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
10 July 2015

Minutes – item no. 3

Centre 0004 (Ninewells Hospital) – Interim Inspection Report

Members of the Panel:	Juliet Tizzard Director of Strategy & Corporate Affairs (Chair) Hannah Verdin Head of Regulatory Policy Ian Peacock Analyst Programmer
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 noted that the Assisted Conception Unit (ACU) at Ninewells Hospital, Dundee, provides a full range of fertility services.

2. The panel noted that the centre's licence is due to expire on 30 September 2017.

3. The panel noted that the inspection took place on 28 April 2015.

4. The panel noted that in the 12 months to 31 March 2015, the centre provided 891 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a medium-sized centre.

5. The panel noted that for IVF and ICSI, HFEA-held register data for the year ending December 2014 showed the centre's success rates were in line with the national average.

6. The panel noted that in 2014, the centre reported 25 cycles of partner insemination with one clinical pregnancy. This pregnancy rate was consistent with the national average.

7. For the year ending December 2014, the centre's multiple pregnancy rate for all IVF, ICSI and frozen embryo transfer (FET) cycles for all age groups was 7%. This means that the centre's live birth rate is likely to be consistent with the 10% maximum multiple live birth rate target for this period.

8. The panel noted that at the time of the interim inspection on 28 April 2015, one critical and two other areas of non-compliance were identified. The panel noted that since the inspection the Person Responsible (PR) has made significant progress in addressing the recommendations and has committed to fully implementing all of them within the prescribed timescales.

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

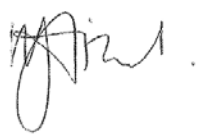
Decision

10. The panel had regard to its decision tree and was satisfied that the centre was fit to have its treatment and storage licence continued.

11. The panel noted the non-compliances identified at the interim inspection and urged the PR to continue making progress and fully implement all of the recommendations within the prescribed timescales.

12. The panel commended the centre for its low multiple pregnancy rate.

13. The panel endorsed the Inspectorate's recommendation to continue the centre's treatment and storage licence.



Signed: Date: 21 July 2015
Juliet Tizzard (Chair)

Interim Licensing Report

Centre name: Ninewells Hospital
Centre number: 0004
Date licence issued: 01 October 2013
Licence expiry date: 30 September 2017
Additional conditions applied to this licence: None
Date of inspection: 28 April 2015
Inspectors: Douglas Gray, Gill Walsh
Date of Executive Licensing Panel: 10 July 2015

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.

The Executive Licensing Panel is asked to note that there are three recommendations for improvement in relation to one critical and two 'other' areas of practice that require improvement:

Critical non-compliance:

- **The PR should review practices relating to the management of medicines, including controlled drugs, to ensure that accurate and complete records are maintained and that medicines are stored supplied, administered and disposed of in accordance with legislation and best practice guidance.**

'Other' areas of practice that require improvement:

- The PR should review the methodology used to audit witnessing practices against compliance with the regulatory requirements and their own approved protocols and quality indicators.
- The PR should consider actions necessary to mitigate the risk of misidentification occurring throughout the entire treatment pathway.

The PR has made significant progress in implementing the recommendations made in this report and has given a commitment to fully implementing the remainder of all of the recommendations. The centre's inspector will monitor progress towards full implementation.

Information about the centre

The Assisted Conception Unit (ACU) at Ninewells Hospital, Dundee, provides a full range of fertility services. Treatments are provided to NHS and self-funded patients. The centre's licence was last renewed following an inspection in April 2013.

The ACU provided 891 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 March 2015. In relation to activity levels this is a medium centre.

Details of Inspection findings

Quality of Service

Each interim inspection focuses on the following themes as 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 year ending December 2014 show the centre's success rates are in line with the national average.

In 2014 the centre reported 25 cycles of partner insemination with one clinical pregnancy. This pregnancy rate is consistent with the national average.

