GCRM Belfast
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Inspectors: Jo Browne & Winnie Maguire
Inspection ID: IN022125

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Announced Care Inspection
of
GCRM Belfast

14 September 2015

The Regulation and Quality Improvement Authority
9th Floor Riverside Tower, 5 Lanyon Place, Belfast, BT1 3BT
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1. Summary of Inspection

An announced care inspection took place on 14 September 2015 from 10.00 to 15.25. Overall on the day of inspection the standards inspected were found to be generally safe, effective and compassionate. One area for improvement was identified and is set out in the Quality Improvement Plan (QIP) within this report.

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's (DHSPPS) Minimum Care Standards for Healthcare Establishments 2014.

1.1 Actions/ Enforcement Taken Following the Last Inspection

Other than those actions detailed in the previous QIP there were no further actions required to be taken following the last inspection.

1.2 Actions/ Enforcement Resulting from this Inspection

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

1.3 Inspection Outcome

	Requirements	Recommendations
Total number of requirements and recommendations made at this inspection	1	0

The details of the QIP within this report were discussed with the Ms Donna Tennant, registered manager, as part of the inspection process. The timescales for completion commence from the date of inspection.

2. Service Details

Registered Organisation/ Registered Person: GCRM Belfast Ltd Dr Anthony Traub	**Registered Manager:** Ms Donna Tennant
Person in Charge of the establishment at the Time of Inspection: Ms Donna Tennant	**Date Registered:** 14 November 2013
Categories of Care: PT (IVF) - Prescribed techniques or prescribed technology: establishments providing in vitro fertilisation	

3. Inspection Focus

The inspection sought to assess progress with the issues raised during and since the previous inspection and to determine if the following standards have been met:

- Standard 4 – Dignity, Respect and Rights
- Standard 5 – Patient and Client Partnerships
- Standard 7 – Complaints
- Standard 11 – Practising Privileges
- Standard 44 – Facilities for Assisted Conception Services
- Standard 45 – Information and Decision Making for Patients and Clients Undergoing Fertility Treatment
- Standard 47 – Management of Patients and Clients Undergoing Fertility Treatment

Other areas inspected: Incidents, insurance arrangements and RQIA registration.

4. Methods/ Process

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

Prior to the inspection the following records were analysed: pre-inspection information and complaints return.

During the inspection the inspectors met with the registered manager, a senior nurse, an embryologist and the quality co-ordinator. The inspectors also briefly spoke with a medical practitioner and a nursing axillary.

The following records were examined during the inspection:

- Ten patient care records
- Policies and procedures
- Patient feedback questionnaires
- Incident/ accident records
- Audits
- Medical treatment protocols
- Complaints records
- Five personnel files
- Standard operating procedures
- Minutes of meetings

5. The Inspection

5.1 Review of Requirements and Recommendations from Previous Inspection

The previous inspection of the establishment was an announced care inspection dated 27 October 2014. The completed QIP was returned and approved by the care inspectors.

5.2 Review of Requirements and Recommendations from the last Care Inspection dated 27 October 2014

Previous Inspection Recommendations		Validation of Compliance
Recommendation 1 **Ref**: Standard 7.1 **Stated:** First time	The registered manager should ensure that the role of RQIA and HFEA are included as regulators within the complaints procedure as outlined in the main body of the report.	**Met**
	Action taken as confirmed during the inspection: The complaints policy and procedure were reviewed and found to be updated to include the role of RQIA and HFEA as regulators.	
Recommendation 2 **Ref**: Standard 10.3 **Stated:** First time	The registered manager should check the Northern Ireland Adverse Incident Centre (NIAIC) website on a regular basis, download and action any alerts which are relevant to the service. A record of the visits made to the website should be retained.	**Met**
	Action taken as confirmed during the inspection: Review of documentation and discussion confirmed that the registered manager checks the NIAIC website on a weekly basis and logs the visits and the action taken.	
Recommendation 3 **Ref**: Standard 44 **Stated:** First time	The registered manager should ensure that clean and used sharps containers are stored in separate locations.	**Met**
	Action taken as confirmed during the inspection: It was observed that clean and used sharps containers are stored in separate and appropriate locations within the premises.	

5.3 Standard 4 – Dignity, Respect and Rights

Is Care Safe?

