Announced Care Inspection Report
11 December 2017

GCRM Belfast

Type of Service: Independent Hospital (IH) – Fertility Services and Assisted Conception
Address: Edgewater House, Edgewater Business Park, Edgewater Road, Belfast BT3 9JQ
Tel No: 02890781335
Inspectors: Winifred Maguire & Carmel McKeegan

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 service from their responsibility for maintaining compliance with legislation, standards and best practice.

1.0 What we look for

2.0 Profile of service

This is a registered independent hospital that provides fertility services and assisted conception.

3.0 Service details

Organisation/Registered Provider: GCRM Belfast Ltd **Responsible Individual:** Dr Anthony Traub	**Registered Manager:** Ms Donna Tennant
Person in charge at the time of inspection: Ms Donna Tennant	**Date manager registered:** 14 November 2013
Categories of care: Independent Hospital (IH) Prescribed technologies (PT) In vitro Fertilisation Private Doctor (PD)	

4.0 Inspection summary

An announced inspection took place on 11 December 2017 from 10.00 to 16.00.

This inspection was underpinned by The Health and Personal Social Services (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 and the Department of Health, Social Services and Public Safety (DHSSPS) Minimum Care Standards for Independent Healthcare Establishments (July 2014).

The inspection assessed progress with any areas for improvement identified during and since the last care inspection and to determine if the establishment was delivering safe, effective and compassionate care and if the service was well led.

Examples of good practice were evidenced in all four domains. These related to: patient safety in respect of staff training and development; recruitment; safeguarding; the provision of assisted conception services; resuscitation arrangements and the management of medical emergencies; infection prevention control; and the environment. Other examples included: the management of the patients' care pathway; communication; records management, practising privileges arrangements and engagement to enhance the patients' experience.

There were no areas requiring improvement were identified during this inspection.

Patients who submitted questionnaire responses indicated a high level of satisfaction with the services provided in GRCM Belfast.

The findings of this report will provide the establishment with the necessary information to assist them to fulfil their responsibilities, enhance practice and patients' experience.

4.1 Inspection outcome

	Regulations	Standards
Total number of areas for improvement	0	0

This inspection resulted in no areas for improvement being identified. Findings of the inspection were discussed with Ms Donna Tennant, 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.

4.2 Action/enforcement taken following the most recent care inspection dated 30 November 2016

Other than those actions detailed in the QIP no further actions were required to be taken following the most recent care inspection on 30 November 2016.

5.0 How we inspect

Prior to the inspection a range of information relevant to the establishment was reviewed. This included the following records:

- notifiable events since the previous care inspection
- the registration status of the establishment
- written and verbal communication received since the previous care inspection
- the returned QIP from the previous care inspection
- the previous care inspection report
- submitted complaints declaration

Questionnaires were provided to patients and staff prior to the inspection by the establishment on behalf of RQIA. Returned completed patient and staff questionnaires were also analysed prior to the inspection.

A poster informing patients that an inspection was being conducted was displayed.

During the inspection the inspector met with Ms Donna Tennant, registered manager; the laboratory director; a trainee embryologist; two registered nurses and the quality manager. . A tour of the premises was also undertaken.

A sample of records was 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

The findings of the inspection were provided to the person in charge at the conclusion of the inspection.

6.0 The inspection

6.1 Review of areas for improvement from the most recent inspection dated 12 October 2017

The most recent inspection of the establishment was an announced medicines management inspection and there were no areas of improvement identified as result of the inspection.

6.2 Review of areas for improvement from the last care inspection dated 30 November 2016

Areas for improvement from the last care inspection		
Action required to ensure compliance with The Minimum Care Standards for Independent Healthcare Establishments (July 2014)		**Validation of compliance**
Area for improvement 1 **Ref:** Standard 16.2 **Stated:** First time	Submit an application to RQIA for a variation of registration to include the provision of a private doctor service.	**Met**
	Action taken as confirmed during the inspection: An application was submitted to RQIA for a variation of registration to include the provision of a private doctor service. The variation of registration for private doctor service was approved by RQIA.	

