Executive Licensing Panel - minutes

Centre 0341 (The Fertility and Gynaecology Academy) Renewal Inspection Report

Friday, 24 March 2017

HFEA, 10 Spring Gardens, London SW1A 2BN

Panel members	Paula Robinson (Chair) Howard Ryan Jessica Watkin	Head of Business Planning Report Developer Policy Manager
Members of the Executive	Bernice Ash	Secretary
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 considered the papers, which included a completed application form, inspection report and licensing minutes for the last three years.

1.2. The panel noted that The Fertility and Gynaecology Academy is in central London. The centre holds a Treatment (including embryo testing) and Storage licence, providing a full range of fertility treatment services.

1.3. The panel noted that the centre has been licensed by the HFEA since March 2015. This was the first inspection report since the licence was granted.

1.4. The panel noted that in the 12 months to 31 October 2016, the clinic provided 151 cycles of treatment (excluding partner intrauterine insemination). In relation to activity this is a small centre.

1.5. The panel noted that an interim inspection occurred in April 2016 during which three major areas of non-compliance had been identified. The panel noted that the recommendations from the interim inspection report had been fully implemented.

1.6. An inspection was carried out at the centre on 20 and 21 December 2016. This was the centre's first full renewal inspection.

1.7. The panel noted that at the time of the inspection there were five major and four 'other' areas of non-compliance that required improvement, particularly noting those relating to the assessment of a donor's medical history, reproductive immunology therapies and medicines management.

1.8. The panel noted there were no critical areas of non-compliance.

1.9. The panel noted that between August 2015 and July 2016, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 48% and this represents performance that is likely to be statistically greater than the 10% multiple live birth rate target. The Person Responsible (PR) stated that the centre's Multiple Birth Minimisation Strategy had recently been changed and the centre's data had shown a reduction in the multiple pregnancy rate. The PR would keep the multiple pregnancy rate under review.

1.10. The panel noted that the PR had initially challenged a number of the non-compliances made within the report, and some of his responses to the recommendations made were deemed, in part, to be unsatisfactory to the Executive. Therefore, in line with the HFEA Compliance Directorate standard operating procedure for post inspection actions, a management review was held 22 February 2017, to discuss the level of compliance within the centre and the PR's responses and challenges to the report.

1.11. The panel noted that, following the management review, the Executive was not sufficiently assured that the PR would fully implement the recommendations and invited him to submit a further response to the report. On receipt of comments from the PR, a further management review was held on 8 March 2017.

1.12. The panel noted that although the PR had challenged some of the recommendations, he had then shown a commitment and willingness to engage with the Executive, and progress had been made in addressing the recommendations.

1.13. The panel noted the inspectorate's recommendation to renew the centre's Treatment (including embryo testing) and Storage licence for a period of four years without additional conditions, subject to the recommendations made in this report being implemented within the prescribed timescales.

2. Decision

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

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

2.3. The panel was satisfied that the qualifications and character of the PR are such as is required for the supervision of licensed activities and that the PR will discharge his duty under section 17 of the HFE Act 1990 (as amended).

2.4. The panel noted the initial response to the non-compliances, and the high multiple birth rate, when considering the period for which to extend the centre's Treatment (including embryo testing) and Storage licence. However, the panel also noted the actions taken by the centre since the inspection to address the recommendations and the centre's multiple birth rate, and the engagement of the PR.

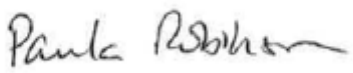
2.5. The panel noted that the majority of outstanding information to demonstrate completion of the recommendations in the report was due for receipt by the HFEA on either 21 March 2017 or 21 June 2017, and requested the Executive to submit an Executive Summary to the Executive Licensing Panel after 21 June 2017, to confirm that all actions had been completed.

2.6. The panel endorsed the inspectorate's recommendation to renew the centre's Treatment (including embryo testing) and Storage licence for a period of four years without additional conditions, subject to the recommendations made in this report being implemented within the prescribed timescales.

3. Chair's signature

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

Signature



Name

Paula Robinson

Date

4 April 2017

Inspection Report

Purpose of the Inspection Report

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

Date of inspection: 20 and 21 December 2016

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

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

Inspectors: Polly Todd (lead), Shanaz Pasha and Lesley Brown

Date of Executive Licensing Panel: 24 March 2017

Centre name	The Fertility & Gynaecology Academy
Centre number	0341
Licence number	L/0341/1/a
Centre address	57A, Wimpole Street, London, W1G 8YP
Person Responsible	Dr Amin Gorgy
Licence Holder	Dr Adel Eskander
Date licence issued	22 May 2015
Licence expiry date	21 May 2017
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:

The Fertility & Gynaecology Academy is located in central London and has held a treatment (including embryo testing) and storage licence with the HFEA since May 2015 and provides a full range of fertility services. This initial licence was granted for two years without additional conditions, which is the standard term for new centres.

A targeted, scheduled interim inspection was performed in April 2016 to review the centre's performance and level of compliance since the licence was granted. This was primarily to provide an opportunity for any areas requiring improvement to be addressed at a much earlier point than the first licence renewal inspection.

The centre provided 151 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 October 2016. In relation to activity levels this is a small centre.

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

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period August 2015 to July 2016 show the centre's success rates are in line with national averages.

In 2016, the centre reported nine cycles of partner insemination with two pregnancies. This is likely to be consistent with the national average.

Multiple births[2]

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

Between August 2015 and July 2016, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 48%. This represents performance that is likely to be statistically greater than the 10% multiple live birth rate target.

Refer to the 'ongoing monitoring of centre success rates' section of this report for further detail.