Multiple births[2]

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

For the year ending December 2014, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 7%: this means that the centre's live birth rate is likely to be consistent with the 10% multiple live birth rate target.

Witnessing

Good witnessing processes are vital in ensuring there are no mismatches of gametes or embryos, and that identification errors do not occur. Witnessing using an electronic witnessing system during egg retrieval and the cryopreservation of sperm was observed. The procedures were witnessed in accordance with HFEA guidance.

Consent to the storage of cryopreserved material

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. During the inspection we reviewed the centres procedures for ensuring gametes and embryos are stored in accordance with the consent of the gamete providers and these were compliant with HFEA requirements. The ACU has a bring-forward system

[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%.

to ensure that all samples are stored in line with the gamete provider's consent. There was effective consent for all gametes and embryos being stored.

Staffing

Having the right numbers of staff, competent to carry out highly technical work in a non-pressured environment is important in infertility services. Staffing levels observed in the course of the on-site inspection appeared to be suitable for the activities being carried out.

Quality Management System (QMS)

It is important that clinics audit all of their practices at least every two years to ensure they are delivering the expected quality of service, that standard operating procedures are followed and that the centre's processes meet regulatory requirements. It is also important that these audits are robust and that any changes that are identified as required are implemented as this helps ensure that clinics continuously improve.

The effectiveness of the centre's QMS was assessed by evaluating a sample of the centre's audits. We also considered whether the clinic's processes for implementing learning are effective

The following audit reports were reviewed: witnessing, consent to storage, and medicines management. The inspection team considered that the centre's audit practices are partially compliant with requirements with the following exceptions.

- There has been no controlled drugs audit within the last two years (see below).
- To audit witnessing, a report of errors ('miss-matches') identified over a set period of time is obtained from the electronic witnessing system. This audit alone did not adequately cover all aspects of witnessing practices or audit against compliance with the regulatory requirements and their own approved protocols and quality indicators. There did not appear to be a set frequency for conducting the audit and no report is drafted documenting corrective actions (see recommendation 2).

Medicines Management

It is important that a clinic follows best practice for medicines management both to protect patients and ensure that medicines are stored, administered and disposed of in the correct way. The centre's processes were reviewed for medicines management and the safe storage, disposal and administration of medicines and were considered partially compliant with guidance.

A number of practices were observed that required improvement relating to the general management of medicines:

- Registered nurses regularly dispense medicines against an 'in-house' prescription completed by the clinician deciding the patient's treatment pathway. The Nursing and Midwifery Council (NMC) consider the dispensing of medicines by registered nurses to be an extension to their role that should only be performed in exceptional circumstance.
- Medicines dispensed by nursing staff were not usually checked by a second person.
- Whilst all nurses have some medicines management training, the practice of dispensing is not covered by that training.
- The disposal of unused medicines returned by patients was not recorded or witnessed.

- Staff said that unused medicines returned by patients for disposal were not placed into stock to be re-dispensed. However, a cupboard containing analgesics and other medicines available to be dispensed contained tablets that had been dispensed by an outside commercial pharmacy and were labelled with the names of patients not currently in treatment.
- In the same cupboard there was a small number of tramadol (a schedule 3 controlled drug) tablets in a part used blister pack. These tablets were not identified as being for a named patient as required by Schedule 3 of The Misuse of Drugs Regulations 2001 and should not have been retained alongside stock medicines

A number of practices were observed that required improvement relating to the management of controlled drugs.