Discussion regarding the consultation and treatment process, with the registered manager and staff confirmed that patients' modesty and dignity is respected at all times. Consultations and treatments are provided within private room with the patient and medical practitioner, nursing staff or embryologist present.

Observations confirmed that patient care records were stored securely in within a locked file room.

Is Care Effective?

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

Patients and their significant others meet with staff providing the service and are fully involved in decisions regarding their treatment. Patients' wishes are respected and acknowledged by the establishment.

Is Care Compassionate?

Discussion with staff and review of ten 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.

Areas for Improvement

No areas for improvement were identified during the inspection.

Number of Requirements:	**0**	**Number of Recommendations**:	**0**

5.4 Standard 5 – Patient and Client Partnership

Is Care Safe?

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

The information from patients' comments are collected in an anonymised format, summarised and used by the establishment to make improvements to services.

Is Care Effective?

GCRM Belfast 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.

The establishment issued feedback questionnaires to patients. Review of 40 completed questionnaires and two quarterly summary reports found that patients were highly satisfied with the quality of treatment, information and care received.

Some of the comments received included:

- "Great first impressions – lovely staff"
- "We received fantastic treatment all staff are fabulous"
- "The person centred approach was brilliant"
- "Overall excellent service"
- "All staff very courteous and professional from reception to discussing with consultant
- "Made to feel at ease by everyone"
- "We were made to feel like people and not just a number"
- "Everything was explained in great detail and I had no concerns about asking questions or picking up the phone"
- "All staff made a stressful experience as pleasant as possible"
- "Extremely professional, supportive and knowledgeable"

The information received from the patient feedback questionnaires is collated into a quarterly summary report which is made available to patients and other interested parties to read in the Patient Guide. The inspectors advised including the arrangements on how to obtain a copy of the summary report within the Patient Guide and appending the actual report to the back of the document to prevent the whole document being reprinted quarterly.

It was confirmed through review of management meeting minutes and discussion with the registered manager and quality co-ordinator that comments received from patients are reviewed by senior management and an action plan is developed and implemented to address any issues identified.

Is Care Compassionate?

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.

Areas for Improvement

No areas for improvement were identified during the inspection.

Number of Requirements:	**0**	**Number of Recommendations**:	**0**

5.5 Standard 7 - Complaints

Is Care Safe?

Review of complaint records and found that complaints are investigated and responded to within 28 working days (in line with regulations) or if this is not possible, complainants are kept informed of any delays and the reason for this.
Discussion with the registered manager confirmed that information from complaints is used to improve the quality of services.

Is Care Effective?

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.

The registered manager demonstrated a good understanding of complaints management. Discussion with staff evidenced that they know how to receive and deal with complaints.

Review of the complaints register and complaints records evidenced that all complaints were well documented, fully investigated and had outcomes recorded in line with the complaints procedure and legislation. Complaints records were observed to be stored securely in line with data protection legislation.

A complaints audit is undertaken. The audit information is used to identify trends and enhance services provided as part of the establishment's quality assurance arrangements.

Is Care Compassionate?

A copy of the complaints procedure is provided to patients and to any person acting on their behalf. The complaints procedure is also contained within the Patient Guide; copies of which are available in the reception area of the premises for patients and/ or their significant others to read.

The complainant is notified of the outcome and action taken by the establishment to address any concerns raised.

Areas for Improvement

No areas for improvement were identified during the inspection.

Number of Requirements:	**0**	**Number of Recommendations**:	**0**

5.6 Standard 11 – Practising Privileges

Is Care Safe?

Review of the personnel files of five medical practitioners and confirmed:

- evidence of confirmation of identity;
- evidence of current registration with the General Medical Council (GMC);
- the medical practitioners are covered by the appropriate professional indemnity insurance;
- the medical practitioners have provided evidence of experience relevant to their scope of practice;
- evidence of enhanced Access NI disclosure check;
- there was evidence of ongoing professional development and continuing medical; education that meets the requirements of the Royal Colleges and GMC to ensure the medical practitioners can safely and competently undertake the treatments and services they offer;
- there was evidence of ongoing annual appraisal by a trained medical appraiser; and
- a responsible officer had been appointed.

