Licence Committee - minutes

Thursday, 17 March 2016

HFEA, Finsbury Tower, 103-105 Bunhill Row, London, EC1Y 8HF

Centre 0316 (Centre for Reproduction & Gynaecology Wales) – application for treatment and storage renewal licence

Committee members	Andy Greenfield (Chair) Lee Rayfield (Deputy chair) Margaret Gilmore Kate Brian Ruth Wilde Anita Bharucha	
Members of the Executive	Trent Fisher	Secretary
Legal Adviser	Jane Williams	Mills & Reeve
Observers	None	

Declarations of interest:

- it was noted that Ruth Wilde declared an interest that she is currently employed by a HFEA licensed centre.

The committee had before it:

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

The following papers were considered by the committee:

- renewal inspection report
- application form
- licensing minutes from the last three years

1. Consideration of application

1.1. The committee noted that the Centre for Reproduction & Gynaecology Wales (0316) has held a Treatment and Storage Licence with the HFEA since 2010 and provides a full range of fertility services. The executive is satisfied that the activities carried out at the centre are necessary or desirable in order to provide licensed treatment services.

1.2. The committee noted the centre provided 878 cycles of treatment (excluding partner intrauterine insemination) in the 12 months leading to 31 December 2015. In relation to activity levels, this is considered to be a medium sized centre.

1.3. The committee noted that, for IVF and ICSI, the HFEA-held register data for the 12 months ending in September 2015 shows the centre's success rates are in line with national averages.

1.4. The committee noted that, for the 12 months ending in September 2015, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups is 27 percent. This represents performance that is statistically divergent from the 10 percent multiple live birth rate target.

1.5. The committee noted that the centre's current licence is due to expire on 8 July 2016.

1.6. The committee noted that at the time of the centre's renewal inspection, 12 to 13 of January 2016, the executive found 14 areas of non-compliance including one critical, three major and 10 other.

1.7. The committee further noted that, since inspection, the PR has implemented the executive's recommendations in relation to one major and three other areas of non-compliance. The PR has also provided assurance that the remaining recommendations will be implemented within the required time scales.

1.8. The committee expressed deep concern regarding the number and seriousness of non-compliances found at inspection, in particular that relating to the centre's multiple pregnancy rate. The committee noted that at the time of the centre's interim inspection, undertaken in 2014, the centre's multiple pregnancy rate was 26 percent. The committee noted that at the time of the centre's renewal inspection its multiple pregnancy rate was still 27 percent.

1.9. The committee noted that, since the inspection, the centre has initiated an independent review of their eSET processes in relation to addressing the centre's multiple pregnancy rate.

1.10. The committee also expressed concern that, at the time of inspection, the centre had not yet carried out a full audit of legal parenthood. The committee noted the PR's response that an audit is currently being undertaken and that the centre is currently reviewing the procedure for recording the information required to establish consent to legal parenthood requirements.

1.11. The committee was also concerned that no one at the centre, including the person providing conscious sedation, was trained in life support to a higher level than basic. The committee noted that the two doctors performing egg collection and giving conscious sedation are attending courses in June.

1.12. The committee also noted that Intralipid continues to be prescribed by the centre off-label, in cases of patient request, despite concerns being raised by the Royal College of Obstetricians and Gynaecologists over a lack of evidence of safety and efficacy.

1.13. The committee had regard to its decision tree. The committee was satisfied that the application made by the Person Responsible (PR) was submitted in the form required and contained the supporting information required by General Direction 0008. Furthermore, it was satisfied that the appropriate fees had been paid.

1.14. The committee was satisfied that the PR possesses the required qualifications and experience and that the character of the PR is such as is required for supervision of the licensed activities. It was further satisfied that the PR will discharge their duties under section 17 of the Act. The

committee noted that the inspectorate was satisfied that the PR had satisfactorily completed the PR entry programme.

1.15. The committee was satisfied that the premises to be licensed are suitable for the conduct of licensed activities there.

1.16. The committee noted that the executive recommends the renewal of the centre's Treatment and Storage licence for a period of four years without any additional conditions. The committee further noted that the executive also recommends that the committee provides advice to the PR regarding the requirements of the independent review to be carried out regarding eSET practices and multiple pregnancy rate.

2. Decision

2.1. Having had regard to the Authority's Guidance on Periods for which New or Renewed Licences Should be Granted, and after weighing the interests of the PR against the Authority's statutory duties and the public interest, the committee decided to renew the Treatment and Storage licence at centre 0316 for a period of 3 years with no additional conditions.

2.2. The committee requests copies of:

- the outcome of the audit into legal parenthood to be made available to the Licence Committee on 5 May 2016 for consideration; and
- the outcome of the independent review regarding multiple pregnancy and eSET practices to be made available to the Licence Committee on 15 July 2016 for consideration.

2.3. The committee also requests a progress report from the executive regarding the centre's multiple pregnancy rate for the Licence Committee meeting in July 2017.

2.4. The committee also requests that the executive conduct the centre's future interim inspection onsite to ensure that corrective action has been taken to address the areas of non-compliance.

2.5. The committee recommends that the areas which should be covered by the independent review should include:

- a review of the policies and standard operating procedures regarding eSET and multiple births;
- the implementation of those policies and procedures; and
- training for staff on communication of eSET principles to patients.

3. Chair's signature

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

Signature

Name

Andy Greenfield

Date

4 March 2016

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 (LC) 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: 12 and 13 January 2016

Purpose of inspection: Renewal of a treatment and storage licence.

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: Douglas Gray (lead), Gill Walsh, Lesley Brown.

