Announced Inspection

Name of Establishment:	**Origin Fertility Care**
Establishment ID No:	**10635**
Date of Inspection:	**27 & 28 May 2014**
Inspector's Name:	**Jo Browne**
Inspection No:	**16603**

The Regulation and Quality Improvement Authority
9th floor Riverside Tower, 5 Lanyon Place, Belfast, BT1 3BT
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1.0 General Information

Name of establishment:	Origin Fertility Care
Address:	380 Belmont Road Belfast BT4 2NF
Telephone number:	028 9076 1713
Registered organisation / registered provider:	Origin Fertility Care Ltd Dr Richard Noel Heasley
Registered manager:	Ms Jennifer McLaughlin
Person in charge of the establishment at the time of inspection:	Ms Jennifer McLaughlin
Registration category:	PT(IVF) – Prescribed techniques or prescribed technology: establishments providing in vitro fertilisation PD- Private doctors (other)
Date and time of inspection:	27 May 2014 10.00am – 17.05pm 28 May 2014 10.15am – 17.45pm
Date and type of previous inspection:	Unannounced 16 January 2014
Name of inspector:	Jo Browne

2.0 Introduction

The Regulation and Quality Improvement Authority (RQIA) is empowered under The Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003 to inspect independent health care establishments. A minimum of one inspection per year is required.

This is a report of the announced inspection to assess the quality of services being provided. The report details the extent to which the regulations and DHSPPS draft Independent Health Care Minimum Standards for Hospitals and Clinics measured during the inspection were met.

2.1 Purpose of the Inspection

The purpose of this inspection was to ensure that the service is compliant with relevant regulations, the draft minimum standards and to consider whether the service provided to patients was in accordance with their assessed needs and preferences. This was achieved through a process of analysis and evaluation of available evidence.

RQIA not only seeks to ensure that compliance with regulations and standards is met but also aims to use inspection to support providers in improving the quality of services. For this reason, inspection involves in-depth examination of an identified number of aspects of service provision.

The aims of the inspection were to examine the policies, procedures, practices and monitoring arrangements for the provision of assisted conception services, and to determine the provider's compliance with the following:

- The HPSS (Quality, Improvement and Regulation) (Northern Ireland) Order 2003
- 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
- The Department of Health, Social Services and Public Safety's (DHSSPS) draft Independent Health Care Minimum Standards for Independent hospitals and clinics.

Other published standards which guide best practice may also be referenced during the inspection process.

2.2 Methods/Process

Committed to a culture of learning, RQIA has developed an approach which uses self-assessment, a critical tool for learning. The self-assessment was forwarded to the provider prior to the inspection and was reviewed by the inspector prior to the inspection. The inspection process has three key parts;

self-assessment, pre-inspection analysis and the visit undertaken by the inspector.

Specific methods/processes used in this inspection include the following:

- Analysis of pre-inspection information and self-assessment
- Discussion with the responsible individual, Dr Noel Heasley
- Discussion with the registered manager, Ms Jennifer McLaughlin
- Discussion with 3fivetwo Healthcare operations director, Mr Glenn Best
- Examination of records
- Tour of the premises
- Evaluation and feedback

Any other information received by RQIA about this registered provider and its service delivery has also been considered by the inspector in preparing for this inspection.

The completed self-assessment is appended to this report.

2.3 Consultation Process

During the course of the inspection, the inspector:

Reviewed patient feedback questionnaires, issued by the establishment	29
Spoke with staff	6

2.4 Inspection Focus

The inspection sought to establish the level of compliance being achieved with respect to the following DHSSPS draft Independent Health Care Minimum Standards for Independent Hospitals and Clinics and to assess progress with the issues raised during and since the previous inspection.

- C4 Patient Partnerships
- C5 Complaints
- C10 Management and Control of Operations
- A5 Practising Privileges
- P5 Qualifications and Training of Staff
- P6 Facilities for Assisted Conception Services
- P7 Information and Decision Making
- P9 Management of Patients

3.0 Profile of Service

Origin Fertility Care has been providing fertility treatments since registration in 2002. A range of specialist infertility investigations and treatments are provided in the establishment by a team of fertility experts including doctors, embryologists and specialist nurses. Counselling can be provided externally for patients who wish to avail of this type of service.

The establishment is registered under the HPSS (Quality, Improvement and Regulation) NI, Order 2003 and is licensed to operate with the Human Fertilization and Embryology Authority (HFEA). This license is renewed regularly further to inspection and audit by the HFEA.

Origin Fertility Care operates within a commercial building located on the outskirts of east Belfast. The premises consists of consulting rooms, dedicated rooms for egg collection and the production of semen specimens, a treatment room, recovery area, embryology laboratories, reception and waiting room, office areas, toilet facilities for staff and patient use and staff changing facilities. There are secure designated areas with access by authorised personnel only for gamete embryos storage.