- A review of the centre's controlled drug register showed serious failings in maintenances of proper records of the administration of controlled drugs used in operative procedures. A sample audit of the controlled drugs record book showed the following non-compliances with the Hospital Board medicines management policy, regulatory requirements or best practice guidance:
    - The name of the patient being treated had not been recorded in all cases. In a number of instances the name of the patient receiving the drug dispensed was missing from the record. In particular it was noted that for one date, on which three patients were treated with the same controlled drug, two patient names were absent and for the third, only her first name was recorded. In all instances, the entries had however been signed by two people (the person administering sedation and a registered nurse).
    - The time at which the drug was administered was frequently not recorded. When the time was recorded, the same time was commonly recorded for all patients being treated that day (i.e. 0800, the start of the first procedure).
    - The amount of the drug administered to the patient was not recorded, only the number of ampoules dispensed.
    - The disposal of the unused portion of each ampoule dispensed but not used was not witnessed or the disposal recorded.
    - Single patient use ampoules were commonly shared between several patients. In one instance six patient names were recorded as having received the drug but only three ampoules of the drug were recorded as having been dispensed. This was noted to be the common practice for one person administering sedation .
- The controlled drugs required for the entire operating list were routinely drawn up at the same time. These syringes were seen to remain in the work area of the person administering sedation in the theatre until required. This introduces an element of unnecessary risk as the drug is not being stored in a controlled environment during this period of time.
- There has been no controlled drugs audit within the last two years. It is important that the use of controlled drugs is audited and action is taken if necessary.

These observations caused sufficient concern that on the day of the inspection the centre was asked to take immediate action. Confirmation was received within a week that requested improvements had been implemented (recommendation 1).

Infection Control

Having suitable procedures in place to ensure that patients experience care in a clean environment is important, as well as ensuring that both patients and staff are protected from acquiring infections. During the inspection, we assessed the ACU's infection control procedures by observation and found that they were 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 use in treatment to ensure the safety of gametes and embryos and patients. The approval of such products is denoted by the issue of a 'CE mark'. The CE mark status of the following medical devices was reviewed in the course of the inspection: embryo culture media, reagents and consumables. The centre is compliant with requirements to use CE marked medical devices wherever possible.

Patient experience

During the inspection visit we spoke to one couple who provided feedback on their experiences and observed interactions between centre staff and patients. A further eight patients also provided feedback directly to the HFEA in the time since the last inspection. Feedback was generally positive with six of the individuals providing written feedback commenting that they had compliments about the care that they received.

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

- has respect for the privacy and confidentiality of patients in the clinic;
- gives prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions;
- maintains an effective system for responding to patient phone calls.

Monitoring of the centre's performance

In addition to commenting on evidence gathered on the inspection it is important to report on the centre's performance since the granting of the licence based on other evidence available to us.

Compliance with HFEA standard licence conditions

From the information submitted by the centre in their self assessment questionnaire and from observations during the visit to the centre, the inspection team identified one further area of practice that could be improved:

- Standard Licence Condition T101 requires that all containers used are labelled with identifying information of the patient or donor. At our last inspection in 2013, we noted that not all tubes used during egg collection were labelled with patient identifying information. In response to this observation, the ACU said they would start labelling all tubes. During the current inspection, staff said that after assessing the risks of miss-identification, they had stopped labelling these tubes, and had instead introduced steps to mitigate the risks by recording on the laboratory sheet that the hood and hot block used in the laboratory were clear of all tubes from the previous procedure. There was however no record made of the check of the hot block used in the theatre (see recommendation 3).

Compliance with recommendations made at the time of the last inspection

Following a renewal inspection in 2013 recommendations for improvement were made in relation to seven major non-compliances and four 'other' areas of practice that required improvement. The PR provided evidence that all these were implemented within the agreed time frames.

On-going monitoring of centre success rates and risk tool alerts

During the period since the last inspection, the centre has not received any alerts relating to success rates or multiple pregnancy rates.

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 compliant with requirements to submit information to the HFEA.

Legal parenthood

The partners of women treated with donated gametes or embryos, where the couple are not married or in a civil partnership, must give written consent in order 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, HFEA asked all centers 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 us and to respond to those findings. A report of the audit was submitted within the required timeframe and the clinic have acted on their findings. During the inspection, we reviewed the centre's audit and found that it had been performed according to the method specified by HFEA.

