

Announced Care Inspection Report 1 and 2 June 2016



Origin Fertility Care

Service Type: Fertility Services and Assisted Conception

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Assurance, Challenge and Improvement in Health and Social Care

1.0 Summary

An announced inspection of Origin Fertility Care took place on 1 and 2 June 2016 from 10:00 to 16:55 and 10:00 to 11:50 respectively.

The inspection sought to assess progress with any issues raised during and since the previous inspection and to determine if the service was delivering safe, effective and compassionate care and if the service was well led.

Is care safe?

Observations made, a review of documentation and discussion with Dr Noel Heasley, Registered Person, Mrs Jennifer McLaughlin, Registered Manager and staff demonstrated that systems and processes were in place to ensure that care to patients was safe and avoids and prevents harm. Areas reviewed included staffing, recruitment and selection, safeguarding, management of patients undergoing fertility treatment, management of medical emergencies, infection prevention control and decontamination and the general environment. Mandatory training was up to date including safeguarding. To consolidate this training and in light of the issuing of regional guidance entitled "Adult Safeguarding Prevention and Protection in Partnership", it was suggested staff undertake refresher safeguarding training. Whilst reviewing the management of medical emergencies decluttering the anaesthetic trolley with the involvement of the anaesthetic staff was suggested for consideration. No requirements or recommendations have been made.

Is care effective?

Observations made, a review of documentation and discussion with Dr Heasley, Registered Person, Mrs McLaughlin, Registered Manager and staff demonstrated that systems and processes were in place to ensure that care provided in the establishment was effective. Areas reviewed included clinical records and patient information and decision making. Origin Fertility Care continues to consolidate systems to ensure effective care is delivered. No requirements or recommendations have been made.

Is care compassionate?

Observations made, a review of documentation and discussion with Dr Heasley, Registered Person, Mrs McLaughlin, Registered Manager and staff demonstrated that arrangements are in place to promote patients' dignity, respect and rights. Whilst the operation of recovery area has been adjusted to enhance privacy, it was suggested the provision of privacy and confidentiality in this area could be further promoted by the implementation of plans to add individual recovery rooms. No requirements or recommendations have been made.

Is the service well led?

Information gathered during the inspection evidenced that there was effective leadership and governance arrangements in place which creates a culture focused on the needs of patients in order to deliver safe, effective and compassionate care. Areas reviewed included organisational and staff working arrangements, the arrangements for policy and risk assessment reviews, the arrangements for dealing with complaints, incidents and alerts, insurance arrangements and the registered person's understanding of their role and responsibility in accordance with legislation.

A review of the complaints register prompted a discussion on the investigation of one complaint and Mrs McLaughlin later confirmed following consultation with Dr Heasley that a further examination of the issues would be undertaken to ensure all action necessary has been taken. No requirements or recommendations have been made.

This inspection was underpinned by The Independent Health Care Regulations (Northern Ireland) 2005, The Regulation and Improvement Authority (Independent Health Care) (Fees and Frequency of Inspections) (Amendment) Regulations (Northern Ireland) 2011 and the Department of Health, Social Services and Public Safety (DHSSPS) Minimum Care Standards for Independent Healthcare Establishments (July 2014).

1.1 Inspection outcome

	Requirements	Recommendations
Total number of requirements and recommendations made at this inspection	0	0

This inspection resulted in no requirements or recommendations being made. Findings of the inspection were discussed with Mrs McLaughlin, Registered Manager, as part of the inspection process and can be found in the main body of the report.

Enforcement action did not result from the findings of this inspection.

1.2 Actions/enforcement taken following the most recent pharmacy inspection

There were no further actions required to be taken following the most recent inspection.

2.0 Service details

Registered organisation/registered person: Origin Fertility Care Limited Dr Noel Heasley	Registered manager: Mrs Jennifer McLaughlin
Person in charge of the home at the time of inspection: Mrs Jennifer McLaughlin	Date manager registered: 22 May 2014
Categories of care: Prescribed technologies(PT)– In vitro Fertilisation IVF ,Private Doctor (PD)	Number of registered places: Not applicable

3.0 Methods/processes

Questionnaires were provided to patients and staff prior to the inspection by the establishment on behalf of the RQIA. Prior to inspection we analysed the following records: notification of incidents, complaints declaration and returned completed staff questionnaires. There were no completed patient questionnaires returned to RQIA.

During the inspection the inspectors met with, two fertility nurses, two embryologists, one medical practitioner and one administrator. A tour of the premises was also undertaken.