Date of Licence Committee: 17 March 2016

Centre name	Centre for Reproduction and Gynaecology Wales (CRGW)
Centre number	0316
Licence number	L/0316/2/b
Centre address	Ely Meadows, Rhodfa Marics, Llantrisant, CF72 8XL
Person Responsible	Lyndon Miles
Licence Holder	Amanda O'Leary
Date licence issued	9 July 2012
Licence expiry date	8 July 2016
Additional conditions applied to this licence	None

Brief description of the centre and its licensing history:

The Centre for Reproduction & Gynaecology Wales (CRGW) has held a HFEA treatment and storage licence since 2010 and provides a full range of fertility services.

The centre provided 878 cycles of treatment (excluding partner intrauterine insemination) during the 12 months to 31 December 2015; in relation to activity levels this is a medium sized centre.

This current licence was varied in 2012 to appoint Lyndon Miles as the Person Responsible.

This inspection was carried out in conjunction with Health Improvement Wales.

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the 12 months ending September 2015 show the centre's success rates are in line with national averages.

In 2014, the centre reported 89 cycles of partner insemination with 11 pregnancies. This equates to a 12% clinical pregnancy rate which is consistent with the national average.

Multiple births[2]

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

For the 12 months ending September 2015 the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups is 27%: this represents performance that is likely to be greater than the 10% multiple live birth rate target and is discussed in more detail elsewhere in this report.

[1]The data in the Register may be subject to change as errors are notified to us by clinics, or picked up through our quality management systems. Centre success rates are considered statistically different from the national averages, and multiple pregnancy rates are considered statistically different from the 10% multiple live birth rate target, when $p \leq 0.002$.

[2]The HFEA use a conversion factor of 1.27 to convert the 10% multiple live birth rate (MLBR) target to a multiple pregnancy rate (MPR) target of 13%.

Summary for licensing decision

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

- the application has been submitted in the form required;
- the application has designated an individual to act as the Person Responsible (PR);
- the PR's qualifications and experience comply with section 16 (2) (c) of the HF&E Act 1990 (as amended);
- the PR has fulfilled 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 Committee is asked to note that at the time of the inspection there was one critical and three major areas of non compliance and ten 'other' areas of practice that require improvement.

Critical areas of non-compliance:

- **Immediate action should be taken to reduce the centre's persistently high multiple clinical pregnancy rate currently at 27%. This should include a full audit of data from 2015, a review of the centre's policy for elective Single Embryo Transfer (eSET), and an independent expert review of the centre's practices relating to multiple births minimisation.**

Major areas of non compliance:

- A full audit of legal parenthood consents should be completed and procedures for recording information necessary to establish if consent to legal parenthood is required should be reviewed.
- Best practice guidance 'Safe Sedation Practice for Healthcare Procedures; Standards and Guidance' should be considered and the training needs of the person(s) providing conscious sedation reviewed, to ensure they are competent to support a patient in an emergency.
- The role of the Controlled Drugs Accountable Officer (CDAO) should be reviewed and practices relating to the management of medicines, including controlled drugs, to ensure that medicines are prescribed and are traceable in accordance with requirements.

'Other' areas of practice that require improvement:

- The PR should assess whether their current practice of screening egg donors is suitable to inform them of the infection status of the donor 'at the time of donation'.
- The PR should confirm whether a sluice facility or separate hand washing facilities in the dirty utility area are required on their premises, and install a hands free soap dispenser and waste bin in the nurses' area.
- The protocol used for laundering clinical linen in-house should be validated to mitigate the risk of cross contamination with potentially infectious material.
- Third party agreements should be compliant with licence conditions.

- Actions should be taken to further improve the centre's quality management system (QMS).
- The clinical policy for pre-employment checks should be followed, and a suitably trained safeguarding lead should be nominated.
- The PR should assess whether patients have enough time to reflect on their decisions before consent is sought.
- Information about success rates presented on the centre's website should be consistent with guidance.
- The PR should ensure the centre's rationale for providing treatment with intralipid 'off label' is consistent with HFEA guidance.
- Procedures should ensure that all necessary information is recorded in patient records and is protected from unauthorised amendment.

The PR has fully implemented recommendations in one major and three 'other' areas of practice, and has provided satisfactory assurance that the remaining recommendations will be implemented within the timescales.

Recommendation to the Licence Committee

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

The centre has a consistently high multiple clinical pregnancy rate and is not likely to meet the current multiple birth rate target of <10%. The PR should ensure the timely implementation of the recommendations made in this report. A further up-date will be submitted to the Licence Committee later in 2016 at which point the inspection team will consider whether further action in line with HFEA's Compliance and Enforcement Policy is necessary.

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

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 notes 11)
It is important that donors are appropriately screened to minimise the risks of cross infection during treatment, processing and storage of gametes and embryos. The centre's procedures for screening donors are broadly compliant with HFEA requirements.

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

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

Screening of donors (Guidance note 11)
Centre staff have not considered how the practice of screening egg donors three months in advance of their donation meets the statutory requirement to screen 'at the time of donation' (SLC T53b and CoP Guidance Note 11.23; recommendation 5). There is a risk that screening too far in advance of egg collection may not give an accurate reflection of whether a donor carries an infection at the time of donation.

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
Equipment and materials
Process validation
Adverse incidents

What the centre does well

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

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

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

Gametes and embryos are processed in a suitable environment with 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, their partners or donors, or their gametes, embryos or any material removed from them, are accredited 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 broadly 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.

Prescribing of intralipid 'off label'
Intralipid is a sterile liquid soybean and egg yolk based fat emulsion which is licensed by the Medicines and Healthcare Products Regulatory Agency (MHRA) as an intravenous nutritional supplement for adults and children.

