Announced Inspection

Name of Establishment:	**GCRM Belfast**
Establishment ID No:	**12177**
Date of Inspection:	**27 October 2014**
Inspector's Names:	**Jo Browne and Winnie Maguire**
Inspection No:	**17383**

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 General Information

Name of establishment:	GCRM Belfast
Address:	Edgewater House Edgewater Road Business Park Edgewater Road Belfast BT3 9JQ
Telephone number:	028 9078 1335
Registered organisation/ registered provider:	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
Registration category:	PT(IVF) – Prescribed techniques or prescribed technology: establishments providing in vitro fertilisation
Date and time of inspection:	27 October 2014 09.50– 16.15
Date and type of previous inspection:	23 September 2013 Pre-Registration Inspection
Names of inspectors:	Jo Browne Winnie Maguire

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 Minimum Care Standards for Independent Healthcare Establishments, July 2014, 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 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) Minimum Care Standards for Independent Healthcare Establishments

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 inspectors prior to the inspection. The inspection process has three key parts; self-assessment, pre-inspection analysis and the visit undertaken by the inspectors.

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

- Analysis of pre-inspection information and self-assessment
- Discussion with the registered manager, Ms Donna Tennant
- Discussion with the laboratory director, Mr Robbie Kerr
- 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 inspectors 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 inspectors spoke with the following:

Staff	3

2.4 Inspection Focus

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

- Standard 5 Patient and Client Partnerships
- Standard 7 Complaints
- Standard 9 Clinical Governance
- Standard 10 Qualified Practitioners, Staff and Indemnity
- Standard 11 Practising Privileges
- Standard 16 Management and Control of Operations
- 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

3.0 Profile of Service

GCRM Belfast is a purpose built assisted conception establishment located within the harbour estate in Belfast. The ground floor of the establishment has three private patient recovery rooms with en-suite facilities, a dedicated room for the production of semen specimens, fertility treatment suite, embryology and andrology laboratories, storage areas for gametes, embryos and reagents. The first floor of the establishment consists of a reception area, toilet facilities, consultation rooms, scanning room, treatment room and offices. All areas of the establishment are designed to enable patient privacy. All treatment and consultation areas are secured by controlled access.

Private car parking is available for patients and visitors at the entrance to the building.

The establishment is accessible for patients with a disability. A passenger lift is available to transport patients between the two floors.

The Statement of Purpose outlines the range of the services provided.

Ms Donna Tennant has been the registered manager of GCRM Belfast since registration with RQIA on 14 November 2013.

GCRM is registered as an independent hospital with the PT(IVF) category of registration.

4.0 Summary of Inspection

An announced inspection was undertaken by Jo Browne and Winnie Maguire on 27 October 2014 from 9.50 to 16.15. 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 DHSPPS Minimum Care Standards for Independent Healthcare Establishments and to assess the progress made to address the issues raised during the previous inspection.

There were five requirements and seven recommendations made as a result of the previous pre-registration inspection on 23 September 2013. All of the requirements and recommendations have been fully addressed.

The inspection focused on the DHSPPS Minimum Care Standards for Independent Healthcare Establishments outlined in section 2.4 of this report.

Ms Donna Tennant, registered manager was available during the inspection and for verbal feedback at the conclusion of the inspection.

The establishment is required to be registered with RQIA and licenced by the Human Fertilisation Embryology Authority (HFEA) to provide assisted conception services. The inspectors reviewed the HFEA licence which due for renewal on 24 November 2015.

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

There are robust systems in place to obtain the views of patients. The inspectors reviewed the completed patient questionnaires, along with the summary report and found that patients were highly satisfied with the quality of care and treatment provided. 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.

The inspectors 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 at the time of this inspection. A recommendation was made to ensure the role of RQIA and HFEA are included as regulators within all complaints procedures as outlined in the main body of the report.

The registered manager is responsible for the day to day running of the establishment and ensuring compliance with the legislation and standards.

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

The inspectors also reviewed incident management and found this to be line with legislation and best practice.

The registered manager confirmed that no research is currently being undertaken within the establishment.

The inspectors reviewed the personnel files of four medical practitioners, two registered nurses and one embryologist and found that they contained all of the information required by legislation.