Arrangements are in place to support medical practitioners, with a licence to practice, to fulfil the requirements for revalidation through:

- acting as a designated body where required under The Responsible Officer Regulations (NI) 2010;
- providing an annual appraisal in line with the GMC's appraisal and assessment framework, for medical practitioners employed directly by the establishment; or
- providing sufficient information to the responsible officer to support their revalidation, for medical practitioners who are not an employee.

Is Care Effective?

GCRM Belfast has a policy and procedure in place which outlines the arrangements for the application, granting, maintenance, suspension and withdrawal of practising privileges. The practising privileges agreement defines the scope of practice for each individual medical practitioner.

All practising privileges are reviewed and approved by the medical advisory committee (MAC) prior to privileges being granted.

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

Is Care Compassionate?

The practising privileges agreement includes arrangements to ensure patients and/ or their significant others are treated with dignity and respect at all times.

Areas for Improvement

No areas for improvement were identified during the inspection.

Number of Requirements:	**0**	**Number of Recommendations**:	**0**

5.7 Standard 44 – Facilities for Assisted Conception Services

Is Care Safe?

The premises were reviewed and found to be maintained to an excellent standard of maintenance and décor. The establishment was found to be clean, tidy and free from clutter.

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

Is Care Effective?

The establishment has three private rooms with en-suite facilities, a dedicated room for the production of semen specimens, fertility treatment suite, cryostorage, embryology and andrology laboratories.

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

The following protocols were reviewed:

- Delivery of specimens to the laboratory
- Labelling of material from individual patients to ensure unique identification of a patient's material and records at all stages of the treatment
- Storage and handling of liquid nitrogen

Is Care Compassionate?

The facilities and layout of the establishment are designed to ensure that the need for patient privacy is optimised.

Areas for Improvement

No areas for improvement were identified during the inspection.

Number of Requirements:	**0**	**Number of Recommendations**:	**0**

5.7 Standard 45 – Information and Decision Making for Patients and Clients Undergoing Fertility Treatment

Is Care Safe?

The establishment is registered with RQIA and licenced by the Human Fertilisation Embryology Authority (HFEA) to provide assisted conception services. The inspectors reviewed the HFEA licence which is due for renewal in November 2015. The registered manager confirmed that following a recent HFEA inspection CGRM Belfast are being recommended for a four year licence.

During the consultation period, the procedures, risks, complications and expected outcomes are discussed with each individual patient.

Is Care Effective?

There are 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, are evidence based and in line with other national best practice guidelines. A range of these documents were reviewed as part of the inspection process.

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

There is written information available for prospective patients regarding the services provided, how to access these and the costs of treatments. The information sets out the factors that will be considered by the establishment before treatment can be confirmed. There is also a website for the establishment which provides information on the services available.

All publicity material used by the establishment conforms to the guidelines of the HFEA, GMC and “The Code” of the Nursing and Midwifery Council (NMC).

Is Care Compassionate?

There are a wide 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.

All information provided to patients and/or their significant others is written in plain English and when required can be made available in an alternative language or format. The registered manager confirmed that an interpreter can be provided if necessary for non-English speaking patients.

Areas for Improvement

No areas for improvement were identified during the inspection.

Number of Requirements:	**0**	**Number of Recommendations**:	**0**

5.8 Standard 47 – Management of Patients and Clients Undergoing Fertility Treatment

Is Care Safe?

The protocols for the prevention and management of ovarian hyper stimulation syndrome (OHSS), 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 pregnancies. 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.

Is Care Effective?

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 registered manager confirmed that they do not provide semen cryostorage in cases where men are undergoing medical treatment likely to make them infertile. Patients requiring this service would be referred to the Regional Fertility Clinic in Belfast.

The registered manager confirmed that appropriate arrangements are in place to report to the Northern Ireland Maternal and Child Health (NIMACH). The incident policy was amended during the inspection to include these arrangements.

The inspectors met with the registered manager, a senior nurse, embryologist and quality co-coordinator to discuss protocols and procedures. The staff all spoke positively regarding the establishment, felt valued as members of the team and supported by management.
The inspectors briefly spoke with a medical practitioner and nursing auxiliary.

There are weekly clinical meetings involving the medical practitioners, nursing staff and members of the embryology team to discuss the management of patients.