The establishment is accessible for patients with a disability.

Private car parking is available for patients and visitors.

Origin Fertility Care is registered as an independent hospital with the following categories of registration: PT (IVF) - Prescribed techniques or prescribed technology: establishments providing in vitro fertilisation and PD - Private doctors (other).

4.0 Summary of Inspection

An announced inspection was undertaken by Jo Browne on 27 May 2014 from 10.00 to 17.05 and 28 May from 10.00 to 17.45. The inspection sought to establish the compliance being achieved with respect to 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, the DHSSPS draft Independent Health Care Minimum Standards for Independent hospital and clinics.

The establishment is registered under the HPSS (Quality, Improvement and Regulation) NI, Order 2003 and is licensed to operate with the Human Fertilization and Embryology Authority (HFEA). This license is renewed following inspection and audit by the HFEA.

As the previous unannounced inspection resulted in no recommendations or requirements being made, no follow up was required during this inspection.

The inspection focused on the DHSSPS draft Independent Health Care Minimum standards outlined in section 2.4 of this report.

Ms Jennifer McLaughlin and Mr Glenn Best were available during the inspection and for verbal feedback at the conclusion of the inspection.

During the course of the inspection the inspector discussed operational issues, examined a selection of records and carried out a general inspection of the establishment.

A recommendation was made to amend the content of the Statement of Purpose and a requirement was made to develop the Patient Guide in line with legislative and best practice guidance.

There are robust systems in place to obtain the views of patients. The inspector reviewed the completed patient questionnaires, along with the summary reports and found that patients were generally highly satisfied with the quality of care and treatment provided. Any issues identified by patients were discussed with the registered manager and action agreed. Comments received from patients can be viewed in the main body of the report. Feedback from patients is used by the management of the establishment to improve patient services. A recommendation was made to include the date on the patient satisfaction questionnaire to facilitate the collection of data and to include in the summary report the action plan implemented by the establishment to address any issues identified.

The establishment's complaints policy and procedure is in line with the DHSSPS guidance and legislation. The inspector reviewed complaints management within the establishment and found that complaints were well documented, fully investigated and had outcomes recorded. One complaint had been recorded since the previous inspection and was ongoing.

There is a defined management structure within the establishment and clear lines of accountability. The registered persons are responsible for the day to day running of the establishment and ensuring compliance with the legislation and standards.

The inspector reviewed the policy and procedures in relation to the absence of the registered manager and whistle blowing. They were found to be in line with legislation and best practice.

The registered persons undertake ongoing training to ensure that they up to date in all areas relating to the provision of services.

The establishment has comprehensive systems in place to audit and monitor the quality of clinical care provided. The inspector reviewed audits as outlined in the main body of the report.

The inspector reviewed incident management and found that incidents were well documented, fully investigated and had outcomes recorded. Audits of incidents were undertaken as part of the establishment's clinical governance systems. Arrangements were in place to disseminate learning outcomes throughout the organisation.

Systems are in place for dealing with alert letters and managing lack of competency or poor staff performance. This includes the registered persons ensuring that all staff abide by their professional codes of conduct and reporting arrangements to professional bodies if necessary.

The inspector reviewed the insurance arrangements for the establishment and found that current insurance policies were in place.

The establishment had a policy and procedure in place for granting practising privileges. A recommendation was made to further develop the practising privileges policy to include arrangements for the application, maintenance, suspension and withdrawal of practising privileges. Requirements were also made in relation to developing practising privileges agreements and ensuring all information required by legislation is retained for each medical practitioner.

A range of specialist infertility investigations and treatments are provided in the establishment by a team of fertility experts including medical practitioners, embryologists, specialist nurses and counsellors. Systems are in place to ensure that all health care professionals have a current registration with their professional body. The inspector reviewed the staff personnel files and found that some staff had commenced employment prior to the required Access NI enhanced disclosure and two appropriate written references being received; a requirement was made in this regard. The inspector acknowledges that at the time of inspection all staff had a current Access NI check in place and the registered manager outlined the action she would take to address the issues identified.

The inspector undertook a review of the premises which were found to be maintained to a good standard of maintenance and décor. The establishment was found to be clean tidy and free from clutter. Recent refurbishment had been

completed which included new carpets, paint, and frosting the glass door to the waiting room to enhance patient privacy.

There are dedicated rooms for specific purposes such as egg collection, production of semen specimens, treatment area for undertaking clinical procedures and laboratories for embryology procedures.

There are a range of information leaflets on each procedure carried out by the establishment and given to patients on consultation to enable them to make informed decisions regarding their treatment. During the consultation period, the procedures, risks, complications and expected outcomes are discussed with each individual patient.