Records were examined during the inspection in relation to the following areas:

- staffing
- recruitment and selection
- safeguarding
- management of medical emergencies
- infection prevention and control
- management of patients undergoing fertility treatment
- clinical records
- patient information and decision making
- practising privileges arrangements
- management and governance arrangements
- maintenance arrangements

4.0 The inspection

4.1 Review of requirements and recommendations from the most recent inspection dated 8 January 2016

The most recent inspection of the establishment was an announced pharmacy inspection. No requirements or recommendations were made during this inspection.

4.2 Review of requirements and recommendations from the last care inspection dated 8 & 9 June 2015

Last care inspection recommendations		Validation of compliance
<p>Recommendation 1</p> <p>Ref: Standard 4.4</p> <p>Stated: First time</p> <p>To be Completed by: 9 September 2015</p>	<p>It is recommended to make arrangements to ensure the provision of privacy for patients in the recovery area.</p> <hr/> <p>Action taken as confirmed during the inspection: Mrs McLaughlin and staff confirmed the following arrangements for the provision of privacy in the recovery area:-</p> <ul style="list-style-type: none"> • if possible no more than 2 patients are accommodated in the recovery area at the one time • privacy curtains are in place and used when patients are accommodated • no confidential or clinical matters are discussed with the patient in the recovery area • music is played in the recovery room • a discharge room has been created on the ground floor for private consultation post treatment. Patients and their partners are spoken to in private by the clinicians in this private room • Mrs McLaughlin has had plans drawn up for the renovation of the recovery area to create three individual patient recovery rooms. These are under consideration by the Board of Directors. Management are aware that if proceeding then a variation to registration application should be submitted to RQIA prior to the new recovery rooms becoming operational 	<p>Met</p>

4.3 Is care safe?

Staffing

Discussion with staff and review of duty rosters confirmed there are appropriately skilled and qualified staff involved in the delivery of services. This includes a team of doctors, nurses and embryologists who have evidence of specialist qualifications and skills in fertility treatments.

Review of records and staff discussion confirmed an induction programme is in place appropriate to the role and arrangements are in place to ensure that staff training and continuing professional development opportunities are available for all staff.

There are rigorous systems in place for undertaking, recording and monitoring all aspects of staff supervision, appraisal and ongoing professional development.

Arrangements are in place for monitoring the registration status and professional indemnity for all clinical staff.

Recruitment and selection

Five personnel files reviewed evidenced that documentation as outlined in Schedule 2 of The Independent Health Care Regulations (Northern Ireland) 2005 has been retained.

Review of recruitment and selection procedures demonstrated good practice in line with legislative requirements.

There was a recruitment policy and procedure available. The policy was comprehensive and reflected best practice guidance.

Safeguarding

Staff spoken with were aware of the types and indicators of abuse and the actions to be taken in the event of a safeguarding issue being identified. Staff were aware of who the nominated safeguarding lead was within the establishment.

Review of records demonstrated that all staff in the establishment had received training in safeguarding children and adults as outlined in the Minimum Care Standards for Independent Healthcare Establishments July 2014.

The policy and procedure for the safeguarding of adults and children has been updated in line with regional guidance issued in July 2015. The policy included the types and indicators of abuse and distinct referral pathways in the event of a safeguarding issue arising with an adult or child. The relevant contact details for onward referral to the local Health and Social Care Trust should a safeguarding issue arise were included. Mrs McLaughlin had emailed all staff to inform them of the updated policy and procedure. To consolidate awareness of the changes to the policy and procedure it was advised consideration should be given to staff undertaking refresher training on safeguarding. Mrs McLaughlin was receptive to this suggestion.

Management of patients undergoing fertility treatment

A range of treatment protocols are in place for the management of patients receiving assisted conception services which have been developed and agreed by all professionals within the establishment.

The protocols for the prevention and management of ovarian hyper stimulation syndrome (OHSS) have been written by Dr Heasley and are evidence based and in line with best practice.

Written protocols are in place for the close monitoring of patients, in order to avoid unnecessary complications including multiple pregnancy. There is an elective single embryo transfer (e SET) protocol. The e SET protocol sets out the number of embryos that can be placed in a woman in any one cycle and it complies with the Human Fertilisation Embryology Authority (HFEA) Code of Practice.

The protocols and procedures were discussed with the lead clinician, embryology manager and nursing staff who demonstrated a detailed knowledge on the matter. The embryologist outlined the implementation in the establishment of the procedure for indelible labelling of material for individual patients to ensure the unique identification of a patient's material and the checking and recording of all stages of treatment.

Staff confirmed there are daily clinical meetings involving nurses, doctors and members of the embryology team to discuss the management of patients and there are also systems in place to regularly review and discuss patient outcomes.