Ten patient care records were reviewed. 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:

- Patient registration form
- Patient health questionnaire
- Pre-Operative and Post-Operative Checklists
- Screening results
- Patient treatment plan including medication regime
- Copy of the treatment plan schedule which was provided to the patient
- Range of signed consents forms for each procedure
- Signed patient contract
- HFEA consent
- Intra-operative records
- Record of consultations with medical practitioners and nursing staff
- Embryology records
- Follow up letters to patient's GP or referring medical practitioners, where appropriate

Systems are in place to audit the patient care records as outlined within the establishment's quality assurance systems. The most recent audit relating to patient care records in August 2015 was reviewed and an excellent compliance rate was noted.

Is Care Compassionate?

The policies, procedures and protocols reviewed were found to be patient centred and reflected the individual circumstances of patients accessing the services.

Discussion with staff confirmed that they were aware of the complex factors involved in assisted conception services and had received training on delivering services in a compassionate and sensitive manner.

Patients were notified of the inspection however none wished to meet with the inspectors.

Areas for Improvement

No areas for improvement were identified during the inspection.

Number of Requirements:	**0**	**Number of Recommendations**:	**0**

5.9 Additional Areas Examined

5.10.1 Incidents

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

Discussion with the registered manager and review of incident management found that incidents were well documented, fully investigated and had outcomes recorded. However, it was noted that two incidents of a similar nature had been reported to the HFEA and not to RQIA. During discussion with the registered manager it was established that it was a misunderstanding and she did not think that particular type of incident required to be reported to RQIA. Types of incidents reportable to RQIA were discussed and advice given. The incidents were retrospectively reported to RQIA during the inspection.

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

5.10.2 RQIA registration and Insurance Arrangements

Review of documentation and discussion with the registered manager regarding the insurance arrangements within the establishment confirmed that current insurance policies were in place. The RQIA certificate of registration was clearly displayed in the reception area of the premises.

Areas for Improvement

Incidents should be reported to RQIA in line with the regulation 28 of The Independent Healthcare Regulations (Northern Ireland) 2005.

Number of Requirements	**1**	**Number Recommendations**:	**0**

6.0 Quality Improvement Plan

The issue identified during this inspection are detailed in the QIP. Details of this QIP were discussed with Ms Donna Tennant, registered manager, as part of the inspection process. The timescales commence from the date of inspection.

The registered person/manager should note that failure to comply with regulations may lead to further enforcement action including possible prosecution for offences. It is the responsibility of the registered person/manager to ensure that all requirements and recommendations contained within the QIP 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.

6.1 Statutory Requirements

This section outlines the actions which must be taken so that the registered person meets legislative requirements based on 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.

6.2 Recommendations

This section outlines the recommended actions based on research, recognised sources and The Department of Health, Social Services and Public Safety's (DHSPPS) Minimum Care Standards for Healthcare Establishments. They promote current good practice and if adopted by the registered person may enhance service, quality and delivery.

6.3 Actions Taken by the Registered Manager/Registered Person

The QIP should be completed by the registered person/ registered manager and detail the actions taken to meet the legislative requirements stated. The registered person will review and approve the QIP to confirm that these actions have been completed. Once fully completed, the QIP will be returned to Independent.Healthcare@rqia.org.uk and assessed by the inspector.

It should be noted that this inspection report should not be regarded as a comprehensive review of all strengths and weaknesses that exist in the establishment. The findings set out are only those which came to the attention of RQIA during the course of this inspection. The findings contained within this report do not absolve the registered person/manager from their responsibility for maintaining compliance with minimum standards and regulations. It is expected that the requirements and recommendations set out in this report will provide the registered person/manager with the necessary information to assist them in fulfilling their responsibilities and enhance practice within the establishment.

Quality Improvement Plan	
Statutory Requirements	
Requirement 1 **Ref:** Regulation 28 (1) (2) **Stated: First time** **To be Completed by: 14 September 2015**	The registered persons must ensure that all incidents are reported to RQIA in line with regulation 28 of The Independent Healthcare Regulations (Northern Ireland) 2005. **Response by Registered Person(s) Detailing the Actions Taken:** ALL BREACHES OF CONFIDENTIALITY WILL NOW BE REPORTED TO THE RQIA

Registered Manager Completing QIP		**Date Completed**	19/10/15
Registered Person Approving QIP		**Date Approved**	19/10/15
RQIA Inspector Assessing Response		**Date Approved**	26/10/15

Please ensure the QIP is completed in full and returned to** independent.healthcare@rqia.org.uk **from the authorised email address