

# Announced Care Inspection Report 30 November 2016



## GCRM Belfast

**Type of Service: Independent Hospital (IH) – In Vitro Fertilisation (IVF)**  
**Address: Edgewater House, Edgewater Business Park, Edgewater  
Road, Belfast BT3 9JQ**  
**Tel No: 02890781335**  
**Inspector: Winnie Maguire**

## 1.0 Summary

An announced inspection of GCRM Belfast took place on 30 November 2016 from 9.50 to 16.00

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

### **Is care safe?**

Observations made, review of documentation and discussion with Mr Anthony Traub, registered person, Ms Donna Tennant, registered manager and staff demonstrated that systems and processes were in place to ensure that care to patients was safe and avoids and prevents harm. Areas reviewed included staffing, recruitment and selection, safeguarding, management of patients undergoing fertility treatment, management of resuscitation and medical emergencies, infection prevention control and decontamination and the general environment. No requirements or recommendations have been made.

### **Is care effective?**

Observations made, review of documentation and discussion with Mr Traub, Ms Tennant and staff demonstrated that systems and processes were in place to ensure that care provided in the establishment was effective. Areas reviewed included clinical records and patient information and decision making. No requirements or recommendations have been made.

### **Is care compassionate?**

Observations made, review of documentation and discussion with Mr Traub, Ms Tennant and staff demonstrated that arrangements are in place to promote patients' dignity, respect and rights. No requirements or recommendations have been made.

### **Is the service well led?**

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

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

## 1.1 Inspection outcome

	Requirements	Recommendations
<b>Total number of requirements and recommendations made at this inspection</b>	0	1

Details of the Quality Improvement Plan (QIP) within this report were discussed with Ms Tennant, registered manager, as part of the inspection process. The timescales for completion commence from the date of inspection.

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

## 1.2 Actions/enforcement taken following the most recent estates inspection

Other than those actions detailed in the QIP there were no further actions required to be taken following the most recent inspection on 21 November 2016 .

## 2.0 Service details

<b>Registered organisation/registered person:</b> GCRM Belfast Ltd Mr Anthony Traub	<b>Registered manager:</b> Ms Donna Tennant
<b>Person in charge of the establishment at the time of inspection:</b> Ms Donna Tennant	<b>Date manager registered:</b> 14 November 2013
<b>Categories of care:</b> Independent Hospital (IH) - Prescribed technologies(PT) – In vitro Fertilisation	

## 3.0 Methods/processes

Questionnaires were provided to patients and staff prior to the inspection by the establishment on behalf of the RQIA. Prior to inspection we analysed the following records: notification of incidents, complaints declaration and returned completed staff and patient questionnaires.

During the inspection the inspector met with Mr Traub, registered person, Ms Tennant, registered manager, a quality officer, a staff nurse and a trainee embryologist. A tour of the premises was also undertaken.

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

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

#### 4.0 The inspection

#### 4.1 Review of requirements and recommendations from the most recent inspection dated 21 November 2016

The most recent inspection of the establishment was an announced estates inspection. This QIP will be validated by the estates inspector at the next estates inspection.

#### 4.2 Review of requirements and recommendations from the last care inspection dated 14 September 2015

Last care inspection statutory requirements		Validation of compliance
<b>Requirement 1</b> <b>Ref:</b> Regulation 28 (1) (2) <b>Stated:</b> First time	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.	<b>Met</b>
	<b>Action taken as confirmed during the inspection:</b> All incidents have been reported to RQIA in accordance with regulation 28 of The Independent Healthcare Regulations (Northern Ireland) 2005.	

#### 4.3 Is care safe?

##### Staffing

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

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

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

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

### **Recruitment and selection**

Discussion with Ms Tennant confirmed that two 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 adults as outlined in the Minimum Care Standards for Independent Healthcare Establishments July 2014. Update training is planned in the early New Year.

Policies and procedures were in place for the safeguarding and protection of adults 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. The relevant contact details for onward referral to the local Health and Social Care Trust should a safeguarding issue arise were included. The establishment had a copy of the regional guidance entitled 'Adult Safeguarding Prevention and Protection in Partnership' and Ms Tennant confirmed the safeguarding policy was being updated in accordance with the guidance.

### **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 single room with en-suite accommodation, 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.

A RQIA estates inspection was conducted on 21 November 2016 and estates issues were reviewed during this inspection.

## **Patient and staff views**

Eighteen patients submitted questionnaire responses to RQIA. All indicated that they felt safe and protected from harm. The following comment was provided:

- “A lot of time and care was taken to explain everything to us both in a way we could understand.”

Six staff submitted questionnaire responses. All indicated that they felt that patients are safe and protected from harm. No comments were included in submitted questionnaire responses.

