Executive Licensing Panel - minutes

Centre 0250 (Glasgow Centre for Reproductive Medicine) Interim Inspection Report

Friday, 15 July 2016

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Juliet Tizzard (Chair) Howard Ryan Anna Rajakumar	Director of Strategy & Corporate Affairs Technical Report Developer Scientific Policy Manager
Members of the Executive	Dee Knoyle Ian Brown	Secretary Head of Corporate Governance
External adviser		
Observers		

Declarations of interest

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

The panel had before it:

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

1. Consideration of application

1.1. The panel noted that Glasgow Centre for Reproductive Medicine is located in Cardonald Business Park on the outskirts of Glasgow. The centre provides a full range of fertility services including embryo testing and has held a licence with the HFEA since November 2006.

1.2. The panel noted that the centre's licence is due to expire on 31 October 2018.

1.3. The panel noted that the inspection took place on 17 May 2016.

1.4. The panel noted that in the 12 months to 29 February 2016, the centre provided 952 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a medium-sized centre.

1.5. The panel noted that for IVF and ICSI, HFEA-held register data for the period 1 December 2014 to 30 November 2015 showed the centre's success rates were in line with national averages with the following exception:

- The clinical pregnancy rate following frozen embryo transfer (FET) in women aged under 38 years was higher than the national average at a statistically significant level.

1.6. The panel noted that in 2015, the centre reported 20 cycles of partner insemination with five clinical pregnancies.

1.7. Between 1 December 2014 and 30 November 2015, the centre's multiple pregnancy rate for all IVF, ICSI and frozen embryo transfer (FET) cycles for all age groups was 17%. This means that the centre's multiple live birth rate is likely to meet the 10% maximum multiple live birth rate target for this period.

1.8. The panel noted that at the time of this interim inspection on 17 May 2016, one critical, three major and two other areas of non-compliance were identified. The panel noted in particular the critical area of non-compliance relating to medicines management and that because the recommendation from the renewal inspection report in 2014 relating to the safe storage of controlled drugs had not been addressed, medicines management issues identified at this inspection were escalated to a critical non-compliance. The panel noted that since the inspection visit the Person Responsible (PR) has reported that controlled drugs are stored in accordance with statutory regulations and has committed to fully implementing the remainder of the recommendation to ensure that medicines management practices are compliant with regulatory standards and practice guidance, within the given timescales. The PR has also committed to implement all of the outstanding recommendations.

1.9. The panel noted that the inspectorate recommends the continuation of the centre's treatment (including embryo testing) and storage licence.

2. Decision

2.1. The panel had regard to its decision tree.

2.2. The panel was concerned about the non-compliance relating to medicine's management and was not completely reassured by the PR's response to the interim inspection report. The panel noted that there are a number of actions due to be completed by 17 August 2016 and therefore adjourned its decision regarding the continuation of the centre's licence until the inspectorate is in a position to provide an update on completion of the outstanding recommendations.

3. Chair's signature

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

Signature

Name

Juliet Tizzard

Date

21 July 2016

Interim Licensing Report

Centre name: Glasgow Centre for Reproductive Medicine
Centre number: 0250
Date licence issued: 1 November 2014
Licence expiry date: 31 October 2018
Additional conditions applied to this licence: None
Date of inspection: 17 May 2016
Inspectors: Polly Todd (Lead), Dr Douglas Gray, Sharon Fensome-Rimmer (observer)
Date of Executive Licensing Panel: 15 July 2016

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 (SLCs).

This is a report of an unannounced interim inspection together with our assessment of the centre's performance based on other information. The inspection team do this at the mid-point of the licence period. For 2015-2017 the focus of an interim inspection is:

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

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

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

Summary for the Executive Licensing Panel

The inspection team recommends the continuation of the centre's licence. In particular, the inspection team note the clinical pregnancy rate for FET < 38 years which is significantly above the national average.