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

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

Summary for licensing decision

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

- the application has been submitted in the form required;
- the application has designated an individual to act as the Person Responsible (PR);
- the PR's qualifications and experience comply with section 16(2)(c) of the HF&E Act 1990 (as amended);
- the PR has discharged his duty under section 17 of the HF&E Act 1990 (as amended);
- the premises (including those of relevant third parties) are suitable;
- the centre's practices are suitable;
- the application contains the supporting information required by 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 PR challenged a number of the non-compliances cited in this report, and his response to the recommendations made were deemed, in part, to be unsatisfactory to the Executive. Therefore, in line with the HFEA Compliance Directorate standard operating procedure (SOP) for post inspection actions, a management review was held 22 February 2017, to discuss the level of compliance within the centre and the PR's responses and challenge to the report. The Executive were unable to reconcile a number of the responses given by the PR with the evidence and information collected during inspection. Similarly, the PR appeared to have failed to understand the nature of some of the non-compliances cited, and therefore the requirements of the subsequent recommendations made. On the basis of this, the Executive was not sufficiently assured that the PR would fully implement the recommendations and felt it was appropriate and proportionate to discuss this with the PR, and invite him to submit a further response to the report, following these discussions. This additional response is noted as an 'update' in the 'Areas of practice requiring action' section of the report.

After the receipt of this additional response from the PR, some concern remained as to the PR's commitment to fully implement the recommendations made. Therefore, in line with the HFEA Compliance and enforcement policy a management review meeting was held on 8 March 2017 to discuss the PR's additional response to this report.

It was considered that, whilst the PR had challenged some of the recommendations, he had shown a commitment and willingness to engage with the Executive, and therefore, further action now would not be proportionate. The Executive will continue to work with the PR and will closely monitor progress in implementing these recommendations.

The ELP is asked to note that at the time of the inspection there were a number of areas of practice that required improvement, including five major and four 'other' areas of non-compliance which resulted in the following recommendations:

Since the inspection visit, the following recommendations have been fully implemented. Where required, and by the dates specified, the PR will provide an update summary of audits conducted, to ensure the corrective actions taken are effective.

Major areas of non-compliance:

- The PR should ensure that a detailed record of the assessment of a donor's medical history, via both the health questionnaire and a personal interview is kept. The PR should ensure that where donors are recruited by an agency, all reasonable steps are taken to ensure compensation paid is within that allowed by Directions.

'Other' areas that require improvement:

- The PR should ensure that all incidents are investigated thoroughly.
- The PR should ensure that satellite agreements are submitted to the HFEA before the start of any new service.
- The PR should ensure that the disclosure consent information supplied to the Authority accurately reflects that given and recorded on disclosure consent forms.

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

Major areas of non-compliance:

- The PR should ensure that controlled drugs use is accurately recorded in patient records.
- The PR should ensure that QIs are established for donor recruitment, assessment and screening.

Other areas that require improvement:

- The PR should ensure that the identity of a patient is reliably confirmed and documented.

The PR has challenged the following recommendations but has demonstrated a commitment to further engagement with the Executive with regards these recommendations:

Major areas of non-compliance:

- The PR should ensure that the clinical indication for the use of any medications in a manner that is different to their intended licenced purpose, is documented in the patient's records.
- The PR should review the information about reproductive immunology treatments provided to patients to make sure they are easy to understand, and follows the guidance provided by the MHRA on the 'off-label' use of medicines.

Recommendation to the Executive Licensing Panel

The centre has no critical areas of concern but does have five major of areas of concern. Their success rates meet the national average however, their multiple clinical pregnancy rate is significantly above the target and although in raw figures this represents a small number of pregnancies, the Executive will continue to closely monitor the centre's performance.

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

The centre's inspector will continue to monitor the centre's performance. Failure to implement the recommendations relating to these major areas of non-compliance within the prescribed timescales may result in the submission of a further report to the ELP with

the recommendation that regulatory action be taken in accordance with the Authority's Compliance and enforcement policy.

The inspection team recommends the renewal of the centre's treatment (including embryo testing) 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.

Section 2: Inspection findings

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

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

1. Protection of the patient and children born following treatment

Witnessing and assuring patient and donor identification

What the centre does well

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

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

Donor selection criteria and laboratory tests

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

What the centre does well

Assessment and screening of donors (Guidance note 11)

The centre's procedures for the screening of donors are compliant with HFEA requirements, however the centre's procedures for the assessment of donors are only partially compliant with requirements. It is important that donors are appropriately screened to minimise the risks of cross infection during treatment, processing and storage of gametes and/or embryos and properly assessed to ensure any donation does not present a health risk to others or indeed the donor.

Payments for donors (Guidance note 13; General Direction 0001)
The centre's procedures are partially compliant with HFEA requirements for giving and receiving money or other benefits in respect to any supply of gametes or embryos. It is important that the principle of altruistic donation be upheld but at the same time donors receive appropriate compensation for their time and any inconvenience caused.

Donor assisted conception (Guidance note 20)
It is important that centres use donated gametes or embryos from identifiable donors and keep records of donor characteristics. This is because patients using donated gametes and embryos in treatment and the parents of donor-conceived children, are able to access non-identifying information regarding the donor from the clinic. Furthermore, donor-conceived persons are entitled to know non-identifying details about their donor and any donor-conceived genetic siblings they may have at the age of 16 years, and donor identifying information at 18 years.

The centre's procedures are compliant with HFEA requirements which ensure the donor-conceived and their parents will be able to receive all required donor-related information.

What the centre could do better

Assessment and screening of donors (Guidance note 11)
Donors must be selected on the basis of their age, health and medical history, provided on a questionnaire and through a personal interview with a clinical professional. A review of donor records on inspection showed that the record of this consultation is scant, and comprehensive donor health and medical history provided by a questionnaire is not obtained (SLC T52a, recommendation 1).

Payments for donors (Guidance note 13; General Direction 0001)
Patients are directed to a third-party donor agency to recruit their own egg donors, who are often from overseas.

The centre could not provide evidence of how much egg donors, recruited by an agency have been paid (General Direction 0001 and CoP Interpretation of mandatory requirements 13A, recommendation 1).

Suitable premises and suitable practices

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

What the centre does well

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

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

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

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

Laboratory accreditation (Guidance note 25)
The centre's laboratories and/or third party laboratories which undertake the diagnosis and investigation of patients, patients' partners or donors, or their gametes, embryos or any material removed from them, are compliant with HFEA requirements to be 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 (Guidance Note 25)
The centre has systems in place to manage and monitor the prevention and control of infection that are compliant with guidance.

Medicines management (Guidance Note 25)
The centre has arrangements in place for obtaining, recording, handling, using, keeping, dispensing, administering and disposing of medicines that are partially compliant with guidance.