Some healthcare professionals consider intralipid therapy has an effect on the immune system and may be beneficial to a particular subset of women having IVF. Intralipid is not licensed for use in fertility treatment. If prescribed in this context, this represents 'off-label' use.

Healthcare professionals' responsibilities when prescribing a medicine off-label may be greater than when prescribing a medicine for use within the terms of its licence. In April 2015 the President of the Royal College of Obstetricians and Gynaecologists (RCOG), published concerns regarding the evidence base for the use of this medicine in IVF in terms of its safety and efficacy. In July 2015 the HFEA published guidance to centres regarding the prescribing of intralipid or other 'off label' therapies to patients. This guidance required centres to take responsibility for prescribing the medicine and for overseeing the patient's care by:

- reviewing and recording the information provided to patients about this therapy to ensure that the reasons for prescribing this medicine 'off-label' are explained, including that there is currently little evidence to support its use in this application;
- recording the reasons for prescribing this medicine in the patient's records and;
- ensuring that patients who are prescribed intralipid are properly monitored and followed up.

The process for administering and monitoring patients during intralipid infusion was reviewed and considered to be broadly suitable.

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.

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;
- keep a record in the gamete provider's medical records if their sperm was procured at home.

Transport and distribution of gametes and embryos (Guidance note 15; General Direction 0009)
It 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.

The centre's procedures for the transport, distribution and recall of gametes and embryos are compliant with HFEA requirements.

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 have enough information with them to permit their storage or use 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;
- to identify the donor and recipient of particular gametes or embryos;
- to identify any person who has carried out any activity in relation to particular gametes or embryos; and
- to identify and locate all relevant data relating to products and materials coming into contact with particular gametes or embryos and which can affect their quality or safety.

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

Third party agreements (Guidance note 24)
The centre's procedures are broadly compliant with HFEA third party agreements requirements.

Equipment and materials (Guidance note 26)
The centre uses equipment and materials that are compliant with HFEA requirements. All 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)
Validation ensures that critical processes are effective and do not render the gametes or embryos clinically ineffective or harmful to the recipient. With one exception described below, the centre has validated all critical processes.

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

What the centre could do better

Infection control
There is no 'sluice' facility for the disposal of liquid waste or separate hand washing facility in the dirty utility room (SLC T17). There is a risk of cross contamination by having no hand wash facility in a room in which clinical waste may be handled. There was also no 'hands free' soap dispenser at a recovery washbasin, and no 'hands free' bin at the nurses' station, both of which are considered good infection control measures (recommendation 6).

Clinical linen and staff uniforms are washed on site using a domestic washing machine. The protocol used for washing has not been validated against guidance/standards to ensure risks of cross contamination are mitigated (SLC T2; recommendation 7). Staff uniforms did however appear clean, and there has been no reported incidence of infection. Having discussed the laundry protocol used, we have limited concern that there is an immediate risk to the safety of staff or patients.

Medicines management
Improvements were required in the following areas (recommendation 4):

- the Controlled Drug Accountable Officer (CDAO) regularly prescribes and administers controlled drugs. It is a requirement that the CDAO does not prescribe or administer controlled drugs as part of their usual duties and should only do so in exceptional circumstances (The Controlled Drugs (Supervision of Management and Use) Regulations 2013; Section 8(8));
- amendments or corrections in the controlled drugs register are not always clear

and unambiguous (The Misuse of Drugs Regulations, 2001; Section 20(c));
- there is no regular check of controlled drugs stock (Nursing and Midwifery Council (NMC), Standards for medicines management; Standard 26 (41-45));
- the waste portion of controlled drugs drawn up but not used is usually recorded in the controlled drugs register but not in all instances (NMC, Standards for medicines management; Standard 26 (37)).

Prescribing of intralipid 'off label'

Written information provided to patients was reviewed and considered to be comprehensive it was however noted that this information had not been reviewed since 2011.

The lead clinician explained that the centre does not advocate the use of intralipid but that it is on occasion prescribed where patients have specifically requested it. The reasons for prescribing intralipid 'off label' are documented in the patient records. The inspection team is concerned that patient request does not constitute a suitable rationale for its use (recommendation 13).

Quality management system (QMS) (Guidance note 23)

- Reviewing the centre's documented audits, it was not always clear how the audit had been completed (SLC T36). For example, an audit of consent lacked detail and whilst it provided some assurance that consents were present in patient's records, it was not possible to determine if the audit had considered whether those consents were appropriate for the treatment offered. Other audits did not identify which patient's records had been reviewed.
- Corrective actions identified in some audits (traceability for example) were not progressive when the same non-conformities had been seen at re-audit (SLC T36). It was also unclear whether corrective actions had been implemented and their effectiveness evaluated.
- There has been no audit of the traceability of equipment (SLC T22 and T36).
- The centre's audit of consent to storage for gametes and embryos did not include a check against the patient's consent forms in their medical records (CoP Guidance 17.20 (a)(i)).
- The inspection team considered that the centre's QMS could be better used to provide assurance that the appropriate information has been provided to patients before seeking their consent (SLC T36; HF&E Act 1990 (as amended) Schedule 3(1)(b)). For example, the provision of information wasn't facilitated by SOPs, and whilst audits confirmed that information had been provided they did not consider whether the information provided was appropriate and satisfied the regulatory requirements.
- There were no SOPs to guide actions in the event of non-clinical emergency or a safeguarding concern (SLC T33b and CoP guidance 25.33).
- There was no SOP that defines the responsibilities and actions required when cryopreserved material has to be recalled (CoP interpretation of mandatory requirements 15C).