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

Due to the non-implementation of the recommendation relating to the safe storage of controlled drugs from the renewal inspection report 2014, medicines management issues identified at this inspection were escalated to a critical non-compliance. Since the inspection visit the PR has provided assurance that the following element of this recommendation has now been fully implemented:

'Critical' areas of non-compliance:

- **The PR should ensure that controlled drugs are stored in accordance with statutory regulations.**

The inspection team are satisfied that this part of the recommendation has been fully implemented and that the PR has given a commitment to fully implement the remainder of the recommendation within the given timescales:

- **The PR must ensure that medicines management practices are compliant with regulatory standards and practice guidance**.

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

'Major' areas of non-compliance:

- The PR should review the audit programme to ensure it is compliant in the range of activities audited as well as in the robustness of the audits performed.
- The PR should ensure that CE marked devices are used where possible.
- The PR should ensure that patients are not provided with treatment services unless a full account has been taken of the welfare of any child who may be born as a result of that treatment, and of any other child who may be affected by that birth.

'Other' areas of non-compliance:

- The PR should ensure that infection control practices and procedures are compliant with practice guidance.
- The PR should ensure that patient/partner consents to disclosure of identifying information to researchers are accurately reported to the HFEA register.

Information about the centre

The Glasgow Centre for Reproductive Medicine is located in Cardonald Business Park on the outskirts of Glasgow and has held a Treatment (including embryo testing) and Storage licence with the HFEA since November 2006.

The centre provides a full range of fertility services. Other licensed activities at the centre include the storage of gametes and embryos.

In October 2014 the ELP granted a variation of the current licence to change the Person Responsible.

The centre provided 952 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 29 February 2016. 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: they are important indicators of a centre's ability to provide high quality patient care and to meet the requirements of the law.

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period 1 December 2014 to 30 November 2015 show the centre's success rates are in line with national averages with the following exception:

- The clinical pregnancy rate following FET in women aged under 38 years is higher than the national average at a statistically significant level.

In 2015, the centre reported 20 cycles of partner insemination with five clinical pregnancies.

Multiple births[2]

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

Between 1 December 2014 and 30 November 2015 the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 17%: This means that the centre's multiple live birth rate is likely to meet the 10% multiple live birth rate target.

Witnessing

Good witnessing processes are vital to ensure there are no mismatches of gametes or embryos and that identification errors do not occur. The following laboratory activity was observed in the course of the inspection: preparation for embryo transfer. The procedure observed was witnessed using an electronic witnessing system. The observation indicated that witnessing procedures are compliant with HFEA requirements.

---

[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%.

Consent: To the storage of cryopreserved material

The storage of gametes and embryos is an important service offered by fertility clinics. It enables patients to undergo further fertility treatment without additional invasive procedures and to preserve their fertility prior to undergoing other medical treatment such as radiotherapy. It is important that the centre has measures in place to ensure that gametes and embryos are stored in accordance with the consent of the gamete providers.

On inspection, the inspection team reviewed reports of audits of all stored gametes and embryos, the accuracy of storage logs and consent records, and storage records. These activities indicate that the centre's processes for storing gametes and embryos in line with the consent of the gamete providers are compliant.

Staffing

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

The inspection team considered that staffing levels in the clinic appeared suitable for the activities being carried out: patients attending for consultations were seen promptly on arrival; the atmosphere in the clinic appeared calm at all times; staff in the laboratory were able to carry out their activities without distraction and were available to carry out witnessing activities when required.

Quality Management System (QMS)

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

The effectiveness of the centre's QMS was assessed by reviewing the reports of the following audits: consent to storage, legal parenthood, 'consent to disclosure' completion, as well as a selection of SOPs.

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

- the centre has not completed the following audits
    - controlled drugs and medicines management;
    - satellite services;
    - staff are unable to provide evidence of an audit of witnessing practices;
- the safeguarding policies for adults and children do not indicate what to do if staff consider a child or adult to be at risk and do not relate to current practice in terms of the frequency and level of staff training undertaken;
- the centre's witnessing SOP does not describe what to do in the event of a mismatch;
- the storage audit identified one sample as 'should have been discarded 25 July 2015', which was not discarded until 18 April 2016, i.e. corrective actions in response to non-compliance were not implemented in a timely manner. The audit did not detail the circumstances of this breach of storage consent or any corrective actions to prevent recurrence.

See recommendation 2.