There are comprehensive standard operating procedures, protocols and clinical guidelines in place relating to all services provided.

The inspector met the lead clinician, embryology manager, nursing and administration staff to discuss their roles within Origin Fertility Care. They all spoke positively regarding the establishment, felt valued as members of the team and confirmed that they were supported by management. No patients wished to meet with the inspector during the inspection.

The inspector reviewed the care records of six patients and found them to be well completed and contain evidence of the patient pathway. A recommendation was made to amend the templates used to document the treatment cycle, sperm storage and embryo storage to include a section for the staff member completing the documents to sign.

Overall, on the day of inspection, the establishment was found to be providing a safe and effective service to patients.

The certificate of registration was clearly displayed in the reception area of the establishment.

There were four requirements and four recommendations made as result of this inspection. These are discussed fully in the main body of the report and in the appended Quality Improvement Plan.

The inspector would like to thank Ms Jennifer McLauglin, Dr Noel Heasley, Mr Glenn Best, patients and staff of Origin Fertility Care for their hospitality and contribution to the inspection process.

5.0 Follow Up on Previous Issues

No requirements or recommendations were made following the previous inspection.

6.0 Inspection Findings

STANDARD C4	
Patient Partnerships:	**The views of patients, carers and family members are obtained and acted on in the evaluation of treatment, information and care.**

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

The establishment issued feedback questionnaires to 53 patients and 29 were returned and completed. The inspector reviewed the completed questionnaires and found that patients were generally highly satisfied with the quality of treatment, information and care received. Comments from patients included:

- "Staff have been really kind and welcoming – makes the whole experience easier – Thanks"
- "Professional, reassuring and ability to put us at ease"
- "Counselling service excellent"
- "Always find staff to be extremely helpful"
- "Everything fully explained from start to finish"
- "Drug cost unclear to us"
- "Nurses were great and showed me everything I needed re injections etc"
- "Overall a positive experience, friendly, efficient and clean"

Some minor issues were identified by patients within the questionnaires regarding the actual cost of treatment, communication by phone and anaesthetists. These issues were discussed with the registered manager during the inspection and it was agreed that she would review the price list to provide clarity to patients. The inspector also advised notifying patients in writing of the full cost of treatment and retaining a record that this information had been provided. Ms McLaughlin stated she was aware of the other issues raised and had already implemented changes to address them.

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 within the patient information file in the waiting room.

A recommendation was made to include the date on the patient satisfaction questionnaire to facilitate the collection of data and to include the action plan implemented by the establishment to address any issues identified within the summary report.

Evidenced by:

Review of patient satisfaction surveys
Review of summary report of patient satisfaction surveys
Summary report made available to patients and other interested parties
Discussion with staff

STANDARD C5	
Complaints:	**All complaints are taken seriously and dealt with.**

The establishment operates a complaints policy and procedure in accordance with the DHSSPS guidance on complaints handling in regulated establishments and agencies and the legislation. There were two standard operating procedures (SOPs) in relation to complaints and the inspector advised the registered manager to amalgamate these documents into one policy and procedure.

The registered manager demonstrated a good understanding of complaints management.

A copy of the complaints procedure is made available to all patients within the patient information file in the waiting room.

The establishment has access to interpreters and can make the complaints procedure available in other formats if required.

The inspector reviewed the complaints register and complaints records. One complaint had been recorded since the last inspection and remained ongoing at the time of inspection. The inspector advised offering to meet with the complainants to assist in achieving resolution. The complaint record was well documented and investigated in line with the complaints procedure and legislation.

The registered manager undertakes an audit of complaints monthly as part of the establishment's quality assurance mechanisms. The audit information is used to identify trends and enhance services provided as part of the establishment's clinical governance arrangements.

Evidenced by:

Review of complaints procedure
Complaint procedure made available to patients and other interested parties
Discussion with staff
Review of complaints records
Review of the audit of complaints

STANDARD C10	
Management and Control of Operations:	**Management systems and arrangements are in place that support and promote the delivery of quality treatment and care.**

There is a defined organisational and management structure that identifies the lines of accountability, specific roles and details responsibilities for all areas of the service.

The registered persons ensure the establishment delivers a safe and effective service in line with the legislation, other professional guidance and draft minimum standards.

The responsible individual is involved in the day to day running of the establishment and participates in meetings with each department on a weekly basis. Weekly management reports are also forwarded to the board of directors.

The establishment has a policy and procedure in place to ensure that RQIA is notified if the registered manager is absence for more than 28 days. The policy includes the interim management arrangements for the establishment.

Review of the training records and discussion with the registered persons confirmed that they undertake training relevant to their role and responsibilities within the organisation.

