

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. 2

Centre 0144 (Nuffield Health Woking Hospital) – Renewal Treatment & Storage Licence Application

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 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 and storage centre which provides a full range of fertility services. The panel noted that in relation to activity levels this is a large centre.
3. The panel noted that the centre has been licensed by the HFEA since 1994.
4. The panel noted that in the 12 months to 28 February 2015 the centre provided 1100 cycles of treatment (excluding partner intrauterine insemination).
5. For IVF and ICSI, HFEA-held register data for the period 1 December 2013 to 30 November 2014 showed the centre's success rates were in line with national averages with the following exceptions:
 - success rates following IVF in women under 38 years are above average
 - success rates following ICSI in women over 38 years are above average
6. The panel noted that in 2014, the centre reported 17 cycles of partner insemination with two pregnancies. This equated to a 12% clinical pregnancy rate which was consistent with the national average.
7. Between December 2013 and November 2014, the centre's multiple pregnancy rate for all IVF, ICSI and frozen embryo transfer (FET) cycles for all age groups was 7%. The means that the centre's multiple live birth rate will be in line with the 10% maximum multiple live birth rate target for this period.
8. The panel noted that at the time of the inspection on 21 and 22 April 2015, the Inspectorate identified one major non-compliance which the PR has addressed.
9. The panel noted that the Inspectorate recommends the renewal of the centre's treatment and storage licence for a period of four years without additional conditions.

Decision

10. 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.
11. 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).
12. The panel noted that the premises to be licensed are suitable for the conduct of the licensed activities.
13. The panel endorsed the Inspectorate's recommendation to renew the centre's treatment and storage licence for a period of four years without additional conditions.

14. The panel commended the centre for its low multiple birth rate and above average success rates for IVF in women under 38 years and ICSI in women over 38 years.

A handwritten signature in black ink, appearing to read 'Juliet Tizzard', with a small dot at the end.

Signed:
Juliet Tizzard (Chair)

Date: 21 July 2015

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 Licence Committee 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: 21 & 22 April 2015

Purpose of inspection: Renewal of a licence to carry out Treatment 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: Janet Kirkland, Susan Jolliffe, David Gibbon, Neil McComb, Tarek Hussain, Lesley Brown (Observer), Shanaz Pasha (Observer).

Date of Executive Licensing Panel: 10 July 2015

Centre name	Nuffield Health Woking Hospital
Centre number	0144
Licence number	L/0144/12/b
Centre address	Victoria Wing, Assisted Conception Services, Shores Road, Woking, Surrey, GU21 4BY, UK
Person Responsible	Mr Andrew Riddle
Licence Holder	Mrs Caroline Lewis
Date licence issued	01/10/2011
Licence expiry date	30/09/2015
Additional conditions applied to this licence	None

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Section 1: Summary report

Brief description of the centre and its licensing history:

The Nuffield Health Woking Hospital has held a Treatment and Storage licence with the HFEA since 1994 and provides a full range of fertility services.

The centre provided 1100 cycles of treatment (excluding partner intrauterine insemination) in the 12 months up to 28/02/2015. In relation to activity levels this is a large centre.

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

Pregnancy outcomes¹

For IVF and ICSI, HFEA held register data for the period 1 December 2013 to 30 November 2014 show the centre's success rates are in line with national averages with the following exceptions:

- success rates following IVF in women under 38 years are above average
- success rates following ICSI in women over 38 years are above average

In 2014 the centre reported 17 cycles of partner insemination with 2 pregnancies. This equates to a 12% clinical pregnancy rate which is consistent with the national average.

Multiple births²

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

Between December 2013 and November 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 multiple live birth rate will be in line with the 10% target.

¹The 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 $p \leq 0.002$.

²The 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 – pre review of draft by PR

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 General Direction 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 was one major non-compliance which resulted in the following recommendation:

The PR has fully implemented the following recommendation:

Major non-compliance

- the PR should ensure that the disposal of controlled drugs is documented in compliance with medicines management regulations.

Recommendation to the Executive Licensing Panel:

The centre has no critical areas of non-compliance but has one major non-compliance. Their success rates are above the national average for IVF (women aged 16-37 years) and ICSI (women aged 38 years and over) and their multiple clinical pregnancy rates are below the target.

The inspection team recommends the renewal of the centre's treatment and storage licence for a period of four years without additional conditions.

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 compliant with HFEA requirements. This ensures that patients receive treatment using the correct gametes or embryos.

What the centre could do better

Nothing identified at this inspection.

▶ 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's procedures for screening donors are compliant with HFEA requirements. It is important that donors are appropriately screened to minimise the risks of cross infection during treatment, processing and storage of gametes and/or embryos.

Payments for donors (Guidance note 13; General Direction 0001)

The centre's procedures are compliant with HFEA requirements for giving and receiving money or other benefits in respect to any supply of gametes or embryos. It is important that the principle of altruistic donation be upheld but at the same time donors receive appropriate compensation for their time and any inconvenience caused.

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 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 and laboratories conducting tests that impact on the quality and safety of gametes and/or embryos (relevant third parties) are suitable.