The inspectors discussed the arrangements in place for dealing with professional alert letters, managing identified lack of competence and poor performance for all staff and reporting incompetence in line with guidelines issues by the DHSSPS and professional regulatory bodies. The registered manager has systems in place to deal with all alert letters issued by the DHSSPS.

A recommendation was made to check the Northern Ireland Adverse Incident Centre (NIAIC) website on a regular basis, download and action any alerts which are relevant to the service.

There is a policy and procedure in place which outlines the arrangements for application, granting, maintenance, suspension and withdrawal of practising privileges. Review of personnel files confirmed that appropriate written practising privileges agreement were in place for medical practitioners.

There is a defined management structure within the establishment and clear lines of accountability.

The inspectors 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 manager undertakes ongoing training to ensure that they are up to date in all areas relating to the provision of services.

A Statement of Purpose and Patient Guide were in place which reflected legislative and best practice guidance, however the complaints procedure within the documents should be updated to include the role of RQIA and HFEA as regulators.

The inspectors confirmed that light refreshments are provided in line with the assessed needs of the patients.

The inspectors reviewed the insurance arrangements for the establishment and found that current insurance policies were in place. The certificate of registration was clearly displayed in the reception area of the premises.

The inspectors undertook a review of the premises which were found to be maintained to an excellent standard of maintenance and décor and suitable for the provision of assisted conception services. The layout of the premises is described fully in the main body of the report.

The inspectors observed that clean sharps containers were stored close to sharps containers which had been closed and were awaiting collection by the waste management company; a recommendation was made to store them in separate locations.

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

The establishment has a wide range of written information available for prospective patients regarding the services provided, how to access these and the costs of treatments.

The inspectors reviewed the care records of six patients and found that they were well documented, contemporaneous and clearly outlined the patient journey.

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

There were three 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 inspectors would like to thank Ms Donna Tennant, Dr Robbie Kerr and staff of GCRM for their hospitality and contribution to the inspection process.

5.0 Follow Up on Previous Issues

No.	Regulation Ref.	Requirements	Action taken as confirmed during this inspection	Number of times stated	Inspector's validation of compliance
1	19 (2) (d)	Ensure that all information required by legislation is retained for all staff working in the establishment. Evidence that this information has been obtained must be submitted to RQIA prior to registration.	Evidence was submitted to RQIA, prior to registration, confirming that all information required by legislation was available for staff working in the establishment.	One	Compliant
2	18 (1)	Evidence that suitable staffing arrangements are in place to provide all aspects of the fertility service must be submitted to RQIA prior to registration.	Evidence was submitted to RQIA, prior to registration, confirming that suitable staffing arrangements were in place to provide all aspects of the service.	One	Compliant
3	18 (2) (a)	Ensure that evidence is submitted to RQIA prior to registration, to confirm that all staff have undertaken the required mandatory training as outlined in the main body of the report.	Evidence was submitted to RQIA, prior to registration, to confirm all staff had undertaken the required mandatory training.	One	Compliant
4	15(7)	Ensure that a full IPC audit is undertaken by an appropriately qualified person and all recommendations made are fully addressed. Evidence of the completed IPC audit and action plan must be submitted to RQIA prior to registration.	A copy of the completed IPC report and confirmation that all recommendations had been fully addressed was submitted to RQIA prior to registration.	One	Compliant

No.	Regulation Ref.	Requirements	Action taken as confirmed during this inspection	Number of times stated	Inspector's validation of compliance
5	21 (1)	Ensure that all proposed patient clinical records are reviewed and amended as outlined in the main body of the report.	Evidence was submitted to RQIA, prior to registration, to confirm that the patient clinical records had been reviewed and amended.	One	Compliant