The inspection team also considered whether the clinic's processes for implementing learning are effective. If a clinic is to achieve continuous improvement and encourage a learning culture then it is important that they act to review their practices when guidance is issued by the HFEA or other bodies. The clinic's procedures for acting on guidance from the HFEA were evaluated with reference to the following:

- the use of CE marked medical devices
- the use of the most recently issued HFEA consent form versions
- the centre's audit of legal parenthood consents
- the HFEA reports of adverse incidents from 2010-2012 and 2013
- HFEA Clinic Focus articles regarding, screening requirements, CE marking and equipment failures.

The centre has been effective in ensuring compliance with guidance issued by the HFEA with one exception related to the use of CE marked medical devices. See 'equipment and materials' section and recommendation 3.

Medicines management

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

During the inspection, the clinic's processes for medicines management and the safe storage, disposal and administration of medicines were reviewed and found to be non-compliant because:

- the centre is currently using a controlled drugs cupboard that is attached to an internal wall, so could easily be removed. This non-compliance was noted at the renewal inspection in 2014, after which the PR provided assurances that the recommendation to correct it had been implemented. The inspection team note that there is a (compliant) controlled drugs cupboard fixed to a solid wall which is not in use.

Examination of the controlled drugs register note that:

- alterations of errors are not made in accordance with regulatory and best practice requirements. Changes should be corrected in a margin note or footnote and specify the date a correction is made and by whom;
- some entries are illegible;
- it is unclear in some instances the amount of drug that has been given to the patient and how much has been discarded;
- in one entry the amount of drug given to the patient has not been recorded but the entry has still been signed and witnessed by two practitioners;
- the 'carry over' of drugs has not been witnessed in all cases;
- some pages are not labelled according to regulatory requirements, the dosage, strength and volume of drugs is missing from a number of pages;
- staff have not received training in controlled drugs or general medicines management;

- drugs are not dispensed according to regulatory and pharmaceutical standards. The name and signature of the dispenser and checker and source of the dispensed medicine is missing from the dispensing label.

See recommendation 1.

Infection Control

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

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

- the chair in the men's production room has a wipe clean surface but there is piping around the edges which would be difficult to clean to infection control standards;
- patients' blood samples are being stored with medicines.

See recommendation 5.

Equipment and Materials

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

The CE mark status of the following medical devices was reviewed in the course of the inspection: Flush media, Origio gas filter, Oosafe 6-well plates and pipettes used for flush media. The inspection team find the centre to be broadly compliant with HFEA requirements to use CE marked medical devices wherever possible because the following medical device is not CE marked: Oosafe 6-well plates. See recommendation 3.

Patient experience

During the inspection, no patients were available to speak with the inspection team about their experiences at the centre. Two patients provided feedback directly to the HFEA in the time since the last inspection giving both positive and negative feedback about the care received. The inspection team reviewed patient feedback provided directly to the centre which was mainly positive about the care 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;
- provides a clean and well organised environment for patient treatment;
- has staff who are supportive and professional;
- gives prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions;

Monitoring of the centre's performance

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

Compliance with HFEA standard licence conditions

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

- In one patient record a referral letter states that the patient has a 'psychiatric history' but the patient has ticked 'no' on the Welfare of the Child (WOC) form to 'history of psychiatric illness'. This form was signed off by a practitioner with no evidence that the patient's mental health history or denial of it had been explored or considered before agreeing to treatment.

See recommendation 4.

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in 2014, recommendations for improvement were made in relation to nine major and nine 'other' areas of non-compliance.

The following recommendations have been implemented but were not completed within the required timescales:

- the PR should ensure that wherever possible CE marked equipment is used;
- the PR should take immediate action to ensure that all relevant data about anything coming into contact with gametes or embryos is traceable;
- the PR should inform the Lead Inspector when the final inspection for accreditation of the blood testing laboratory takes place;
- the PR should ensure register submissions are accurate;
- the PR should ensure all critical equipment is validated.

The following recommendation has not yet been implemented:

- The PR should ensure that controlled drugs are stored appropriately.

In responding to the renewal inspection report immediately after the inspection in 2014, the PR agreed to implement the recommendation and provided confirmation that the controlled drugs were being stored properly in a cabinet attached to a brick wall. This cabinet was found not to be in use during this inspection.