6.3 Inspection findings

6.4 Is care safe?

Avoiding and preventing harm to patients and clients from the care, treatment and support that is intended to help them.

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

Review of the submitted staffing information and discussion with Ms Tennant confirmed that three staff have been recruited since the previous inspection. Review of the personnel files for these staff demonstrated 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. Ms Tennant confirmed adult safeguarding training, to be provided by Volunteer Now, had been arranged for January 2018.

Policies and procedures were in place for the safeguarding and protection of adults and children at risk of harm. 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.

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 the lead clinician, 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 pregnancies.

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 staff who demonstrated a detailed knowledge on the matter.

It was confirmed the establishment has a 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 is also a weekly meeting to review and discuss patient outcomes.

Resuscitation and 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 emergency trolley and a written record retained of daily checks carried out by a designated member of staff.

Staff spoken with demonstrated knowledge and understanding of managing resuscitation and other medical emergencies and 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 were clear lines of accountability for infection prevention and control (IPC). The establishment has a designated IPC lead nurse.

A range of information for patients and staff regarding hand washing techniques was available.

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
- hand hygiene

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

There were a range of IPC policies and procedures in place which were 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 very high standard of maintenance and décor.

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

There were 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

Four patients submitted questionnaire responses to RQIA. All indicated that they felt safe and protected from harm and were very satisfied with this aspect of care. Comments provided included the following

- "I have been very well looked after."
- "The standard of care was great."

Five staff submitted questionnaire responses. All indicated that they felt that patients are safe and protected from harm. Four staff indicated they were very satisfied with this aspect of care and one indicated they were satisfied. Staff spoken with during the inspection concurred with this. No comments were included in submitted questionnaire responses.

Areas of good practice

There were examples of good practice found in relation to staff recruitment, induction, training, the provision of assisted conception services, supervision and appraisal, safeguarding, management of medical emergencies, infection prevention control and the environment.

Areas for improvement

No areas for improvement were identified during the inspection.

	Regulations	Standards
Total number of areas for improvement	0	0

6.5 Is care effective?

The right care, at the right time in the right place with the best outcome.

Clinical records

Four 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
- 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 an excellent 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 within the establishment was found to be in line with legislation and best practice.

Patient information and decision making

The establishment has written information available for prospective patients regarding the services provided how to access these and costs of treatment. This information is written in plain English and when required is available in an alternative language or format. The service has a very informative website which provides external contact details for prospective patients. A 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.

Discussion with staff confirmed there is procedure on breaking bad news to patients and staff demonstrated a very good understanding of it.

Patients are aware of who to contact if they want advice or have any issues/concerns.

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

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

Patient and staff views

All patients who submitted questionnaire responses indicated that they get the right care, at the right time and with the best outcome for them. Three patients indicated they were very satisfied with this aspect of care and one indicated they were satisfied. Comments provided included the following:

- "They are a professional team."

All submitted staff questionnaire responses indicated that they felt that patients get the right care, at the right time and with the best outcome for them. Two staff indicated they were very satisfied with this aspect of care and three indicated they were satisfied. Staff spoken with during the inspection concurred with this. No comments were included in submitted questionnaire responses.

Areas of good practice

There were examples of good practice found in relation to completion of clinical records, the arrangements for records management and ensuring effective communication between patients and staff.

Areas for improvement

No areas for improvement were identified during the inspection.

	Regulations	Standards
Total number of areas for improvement	0	0

6.6 Is care compassionate?

Patients and clients are treated with dignity and respect and should be fully involved in decisions affecting their treatment, care and support.

Dignity, respect and rights

Discussion regarding the consultation and treatment process with Ms Tennant and staff, 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.

Observations confirmed that patient care records were stored securely in a locked records room and electronic records are password protected.

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 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. Details of a free independent counselling service are provided to patients. A counselling brochure was also available. Mandatory counselling is in place for the donor egg and/or sperm programme.