Prescription of intralipid 'off label'
Intralipid is a sterile liquid soybean and egg yolk based fat emulsion which is licensed as an intravenous nutritional supplement for adults and children. Some healthcare professionals consider intralipid therapy may be beneficial to a particular subset of women having IVF. Intralipid is however, not licensed for use in fertility treatment and if prescribed in this context, it 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.

The centre also offers other reproductive immunology treatments (adalimumab, IVIg and Neupogen). These are similarly, not licensed for use in fertility treatment.

In April 2015, the President of the Royal College of Obstetricians and Gynaecologists, published concerns regarding the evidence base for the use of intralipid in IVF treatment, 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 intralipid therapy to ensure that the reasons for prescribing it 'off-label' are explained,

including that there is currently little evidence to support its use in fertility treatment;
- recording the reasons for prescribing intralipid in the patient's records and;
- ensuring that patients who are prescribed intralipid are properly monitored and followed up.

The centre is partially compliant with these requirements.

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

Pre-operative assessment and the surgical pathway (Guidance Note 25)
The centre has policies and procedures in place that are compliant with professional body guidelines for pre-operative assessment and management of the surgical pathway. This is important to ensure that all patients are safely assessed and cared for pre, peri and post operatively.

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

Procurement of gametes and embryos (Guidance note 15)
The centre's procedures are compliant with HFEA requirements to:
- document the justification for the use of the patient's gametes (or embryos created with their gametes) in treatment, based on the patient's medical history and therapeutic indications;
- where the sperm is procured at home, the centre keeps a record of this in the gamete provider's records.

Transport and distribution of gametes and embryos (Guidance note 15; General Direction 0009)
The centre's procedures for the transport, distribution and recall of gametes and embryos are compliant with HFEA requirements. This is important to ensure that all gametes/embryos sent to other licensed centres within or outside the UK are:
- packaged and transported in a manner that minimises the risk of contamination and preserves the characteristics and biological functions of the gametes or embryos;
- shipped in a container that is designed for the transport of biological materials and that maintains the safety and quality of the gametes or embryos;
- appropriately labelled with the transport conditions, including temperature and time limit being specified;
- the container/package is secure and ensures that the gametes or embryos are maintained in the specified conditions. All containers and packages are validated as fit for purpose.

Receipt of gametes and embryos (Guidance note15)
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 they are appropriately labelled and are accompanied by

enough information to permit them to be stored or used in treatment in a way that does not compromise their quality and safety.

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

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

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

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

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

Transport and satellite agreements (Guidance note 24; General Direction 0010)
The centre has systems in place to manage satellite activities that are compliant with HFEA requirements, with an exception detailed below. This is important to ensure that activities performed by satellite clinics on behalf of the licensed centre are suitable and meet the HFEA requirements.

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

The centre is compliant with HFEA requirements to validate critical equipment. The centre has documented procedures for the operation of critical equipment and procedures to follow if equipment malfunctions.

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

Adverse incidents (Guidance note 27)
The centre's procedures for reporting adverse incidents are broadly compliant with HFEA requirements. The centre reports all adverse incidents (including serious adverse events and reactions) to the HFEA. The centre investigates all adverse incidents that have occurred. Reporting and investigation of adverse incidents is important to ensure that

centres share the lessons learned from incidents and continuously improve the services it offers.

What the centre could do better

Medicines management (Guidance Note 25)
On inspection, the following issues were noted:

- An audit of five patient records showed that:
  - in one case the controlled drug administered to the patient had not been recorded on the anaesthetics chart;
  - in one case the amount of controlled drug given as recorded on the anaesthetics chart did not match that recorded on the controlled drugs register;
  - in one case the amount of controlled drug administered was not documented on the controlled drugs register.

SLC T2, Controlled Drugs in Perioperative Care (2006), The Misuse of Drugs Regulations 2001 and NMC (2010) Standards for Medicines Management, recommendation 2.

- The centre provides occasional 'top up' drugs to patients. The centre's medicines management policy does not describe the procedure to follow for this (SLC T33b; recommendation 2).

Prescription of intralipid 'off label'
The inspection team did not consider that the reasons for prescribing reproductive immunology treatments were recorded clearly in the patient's medical records. The records reviewed included a patient history, details of the immune test results and the immune therapy administered. The rationale could be inferred from this, but it was not explicitly documented.

The centre does not have SOPs to guide the use of reproductive immunology treatments and limited records were kept in the patients' notes (SLC T33b; recommendation 3).

The inspection team did not consider that the written information about reproductive immunology treatments was easy to understand or made it sufficiently clear about the lack of strong evidence for the use of these treatments in IVF to enable patients to make an informed decision (SLC T58; recommendation 4).

Post inspection, a review of one of the treatments offered also generated further concern. NHS guidance suggests adalimumab can have an effect on the immune system of any child born, however it is recognised that this information relates to the medicine being used in its licensed application and at doses therapeutic to that condition. This is not however acknowledged or addressed in the patient information (SLC T58; recommendation 4).

Quality management system (QMS) (Guidance note 23)
QIs have not been established for: donor recruitment, assessment and screening (SLC T35).

The centre has audited its counselling procedures, but the inspection team did not consider the audit to be comprehensive, for example it did not audit practice against the centre's counselling SOPs. The British Infertility Counselling Association (BICA) developed QIs and audit methodology were also discussed and it is suggested that these

be considered for auditing counselling practice at the centre (SLC T36; recommendation 5).

Transport and satellite agreements (Guidance note 24; General Direction 0010)
The centre has satellite arrangements with three clinics. These arrangements were disclosed on the centre's renewal application form, but the agreements had not been submitted to the HFEA before the services started as required by General Direction 0010 (recommendation 7).

Adverse incidents (Guidance note 27)
The investigation report of one incident that had occurred at the centre was reviewed and discussed with centre staff. The incident involved an apnoeic (temporarily stopping breathing) episode of a patient during egg collection. The patient was managed safely and recovered appropriately. It was reported and investigated as an incident because one of the members of staff did not consider the correct process had been followed. The inspection team was concerned that the incident report did not fully document the incident or the concerns of centre staff which could limit the identification of effective corrective action. The incident had not yet been 'closed' on the centre's system either, over three months after the incident occurred. Additionally, the patient was not informed of the episode. The inspection team considers that it would have been in the best interest of the patient to be informed, both as part of a centre's general duty of candour and also in case it was of relevance for her should she have further operations (SLC T118, recommendation 6).