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	Executive review
1. The centre's processes for medicines management and the safe storage, disposal and administration of medicines were not compliant with requirements. (Section 27, The Misuse of Drugs Regulations, 2001; Nursing & Midwifery Council,	The PR should review practices relating to the management of medicines, including controlled drugs, to ensure that accurate and complete records are maintained and that medicines are supplied, stored, administered and disposed of in accordance with legislation and best practice guidance. Immediately after the inspection it was recommended that the PR should take action with respect to the	Recommendations regarding management of medicines were initiated from 29th April 2015. Accurate and complete records are maintained. The medicines are supplied, stored and dispensed in accordance to NMC guidelines from 29th April 2015. A retrospective audit on controlled drug book was performed for the period 12th January – 30th April	The PR has made significant progress implementing the recommendation. Further action is required to complete the audit due in October 2015.

Standards for Medicines Management, 2010, standards 4 and 26; SLC T36.)	observations made during the inspection. This included implementing a stock check of controlled drugs and conducting an audit of their use; ensuring records relating to the administration of medicines, including the controlled drug register, were completed with all information that was required. We also recommended that the PR should initiate an expert review of medicines management practices by their trusts pharmacy team. On 12 May 2015 the centre responded indicating that the recommendations had been implemented or initiated. A summary report of the findings of the expert review of medicines management practices including corrective actions and a timescale for their implementation was received from the PR on 2 June 2015. The PR also explained that staff training needs had been identified and that new competency assessments would be completed by 30 June 2015. Within three months of the implementation of corrective actions the centre should complete an audit of	2015.Record related to controlled medicines were completed including missed data were recorded. Meeting was held with Tayside NHS trust pharmacy on 29/04/2015 and 15/05/2015, and ACU prescription sheets were amended. Trust pharmacy has approved the use of IDEAS software for printing prescriptions. SOP on management of medicines and Intraoperative patient journey have been updated on 31/05/2015. Staff competency record has been devised and staff are doing Learn-Pro module on safe prescribing (which is hope to complete by 30/05/2015). Information regarding implementations and corrective actions will be audited and summary will be forwarded to HFEA by 28/10/2015	

	medicines management practices to ensure that corrective actions have been effective. A summary of this audit should be forwarded to the centre's inspector by 28 October 2015.		

‘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	Executive Review
None			

► **'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	Executive Review
2. The centre's audit of witnessing was not compliant with requirements. SLC T36	The PR should review the methodology used to audit witnessing practices against compliance with the regulatory requirements and their own approved protocols and quality indicators. The PR should ensure that these audits form part of the audit schedule, and explore ways in which learning identified following these audits feeds back into the QMS. The PR should provide a summary of actions taken by 28 October 2015.	Quarterly audit of witnessing will be undertaken by the Laboratory Embryology Lead and the PR for feedback to QMS/ Quality manager.	No further action required.
3. Not all containers used during egg collection were labelled with identifying patient information. SLC T101	The PR should consider actions necessary to mitigate the risk of misidentification occurring throughout the entire treatment pathway. A summary of actions taken should be provided to their inspector by 28 October 2015.	Action was taken following previous inspection and the theatre hot block is checked and signed off in the theatre record form. Also the laboratory hot block is checked and signed off in the lab record form ensuring that no tubes from the previous procedure remains on the block (its is not practical to label the aspiration tubes) In the absence of nurses	The revised 'labelling' SOP does not cover steps to record checks of the hot blocks (in either the laboratory or theatre). The PR has however provided assurance that this step is recorded on the theatre record form. No further action required.

		at the time of feedback , this information was omitted. Revised 'Labelling' SOP attached.	

Additional information from the Person Responsible
1. Email dated 14/2/14 sent separately regarding implementation of recommendations from previous inspection within agreed timeframes. 2. Anonymised spreadsheet attached regarding audit of legal parenthood