## Areas for improvement

No areas for improvement were identified during the inspection.

<b>Number of requirements</b>	0	<b>Number of recommendations</b>	0
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### 4.4 Is care effective?

#### Clinical records

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

The care records reviewed contained the following;

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

Systems are in place to audit the patient care records as outlined in the establishments quality assurance programme. A number of audits relating to patient care records were reviewed and 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. Comments provided included the following:

- “Yes, very professional staff.”
- “Excellent care.”
- “Dr xxxxx was excellent.”
- “More information if the results are not positive.”
- “More information regarding the process before I attend for the consent appointment.”

The patient comments were discussed with Mr Traub and Ms Tennant who gave assurances to review the matters raised.

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. No comments were included in submitted questionnaire responses.

**Areas for improvement**

No areas for improvement were identified during the inspection.

<b>Number of requirements</b>	0	<b>Number of recommendations</b>	0
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## 4.5 Is care compassionate?

### Dignity, respect and rights

Discussion regarding the consultation and treatment process with Mr Traub, 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:

- "We were extremely comfortable throughout and staff were amazing."
- "The staff were very good."
- "Our overall experience with GCRM has been very positive."
- "We have found GCRM to be very professional and have always been treated with empathy and kindness."

The quality officer confirmed 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.

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 their rights respected. Comments provided included the following:

- “Great staff.”
- “Excellent care, we felt at ease.”

All submitted staff questionnaire responses indicated that they felt that patients are treated with dignity and respect and their rights are respected. No comments were included in submitted questionnaire responses.

**Areas for improvement**

No areas for improvement were identified during the inspection.

<b>Number of requirements</b>	0	<b>Number of recommendations</b>	0
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**4.6 Is the service well led?**

**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.

Mr Traub, the registered person confirmed he 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 practitioner's personnel files were reviewed and confirmed that there was a written agreement between each medical practitioner and the establishment setting out the terms and conditions of practising privileges which has been signed by both parties. It was suggested to be more explicit in relation to the scope of practice for medical practitioners. 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.

It was confirmed that two of the medical practitioners are private doctors and a recommendation was made to submit an application to RQIA for a variation of registration to include the provision of a private doctor service.

Ms Tennant and the quality officer 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. Comments provided included the following:

- “Kept well informed and not patronised.”
- “Yes, everyone is lovely and very friendly and always kept up to date with what is happening.”
- “Well managed clinic. Very happy with treatment and staff.”
- “I felt that staff were very interested in me and providing a very high quality standard of care.
- “XX is an asset to GCRM, so helpful and friendly.”
- “Some reception staff are amazing.”

All submitted staff questionnaire responses indicated that they felt that the service is well led. The following comment was provided:

- “Fantastic place to work, well managed, brilliant team and pleasant working environment.”

**Areas for improvement**

Submit an application to RQIA for a variation of registration to include the provision of a private doctor service.

<b>Number of requirements</b>	0	<b>Number of recommendations</b>	1
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**5.0 Quality improvement plan**

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

The registered provider/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 provider 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 the independent hospital – in vitro fertilisation. The registration is not transferable so that in the event of any future application to alter, extend or to sell the premises RQIA would apply standards current at the time of that application.

**5.1 Statutory requirements**

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

## 5.2 Recommendations

This section outlines the recommended actions based on research, recognised sources and The DHSSPS Minimum Care Standards for Independent Healthcare Establishments(July 2014). They promote current good practice and if adopted by the registered provider/manager may enhance service, quality and delivery.

## 5.3 Actions to be taken by the registered provider

The QIP should be completed and detail the actions taken to meet the legislative requirements and recommendations stated. The registered provider should confirm that these actions have been completed and return the completed QIP to [Independent.Healthcare@rqia.org.uk](mailto:Independent.Healthcare@rqia.org.uk) for assessment by the inspector.

It should be noted that this inspection report should not be regarded as a comprehensive review of all strengths and areas for improvement that exist in the service. The findings reported on are those which came to the attention of RQIA during the course of this inspection. The findings contained within this report do not exempt the registered provider from their responsibility for maintaining compliance with the regulations and standards. It is expected that the requirements and recommendations outlined in this report will provide the registered provider with the necessary information to assist them to fulfil their responsibilities and enhance practice within the service.

## Quality Improvement Plan

### Recommendations

<p><b>Recommendation 1</b></p> <p><b>Ref:</b> Standard 16.2</p> <p><b>Stated:</b> First time</p> <p><b>To be completed by:</b> 30 December 2016</p>	<p>Submit an application to RQIA for a variation of registration to include the provision of a private doctor service.</p> <p><b>Response by registered provider detailing the actions taken:</b> GCRM-BELFAST has submitted an application for a variation of licence to include the category Private Doctor (PD)</p>
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