Staff engaged in licensed activity
Person Responsible (PR)
Staff

What the centre does well

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

Staff (Guidance note 2)
The centre is 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
Nothing identified at this inspection.

Welfare of the child and safeguarding

What the centre does well

Welfare of the child (Guidance note 8)
The centre's procedures to ensure that the centre takes into account before licensed treatment is provided, 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, are compliant with HFEA requirements.

Safeguarding (Guidance Note 25)
The centre's procedures are compliant with safeguarding guidance. This ensures that the centre's patients and staff are protected from harm where possible.

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

Embryo testing

Preimplantation genetic screening
Embryo testing and sex selection

What the centre does well

Preimplantation genetic screening (Guidance note 9);
Embryo testing and sex selection (Guidance note 10)
The centre's procedures for performing embryo testing are compliant with HFEA requirements. This ensures that:

- no embryo is transferred to a woman where that embryo or material removed from it, or the gametes that produced it, has been subject to genetic testing unless expressly authorised by the HFEA
- no information derived from tests conducted has been used to select embryos of a particular sex for social reasons
- no embryo is tested unless the statutory tests are met i.e. that the embryos is at a significant risk of having a series genetic condition.

The centre ensures that people seeking embryo testing are given written information, are given every opportunity to discuss the implications of their treatment and have access to clinical geneticists, genetic counsellors and infertility counsellors where required.

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

2. The experience of patients

Patient feedback

What the centre does well
During the inspection visit the inspectors spoke to one patient who provided positive feedback on her experiences. Inspectors also reviewed the outcomes of the clinic's own patient survey which were also positive.

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 patients with satisfactory facilities for their care.

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

Treating patients fairly

Counselling
Egg sharing arrangements
Surrogacy
Complaints
Confidentiality and privacy

What the centre does well

Treating patients fairly (Guidance note 29)
The centre's procedures are compliant with the HF&E Act 1990 (as amended) to ensure that staff members understand the requirements for a conscientious objection to providing a particular licensed activity governed by the Act.

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

Counselling (Guidance note 3)
The centre's counselling procedures are compliant with HFEA requirements, with the exception noted in the 'quality management system' section of this report. This is important to ensure that counselling support is offered to patients and donors providing relevant consent (and prior to consenting to legal parenthood).

Egg sharing arrangements (Guidance note 12; General Direction 0001)
This service is not provided at this clinic.

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

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

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

What the centre could do better

Nothing identified at this inspection.

Information

What the centre does well

Information (Guidance note 4; Chair's Letter CH (11)02)
The centre's procedures for providing information to patients and donors are partially 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

Refer to the 'prescription of intralipid 'off label'' section of this report and recommendation 4.

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

What the centre does well

Consent (Guidance note 5;6)
The centre's procedures for obtaining consent are compliant with HFEA requirements, with an exception detailed in the 'record keeping and document control' section of this report. This ensures that patients and donors have provided all relevant consents before carrying out any licensed activity.

Legal parenthood (Guidance note 6)
Where a couple to be treated with donated gametes or embryos is 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 its effectiveness and in some cases it may be necessary for a patient couple to obtain a court declaration to establish legal parenthood.

In October 2015, the HFEA's Chief Inspector asked all newly licensed 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 evidence that an audit

had been conducted and submitted a report to the HFEA. The audit found that since undertaking donor treatment cycles, only three cycles of treatment had been completed, consent to legal parenthood was not required in each case.

To date, the centre has still only provided very few donor treatment cycles where legal parenthood consent is required. On this inspection, the team reviewed the one set of records where treatment with donor sperm had been provided since the last inspection in circumstances where consent to legal parenthood was required. Effective consent to legal parenthood with a prior offer of counselling was in place before treatment in this case.

In summary, the inspection team considers the processes used to obtain consent to legal parenthood at this centre to be compliant with HFEA requirements.

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 broadly compliant with HFEA requirements.

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

What the centre could do better

Disclosure of information, held on the HFEA Register, for use in research (General Direction 0005)
The centre was asked to audit a sample of 10 patient and partner consent to disclosure records after the inspection to determine whether the disclosure consent recorded in the couple's files is accurately reflected on the HFEA register. Four discrepancies were found between completed patient/partner disclosure consents on patient files and the related consent information submitted by the centre for inclusion on the register. In each instance the consent recorded in the patient/partner record gave consent to disclosure however the decision recorded on the HFEA register stated that consent was not given. Whilst this does not pose a risk that the HFEA could inadvertently disclosure information to researchers without consent it does not accurately reflect the consent provider's wishes (CH(10)05 and General Direction 0005, recommendation 8).

3. The protection of gametes and embryos

Respect for the special status of the embryo

What the centre does well
The centre's procedures are compliant with the requirements of the HF&E Act 1990 (as amended) and ensure that the special status of the embryo is respected when licensed activities are conducted at the centre because:

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

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

Screening of patients
Storage of gametes and embryos

What the centre does well

Screening of patients (Guidance note 17)
The centre's procedures for screening patients are compliant with HFEA requirements. It is important that gamete providers are appropriately screened to minimise the risks of cross infection during treatment, processing and storage of gametes and/or embryos.

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

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

Use of embryos for training staff (Guidance note 22)
What the centre does well **Use of embryos for training staff (Guidance note 22)** The centre's procedures for using embryos for training staff are compliant with HFEA requirements. Embryos are only used for the purpose of training staff in those activities expressly authorised by the Authority.
What the centre could do better Nothing identified at this inspection.

4. Information management

Record keeping
Obligations and reporting requirements

What the centre does well

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

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

The HFEA register audit team found no evidence of 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)
The centre uses photographic identification to reliably identify its patients and donors. In four out of five records reviewed, the centre had not recorded how, and by whom, the patient/donor has been reliably identified (SLC T46b, recommendation 9).

In one case where the donor's records had been scanned to form electronic records, the copy of her photographic identification had not been scanned properly. This could lead to difficulties in reliably identifying the donor (SLC T47, recommendation 9).