Management of medical emergencies

A review of medical emergency arrangements evidenced that emergency medicines were provided in keeping with the British National Formulary (BNF), and that emergency equipment as recommended by the Resuscitation Council (UK) guidelines was retained.

A record of all emergency medicines and equipment is attached to the anaesthetic trolley and a written record retained of daily checks carried out by a designated member of staff.

It was noted there were numerous packs of some equipment which led to some difficulty checking all items. It was suggested that the anaesthetic trolley was decluttered in consultation with the anaesthetic staff.

Staff spoken with demonstrated knowledge and understanding of managing resuscitation and other medical emergencies and they were aware of the location of medical emergency medicines and equipment.

Staff confirmed resuscitation equipment is cleaned and decontaminated after each use.

A review of training records confirmed staff have received basic life support training, nurses have received immediate life support training and anaesthetists have advanced life support skills.

There is a written resuscitation policy and procedure in place.

Infection prevention control and decontamination procedures

There are clear lines of accountability for infection prevention and control (IPC). The establishment has a designated IPC lead nurse.

There is a range of information for patients and staff regarding hand washing techniques.

There are arrangements in place to ensure the decontamination of equipment and reusable medical devices in line with manufacturer's instructions and current best practice. Staff confirmed single use equipment is used where possible.

The establishment was found to be clean, tidy and well maintained. Detailed cleaning schedules are in place and completed records of cleaning were displayed in various areas.

Staff are provided with IPC training commensurate with their role.

Discussion with staff confirmed they had a good knowledge and understanding of IPC measures.

A range of IPC audits are carried out including:

- environmental audit
- hand hygiene audit
- post treatment infection audit

The compliance rate was noted to be very high and an action plan was in place for areas of non-compliance.

There are a range of IPC policies and procedures in place which are held within an IPC manual.

A review of infection prevention and control arrangements indicated very good infection control practices are embedded in the establishment.

Environment

The premises were reviewed and found to be maintained to a good standard of maintenance and décor.

The establishment has a recovery area, a dedicated room for the production of semen specimens, a fertility treatment room, embryology and andrology laboratories, a discharge room and consultation rooms.

There are secure designated areas, with access by authorised personnel only, for the atmospheric and temperature controlled storage of gamete and embryos.

The room used for egg collection for in vitro fertilisation is close to the laboratory where fertilisation is to take place.

Patient and staff views

No patients submitted questionnaire responses to RQIA. Mrs McLaughlin confirmed patient questionnaires were made available to patients and their partners in the waiting area of the establishment.

Five staff submitted questionnaire responses. All indicated that they felt that patients are safe and protected from harm. Staff spoken with during the inspection concurred with this. The following comment was provided:

- “Staff are highly trained and compliance with mandatory training is fulfilled.”

Areas for improvement

No areas for improvement were identified during the inspection.

Number of requirements:	0	Number of recommendations:	0
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4.4 Is care effective?

Clinical records

Six patient care records were reviewed. The establishment retain hard copy care records which are supplemented with an electronic record system. The patient care records were well documented, contemporaneous and clearly outlined the patient journey.

The care records reviewed contained the following;

- patient registration form
- patient health questionnaire
- pre-operative and post-operative checklists
- intraoperative records
- screening results
- patient treatment plan including medication regime
- copy of the treatment plan schedule which was provided to the patient
- a range of signed consent forms for each procedure
- signed patient contract
- HFEA consent
- record of consultation with the medical practitioner
- embryology records and
- follow up letters to patient's GP or referring medical practitioners

Systems are in place to audit the patient care records as outlined in the establishments quality assurance programme. A number of audits relating to patient care records were reviewed and a high compliance rate was noted.

Information was available for patients on how to access their health records, under the Data Protection Act 1998.

The establishment is registered with the Information Commissioner's Office (ICO).

Discussion with staff confirmed they had a good knowledge of effective records management.

The establishment has a range of policies and procedures in place for the management of records which includes the arrangements for the creation, use, retention, storage, transfer, disposal of and access to records.

The establishment also has a policy and procedure in place for clinical record keeping in relation to patient treatment and care which complies with the General Medical Council (GMC) guidance and Good Medical Practice.

The management of records was found to be in line with legislation and best practice.

Patient information and decision making

Written information is available for prospective patients regarding the services provided, how to access services and costs of treatment. This information is written in plain English and when required is available in an alternative language or format. There is a website for the service which provides external contact details for prospective patients. The patient guide is available on the website and in the waiting area.