It is noted that there was a change of PR in October 2014.

In addition, because discrepancies were found between patient/partner disclosure consent decisions recorded in patient files and the related consent data submitted for inclusion on the register at the previous inspection, the inspection team conducted an audit in the same manner on seven sets of patient files on this inspection.

It is important to ensure that the HFEA holds an accurate record of patients' consent decisions, so that it only releases the patient's identifying information to researchers if the

patients have provided consent. Information can be used by researchers to improve the knowledge about the health of patients undergoing assisted reproductive techniques (ART) and those born following ART treatment. Of the seven records reviewed on inspection, one discrepancy was found between patient/partner disclosure consents in the patient files and the related consent data submitted for inclusion on the register. This failing does not lead to a risk that the HFEA may release patient identifying information to researchers without consent, but does mean that the consent wishes of the patient may not be followed. The patient record in question has been made known to the PR for correction. The inspection team therefore find the centre to be broadly compliant with requirements related to disclosure consent reporting to the HFEA. See recommendation 6.

On-going monitoring of centre success rates

For IVF and ICSI, HFEA register data show the centre's success rates are in line with national averages with the following exception:

- clinical pregnancy rates for FET < 38 years are above national averages at a statistically significant level.

The centre has received two risk tool alerts relating to performance since the last inspection in May 2014:

- Clinical pregnancy rate per cycle – fresh cycle ICSI only, patients > 38 years (risk tool alert received August 2014);
- Multiple pregnancy rate for all treatment cycles (risk tool alert received June 2015).

The PR responded appropriately to these risk tool alerts.

Provision of information to the HFEA

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

The clinic is generally compliant with requirements to submit information to the HFEA, the one exception being related to the reporting of disclosure consent decisions to the HFEA, discussed above in 'Compliance with recommendations made at the time of the last inspection'.

Legal parenthood

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

In February 2014, the HFEA asked all centres to audit their practices in this area to ensure they are suitable, to report the findings of the audit to the HFEA and to respond to those findings. The centre sent the report of the audit to the HFEA within the required timeframe. The centre's original audit did not include patients treated with frozen embryos from donated sperm, these patients were subsequently audited. The audit found that children had been born to two couples treated with donated gametes without the required legal parenthood consent forms being appropriately completed. One patient couple was later

found to have been married at the time of treatment, so the issue of legal parenthood does not apply. The PR has reported to the HFEA the actions taken to support the remaining couple affected and to address the consenting anomalies, which the Executive considers to be appropriate.

As part of the HFEA's ongoing activities relating to 'legal parenthood', in October 2015 all PRs were asked to confirm that specific actions had been undertaken; that there are effective methods for assessing the on-going competence of staff to take this consent; and that effective audit procedures are in place to ensure on-going compliance with consent taking requirements. The PR responded to this correspondence and has also provided assurance that he considers the current procedures for obtaining consent to legal parenthood to be robust.

To provide further assurance of the effectiveness of the centre's procedures, the inspection team reviewed three sets of records where treatment with donor sperm had been provided in circumstances where consent to legal parenthood was required. Effective consent to legal parenthood and the offer of counselling was seen to be in place prior to consent and treatment.
In summary, the inspection team considers the processes used to collect legal parenthood consent at this centre to be compliant with HFEA requirements.

Annex 1

Areas of practice that require the attention of the Person Responsible

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

Critical areas of non-compliance

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

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team's response to the PR's statement
1. Medicines management: The following issues were noted on inspection: • the centre is currently using a controlled drugs cupboard that is attached to an internal wall so can easily be removed. Examination of the controlled drugs register notes that: • alterations of errors are not made in accordance with regulatory and best practice	The PR should ensure that controlled drugs are stored in accordance with statutory regulations. Considering the reoccurring nature of this non-compliance, the PR should provide, when responding to this report, assurance that the controlled drugs cabinet attached to an internal wall will not again be used for the storage of controlled drugs. If the PR	All controlled drugs have been relocated to CD cupboard on external wall. Key removed from previous CD cupboard in theatre.	The inspection team acknowledge the actions taken by the PR by relocating the controlled drugs. The PR should provide a summary of the required review of medicines management practices by 17 August 2016 and a summary of the subsequent audit by 17 November 2016.