(see recommendation 9)

Third party agreements (Guidance note 24)

A review of four third party agreements showed that:

- one did not identify the person(s) responsible for managing the arrangement between the centre and the third party (SLC T114 (b));

- two agreements with pathology laboratories testing patients' blood for infections did not include a description of how any test/diagnostic results are relayed to the commissioning centre, including sign off and confirmation that the result applies to the correct sample (SLC T114(f));
- all four agreements did not include a condition that the third party meets the requirements of the relevant licence conditions and the guidance set out in the HFEA Code of Practice (SLC T116).

(see recommendation 8)

Staff engaged in licensed activity

Person Responsible (PR)
Staff

What the centre does well

Person Responsible (Guidance note 1)
The PR has academic qualifications in the field of biological sciences and has more than two years of practical experience which is directly relevant to the activity to be authorised by the licence. The PR has successfully completed the HFEA PR Entry Programme (PREP number T/1164/8).

Staff (Guidance note 2)
The centre is partially compliant with HFEA requirements to have 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

Staff (Guidance note 2)
None of the team, including the person providing conscious sedation, was trained in life support to a higher level than basic life support (CoP guidance 25.32; recommendation 3).

In one employee's file there was no evidence of references being sought or disclosure and barring service (DBS) checks having been taken up before employment, as should have occurred in line with the clinic's recruitment policy (HF&E Act 1990 (as amended), Section 17(1)(a); recommendation 10).

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 before treatment is provided, 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, are compliant with HFEA requirements.

Safeguarding
The centre's procedures are broadly compliant with safeguarding guidance.

What the centre could do better

Safeguarding
Although staff were aware of their responsibilities with regard to safeguarding, there was no nominated safeguarding lead (CoP guidance 25.33; recommendation 10).

Embryo testing

Preimplantation genetic screening
Embryo testing and sex selection

The centre is not licensed for this activity.

Multiple Births

What the centre does well

Multiple births (Guidance note 7; General Direction 0003)
The single biggest risk of fertility treatment is a multiple pregnancy.

At the interim inspection in 2014 and at this inspection, the centre's compliance against the requirements of General Direction 0003 was reviewed in detail. The centre's procedures were compliant with the requirements to maintain a multiple births minimisation strategy and for keeping records of cases in which multiple embryos have been transferred. The written and verbal information provided to patients included a clear explanation of risks associated with multiple pregnancies.

What the centre could do better
The HFEA sets a maximum multiple live birth rate that centres should not exceed; since October 2012 this has been 10%. At the time of the centre's interim inspection in 2014, the centre's multiple clinical pregnancy rate was 26%. At the time of this inspection, the centre's multiple clinical pregnancy rate was 27%. Immediate action is required to reduce the persistently high multiple clinical pregnancy rate (recommendation 1).

After the inspection in 2014 a recommendation was made that the centre should continue six monthly audits of the effectiveness of their multiple births minimisation strategy and should organise an independent review of the strategy and the processes by which it is implemented, including how information essential to the strategy is communicated to patients. The centre have not implemented this recommendation; the last formally documented audit was completed in October 2014 and an independent review has not been sought (recommendation 1).

Between May and November 2015, the centre was unable to submit treatment forms to the HFEA and the Executive did not have accurate data to monitor the centre's performance. Following a management review meeting, held in accordance with the HFEA's Compliance and Enforcement policy, a decision was taken to defer considering if regulatory action was necessary until the data submission issue was resolved. The PR provided assurance during this period that he continued to monitor the centre's key performance indicators using their own data.

2. The experience of patients

Patient feedback

What the centre does well

During the inspection visit, inspectors spoke to two couples who provided feedback on their experiences. A further eight patients also provided feedback directly to the HFEA in the time since the last inspection. Feedback was generally positive, with four of the individuals providing written feedback to the HFEA commenting that they have compliments about the care that they received.

Patient feedback, supported by the inspection teams observations, indicates that patients could expect to be treated by staff that were caring, professional and supportive.

What the centre could do better

Nothing identified at this inspection.

Treating patients fairly

Counselling
Egg and sperm 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 and sperm sharing arrangements (Guidance note 12; General Direction 0001)
The centre's procedures for egg and sperm sharing arrangements are compliant with HFEA requirements. This is important to ensure that:

- care is taken when selecting egg and/or sperm providers donating for benefits in kind
- egg and sperm providers are fully assessed and medically suitable, and
- the benefit offered is the most suitable for the egg or sperm provider and

recipient(s).

Surrogacy (Guidance note 14)
The centre's procedures for treatment involving surrogacy are compliant HFEA requirements. This is important to protect the surrogate and any children born as a result of the treatment.

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

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

What the centre could do better
Nothing identified at this inspection.

Information

What the centre does well

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

What the centre could do better
Information provided to patients on centres' websites should adhere to HFEA guidance to ensure it is reliable and accurate (CoP Guidance Note 4.5). A review of the centre's website against that guidance showed:

- live birth rate per treatment cycle in each age/treatment category is not given
- data are not broken down by treatment type, and
- the national rate for the same year, maternal age, treatment type, is not provided.

(recommendation 12)

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

What the centre does well

Consent (Guidance note 5;6)
It is important to ensure that patients and donors have provided all relevant consents

before carrying out any licensed activity. The centre's procedures for obtaining consent are broadly compliant with statutory requirements.

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. In some of these 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 provided the report of the audit to the HFEA within the required timeframe and took appropriate action with respect to the issues identified by the audit.

Evidence has previously been provided by the centre that their audit was comprehensive and that their current procedures for obtaining consent to parenthood are robust.

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 assisted reproduction therapies (ART) and those born following ART.