The centre does not keep a record in the patient/donor notes of the information that has been provided to the patient/donor. The PR should consider using the HFEA's 'record of information provided before obtaining consent' form. This form has been designed to help centres demonstrate that they have met the requirements of the HF&E Act relating to the provision of information prior to obtaining consent.

In one of the five records reviewed, the patient's HFEA treatment consent form had been amended, but this amendment had not been countersigned. In another set of records, an amendment to a consent form had been signed but not dated (SLC T47, recommendation 9).

Section 3: Monitoring of the centre's performance

Following the interim inspection in 2016, recommendations for improvement were made in relation to three areas of major non-compliance.

The PR provided information and evidence that all of these recommendations were fully implemented.

On-going monitoring of centre success rates

Since the grant of the licence in May 2015 the centre has received one performance related risk tool alert. This was in December 2016 for its multiple pregnancy rate.

Between August 2015 and July 2016, the centre's multiple pregnancy rate was 48%. Although this represents performance likely to be greater than the 10% target, this involves only 27 pregnancies of which 13 were multiple pregnancies.

This was discussed in detail with staff on inspection and the PR explained that the centre's MBMS had recently been changed and their own data has shown a reduction in the multiple pregnancy rate. The PR has provided a commitment to keep success rates under review. Due to the small numbers involved and the fact that the first alert was only raised in December 2016 it is considered disproportionate to make a recommendation at this time. The Executive will, however, keep the centre's performance under close review.

Areas of practice requiring action

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

Critical area of non-compliance

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
None identified at this inspection.			

Major area of non-compliance

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

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
1. Donor assessment and payment **Assessment** Donors must be selected on the basis of their medical history, provided on a health questionnaire and through a personal interview with a clinical professional. A review of donor records on inspection found that the record of the consultation is scant and a comprehensive patient history through a questionnaire is not obtained. SLC T52a. **Payments** The centre could not provide evidence of how much egg	The PR should ensure that a detailed record of the assessment of a donor's medical history, via both questionnaire and a personal interview is kept in the donor's medical record. The PR should conduct a review of the centre's procedure for assessing donors. A summary report of the review, including actions taken, should be forwarded to the centre's inspector by 21 March 2017. Within three months of having implemented corrective actions, the centre should audit its donor assessment	PR currently takes a donor's full social, personal and medical history and a record is kept in the donor's medical record. However, we are developing a questionnaire, as advised by the inspectors, to ensure that we meet this requirement. The PR will conduct a review of the centre's procedure for assessing donors. A summary report of the review, including actions taken will be forwarded to the HFEA by 21 March 2017.	The Executive acknowledges the PR's response and commitment to implementing this recommendation. However, it is should be noted that the inspection team have made no reference to non-compliance with sperm donor assessment in this report. This non-compliance relates to the centre's practices in relation to egg donors. The Executive expects the PR to provide a further response to this non - compliance to provide commitment and assurance of implementing the recommendation. Further action required.

donors recruited by an agency have been paid. General Directions 0001 and CoP Interpretation of mandatory requirements 13A.	procedures to determine whether the actions taken have been effective. A summary report of the audit should be forwarded to the centre's inspector by 21 June 2017. The PR should ensure that where donors are sourced by another agency, reasonable steps are taken to ensure compensation is within that allowed by General Directions and that the centre does not directly or indirectly pay the overseas travel of non UK donors. The PR should provide details of the procedure for this when responding to the report. Within three months of having implemented corrective actions, the centre should audit its procedures to determine whether the actions taken have been effective. A summary report of the audit should be forwarded to the centre's inspector by 21 March 2017.	The audit, as advised, will be added to the audit schedule and a summary report will be forwarded to the HFEA by 21 June 2017. All imports of sperm are from Xytex and come with evidence that meets regulatory requirements including requirements for compensation. This was reviewed at inspection and no non compliances were noted. The FGA does not and has never, directly or indirectly sourced donors from an agengy or paid any overseas travel of non UK donors. We have no plans to do this. However, we will review our processes for all donors,as advised. Within three months of having implemented corrective actions, we will carry out the audit as requested. We will forward the summary audit	The Executive cannot reconcile the PR's response regarding the sourcing of egg donors with the evidence and information received on inspection. The PR conducts treatments using egg donors and registers egg donors with the HFEA. This requires compliance with GD0001 and CoP mandatory requirement 13A. The Executive will have further discussion with the PR to ensure he fully understands his responsibilities.

		report to the HFEA but please would you clarify the dates given here as three months after implementation of corrective actions is not 21 March 2017. We look forward to receiving this clarification. UPDATE As previously mention all egg donors attend a consultation before they are accepted to donate eggs through The Fertility & Gynaecology Academy. During this consultation a detailed medical, family, social and personal history is taken. Further investigations e.g. scan and blood tests are then arranged to be done on the same day or at a later stage. Although this should be enough to comply with the HFEA requirement for donor assessment, as advised by the Executive a newly created egg donor questionnaire has been developed, implemented and	The Executive acknowledges the PR's comments and has confirmed with the PR that the summary audit report will be expected by 21 June 2017. Further action required. **Executive response to the PR's update** The Executive acknowledges the PR's response and actions taken to implement this recommendation within the agreed timeframes. No further action beyond submission of the audit report due 21 June 2017.

		kept in the donor's medical records. Although the inspection team might have meant egg donors but the Executive mentioned "donors" in the report without reference to sperm or egg donors. The Xytex information provided at the PR reply to the inspection report was an example of compliance with the HFEA guidelines on donors compensation scheme that can be applied as a model to egg donors as well. Subsequent to the inspection, where donors are sourced by the patients directly or through an agency any compensation made to them have to be in compliance with the HFEA requirements. All sourcing agencies are required to provide a documented confirmation of this to the clinic. This has now been implemented. A review of the centre's process of for assessing donors will be conducted to establish the effectiveness of	

		the revised practice and the findings of the review and an audit report will be forwarded to the HFEA by 21 June 2017. The PR is prepared to have a further discussion with the Executive to highlight the action taken by the clinic to fully comply with this recommendation.	
2. **Medicines management** An audit of five patient records showed that: • In one case the controlled drug administered to the	The PR should ensure that controlled drugs use is accurately recorded in patient records.	The use of controlled drugs is accurately recorded in patient records. It is recorded in the patient's notes section of the file.	The Executive is concerned that the PR lacks understanding of this non-compliance and has not acknowledged the inspection findings in his response. This