The inspector reviewed the establishment's Statement of Purpose and the following was recommended:

- Update the complaints procedure with the Statement of Purpose regarding the role of RQIA as a regulator and not as a referral route for stage two complaints
- Include the arrangements in place for consultation with patients about the operation of the establishment. Information could be included on how to obtain a copy of the summary report of the patient satisfaction survey.

The patient information file was provided to the inspector as the Patient Guide, however the file did not contain all of the information required by regulation 8 of the Independent Health Care Regulations (Northern Ireland) 2005 and a requirement was made to address this.

The establishment has systems in place to audit the quality of service provided. A comprehensive audit schedule has been developed for the year. Some of the audits reviewed by the inspector included:

- Infection prevention and control audit
- Consent to disclosure audit
- Oocyte retrieval audit
- Chart file audit
- Chart location audit

- Patient treatment pathway audit
- Supporting process audit
- Compliance audits

Action plans are developed following each audit to address any issues identified.

The establishment has an incident policy and procedure in place which includes reporting arrangements to RQIA.

The inspector reviewed incident management and found that incidents were documented, fully investigated and had outcomes recorded. The incident investigation report template includes a section to document when the Person Responsible (PR) has been informed in line with HFEA guidance. Historically the PR and the responsible individual (RI) under RQIA legislation had been the same person. However recently this has changed to two separate individuals and the inspector advised also adding the date the RI had been informed to the report template.

Audits of incidents are undertaken monthly and learning outcomes are identified and disseminated throughout the organisation.

The registered manager has systems in place to deal with all alert letters issued by the DHSSPS.

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. The registered persons 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 health care professionals with their appropriate professional bodies on an annual basis.

There is a written policy on "Whistle Blowing" and written procedures that identify to whom staff report concerns about poor practice and the support mechanisms available to those staff.

The inspector discussed the insurance arrangements within the establishment and confirmed current insurance policies were in place. The certificates of registration and insurance were clearly displayed in the reception area of the premises.

Evidenced by:

Review of policies and procedures
Review of training records
Review of Patient Guide
Review of Statement of Purpose
Discussion with registered persons

STANDARD A5	
Practising Privileges:	**Consultants and other practitioners may only use facilities in the establishment if they have been granted practising privileges.**

Origin Fertility Care had a policy and procedure in place in relation to practising privileges which outlined how they were granted. It was recommended that the policy and procedure is further developed to outline the arrangements for application, maintenance, suspension and withdrawal of practising privileges.

The inspector noted that a range of practising privileges agreements were in place for medical practitioners. Some agreements related to Kingsbridge Private Hospital which is also part of the 3fivetwo healthcare care; however they were not relevant to Origin Fertility Care. It is required that practising privileges agreements are developed that relate to the scope of practice of medical practitioners within Origin Fertility Care and this agreement should be signed, reviewed and updated every two years.

A review of the medical practitioners' personnel files confirmed:

- A written agreement between each medical practitioner and the establishment setting out the terms and conditions of granting practising privileges, however the agreement requires to be further developed as stated above
- There was evidence of current registration with the GMC
- The majority of medical practitioners are covered by the appropriate professional indemnity insurance
- The medical practitioners have provided evidence of experience in assisted conception services or anaesthetics
- There was evidence of ongoing professional development and continuing medical education that meet the requirements of the Royal Colleges and General Medical Council
- There was evidence of ongoing annual appraisal by a trained medical appraiser for the majority of medical practitioners
- Evidence of an appointed responsible officer

Some medical practitioners had not provided the establishment with their updated annual appraisal document or evidence of their current professional indemnity insurance. A requirement was made to address this.

Evidenced by:

Review of practising privileges policy and procedures
Review of practising privileges agreements
Review of medical practitioner's personnel files
Discussion with staff

STANDARD P5	
Qualifications and Training of Staff	**Infertility treatment is provided by trained, experienced and skilled staff.**

The responsible individual is the lead consultant within the establishment. Dr Heasley is a registered obstetrician and gynaecologist with experience in reproductive medicine and assisted conception services.

There is an identified embryology manager who is responsible for managing the laboratory services and appropriately skilled and trained embryology team.

A team of nursing staff are employed within the establishment. Arrangements are in place to ensure that nursing staff are appropriately skilled and competent in assisted conception techniques and procedures.

There is a process in place to review the registration details of all health and social care professionals.

The inspector reviewed the personnel records of nine medical practitioners, one embryologist, three registered nurses, two healthcare assistants and two administration staff.

The inspector observed during the review of personnel files that some staff within the establishment had commenced employment prior to their Access NI enhanced disclosure checks or two appropriate written references being received; a requirement was made to address this. However at the time of the inspection all staff within the establishment had a valid Access NI certificate in place.

The registered manager informed the inspector that recruitment and selection is undertaken by human resources at the company's head office, however in light of the findings all future recruitment and staff personnel files would be overseen directly by her.