What the centre could do better

Consent (Guidance note 5;6)
The Code of Practice states that anyone seeking treatment should be given enough time to reflect on their decisions before obtaining their consent (CoP Guidance 5.8). During the inspection the centre's procedures for providing information to patients, offering them counselling and seeking their consent were reviewed. Following a medical consultation at which the treatment pathway is decided, patients attend an appointment with a member of the nursing team. In this appointment they are provided with all relevant information, receive an offer of counselling, complete a welfare of the child assessment and review and sign their consent forms. Whilst the inspection team had no concerns regarding the quality of the information provided, it was concerned that the patients had no opportunity to reflect upon the information they had received and the implications of their decisions before obtaining their consent (recommendation 11).

Legal parenthood
To provide assurance of the effectiveness of the centre's procedures for seeking consent to legal parenthood, the inspection team reviewed eight sets of patient notes, where treatment with donor sperm had recently been provided in circumstances where consent to legal parenthood may be required. This review showed that the marital or civil

partnership status could not be easily determined from the records. This may affect the ability of centre staff to ensure consent to legal parenthood has been sought in all applicable cases and could impair the quality of the centre's legal parenthood audits (recommendation 2).

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)

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. The centre's procedures for screening patients are compliant with HFEA requirements.

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)
Good medical records are essential for the continuity of the patient's care. The centre's procedures for keeping records are broadly compliant with HFEA requirements to ensure that accurate medical records are maintained.

Disclosure of information, held on the HFEA Register, for use in research
The HFEA Register is a rich source of information about treatment using ART. It can be used by researchers and linked to other health registers, to improve knowledge about the health of patients who have undergone ART and those born following ART treatment. The HFEA is permitted to disclose non-identifying information to researchers but can only provide patient identifying information with the consent of the patient. Therefore, it is important that patients are asked to give their consent and that their wishes are accurately recorded and passed on to the HFEA. The centre's procedures for doing this ensure that the HFEA holds an accurate record of such consent, so that it only releases patient identifying information to researchers when consent has been provided.

Obligations and reporting requirements (Guidance note 32)
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 no problems with the timeliness and accuracy of the centre's submission of data to the Register.

What the centre could do better

Record keeping and document control (Guidance note 31)
Observations were made in three areas relating to good record keeping (recommendation 14):

- in a number of patient records, there was no copy of a photo identification record of the patient (contrary to the clinic's policy) or evidence of another method by which the patient's identity had been verified by a member of staff (CoP Guidance 5.12 and 5.13);
- in one patient's file, although medication had been prescribed there was no record of the patient's prescription (SLC T46);
- the intraoperative record observed for one patient in the centre's electronic records management system was a fully editable word document, and any amendments to it could not be identified (SLC T47).

Following an interim inspection in 2014, recommendations for improvement were made one area of critical non-compliance: the centre's persistently high multiple pregnancy rate. The implementation of this recommendation is discussed elsewhere in this report.

On-going monitoring of centre success rates

Since the centre's last inspection in 2014, the centre has continued to receive alerts issued by the HFEA's Risk Based Assessment Tool in relation to the persistently high multiple pregnancy rates. Alerts were issued in April, June, November and December 2014 and in March 2015.

In June, October, November and December 2015 alerts were also issued in relation to the centre's pregnancy rates for women over 38 years old having IVF and in September, October and November 2015 for patients under 38 years old having IVF. These alerts were issued at a time when the HFEA did not hold up-to-date information due to problems receiving treatment outcome data from the centre. The PR did however provide assurance that they continued to monitor their success rates during this period taking appropriate actions as necessary.

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, General Direction 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
1. Multiple births The centre's multiple clinical pregnancy rate is 27% meaning that the <10% multiple births target is likely to be exceeded. Considering the on-going nature of this observation, and the risk to a patient or child who may be born as a result of treatment, this non-	Following the inspection the PR was asked to complete an audit of the centre's multiple pregnancy rate since the implementation of their new eSET policy in January 2015. A full audit was provided by the PR on 5 February 2016 which shows that improvements have been made since 2014 and identifies where further gains can be made. The PR was also asked to initiate the independent expert review recommended in the 2014 interim inspection report. Whilst this may	Full audit of MPR done submitted to you on 5/2/16 shows that we have doubled the percent of patients taking up eSET compared to the currently available HFEA data. There is clear evidence of us improving in eSET uptake and decreasing MPR. We believe our algorithm is perfectly fine (we adopted the ACE/BFS eSET guidance) but but still need to increase patient uptake and are taking measures to improve the uptake beyond the current level. The whole team are	The inspection team are satisfied that appropriate action is being taken; the requested audit has been completed and an independent review is being commissioned. We recommend that the Licence Committee considers and provides advice to the PR regarding the requirements of the review. We await the outcome of the review and will provide an up-date to the Committee as described.

compliance has been graded as 'critical'. (CoP Guidance Note 7; General Direction 0003)	not be completed by the time this report is considered by a Committee, the PR should provide assurance when responding to this report that the review has been scheduled and a reviewer identified. The PR should ensure that their audit of data from 2015 is considered as part of this review. Following the independent review, the Executive will meet with the PR to discuss its outcomes and the PR's plan of action. A summary of actions that have been agreed will be presented to the next available Licence Committee after the meeting has taken place. As part of this up-date it will considered whether further action in accordance with the Compliance and Enforcement Policy is necessary.	addressing this to ensure we are all giving patients the same message. Since the inspection we have publicised our half price frozen transfers for eSET patients on our homepage of the website to further aid patients decision making when financial consideration has any baring.I contacted Woking, Midland Ferility, Bristol, ARGC and Bath regarding practice with eSET and have intiated the process of independant review. Caroline Franklin from Woking has agreed to do this for us and at the time of typing are looking at dates to enable her visit to CRGW in March / April. It would be helpful if the HFEA could provide a list of requirements for this review to ensure nothing is overlooked in terms of looking at paperwork, meeting team members, looking at patient presentations, eSET consents, previous audits etc unless you deem this unnecessary. It is important to clarify for executive review that at 2014 interim inspection independent review was requested by the	

		HFEA but my correspondance with the HFEA after this request was not responded to. The HFEA are aware that this was the case even though wording in the actions required (above left) hint otherwise.	