patient had not been recorded on the anaesthetics chart. • In one case the amount of controlled drug given as recorded on the anaesthetics chart did not match that recorded on the controlled drug register. • In one case the amount of controlled drug administered was not documented in the controlled drugs register. SLC T2, Controlled Drugs in Perioperative Care (2006), The Misuse of Drugs Regulations 2001 and NMC (2010) Standards for Medicines Management. The centre provides occasional 'top up' drugs to patients. The centre's medicines management policy does not describe the procedure to follow for this. SLC T33.	The PR should conduct a review of the centre's controlled drugs procedures and this should include staff training requirements. A summary report of the review, including corrective actions taken, should be sent to the centre's inspector by 21 March 2017. Within three months of having implemented corrective actions, the centre should audit the recording of controlled drug administration in patient records to ensure actions taken are effective and ensure ongoing compliance with regulatory requirements and practice guidance. A summary report of the audit should be sent to the centre's inspector by 21 June 2017. The centre's medicine management policy should be reviewed and revised appropriately to include the procedure for providing 'top up' drugs to patients. A copy of this policy should be provided	Controlled Drugs procedures are reviewed and audited every three months. Staff training is provided as part of audit CAPAs. The next audit is planned for February 2017. The summary audit report will be sent to the HFEA by 21 March 2017. The second audit will be done in May 2017. This audit report will be sent to the HFEA by 21 June 2017. In addition to the Management of Medicines SOP, the centre has a separate SOP for 'top up' drugs to patients (attached separately). If inspectors had asked about this specific issue, we would have provided the SOP for review.	causes concern to the Executive that he may fail to implement the recommendation. Further action required. The Executive cannot reconcile the PR's response with the inspection findings. The Executive acknowledges receipt of the SOP with the PR's response and awaits receipt of the revised policy due by 21 March 2017.

	to the centre's inspector by 21 March 2017.	The centre's medicine management policy will be reviewed and revised as appropriate. A copy of the revised policy will be sent to the HFEA by 21 March 2017. UPDATE The PR acknowledges inspectors finding of the discrepancy between the anaesthetic charts and CD register and that the response was not adequate. The PR is in the process of reviewing our policies. The CD register was signed by the anaesthetist and counter signed by the theatre nurse. The anaesthetic chart was signed by the anaesthetist only. Measures have been put in place to ensure that both CD register and anaesthetic chart are double checked and counter signed by the anaesthetist and the theatre nurse. The anaesthetists have been informed. The clinic's Management of Medicines	Further action required. **Executive response to the PR's update** The Executive acknowledges the PR's response and actions in implementing this recommendation and is satisfied that the PR will fully implement this recommendation. Further action required.

		SOP has been updated to address this controlled drugs issues. The use of controlled drugs is documented in patients' records (anaesthetic charts) and this procedure recently has been reviewed to ensure this takes place. Patient records are audited every three months and any non-conformity is addressed accordingly including any staff training.	
3. **Reproductive immunology therapies**	The PR should ensure that the clinical indication for use of	The clinical indication for use of any medications is currently	The Executive acknowledges the PR's commitment and

The inspection team did not consider that the reasons for prescribing reproductive immunology treatments were recorded clearly in the patient's medical records. The records reviewed included the patient history, details of the immune test results and then the immune therapy administered. The rationale could be inferred from this, but it was not clearly documented. SLC T58. The centre does not have SOPs to guide its use of reproductive immunology treatments. SLC T33b.	any medications in a manner that is different to their intended licenced purpose, is documented in the patient's records. Within six months of the inspection the PR should conduct an audit of medical records for patients who have been treated with reproductive immunology therapies to ensure that the clinical indication is being documented in patient records and a summary report of the findings of the audit should be provided to the centre's inspector by 21 June 2017. The PR should ensure SOPs to guide the centre's use of reproductive immunology treatments are developed. Copies of these SOPs should be provided to the centre's inspector by 21 March 2017.	documented in all patient's records. The internal audits of patient files already conducted looks at this element and so far, no corrective actions have been identified by our audits. The PR believes that to gather appropriate evidence in this area of our work, the inspectors should have asked specific questions when speaking with the PR who is the only one at FGA who prescribes immunology treatments. The inspection agenda had time allocated to speak to the PR about this area of work. By not speaking with the relevant member of staff, the inspectors have left this inspection without being properly infomed. During the inspection, the PR volunteered to speak to the inspectors about this but the opportunity was not taken up. We do not believe this to be a non-compliance.	passion for the use of immunology therapies. The inspection team spoke at length with the PR who was able to give his rationale for prescribing these therapies. However, in his response, the PR appears to have mis-understood the nature of this non-compliance which relates to the documented rationale for the use of these therapies in the patient records. The senior nurse, when asked, could not find a clear indication in the patient records reviewed during the inspection, for the use of these therapies and there was no documented procedure for their administration. The Executive will have further discussions with the PR to ensure he fully understands the requirements to achieve compliance with this recommendation. The Executive is reassured that the PR has made a commitment to implementing a SOP to guide the use of

		The centre is working on documenting the SOPs to guide reproductive immunology treatments; these will be submitted to the HFEA by 21 March 2017. UPDATE Immune theraphy is individualised and is based on each patient's circumstances including history, examination, test results, previous treatment and updated test results. Strict rigid protocols do not serve this type of complicated treatment. In the senior staff meeting the senior nurse stated that when was asked by the inspectors she took them through the immune test results leading to the prescribed therapy. The rationale for use of immunology therapies is documented in patients' records. The PR appreciates that it is not that easy to understand the rationale of treatment just by looking at the test results as it is based on so	reproductive immunology therapies. Further action required. **Executive response to the PR's update** The Executive acknowledges the PR's response and willingness to have further discussions regarding this recommendation, and his commitment to providing individualised patient care, which is to be commended. The Executive will continue to have further discussions with the PR and is confident that a compliant resolution can be achieved. Further action required.