A range of information leaflets on each procedure outlining risks, complications and expected outcomes are available and staff confirmed these are given to patients on consultation.

There is a procedure on breaking bad news to patients and staff demonstrated a good understanding of it.

Patients are aware of who to contact if they want advice or have any issues/concerns. There is an experienced fertility nurse on call out of hours and if necessary they can contact the consultant obstetrician for further advice and support.

Template referral forms and letters to healthcare practitioners have been developed in association with HFEA guidelines.

Staff confirmed there is good communication within the each team, with management and learning from complaints, incidents or near misses is effectively disseminated to staff.

Mrs McLaughlin confirmed she continues to develop systems to ensure effective care is delivered.

Patient and staff views

No patients submitted questionnaire responses to RQIA

All staff questionnaire responses indicated that they felt that patients get the right care, at the right time and with the best outcome for them. Staff spoken with during the inspection concurred with this. The following comments were provided:

- "Patients care and treatment is considered to the highest degree at OFC"

Areas for improvement

No areas for improvement were identified during the inspection.

Number of requirements:	0	Number of recommendations:	0
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4.5 Is care compassionate?

Dignity, respect and rights

Discussion regarding the consultation and treatment process confirmed that patients' modesty and dignity is respected. Consultations and treatments are provided within private rooms with the patient and medical practitioner/nursing staff/embryology staff present.

Whilst the operation of recovery area has been adjusted to enhance privacy, it was suggested the provision of privacy and confidentiality in this area could be further promoted by the implementation of plans to add individual recovery rooms.

Patient care records were stored securely in a locked records room and electronic records are password protected

It was confirmed that patients are treated in accordance with the DHSSPS standards for Improving the Patient & Client Experience.

Patients meet with staff providing the service and are fully involved in decisions regarding their treatment. Discussion with staff and review of patient care records confirmed that patients are treated and cared for in accordance with legislative requirements for equality and rights.

Staff were observed treating patients with compassion, dignity and respect.

Patients can choose to have their significant other present during consultations and certain treatments as agreed with staff.

Patients' wishes are respected and acknowledged by the establishment.

The establishment provides details of an independent counselling service to patients. A counselling information leaflet is included in the initial information pack and outlines the contact number and email address of an independent qualified counsellor. Patients can then organise an appointment directly. Mrs McLaughlin and staff confirmed the counselling service is completely confidential and free of charge to the patient.

Origin Fertility Care obtains the views of patients and/or their significant others on a formal and informal basis as an integral part of the service they deliver.

Patients are asked for their comments in relation to the quality of treatment provided, information and care received.

The establishment issue feedback questionnaires on an ongoing basis.

The information received from the patient feedback questionnaires is collated into an annual summary report which is made available to patients and other interested parties to read in the waiting area of the establishment.

It was confirmed that comments received from patients are reviewed by the registered manager and discussed at monthly management meetings. An action plan is developed to address any issues identified.

Review of the most recent annual summary report dated March 2016 evidenced that patients had the opportunity to provide feedback on their experience of the service and the following comments were outlined in their submitted questionnaires:

- “Felt very reassured by explanations and manner”
- “Keep up the brilliant work. Brilliant staff”
- “Overall a very positive dignified experience. Exceeded all my expectations. A big thank you to all the team”
- “Very friendly and reassuring staff at all levels”
- “Just to say thank you for the sensitive way in which we were led through the entire process. Cannot fault any part of our experience”
- “Excellent professional service”

Discussion with staff confirmed that patients and/or their significant others have the opportunity to comment on the quality of care and treatment provided, including their interactions with staff who work within the establishment.

Review of care records and discussion with staff confirmed that treatment and care are planned and developed with meaningful patient involvement; facilitated and provided in a flexible manner to meet the assessed needs of each individual patient.

Patient and staff views

No patients submitted questionnaire responses to RQIA.

All submitted staff questionnaire responses indicated that they felt that patients are treated with dignity and respect and their rights are respected. Staff spoken with during the inspection concurred with this. The following comment was provided:

- “Patients are consulted and are fully informed throughout every stage of their treatment. Patients dignity/respect and confidentiality are always maintained.”

Areas for improvement

No areas for improvement were identified during the inspection.

Number of requirements:	0	Number of recommendations:	0
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4.6 Is the service well led?

Management and governance arrangements

In May 2016 Origin fertility Care had its licence with HFEA renewed for four years without conditions.

There was a clear organisational structure within the establishment and staff were able to describe their roles and responsibilities and were aware of who to speak to if they had a concern.