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
2. Legal parenthood Difficulties establishing retrospectively whether patients were married or in a civil partnership at the time of their treatment may affect the ability of centre staff to ensure consents to legal parenthood have been sought appropriately and impair the quality of the centre's legal parenthood audits. (CoP Guidance Note 6; SLC T36)	Following the inspection the PR was asked to complete a full audit of legal parenthood following the same protocol as that specified in 2014: http://www.hfea.gov.uk/8659.html. To be done robustly, this may take some time. The PR should provide an up-date and expected date of completion when responding to this report. The PR should also review the procedure for recording the information required to establish consent to legal parenthood requirements, so that that information is clear to those checking consents are in place before treatment and those auditing treatments provided. A summary of this review should be provided to the inspector by 13 April 2016.	We are currently Re-auditing all legal parenthood patients from the clinic opening in 2010. As you will recognise there are a lot of patients and a large audit but I believe the April deadline will be met. Relationship status is now recorded at initial consultation on the patient registration sheets and also electronically on ideas making future audits straightforward. Additionally the way all audits are carried out have been altered (described below) to	Appropriate action has been taken to ensure the marital / civil partnership status of couples is clearly documented in their medical records, and that quality of future audits is assured. We await the outcome of the audit.

		encompass a methodology to ensure the audit process is robust.	
3. Staff None of the team, including the person providing conscious sedation, is trained in intermediate life support. (CoP Guidance Note 2; SLC T12 and T15; CoP guidance 25.32).	The PR should consider best practice guidance 'Safe Sedation Practice for Healthcare Procedures; Standards and Guidance' and review the training needs of the person(s) providing conscious sedation to ensure they are competent to support a patient in an emergency to at least intermediate life support standard. A time frame for the completion of this training should be provided to their inspector by 13 July 2016.	The two doctors performing egg collections and giving conscious sedation are going on Intermediate Life Support courses. Courses in both Newport and Brisol have been identified and the doctors are due to attend a course in June.	Appropriate action has been taken and we request that the PR confirms once training has bee completed.
4. Medicines management The CDAO regularly prescribes and administers controlled drugs (The Controlled Drugs (Supervision of Management and Use) Regulations 2013; Section 8(8)). There is no regular check of controlled drugs stock (Nursing and Midwifery Council	The PR should review the requirements of the CDAO to ensure the person fulfilling this role does not routinely prescribe or administer controlled drugs. The PR should provide a summary of actions taken in response to this observation by 13 April 2016. The PR should ensure that there is a regular check of controlled drugs stock. A summary of actions taken in response to this observation should be provided by 13 April 2016. An audit to evidence that checks are taking place should be completed in October 2016 and a summary forwarded to their inspector.	The controlled drugs officer has been to changed to Amanda O'Leary since inspection who does not have daily access to the controlled drugs as Hatel Tejura did when giving conscious sedation. This change can be observed / confirmed on the HIW website. Therefore the prescribing docs and the CDAO are no longer the same person. A controlled drugs stock	The SOPs submitted have been reviewed and based on these and the PR's response, we are satisfied that appropriate action has been taken to address each observation noted in this recommendation. We await the outcome of the audit due in October 2016.

(NMC), Standards for medicines management; Standard 26 (41-45)). Amendments or corrections in the controlled drugs register are not always clear and unambiguous (The Misuse of Drugs Regulations, 2001; Section 20(c)). The waste portion of controlled drugs drawn up but not used is usually recorded but not in all instances seen in the controlled drugs register (Nursing and Midwifery Council (NMC), Standards for medicines management; Standard 26 (37)).	The PR should identify corrective actions to ensure amendments or corrections in the drugs register are clear, and that the waste portion of controlled drugs drawn up but not used is always recorded in the register. The PR should provide a summary of the corrective actions identified by 13 April 2016. An audit to evidence that the corrective actions are effective should take place in October 2016 and a summary forwarded to their inspector.	check is now performed daily by 2 members of staff (lead nurse +1), the ammended SOP reflects this new practice. The updated SOP also describes exactly how ammendments or corrections are recorded and also how unused drawn up controlled drugs are recorded in the register. These new practices are subject to a new audit in October.	

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
5. Donor screening The centre had not considered how their practice of screening egg donors three months before their egg collection meets the statutory requirement to screen 'at the time of donation'. (CoP Guidance 11.23 and SLC T53(b))	The PR should assess whether their current practice of screening egg donors three months before their egg collection is suitable to inform them of the infection status of the donor 'at the time of donation', as is required by Annex III of the Second European Tissues and Cells Directive (2006/17/EC). A summary of this assessment and any changes to practice implemented as a consequence should be forwarded to their inspector by 13 October 2016.	I contacted Dr Cheuk Yan William Tong (Consultant Virologist at Barts) who spoke at Fertility 2016 in Gateshead. I emailed him on 14.1.16 explaining the aim to tighten the screening window while allowing sufficent time to receive virology results and prevent patients starting stimulation medication unnecessarily before we have the results in the event of a seroconversion. His response was "…With this in mind, screening within 3 weeks before donation would give the lowest possible risk of transmission through seroconversion. As it usually takes 1 -2 weeks for results to be reported back to the clinic, 3 weeks seems a very reasonable time frame as well". As such this is now current practice for egg donors	Appropriate action has been taken. No further action required.