		many factors as mentioned at the top of this paragraph. A SOP has been developed for the administration of immunology therapies and will be submitted to the HFEA by 21 March 2017. The PR is willing to have further discussion with the Executive to come an understanding regarding the rationale for the use of immunology therapies.	
4. Patient information – reproductive immunology therapies The inspection team did not consider that the written information about reproductive immunology treatments was easy to understand or made it sufficiently clear about the lack of strong evidence for the use of these treatments in IVF to enable patients to make an informed decision. Post inspection review of one of the treatments offered also	The PR should review the information about reproductive immunology treatments provided to patients to make sure it is easy to understand, and follows the guidance provided by the MHRA on the off-label use of medicines. Copies of the revised patient information should be submitted to the centre's inspector by 21 March 2017. The PR should also provide the centre's inspector with his justification for use of	We feel that this area was not discussed fully at inspection and/or there is misunderstanding. Patient information is given verbally and in writing. This is in line with current medical published information. The information on our website includes links to the RCOG and HFEA websites for further information. Additionally, patients have an opportunity to ask further questions during the course of their treatment	The Executive cannot reconcile the PR's response with the extensive discussions that took place at the inspection. The Executive is concerned that the current information being provided to patients is not compliant with SLCs and therefore require a commitment from the PR that this information will be revised in line with SLC and practice guidance requirements. Further action required.

generated further concern. NHS guidance suggests adalimumab can have an effect on the immune system of any child born, however it is recognised that this information relates to the medicine being used in its licensed application and at doses therapeutic to that condition. This is not however acknowledged or addressed in the patient information. SLC T58.	adalimumab during IVF treatment, based on NHS guidance that it not be used when trying to conceive. This should be provided when responding to this report.	and do so by by email, in person and/or telephone. Most of the immunology patients come to the FGA already informed about immunology, seeking further testing and supportive therapy. However, we will review the current patient information as advised. The PR is aware of the NHS guidance and does not use Hummira (adalimumnab) during pregnacy. We therfore, do not believe this to be a non- compliance and would like to welcome the ELP's feedback on this. UPDATE The centre's patient information for reproductive immunology therapies provided to patients verbally and in writing was current at the time of the inspection and is subject to an ongoing review	NHS guidance states that women who have been given Humira (adalimumnab), should have effective contraception for five months after the last dose has been given, which indicates this should not be used in women trying to conceive. The Executive remain concerned that the PR has failed to acknowledge this non-compliance and will be having further discussions with him. Further action required. **Executive response to the PR's update** The Executive acknowledges the PR's commitment and dedication to practicing evidenced based care. However, the Executive remains concerned that the information being provided to patients does not indicate the

		when any new evidence becomes available. The PR is aware of NHS guidance on use of Humira (adalimumnab) and is concerned about the misinterpretation made by the Executive. The guidance states “IF the decision is that it’s better for you to stop …… you should continue to use contraception ….”. The guidance gives the treating physician and the patient the option to decide if to continue or stop Humira treatment based on benefit / risk balance. Having said that there is a plethora of evidence in the Medical literature about the safety of TNFa antagonist for those trying for pregnancy and even during pregnancy. The PR would like to refer the Executive to the Rheumatology Guidelines by BSR and BHPR. It will also be helpful to review the article “Biologics in pregnancy – for the obstetrician” in TOG vol 18 #1, 2016. TOG is the educational journal of the	lack of strong evidence for the use of these therapies in fertility treatment or the potential risks involved for patient safety when treatments are used “off label”. The Executive has had extensive discussions with the PR regarding amendments to the patient information that would achieve compliance. The Executive acknowledges that what is deemed appropriate information for patients is a subjective matter. However, the Executive expects that any information provided to patients is in line with HFEA and practice guidance and enables patients to make a fully informed consent. The Executive will clarify its concerns with the PR and is confident that the PR will commit to making the required amendments. Further action required.

		RCOG to update the Obstetrician and Gynaecologists. This is a hot issue that is currently being debated in the Medical field and might be well over and beyond the HFEA inspection. The Doctors at the Fertility & Gynaecology Academy are qualified and experienced enough to prescribe medicine for un-licensed indication on named patient bases and they are aware of their responsibility in doing that. The PR would appreciate if the Executive could be more specific regarding what is incorrect in the centre's current patient information.	
5. Quality management system QIs have not been established for: donor recruitment, assessment and screening. The centre has audited its counselling procedures, but the inspection team did not consider the audit to be	The PR should ensure that QIs are established for donor recruitment, assessment and screening. The PR should provide evidence of these when responding to this report. The PR should ensure that the counselling practices at the centre are audited against regulatory requirements, their	We do not recruit donors. We have QIs for donor screening. The inspectors reviewed this at inspection and were given a copy of all our QIs (attached separately). Counselling practice: the centre has conducted an initial audit/review of counselling practice; this is	The PR conducts treatments using egg donors and registers egg donors with the HFEA, as such he must ensure compliance with GD0001 and CoP mandatory requirements. The Executive will be having further discussions with the PR to outline his responsibilities with these requirements.

comprehensive, for example it did not audit practice against the centre's counselling SOPs. The BICA QIs and audit methodology were also discussed and it is suggested that these be considered for auditing counselling practice at the centre. SLC T35 and T36.	own approved protocols and QIs. It is recommended that the BICA QIs and audit methodology be used. A copy of the audit, including any corrective actions identified, should be provided to the centre's inspector by 21 March 2017.	what the inspectors reviewed at inspection. A full audit of the centre's counselling practice against regulatory requirements, protocols and QIs is planned within the two year cycle(SLC T36). However, we will bring this audit forward to meet the inspector's timeline and submit the audit report corrective actions by 21 March 2017. UPDATE Additional QIs will be developed to ensure HFEA requirements are met when using donors in treatment services provided by the centre.	The Executive acknowledges the receipt of the quality indicators, is appreciative of the centre bringing forward the counselling audit and awaits receipt of the audit due 21 March 2017. Further action required. **Executive response to the PR's update** The Executive acknowledges the PR's additional response and commitment to implementing this recommendation. No further action beyond submission of the audit report and quality indicators developed for donor treatment services due by 21 March 2017.