The registered manager agreed to review all existing personnel files and ensure that they fully comply with the requirements of Schedule 2 of the Independent Health Care Regulations (Northern Ireland) 2005. A requirement was made in this regard.

Evidenced by:

Review of staff personnel files
Review of staffing
Discussion with registered manager

STANDARD P6	
Facilities for Assisted Conception Services:	**The facilities are appropriate for infertility treatment**

The inspector undertook a review of the premises which were found to be maintained to a good standard of maintenance and décor. The establishment was found to be clean, tidy and free from clutter. Recent refurbishment had been completed which included new carpets, paint, and frosting the glass door to the waiting room to enhance patient privacy.

There are dedicated rooms for specific purposes such as egg collection, production of semen specimens, treatment area for undertaking clinical procedures and laboratories for embryology procedures.

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

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

Evidenced by:

Review of the environment
Review of laboratories
Review of embryo and gamete storage facilities
Discussion with staff

STANDARD P7	
Patient Information and Decision Making:	**Patients are effectively involved in making decisions about treatment.**

The establishment has a written policy and procedure for ensuring that written information provided to patients seeking treatment includes risks and safeguarding confidentiality.

The establishment has written information available for prospective patients regarding the services provided, how to access these and the costs of treatments. This information is written in plain English and when required is available in an alternative language or format. As previously stated the registered manager agreed to review the price list for treatments to provide clarity of costs for patients.

There is a website for the establishment which provides information on the services available. The establishment is in the process of updating their website in relation to success rates to ensure that they fully comply with HFEA guidelines.

A patient information file is available within the waiting area of the establishment.

There are a range of information leaflets on each procedure carried out by the establishment and given to patients on consultation to enable them to make informed decisions regarding their treatment. During the consultation period, the procedures, risks, complications and expected outcomes are discussed with each individual patient.

There is a comprehensive range of standard operating procedures, protocols and clinical guidelines in place. These guidelines relate to all areas of the provision of safe, effective, patient-centred care and adhere to the HFEA Code of Practice and other national best practice guidelines.

All publicity material used by the establishment conforms to the guidelines of the HFEA, General Medical Council (GMC), and the code of professional conduct of the Nursing and Midwifery Council (NMC).

Evidenced by:

Review of policies and procedures
Review of information provided to patients
Review of standard operating procedures and protocols
Discussion with staff

STANDARD P9	
Management of Patients:	**Patient care is managed, delivered and reviewed by professional staff who provide care safely and effectively.**

The establishment has a current licence with the Human Fertilisation Embryology Authority (HFEA) which is subject to ongoing regulatory review. The HFEA recently undertook a licensing inspection and have made a recommendation to the licensing committee to renew the licence of the establishment for three years.

There are a range of treatment protocols in place for the management of patients receiving assisted conception services which have been developed and agreed by all professionals within the establishment. Systems are in place to regularly review protocols and discuss patient outcomes.

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

There are written protocols in place for the close monitoring of patients, in order to avoid unnecessary complications including multiple pregnancy. There are up to date elective single embryo transfer (eSET) protocols setting out the number of embryos placed in a woman in any one cycle that comply with the HFEA's Code of Practice.

The inspector met with the lead clinician, embryology manager and nursing staff to discuss protocols and procedures. The staff all spoke positively regarding the establishment, felt valued as members of the team and supported by management.

No patients wished to meet with the inspector during the inspection.

The embryology manager informed the inspector that he is currently reviewing and updating information provided to patients who wish to use donor sperm to help patients make informed decisions.

There are weekly clinical meetings involving the nurses, doctors and members of the embryology team to discuss the management of patients.

The establishment has introduced new governance arrangements and developed a quality committee which feeds into the 3fivetwo Healthcare corporate governance committee.

The inspector reviewed the care records of six patients. The establishment hold 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:

- Record of consultation with medical practitioner
- Record of consultation with other health care professionals

- Signed consent forms
- Patient care plan
- Patient treatment plan
- Embryology records
- Patient medication regime

The inspector noted that the templates used within the care records to document the treatment cycle, sperm storage and embryo storage did not include a section for the staff member completing the records to sign. A recommendation was made to address this.

The medical practitioners record the outcome of assisted conception procedures within the care records. The inspector advised adding nursing notes to care records in relation to procedures undertaken.

The following meetings take place and minutes of these meetings were available for review:

- Management review meetings
- Nurse meetings
- Team meetings
- Quality meetings

The inspector advised including a signed attendance with the minutes of each meeting.

The registered manager provides a weekly 'director's report' to the 'Board of Directors, outlining the number of patient treatment cycles undertaken and any other issues. The inspector reviewed the director reports as part of the inspection process.