		at CRGW.	
6. Premises, practices and facilities. There was no 'sluice' facility for the disposal of liquid waste in the dirty utility room and no separate hand washing facility. There was also no hands free soap dispenser at a recovery washbasin, and no hands free bin at the nurses' station. (CoP Guidance 25.19 and 25.20)	The PR should confirm whether a sluice facility or separate hand washing facilities in the dirty utility area are required on their premises. The PR should provide confirmation of their decision and, if necessary, any actions taken along with an anticipated timeframe for completion by 13 April 2016. The PR should provide confirmation that a hands free soap dispenser and waste bin are in place by 13 April 2016.	We have requested our plumber attend the clinic to look at the 'dirty' utility to see if there is a solution to the sluice given the room size, existing sink and current building / plumbing regulations. I will feedback on this point once he has visited prior to 13 April. Two hands free soap dispensers have are now in the building pending fitting at the sink at the nurses station and for the adjacent patient toilet. A pedal bin is now in place of the previous bin which required hand depression of the lid for opening.	Appropriate action has been taken. We await feedback from the PR following their meeting with their plumber.
7. Infection control The centre could not provide assurance that the protocol used to wash clinical linen is appropriate to prevent the potential spread of infections.	The PR should be able to provide assurance that the protocol used to wash clinical linen in-house is suitable to prevent cross contamination of potentially infections material. We suggest that the PR approaches this in a similar way to process validation reviewing relevant literature and guidance that is readily available. A summary	Currently investigating. We have a contact (Mike Walsall) who we are communicating with regarding the validation of our system for laundering linen – we chose to have an external company come to CRGW to validate this for us as more robust evidence than an in-house validation. As PR I have already scrutinied the literature for best practice in terms of	Appropriate action is being taken and we await a further summary in July 2016.

	should be forwarded to their inspector by 13 July 2016.	washing times / temperatures etc which we adhere to but need to validate yearly.	
8. Third party agreements Not all third party agreements reviewed during the inspection were compliant with licence conditions. (CoP Guidance Note 24; SLC T114 and T116)	The following recommendation is based on potential risks to patients, their gametes and embryos taking into consideration that the centre reviews and re-issues all third party agreements on a two yearly basis and new agreements had been issued shortly before the inspection. The PR should identify all third parties with laboratories that are used for diagnostic tests and seek additional clarification of how any test/diagnostic results are relayed to them, including sign off and confirmation that the result applies to the correct sample. Confirmation should also be sought that the third party is able to meet relevant standards set out in the Code of Practice. Confirmation that this additional information has been received should be sent	We have a detailed list of all third parties so have already identified the small number of labs that do diagnostic tests for us. We have already addressed this issue with these labs and have sent a bolt on letter (attached to email) to clarify the additional points required by these companies as identified at inspection (attached in the email). This bolt on letter will additionally be incorporated into all TPA letters sent out at our next full TPA re-issue of all third party agrements. These new letters are produced using the wording of the standards in the CoP. All of the above actions will ensure we meet in full the relevant standards of the CoP. Copies of any new documentation will be forwarded to you upon completion before October 13.	Appropriate action has been taken. We await confirmation from the PR that they have received responses to their 'bolt on letter', and copies of documentation/templates amended as a consequence of this recommendation in October 2016.

	to their inspector by 13 October 2016. The PR should review the template they use for all third party agreements to ensure it is compliant with requirements taking into consideration the nature of the service being provided. This template should be used when the agreements are next re-issued. A copy of any documents revised as a consequence of this review should be provided to their inspector by 13 October 2016.		
9. QMS SOPs are required to cover some activities and the centre's audit process could be improved as described in this report. (SLC T33 and T36)	The PR should ensure that actions are taken to correct those deficiencies noted in this report. A summary of actions taken should be provided by 13 July 2016. Six months after the implementation of these changes, audits should be completed to show that the actions have been effective. Summaries of these audits should be sent to their	All CRGW audit templates have been ammended post inspection. These now include a question of why the audit is being performed, a methodology, number audited and rationale for number chosen, which patients records were audited, corrective actions, date of corrective actions implemented and later evaluation of implementations (~6 months later). An audit of equipment	The PR has provided a suitable summary of actions, including audits, that have been taken. We request the PR forwards copies of new SOPs drafted in response to this recommendation by 13 July 2016. We await further audit summaries due January 2016.

	inspector by 13 January 2017.	traceability was performed post inspection on 16/2/16 and showed 100% compliance in randomly selected patient notes. This in now a routine part of our traceability audit. Consent to storage of gametes and embryos: We have begun a full audit of all stored gametes and embryos in regards to checking consent forms against medical records and will have the results of this audit in the next few months. We have added this also to our routine full yearly audit of stored gametes and embryos so that each years storages are audited against consents. As part of QMS improvement we will develop the facilitation of the provision of information by SOP's and have made part of the audit of information to question whether information provided is appropriate. I have begun an SOP for non clinical emergency which will be completed by the end of March.	

