005.	and recorded on completed disclosure consent forms. A summary report of the findings of the review including corrective actions and the timescale for implementation of the corrective actions should be submitted to the centre's inspector by 25 May 2015. Three months after the implementation of corrective actions, the centre should perform an audit to ensure that these corrective actions have been effective. This audit should be submitted by 25 August 2015. The centre should correct the submissions that have been identified as being incorrect by the time of responding to this report.	recording and checking of patient consents. Information submitted by inspection audit team updated to reflect accurate information	The centre has confirmed that a summary report of the findings of the review will be submitted by 25 May 2015. Further action is required.
9. **Reporting requirements** The HFEA register audit team found some evidence of problems with the timeliness and accuracy of the centre's submission of data to the Register.	The PR must ensure that all licenced treatment activity is reported to the Authority within the timeframe required by Directions 0005. The treatment identified as unreported at the time of	Following the audit team recommendations, all discripancies validated and updated information was provided to the audit inspection team.	The executive acknowledges the PR's response and his commitment to fully implementing this recommendation. The centre has confirmed that a summary report of the

Eleven percent (13/121) of the IVF and one of eight of the DI treatments reviewed at inspection had not been reported to the HFEA as required. A number of IVF and DI treatments reviewed at inspection had been reported to the HFEA outside the period required. The centre informed the HFEA in October 2014 that they had issues with EDI which was outside of their control and took some time to resolve. These issues account for a significant number, but not all, of these late reported cycles. SLC T9e/T41 and Directions 0005.	inspection should be reported immediately. It is acknowledged that the EDI issues reported by the centre in October were a significant factor in the late reporting of treatments. However, the systems and processes used for licensed treatment data submission should be reviewed to enable any other reasons to be identified. A summary report of the findings of the review, including corrective actions and the timescale for implementation of the corrective actions should be submitted to the centre's inspector by 25 May 2015. Three months after the implementation of corrective actions, the centre should perform an audit to ensure that these corrective actions have been effective. This audit should be submitted by 25 August 2015.	The EDI data input is now included on both the laboratory and nursing team rotas. This will ensure compliance with required reporting timescales. Please see attached file regarding issues experienced with regards to the EDI problem resolution. An internal Centre audit is planned and will be submitted to the Centre's inspector by the required date.	findings of the review will be submitted by 25 May 2015. Further action is required.

Reponses from the Person Responsible to this inspection report
I would like to thank the inspection team for providing the WFI staff will the opportunity to raise queries and have these clarified during open discussions. The WFI team felt that the inspection team were able to assist in supporting some areas of good practice raised by the WFI team which although not formally required by the HFEA are useful in ensuring the WFI service is able to share the knowledge and experience provided by the inspection team.