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

Laboratory accreditation (Guidance note 25)

The centre's laboratories and/or 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 partially 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.

Multiple births (Guidance note 7; General Direction 0003)

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

Procurement of gametes and embryos (Guidance note 15)

The centre's procedures are 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; General Direction 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 has 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; General Direction 0006)

The centre's procedures for import and export of gametes and embryos are compliant with HFEA requirements.

Traceability (Guidance note 19)

The centre's procedures are 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,
- 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 third party agreements are compliant with HFEA requirements.

Transport and satellite agreements (Guidance note 24; General Direction 0010)

The centre does not have any transport or satellite agreements.

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 their services.

What the centre could do better:

Nothing identified at this inspection.

Medicines management

An audit of three sets of notes against the controlled drugs book showed that on one occasion the disposal of a controlled drug had not been recorded. This is contrary to the requirements of the Misuse of Drugs Regulation 2001, Schedule 27 (SLC T2).

▶ Staff engaged in licensed activity

Person Responsible (PR)

Staff

What the centre does well

Person Responsible (Guidance note 1)

The PR has complied with HFEA requirements.

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 (T/1170/7).

Staff (Guidance note 2)

The centre is compliant with HFEA requirements.

The centre has suitably qualified and competent staff, in sufficient number, 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

Nothing identified at this inspection.

▶ 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

The centre does not perform embryo testing therefore this area of practice is not applicable to this inspection.

What the centre could do better

Not applicable

2. The experience of patients

▶ Patient feedback

What the centre does well

During the inspection visit the inspector spoke to three patients who provided feedback on their experiences. A further 57 patients also provided feedback directly to the HFEA in the time since the last inspection. Feedback was predominately positive, with 44 of the individuals providing written feedback to the HFEA commenting that they had compliments about the care they had received and six commenting that they had complaints.

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 the HF& E Act 1990 (as amended) to ensure that staff members understand the requirements for a conscientious objection to providing a particular licensed activity governed by the Act.

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 compliant with HFEA requirements. This is important to ensure that counselling support is offered to patients and donors providing relevant consent [and prior to consenting to legal parenthood].

Egg sharing arrangements (Guidance note 12; General Direction 0001)

The centre's procedures for egg sharing arrangements are compliant with HFEA requirements. This is important to ensure that:

- care is taken when selecting egg providers donating for benefits in kind
- egg providers are fully assessed and medically suitable, and

- the benefit offered is the most suitable for the egg provider and recipient(s)

Surrogacy (Guidance note 14)

The centre does not provide treatment involving surrogacy.

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

Nothing identified at this inspection.

Information

What the centre does well

Information (Guidance note 4; CH(11)02)

The centre's procedures for providing information to patients and/or donors are 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

Nothing identified at this inspection.

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 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 (General Direction 0005)

The centre's procedures for taking consent to disclosure to researchers are 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 ART and those born following ART treatment.

What the centre could do better

Nothing identified at this inspection.

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/or 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 identified at 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 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

Nothing identified at this inspection.

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 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 ; Direction 0005)

The centre's procedures for submitting information, about licensed activities to the Authority are 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.

The HFEA register audit team found the timeliness and accuracy of the centre's submission of data to the Register was compliant with HFEA requirements.

What the centre could do better

Nothing identified at this inspection.

Section 3: Monitoring of the centre's performance

Following the interim inspection in 2013, recommendations for improvement were made in relation to one 'other' area of non-compliance.

The PR provided information and evidence that the recommendation was fully implemented within the prescribed timescales.

On-going monitoring of centre success rates

In 2015, the centre did not receive any performance related alerts.

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
<p>1. Medicines Management:</p> <p>An audit of three sets of notes showed that on one occasion the disposal of a controlled drug had not been recorded. This is contrary to the requirements of the Misuse of Drugs Regulation 2001, Schedule 27.</p> <p>SLC T2</p>	<p>The PR should ensure compliance with medicines management regulations.</p> <p>The PR should undertake a review to identify the factors that have led to this non compliance. A summary report of the review including corrective actions and the timescale for their implementation should be provided to the centre’s inspector by 21 July 2015.</p> <p>Within three months, the centre should carry out an audit of medicines management procedures to ensure that the corrective actions have been effective in</p>	<p>We have performed audits of medicine mangement for every month from January 2015 onwards with 100% compliance noted. A CAPA has been raised, the relevant clinicians involved with the one identified case have been interviewed by the PR and the lead clinician for anaesthetic services has read the report noting that apart from this one are of non compliance we appear to have no other areas of non compliance. Furtehr rolling audits as per the CAPA will continue. The audits of medicine management performed so far have been submitted to the HFEA</p>	<p>We acknowledge receipt of the corrective and prevention action plan (CAPA) and controlled drugs audits conducted for the periods January to June 2015.</p> <p>In acknowledgement of the findings of the review and subsequent audits already submitted to HFEA then no further action is required by the centre.</p>

	ensuring compliance. A summary report of the audit detailing the corrective actions with evidence supporting their implementation should be supplied to the centre's inspector by 21 July 2015.		
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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
None			

Response from the Person Responsible to this inspection report