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
6. Adverse incidents One centre incident involved an apnoeic episode of a patient during egg collection. The patient was managed safely and recovered appropriately. It was reported and investigated as an incident because one of the members of staff did not consider the correct process had been followed. The inspection team was concerned that the incident report did not fully document the incident or the concerns of centre staff which could limit the identification of effective corrective action. The incident had not yet been 'closed' on the centre' system either, over three months after the incident occurred. The patient was not informed after recovery of the episode. The inspection team considers that it would have been in the best	The PR should ensure that incidents are investigated thoroughly. The centre's procedures for incident investigation and management should be reviewed and a summary report of the findings of the review including corrective actions and the timescale for implementation of the corrective actions should be submitted to the centre's inspector by 21 June 2017.	Adverse incidents are investigated throughly. Discussion with the relevant staff member has clarified that she was seeking the inspectors advice on whether this is an incident that is reportable to the HFEA and not an allegation that the correct process was not followed. At the time of inspection, the incident was open as information was awaited from all members of the team before closing the incident. At that time, it was clearly documented that advice from other anesthetists had been that this is not reportable incident and that the PR had informed the patient. The procedure (SOP) is reviewed frequently, including following an incident, staff feedback and changes to our ways of working. The centre's procedures for incident investigation and management will be reviewed as advised and the summary report will be sent to the HFEA by 21 June 2017.	The Executive acknowledges the PR's commitment to review the procedures for investigating and managing incidents. The PR is reminded that in order to learn from incidents, it is important to discuss them and the actions taken with staff. The lead nurse was unaware that the PR had informed the patient and this was not documented on the form seen by the inspection team. No further action beyond submission of the summary report due 21 June 2017.

interest of the patient to be informed, both as part of a centre's general duty of candour and also in case it was of relevance for her should she have further operations. SLC T118.			
7. Satellite agreements The centre has satellite arrangements with three clinics. These arrangements were disclosed on the centre's renewal application form, but the agreements had not been submitted to the HFEA before the service started, as required by General Direction 0010.	The PR should ensure that prior to starting any new satellite service, the written agreement together with related patient information with the satellite centre is submitted to the HFEA. The written agreements with the centre's current satellite clinics were provided post inspection. No further action is required unless a new satellite service is established.	The PR is aware of the requirement but in the past has always been advised to have the documents available for inspection without the need for submission to the HFEA. If the PR had been made aware of this change in policy, the PR would have submitted them. The written agreements were reviewed at inspection by the lead inspecor who was given copies of all three agreements and sent by email post inspection, as requested.	There has been no change in policy regarding the submission of satellite agreements as required by GD 0010 since the PR has held a licence at this centre. The PR is reminded that he has a responsibility to ensure that he complies with current requirements of the HF&E Act 1990 (as amended), CoP and General Directions. The Executive acknowledges the receipt of the written agreements. No further action required.
8. Disclosure of information held on the HFEA register, for use in research. Four discrepancies were found between 10 completed	The PR should ensure that the disclosure consent information supplied to the Authority, accurately reflects that given	The audit of register forms is part of the 2017 data validation exercise.	The Executive acknowledge the PR's response to this recommendation. No further action beyond submission of the audit due 21 June 2017.

patient/partner disclosure consents on patient files and the related consent data submitted for inclusion on the register. It is noted that the centre has been provided with the relevant patient and partner numbers so that the form data can be reviewed and corrected. CH(10)05 and General Direction 0005.	and recorded on disclosure consent forms. The PR should review procedures for the submission of consent to disclosure decisions provided to the HFEA register to ensure that the decision recorded on the register accurately reflects the consent decision given and recorded on disclosure consent forms. The PR should ensure that the consents identified as being incorrect are corrected and provide confirmation that this has been done when responding to this report. The PR should conduct an audit six months after implementing any corrective actions, to confirm that the actions have been effective. A summary report of the audit should be provided to the centre's inspector by 21 June 2017.	The errors identified were a staff training issue. Training has been updated to ensure that relevant staff understand not only the consent to disclosure forms but also how to submit the information to the HFEA. We conducted an audit of the data submissions of the patient numbers that we were asked to submit the raw data for against the patient's signed consent forms, post inspection (24 Jan 2017). The necessary corrections were made at the time of that audit and before submitting the information to the HFEA so as at 24 January 2017, the data submitted to the HFEA Register was correct. Please confirm. The audit of submission of Register forms to the HFEA will be added to the audit schedule. A summary report will be provided to the HFEA by 21 June 2017.	

9. Record keeping The centre uses photographic identification to reliably identify its patients and donors. In four out of five records reviewed, the centre had not recorded how, and by whom, the patient/donor has been reliably identified. SLC T46b. In one case where the donor's records had been scanned to form electronic records, the copy of her photographic identification had not been scanned properly. This could lead to difficulties in reliably identifying the donor. In one of the five records reviewed, the patient's HFEA treatment consent form had been amended, but this amendment had not been countersigned. In another set of records, an amendment had been signed but not dated. SLC T47.	The PR should ensure that the identity of a patient is reliably confirmed and documented. The PR should ensure that the patient's HFEA treatment consent forms are completed correctly. The PR should undertake a review of the centre's processes for the above. A summary of the findings of the review including corrective actions and the timescales for implementation should be provided to the centre's inspector by 21 March 2017. Within three months, the centre should carry out an audit of records to ensure that the proposed corrective actions have been effective in ensuring compliance. A summary report of the findings of the audit should be provided to the centre's inspector by 21 June 2017.	The identity of patients is reliably confirmed by use of a 'photo' ID. Staff training has been provided to ensure that staff identifying the patient, sign and date the copy of the ID. The records reviewed at inspection were historical and that process has been changed to ensure that 'how and by whom' are recorded. We will review our processes and submit a summary report by 21 March 2017. There is confusion with regard to the donor's records that have been 'scanned to form electronic records…' The FGA do not have electronic records currently. We are in the process of having old patient files profesionally scanned. Currently we are working with paper records only. We will audit and send to the HFEA the summary report by 21 June 2017.	The Executive acknowledges the PR's response and commitment implementing this recommendation. The inspection team reviewed a range of records, both historical and current and the PR is reminded that he should ensure that staff are aware of the centre's processes for confirming patients' identity. The Executive can confirm that the photographic identification referred to in this report related to a photocopy contained within the paper patient record. The Executive acknowledges the PR's commitment to undertake a review of the patient records and must ensure that he includes patient treatment consents within this review, in order to achieve full compliance with this recommendation. Further action required.

Reponses from the Person Responsible to this inspection report