10. Staff In one employee file seen there was no evidence of references having been sought or disclosure and barring service (DBS) checks having been taken up before employment in line with the centre's policy. There was no nominated safeguarding lead. (HF&E Act 1990 (as amended) Section 17(1)(a))	The PR should investigate why their policy had not been followed in this instance and identify corrective actions as necessary. A summary of their findings should be forwarded to their inspector by 13 October 2016. The PR should ensure that there is a nominated safeguarding lead and consult with the Area Adult Protection Committee (AAPC) for South Wales for advice to ensure that all safeguarding requirements applicable in Wales are met. A time frame for the completion of this training should be provided to their inspector by 13 July 2016.	Amanda O'Leary (Gynacologist) has taken a safeguarding course since the inspection and is therefore the nominated lead. I have contacted the Vale of Glamorgan AAPC to ensure that we are meeting safeguarding requirements for Wales. I have requested further information from them in this regard and requested a designated point of contact at the AAPC who we may liase with should safeguarding be required. At the time of typing this contact has not received response.	Appropriate action has been taken to appoint a nominated safeguarding lead trained to the required standard. We request the PR provides an up-date by 13 October 2016. We also await the summary by the PR following their investigation into our observation of references/DBS being absent in a member of staff's file.
11. Consent Anyone seeking treatment may not be given enough time to reflect on their decisions before their consent is sought.	The PR should document an assessment of whether their current practice allows enough time for patients to reflect on their decisions before consent is sought. Their assessment should take into consideration the views of patients. A summary of the	Following consideration of the code of practice after inspection we have changed practice which we did beleve to orginally be following guidance. The system now follows that after consultation the patient(s) come back for a follow up appointment where	Appropriate action has been taken by the PR, and we are satisfied that no further action is required.

(CoP Guidance 5.8 and 5.11)	outcomes of this assessment, and any actions taken, should be forwarded to their inspector by 13 October 2016.	consents are explained and given to patient(s) to take away with them. The patient then signs the consents at their treatment planning appointment which is typically two weeks later. We believe that this two week gap allows sufficient time to reflect on their decisions prior to consenting.	
12. Information. Success rates on the centre's website are not presented in accordance with HFEA guidance. (CoP Guidance 4.5)	The PR should audit the centre's website against the regulatory requirements and arrange for any amendments required. A summary of changes made should be received from the PR by 13 July 2016.	This is being addressed currently with the data used for the MPR 2015 audit to enable us to add up to date results that are in accordance with HFEA guidance to our website.	We await the summary due July 2016.
13. Prescribing of intralipid 'off label'. Patient information, and the documented justification for the use of intralipid was not consistent with guidance offered by HFEA. (RCOG guidance April 2015; HFEA Clinic Focus July 2015)	The PR should consider the guidance provided by the RCOG and the HFEA and conduct a review of the centre's rationale for providing treatment with intralipid 'off label'. The PR should provide a summary of this review and detail of any actions taken by 13 April 2016.	I emailed the team my monthly email in response to my receipt of the HFEA Focus email in July 2015 (as I do each month) which detailed potential issues with off label intralipid use. Using the Focus HFEA bullet point recommendations and the MHRA guidance on off-label use of medicines on its website, I personally formulated the attached intralipid off label use waiver. I	The PR's response and accompanying patient waiver clearly outlines that the use of intralipid is off-label and is consistent with HFEA guidance. No further action required.

	Information for patients regarding the prescription and use of intralipid should be reviewed to ensure it is current. A copy of the reviewed information should be provided by 13 April 2016.	believe that this patient information sheet addresses HFEA and MHRA requirements. We did, have and continue to consider the RCOG guidance in the use of intralipids at CRGW. We have since inspection added a system of tracability of batch numbers for intralipid with the SOP being ammended accordingly. While there is still a lack of solid evidence, intralipids are very cheap (certainly at CRGW), well tolerated, have few side effects (we screen for allergies at consent) and relatively no risks compared to blood products like IVIG used elsewhere (at very high cost) with the same outcome. Studies have shown suppression of NK cell cytotoxicity by the action of intralipids modulating NK cell activity and with the small costs and risks mentioned above this could be the difference between being pregnant and not in occasional patients.	

14. Record keeping Intraoperative records seen for one patient were not protected from unauthorised amendment. In a number of patient records seen there was no copy of a photo identification record provided by the patients or note of the verification of patient identity by a member of staff (CoP 5.12 and 5.13). In one patient's file there was no record of the patient's prescription (SLC T46). (CoP Guidance Note 31; SLC T47)	Assurance was provided on the day of inspection and by email on 27 January 2016 that actions had been taken to ensure intraoperative records were protected. The actions taken are suitable and therefore require no further action in relation to this observation. The PR should review procedures to ensure that all necessary information is recorded in patient records. Corrective actions should be identified and implemented. Six months after their implementation audits should be completed to evidence they have been effective. Summaries of these audits should be forwarded to the centre's inspector by 13 January 2017.	All intraoperative records became protected after the issue of possible retrospective ammendment of the care pathways was highlighted at inspection. The IDEAS IT team have additionally been booked to come to the clinic on 16th/17th March to formulate a protected electronic care pathway. In the interim period we are handwriting on the care pathway and then scanning the document into IDEAS to prevent ammendment. Patient photos: The SOP now states that these are done at initial consultation and treatment planning cannot later proceed without a patient photo and identifying information (passport etc) having been seen. Patients prescriptions: When the IDEAS team come to CRGW in March they are going to build CRGW specific electronic prescriptions into ideas that are printed and signed ensuring a traceable patient record.	Appropriate action has been taken. We request that the PR provides a copy of their SOP amended as a consequence of this recommendation by 13 January 2017.

Reponses from the Person Responsible to this inspection report

In the multiple birth section above it is stated on page 14 that CRGW's last formally documented audit was in October 2014. The attached MPR audit history evidences that this is indeed not the case and that we have audited MPR twice in 2012, 2013 and 2014, and significantly in regards to this point once in July 2015 which incorporated dates commencing November 2014 to May 2015.