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.

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

The establishment issued feedback questionnaires to patients on a three monthly basis. The quality officer collates the findings and provides a summary report which is made available to patients and other interested parties to read in the waiting area of the establishment. Review of the completed questionnaires found that patients were satisfied with the quality of treatment, information and care received. Some of the comments received included:

- "During the embryo transfer it is very reassuring to be scanned and be able to see the embryo in the womb. Very clean clinic and very friendly staff."
- "Very relaxing environment, lovely staff."
- "Patient care very good. I felt in safe hands. All staff really nice, would be helpful and it was nice to know which consultant is doing the procedure in advance of the treatment."
- "The experience was very positive."
- "Excellent information and patient care provided."

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 through discussion that comments received from patients are reviewed by the registered manager and discussed at monthly management meetings. Action is implemented to address any issues identified.

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 is 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

All patients who submitted questionnaire responses indicated that they are treated with dignity and respect and are involved in decision making affecting their care and were very satisfied with this aspect of care. Comments provided included the following:

- "Staff all very good at all times."

- "Staff have been caring, informative and very helpful. I have felt more at ease and the standard of care was great."

All submitted staff questionnaire responses indicated that they felt that patients are treated with dignity and respect and are involved in decision making affecting their care. Four staff indicated they were very satisfied with this aspect of care and one indicated they were satisfied. Staff spoken with during the inspection concurred with this. No comments were included in submitted questionnaire responses.

Areas of good practice

There were examples of good practice found in relation to maintaining patient confidentiality, ensuring the core values of privacy and dignity were upheld and providing the relevant information to allow patients to make informed choices.

Areas for improvement

No areas for improvement were identified during the inspection.

	Regulations	Standards
Total number of areas for improvement	0	0

6.7 Is the service well led?

Effective leadership, management and governance which creates a culture focused on the needs and experience of service users in order to deliver safe, effective and compassionate care.

Management and governance arrangements

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. Staff confirmed that there were good working relationships and that management were responsive to any suggestions or concerns raised. Ms Tennant has overall responsibility for the day to day management of the establishment.

It was confirmed Mr Traub, registered person, is involved in the day to day running of the establishment and participates in meetings with each department on a weekly basis.

Policies and procedures were available for staff reference. Observations made confirmed that 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 available 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 and a review of complaints records indicated that complaints have been managed in accordance with best practice.

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 to guidance.

Ms Tennant ensures 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.

Ms Tennant outlined the process for granting practising privileges and confirmed medical practitioners meet with the board of directors prior to privileges being granted.

Five medical practitioners' 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. GCRM Belfast has a policy and procedure in place which outlines the arrangements for application, granting, maintenance, suspension and withdrawal of practising privileges.

Ms Tennant and the quality manager 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. The following audits had been undertaken;

- IPC audit
- patient information
- laboratory process
- patient charts
- pregnancy rate
- embryo survival rate
- storage of frozen embryos
- complaints

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.

Mr Traub and Ms Tennant demonstrated a clear understanding of their role and responsibility 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

All patients who submitted questionnaire responses indicated that they felt that the service is well led. Two patients indicated they were very satisfied with this aspect of the service and two indicated they were satisfied. The following comment was provided:

- "We saw different doctors but all seemed to know about us."

All submitted staff questionnaire responses indicated that they felt that the service is well led. Four staff indicated they were very satisfied with this aspect of the service and one indicated they were satisfied. Staff spoken with during the inspection concurred with this. The following comment was provided:

- "Manager of the clinic always available if advice needed."

Areas of good practice

There were examples of good practice found in relation to governance arrangements, management of complaints and incidents, quality improvement and maintaining good working relationships.

Areas for improvement

No areas for improvement were identified during the inspection.

	Regulations	Standards
Total number of areas for improvement	0	0

7.0 Quality improvement plan

There were no areas for improvement identified during this inspection, and a QIP is not required nor included as part of this inspection report.

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