Dr Heasley, the registered person is involved in the day to day running of the establishment and participates in meetings with each department on a weekly basis. Mrs McLaughlin confirmed weekly management reports are also forwarded to the board of directors.

There are well developed quality assurance systems in place. The service is accredited by an external quality assurance organisation ISO9002 and this accreditation is due for renewal in September 2016.

A detailed Quality Management System (QMS) is fully implemented and outlines quality indicators and key performance indicators. A quality manual is in place for 2016 which supports the QMS. Observation of minutes of monthly quality meetings and discussion with staff confirmed there is a culture of continuous improvement embedded in the establishment.

Policies and procedures were available for staff reference. Policies and procedures were indexed, dated and systematically reviewed on a three yearly basis. Staff spoken with were aware of the policies and how to access them.

Arrangements were in place to review risk assessments.

A copy of the complaints procedure was displayed in the establishment. Staff demonstrated a good awareness of complaints management. A complaints questionnaire was forwarded by RQIA to the establishment for completion. The evidence provided in the returned questionnaire indicated that complaints have been managed in accordance with best practice. A review of the complaints register prompted a discussion on the investigation of one complaint and Mrs McLaughlin later confirmed following consultation with Dr Heasley that a further examination of the issues would be undertaken to ensure all action necessary has been taken.

A system was in place to ensure that notifiable events were investigated and reported to RQIA or other relevant bodies as appropriate. A system was also in place to ensure that urgent communications, safety alerts and notices are reviewed and where appropriate, made available to key staff in a timely manner.

The establishment has arrangements in place to monitor the competency and performance of all staff and report to the relevant professional regulatory bodies in accordance with guidance, if required.

Mrs McLaughlin and Dr Heasley ensure that all health care professionals adhere to their published codes of professional conduct and professional guidelines.

There are systems in place to check the registration status of the health care professionals with their appropriate professional bodies on an annual basis.

Mrs McLaughlin outlined the process for granting practising privileges and confirmed medical practitioners details are assessed by the medical director for the organisation prior to privileges being granted.

Nine medical practitioner's personnel files were reviewed and confirmed that there was a written agreement between each medical practitioner and the establishment setting out the terms and conditions of practising privileges which has been signed by both parties.

There are systems in place to review practising privileges agreements every two years.

Origin Fertility Care has a policy and procedure in place which outlines the arrangements for application, granting, maintenance, suspension and withdrawal of practising privileges.

Mrs Mc Laughlin confirmed that arrangements were in place to monitor, audit and review the effectiveness and quality of care delivered to patients at appropriate intervals. If required an action plan is developed and embedded into practice to address any shortfalls identified during the audit process. There is an internal audit schedule for 2016/17 in place. The following sample of audits was reviewed:-

- IPC and hand hygiene audit
- inspection of surgical procedures audit
- oocyte retrieval audit
- chart location audit
- EDI submission audit
- IVF/ICSI pathway audit
- emergency preparedness /response audit
- traceability of lab stocks audit
- witnessing audit
- repeat cycle patient pathway audit
- maintenance and management of stored material records audit
- semen analysis audit
- schedule 2 drug audit

A high compliance rate was noted in all audits.

A whistleblowing/raising concerns policy was available. Discussion with staff confirmed that they were aware of who to contact if they had a concern.

Discussion with staff confirmed there are very good working relationships. They all spoke positively regarding the establishment, felt valued as members of the team and confirmed they were supported by management.

Dr Heasley and Mrs McLaughlin demonstrated a clear understanding of their roles and responsibilities in accordance with legislation. Information requested by RQIA has been submitted within specified timeframes. It was confirmed that the Statement of Purpose and Patient's Guide are kept under review, revised and updated when necessary and available on request.

The RQIA certificate of registration was up to date and displayed appropriately.

Observation of insurance documentation confirmed that current insurance policies were in place.

Patient and staff views

No patients submitted questionnaire responses to RQIA.

All staff questionnaire responses indicated that they felt that the service is well led. Staff spoken with during the inspection concurred with this. The following comments were provided:

- “Managers have a full role within the clinic. They are approachable and are readily available if needed.”

Areas for improvement

No areas for improvement were identified during the inspection.

Number of requirements:	0	Number of recommendations:	0
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5.0 Quality improvement plan

There were no issues identified during this inspection, and a QIP is neither required, nor included, as part of this inspection report.

It should be noted that this inspection report should not be regarded as a comprehensive review of all strengths and areas for improvement that exist in the service. The findings reported on are those which came to the attention of RQIA during the course of this inspection. The findings contained within this report do not exempt the registered provider from their responsibility for maintaining compliance with the regulations and standards.



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