Evidenced by:

Review of patient care records
Review of treatment protocols
Review of standard operating procedures
Review of management minutes
Review of audits
Discussion with staff

7.0 Quality Improvement Plan

The details of the Quality Improvement Plan appended to this report were discussed with Ms Jennifer McLaughlin and Mr Glenn Best as part of the inspection process.

The timescales for completion commence from the date of inspection.

The registered provider / manager is required to record comments on the Quality Improvement Plan.

Matters to be addressed as a result of this inspection are set in the context of the current registration of your premises. The registration is not transferable so that in the event of any future application to alter, extend or to sell the premises the RQIA would apply standards current at the time of that application.

Enquiries relating to this report should be addressed to:

Jo Browne
The Regulation and Quality Improvement Authority
9th Floor
Riverside Tower
5 Lanyon Place
Belfast
BT1 3BT

_____ _____

Jo Browne **Date**
Inspector / Quality Reviewer

The Regulation and Quality Improvement Authority

Quality Improvement Plan

Announced Inspection

Origin Fertility Care

27-28 May 2014

The areas where the service needs to improve, as identified during this inspection visit, are detailed in the inspection report and Quality Improvement Plan.

The specific actions set out in the Quality Improvement Plan were discussed with Ms Jennifer McLaughlin and Mr Glenn Best during the inspection visit.

Any matters that require completion within 28 days of the inspection visit have also been set out in separate correspondence to the registered persons.

Registered providers / managers should note that failure to comply with regulations may lead to further enforcement and/ or prosecution action as set out in The HPSS (Quality, Improvement and Regulation) (Northern Ireland) Order 2003.

It is the responsibility of the registered provider / manager to ensure that all requirements and recommendations contained within the Quality Improvement Plan are addressed within the specified timescales.

Matters to be addressed as a result of this inspection are set in the context of the current registration of your premises. The registration is not transferable so that in the event of any future application to alter, extend or to sell the premises the RQIA would apply standards current at the time of that application.

STATUTORY REQUIREMENTS

This section outlines the actions which must be taken so that the registered person/s meets legislative requirements based on The HPSS (Quality, Improvement and Regulation) (Northern Ireland) Order 2003, The Independent Health Care Regulations (Northern Ireland) 2005 and The Regulation and Improvement Authority (Independent Health Care) (Fees and Frequency of Inspections) (Amendment) Regulations (Northern Ireland) 2011.

NO.	REGULATION REFERENCE	REQUIREMENTS	NUMBER OF TIMES STATED	DETAILS OF ACTION TAKEN BY REGISTERED PERSON(S)	TIMESCALE
1	8 (1)	The registered manager must ensure that a Patient Guide is developed which complies with regulation 8 of the Independent Health Care Regulations (Northern Ireland) 2005. **Ref: Standard C10**	One	The patient guide is currently under review and will be complete by 28/7/14	Within two months
2	9A (1) (i) The Regulation and Improvement Authority (Independent Health Care) (Fees and Frequency of Inspections) (Amendment) Regulations (Northern Ireland) 2011	The registered manager must ensure that practising privileges agreements are developed that relate to the scope of practice of medical practitioners within Origin Fertility Care and this agreement should be signed, reviewed and updated every two years. **Ref: Standard A5**	One	Practising privileges agreements have been developed and will be reviewed and signed every two years	Within three months
3	19 (2) (d)	The registered manager must ensure that records are retained of the most recent appraisal documentation and professional indemnity insurance for all medical practitioners who are granted practising privileges. **Ref: Standard A5**	One	All records have been updated in regards to appraisals and indemnity insurance. This will be continually monitored	Within two months

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NO.	REGULATION REFERENCE	REQUIREMENTS	NUMBER OF TIMES STATED	DETAILS OF ACTION TAKEN BY REGISTERED PERSON(S)	TIMESCALE
4	19 (2) (d)	The registered manager must ensure that all staff have all the information required by Schedule 2 of the Independent Health Care Regulations (Northern Ireland) 2005 in place prior to commencing employment. All existing personnel files must be reviewed any deficits addressed. **Ref: Standard P5**	One	All HR folders are now kept in Origin Fertility Care and overseen directly by the Registered Manager. All HR folders have been reviewed and in future all files will be signed off by the Registered Manager prior to the commencement of employment.	Immediately and ongoing

RECOMMENDATIONS

These recommendations are based on the DHSSPS draft Independent Health Care Minimum Standards for Hospitals and Clinics, research or recognised sources. They promote current good practice and if adopted by the registered person/manager may enhance service, quality and delivery.