requirements; • some entries are illegible; • it is unclear in some instances the amount of drug that has been given to the patient and how much has been discarded; • in one entry the amount of drug given to the patient has not been recorded but the entry has still been signed and witnessed by two practitioners; • the 'carry over' of drugs has not been witnessed in all cases; • some pages are not labelled according to regulatory requirements, the dosage, strength and volume of drugs is missing from a number of pages; • staff have not received training in controlled drugs or general medicines management; • drugs are not dispensed according to regulatory and pharmaceutical standards. The name and signature of dispenser and checker and source of the dispensed	cannot provide adequate assurance, he should consider whether it is appropriate to remove the cabinet. The PR should ensure that medicines management practices are compliant with regulatory standards and practice guidance. The PR should review medicines management practices, including staff training requirements, to identify the factors that have led to these non-compliances and to ensure appropriate actions are taken to address each and every factor, so that medicines management practices thereafter comply with all regulatory requirements. A summary report of this review, with corrective actions, should be provided to the centre's inspector by 17 August 2016. Within three months of the implementation of the corrective actions, the PR	 Noted Noted Noted	Further action required.

medicine is missing from the dispensing label. This non-compliance has been upgraded to critical because of to the non-implementation of a previous recommendation made after the inspection in 2014 and the cumulative nature of the multiple concerns regarding medicines management at this inspection. Department of Health (DH) (2007) 'Safer Management of Controlled Drugs; a guide to good practice in secondary care (England) section 4.7.14 and section 4.11.1.1; DH (2013) Controlled Drugs (Supervision of management and use) Regulations 2013; Misuse of Drugs (Safe Custody) Regulations 1973; Misuse of Drugs Regulations (2001) Regulation 19, 20 (c) and 27; NMC 'Standards for medicines	should conduct a full audit of medicines management practices, to ensure the corrective actions implemented have been effective in achieving and maintaining compliance. A summary report of this audit should be provided to the centre's inspector by 17 November 2016.	Noted	

management' (2010) Standard 4 section 4, standard 26, sections 31-36 and standard 32; SLC T2 and T15.			

‘Major’ area of non-compliance

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

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

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team’s response to the PR’s statement
2. Quality management system: The centre’s audit programme is not suitably robust because: a) The centre has not completed the following audits; • controlled drugs and medicines management • satellite services. b) Staff were unable to provide evidence of a witnessing audit having been completed. c) The safeguarding policies for adults and children do not indicate what to do if staff become aware of a risk to an adult or child and do not relate	The PR should review the audit programme to ensure it is compliant in the range of activities audited as well as in the robustness of the audits performed; i.e. audits should review (at least every two years) all activities authorised by the centre’s licence and other activities carried out in the course of providing treatment services, against the CoP requirements, the centre’s SOPs and the quality indicators. The PR should provide a summary report of this review including the necessary corrective actions with	Noted Noted	Since the inspection the PR has provided evidence that a witnessing audit has been undertaken. The PR should provide evidence of implementation of the outstanding areas for action by 17 August 2016. Further action required.

to current practice in terms of the frequency and level of staff training undertaken. d) The centre's witnessing SOP does not describe what to do in the event of a mismatch. e) Review of the audit of storage consent shows that one sample should have been discarded on 25 July 2015 but was not discarded until 18 April 2016 i.e. effective corrective actions in response to non-compliance were not implemented in a timely manner. The audit also does not detail the circumstances of this breach of storage consent or any corrective actions to prevent recurrence. SLC T9 (b); T33(b); T36; HFEA Clinic Focus (March 2016).	timescales for implementation, and also the audit programme, to the centre's inspector by 17 August 2016. A sample of audits will be requested thereafter to confirm their robustness. Considering the importance of the audit of satellite services the PR should conduct this audit and provide the centre's inspector with a summary report of the findings by 17 August 2016. The PR should address the other concerns within the QMS outlined in this report and provide a summary report to the centre's inspector detailing the actions taken by 17 August 2016.	Noted	
3. **Equipment and materials**: • The Oosafe 6-well plates in use at the centre are not CE marked.	The PR should ensure that CE marked devices are used where possible.	Alternative CE plates are being investigated but we are aware that options are limited.	The inspection team acknowledge the PR's response and commitment to implement this