NO.	MINIMUM STANDARD REFERENCE	RECOMMENDATIONS	NUMBER OF TIMES STATED	DETAILS OF ACTION TAKEN BY REGISTERED PERSON(S)	TIMESCALE
1	C4.1	The registered manager should include the date on the patient satisfaction questionnaire to facilitate the collection of data and to include in the summary report the action plan implemented by the clinic to address any issues identified. **Ref: Standard C4**	One	The date the pat sat was given in will now be stamped on (month only as reviewed monthly). Any comments requiring action will be taken through the monthly meeting and action plan designed for each.	Immediately and ongoing
2	C10.6	The registered manager should update the Statement of Purpose as outlined in the main body of the report. **Ref: Standard C10**	One	The Statement of Purpose has been amended to reflect the report findings.	Within two months
3	A5.1	The registered manager should further develop the practising privileges policy to outline the arrangements for the application, maintenance, suspension and withdrawal of practising privileges. **Ref: Standard A5**	One	The practising privileges policy has been amended to include all of the mentioned.	Within two months

RECOMMENDATIONS

These recommendations are based on the DHSSPS draft Independent Health Care Minimum Standards for Hospitals and Clinics, research or recognised sources. They promote current good practice and if adopted by the registered person/manager may enhance service, quality and delivery.

NO.	MINIMUM STANDARD REFERENCE	RECOMMENDATIONS	NUMBER OF TIMES STATED	DETAILS OF ACTION TAKEN BY REGISTERED PERSON(S)	TIMESCALE
4	C17.2	The registered manager should ensure that the templates used to document the treatment cycle, sperm storage and embryo storage has a section for the staff member completing the documents to sign. **Ref: Standard P9**	One	These documents have been updated to include an area to sign.	Within one month and ongoing

The registered provider/manager is required to detail the action taken, or to be taken, in response to the issues raised in the Quality Improvement Plan. The Quality Improvement Plan is then to be signed below by the registered provider and registered manager and returned to:

Jo Browne
The Regulation and Quality Improvement Authority
9th floor
Riverside Tower
5 Lanyon Place
Belfast
BT1 3BT

SIGNED: _____ **SIGNED:** _____

NAME: R N HEASLEY **NAME:** Jennifer McLaughlin
Registered Provider **Registered Manager**

DATE 7/7/14 **DATE** 7/7/14

	QIP Position Based on Comments from Registered Persons	Yes	No	Inspector	Date
A	Quality Improvement Plan response assessed by inspector as acceptable	✓		JBrowne	22/7/14
B	Further information requested from provider		✓	JBrowne	22/7/14

The Regulation and Quality Improvement Authority

Pre-Inspection Self-Assessment
Assisted Conception Services

Name of Establishment:	**Origin Fertility Clinic**
Establishment ID No:	**10635**
Date of Inspection:	**27-28 May 2014**
Inspector's Name:	**Jo Browne**
Inspection No:	**16603**

THE REGULATION AND QUALITY IMPROVEMENT AUTHORITY
9th floor Riverside Tower, 5 Lanyon Place, Belfast, BT1 3BT
Tel: 028 9051 7500 Fax: 028 9051 7501

1.0 Introduction

The Regulation and Quality Improvement Authority (RQIA) is empowered under The Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003 to inspect independent health care establishments. A minimum of one inspection per year is required.

The aim of inspection is to examine the policies, procedures, practices and monitoring arrangements for the provision of assisted conception services, and to determine the provider's compliance with the following:

- The HPSS (Quality, Improvement and Regulation) (Northern Ireland) Order 2003
- 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
- The Department of Health, Social Services and Public Safety's (DHSSPS) draft Independent Health Care Minimum Standards for Hospitals and Clinics

Other published standards which guide best practice may also be referenced during the inspection process.

2.0 Self-Assessment

Committed to a culture of learning, RQIA has developed an approach which uses self-assessment.

Where asked in the self-assessment you are required to indicate a yes or no response. You are also asked to provide a brief narrative in the "text box" where applicable.

Following completion of the self-assessment, please return to RQIA by the date specified.

The self-assessment will be appended to the report and made available to the public. No amendments will be made by RQIA to your self-assessment response.

3.0 Self-Assessment Tool

Management of Operations

	YES	NO
Has any structural change been made to the premises since the previous inspection?		✓
Have any changes been made to the management structure of the establishment since the previous inspection?	✓	
Yes, please comment Sarah Marks has moved to KPH. Jennifer McLaughlin is Operations Manager. Jacqui Taylor has became Nurse Lead		

Policies and Procedures

	YES	NO
Does the establishment have a policy and procedure manual in place which is reviewed at least every 3 years or as changes occur?	✓	
Are the policies and procedures for all operational areas in line with legislation, HFEA Code of Practice and best practice guidelines?	✓	
Do all policies and procedures contain the date of issue, date of review and version control?	✓	
Are all policies and procedures ratified by the registered person?	✓	
No, please comment		

Records Management

	YES	NO
Does the establishment have a policy and procedure in place for the creation, storage, transfer, retention and disposal of and access to records in line with the legislation?	✓	
Are care records maintained for each individual patient?	✓	
Are arrangements in place to securely store patient care records?	✓	
No, please comment		