The use of non CE marked equipment was a non-compliance at the inspection in 2014 and was fully implemented. This non-compliance relates to different equipment in use at the centre. SLC T30	We would not recommend the implementation of precipitous changes that might impact on the quality of treatment provided. In consideration of this, the PR should provide the centre's inspector with information which should document either the anticipated time by which a CE mark is expected to be obtained or the action that will be taken to ensure compliance with this recommendation. This information should be submitted to the centre's inspector by 17 August 2016.		recommendation. The PR should provide an update regarding the sourcing of a suitable CE marked alternative or a plan of action to address this area of non-compliance by 17 August 2016. Further action required.
4. **Welfare of the child:** • In one patient record, a referral letter states that the patient has a 'psychiatric history' but the patient has ticked 'no' on the WOC form to 'history of psychiatric illness'. This form was signed off by a practitioner with no evidence that the patient's mental health history or denial of it had been explored or considered	The PR should ensure that patients are not provided with treatment services unless a full account has been taken of the welfare of any child who may be born as a result of that treatment, and of any other child who may be affected by that birth. The PR should review the procedure for WOC assessment, including staff training requirements, and	Noted Noted	The inspection team acknowledge the PR's acceptance of the required actions and timescales for providing a summary of the review and subsequent audit. Further action required.

before agreeing to treatment. HF&E Act 1990 (as amended) Section 13 (5); SLC T56.	provide a summary report of this review, including any corrective actions, to the centre's inspector by 17 August 2016. Within three months of this review the PR should perform an audit of WOC assessment, to ensure the assessments performed are robust. A summary report of the audit's findings should be provided to the centre's inspector by 17 November 2016.	Noted	

‘Other’ areas of practice that requires improvement

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

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team’s response to the PR’s statement
5. **Infection control:** • The chair in the men’s production room has a wipe clean surface but has piping around the edges which would be difficult to clean to infection control standards; • patients’ blood samples are stored with medicines. The Health and Social Care Act 2008; Code of Practice on the prevention and control of infections and related guidance SLC T17	The PR should ensure that infection control practices and procedures are compliant with practice guidance. The PR should ensure that all equipment can be cleaned and disinfected in accordance with statutory and practice guidance. The PR should ensure that blood and other biological samples are not stored with medicines. The PR should inform the centre’s inspector of the measures taken to implement this recommendation, with timescales, by 17 August 2016.	Noted Bloods are now stored separately	The inspection team acknowledge the PR’s actions to date and commitment to implement this recommendation. Evidence of implementation of the remaining requirement should be provided by 17 August 2016. Further action required.
6. Consent to disclosure to	The PR should ensure that		Since the inspection the PR has

researchers: • Of the seven records reviewed on inspection, one discrepancy was found between completed patient/partner disclosure consents in the patient files and the related consent data submitted for inclusion on the register. This discrepancy does not lead to a risk that the HFEA may release patient identifying information to researchers without consent, but may mean that the consent wishes of the patient are not followed. SLC T9e, CH (10)05 and General Direction 0005.	patient/partner consents to disclosure of identifying information to researchers are accurately reported to the HFEA register. The PR should correct the submission that has been identified as incorrect. The PR should review procedures and take appropriate corrective actions to ensure that the disclosure consent information supplied to the HFEA accurately reflects that given by the patient and recorded on disclosure consent forms. A summary report of the review and of the actions taken, should be provided to the centre's inspector by 17 August 2016. Within three months of the implementation of the corrective actions the PR should re-audit practice to ensure these actions have been effective in achieving and	Noted Noted	confirmed that the HFEA have been provided with the corrected consent data. The PR should provide a summary of the review by 17 August and of the subsequent audit by 17 November 2016. Further action required.

	maintaining compliance. A summary report of this audit should be provided to the centre's inspector by 17 November 2016.	Noted	

Additional information from the Person Responsible