Patient Partnerships

	YES	NO
Does the establishment have systems in place to obtain the views of patients regarding the quality of treatment, care and information provided?	✓	
Does the establishment make available a summary report of patient feedback to patients and other interested parties?	✓	
No, please comment		

Resuscitation

	YES	NO
Does the establishment have a resuscitation policy and procedure in place which is in line with the Resuscitation Council (UK) guidance?	✓	
Is resuscitation equipment readily accessible in all clinical areas?	✓	
Are arrangements in place to ensure resuscitation equipment is checked regularly and restocked to ensure all equipment remains in working order and suitable for use at all times?	✓	
No, please comment		

Complaints

	YES	NO
Does the establishment have a complaints policy and procedure in place which is in line with the legislation and the DHSSPS guidance on complaints handling in regulated establishments and agencies April 2009?	✓	
Are all complaints documented, fully investigated and have outcomes recorded in line with the legislation and the establishment's complaints policy and procedure?	✓	
No, please comment		

Incidents

	YES	NO
Does the establishment have an incident policy and procedure in place which complies with the legislation and RQIA guidance?	✓	
Are all incidents reported, documented, fully investigated and have outcomes recorded in line the legislation, RQIA guidance and the establishment's policy and procedure?	✓	
No, please comment		

Infection Prevention and Control

	YES	NO
Does the establishment have an infection prevention and control policy and procedure in place?	✓	
Are appropriate arrangements in place to decontaminate equipment between patients?	✓	
Does the establishment use single use surgical instruments?	✓	
Does the establishment have appropriate service level agreements in place for the sterilisation of surgical equipment?	✓	
No, please comment		

Recruitment of staff

	YES	NO
Does the establishment have a recruitment and selection policy and procedure in place?	✓	
Is all information outlined in Schedule 2 of the Independent Health Care Regulations (Northern Ireland) 2005 retained and available for inspection?	✓	
Have all staff (recruited since registration with RQIA) had an enhanced AccessNI disclosure undertaken, prior to commencing employment?	✓	
No, please comment NB/ training can begin before Access NI through, but employment does not start		

Staffing

	YES	NO
Is there appropriate numbers of suitably qualified, skilled and experienced staff on duty to meet the assessed needs of the patients and the operational requirements of the establishment?	✓	
No, please comment		

Mandatory Training

	YES	NO
Are arrangements in place for all new staff to participate in an induction programme?	✓	
Are training records available which confirm that the following mandatory training has been undertaken:		
	YES	**NO**
Infection prevention and control training – annually	✓	
Fire safety – annually	✓	
Basic life support – annually	✓	
If No, please comment		

Appraisal

	YES	NO
Does the establishment have an appraisal policy and procedure in place?	✓	
Are systems in place to provide recorded annual appraisals for staff?	✓	
No, please comment		

Medical Practitioners, Nurses & Allied Health Professionals

	YES	NO
Are systems in place to ensure medical, nursing staff and allied health professionals have a current registration with their relevant professional bodies?	✓	
Are policies and procedures in place to grant, review and withdraw practising privilege agreements for medical practitioners?	✓	
Are practising privileges agreements in place for all medical practitioners? (where applicable)	✓	
Are systems in place to ensure that medical practitioners have up to date professional indemnity insurance?	✓	
Are systems in place to ensure that medical practitioners have an annual appraisal undertaken with a trained medical appraiser?	✓	
Are arrangements in place to ensure medical practitioners have a responsible officer?	✓	
No, please comment		

Assisted Conception Services

	YES	NO
Are the service facilities and layout of the establishment designed to promote patient confidentiality?	✓	
Is there a dedicated room for the production of semen samples?	✓	
Are there protocols in place for the various services provided within the establishment?	✓	
Is there secure, atmospheric and temperature controlled storage for gametes, embryos and reagents?	✓	
Are there guidelines in place for diagnosis and infertility treatment which are in line with current best practice and HFEA Code of Practice?	✓	
Are patients provided with written information regarding the various types of fertility treatment available, the risks, complications and expected outcomes?	✓	
Are there arrangements in place for providing counselling and support to patients?	✓	
Are there suitable arrangements in place to provide appropriate pre-		

operative, peri-operative and post-operative care for patients.	✓	
Are there suitable arrangements in place for patient review?	✓	
Are there suitable arrangements in place for patients to contact the establishment out of hours?	✓	
No, please comment		

4.0 Declaration

To be signed by the registered provider or registered manager for the establishment.

I hereby confirm that the information provided above is, to the best of my knowledge, accurately completed.

Name	Signature	Designation	Date
Jennifer McLaughlin	J. McLaughlin	Operations Manager	28/4/14

P. NHEASLEY
(Responsible person)