No.	Minimum Standard Ref.	Recommendations	Action taken as confirmed during this inspection	Number of times stated	Inspector's validation of compliance
1	C13.1	Review the induction programme and ensure that is applicable to all roles and responsibilities, particularly medical practitioners.	The inspectors reviewed the induction programmes and confirmed that they were applicable to all roles and responsibilities.	One	Compliant
2	C16.2	Develop an overarching management of records policy as outlined in the main body of the report.	The management of records policy was developed and submitted to RQIA, prior to registration.	One	Compliant
3	C16.2	Ensure the establishment is registered with the Information Commissioner's Office (NI)	The inspectors confirmed that the establishment had registered with the Information Commissioner's Office (NI).	One	Compliant
4	A5.1	Ensure that the practising privileges policy and procedure is updated to reflect the Northern Ireland legislation.	The practising privileges policy was amended and submitted to RQIA, prior to registration.	One	Compliant
5	C6.1 & C7.1	Ensure the safeguarding vulnerable adults and children policy is updated to include the contact details for onward referrals.	The safeguarding vulnerable adults and children policy was amended and submitted to RQIA, prior to registration.	One	Compliant
6	P9.1	Clarify within the unexpected results policy that information is only provided to patients by medical practitioners.	The inspectors reviewed the unexpected results policy and confirmed that it had been amended as previously recommended.	One	**Compliant**

No.	Minimum Standard Ref.	Recommendations	Action taken as confirmed during this inspection	Number of times stated	Inspector's validation of compliance
7	C23.1	Review and amend the incident policy and procedures as outlined in the main body of the report.	The incident policy and procedure was amended and submitted to RQIA, prior to registration.	One	Compliant

6.0 Inspection Findings

STANDARD 5	
Patient and Client Partnerships:	**The views of patients and clients, carers and family members are obtained and acted on in the evaluation of treatment, information and care**

GCRM Belfast 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 all patients. The inspectors reviewed a sample of 30 completed questionnaires and found that patients were highly satisfied with the quality of treatment, information and care received. Comments from patients included:

- "Very pleased with the care"
- "Overall experience positive"
- "Nursing staff all excellent"
- "We really have found all aspects of the service to be of a high standard"
- "The fertility experience is not a pleasant one, but the staff at GCRM made it most personable and uncomplicated"
- "The staff are all amazing"
- "All staff very helpful, friendly and professional"
- "A very positive experience. Loved seeing our embryo before transfer, thank you"
- "Very very pleased with overall professional informative service we received, no matter what the outcome is from all staff"
- "Great clinic, warm friendly atmosphere and totally professional"

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 Guide and on the establishment's website.

All comments received from patients are reviewed and discussed at senior management level and used to improve services provided.

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 7	
Complaints:	**All complaints are taken seriously and dealt with appropriately and promptly.**

The establishment has complaints policies and procedures in place. The registered manager is the complaints manager and demonstrated a good understanding of complaints management.

A copy of patients' guidance on how to make a complaint was displayed in the reception area of the establishment. The inspectors reviewed this document and found it to be in line with the legislation and DHSSPS guidance on complaints management in regulated establishments and agencies. On review of the following documents a recommendation was made to ensure that the role of RQIA and HFEA are included as regulators within the complaints procedure:

- Statement of Purpose
- Patient Guide
- Complaints policy and procedure (electronic version)

The registered manager confirmed that the complaints procedure could be made available in alternative formats and languages on request.

The inspectors reviewed the complaints register and complaints records. All complaints were well documented, fully investigated and had outcomes recorded in line with the complaints procedure and legislation.

There are systems in place to audit complaints. The audit information will be 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

STANDARD 9	
Clinical Governance:	**Patients and clients are provided with safe and effective treatment and care based on best practice guidance, demonstrated by procedures for recording and audit.**

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

The establishment is working towards achieving ISO 9001 accreditation.

Discussion with the registered manager and review of training records and orientation packs confirmed that systems are in place to ensure that staff receive appropriate training when new procedures are introduced.

The establishment has robust clinical governance systems in place to audit the quality of services provided. The inspectors reviewed the clinical governance policy, along with the quality management system and manual.

The inspectors met with the laboratory director who also has responsibility for the quality management system discussed the comprehensive arrangements in place and reviewed the following audits and key performance indicators (KPI) as part of the inspection process:

- Customer focus
- Customer property
- Early embryo viability assessment (Eeva)
- Consents and welfare of the child completed
- Uptake of counselling
- Faulty equipment
- Monitoring equipment
- Single embryo transfer
- Purchasing
- Quality control marking (CE)
- Pregnancy rate by age range
- Fertilisation rate
- Pregnancy and miscarriage rate
- Individual performance of medical practitioners
- Individual performance embryologists
- Clinical incidents
- Admission procedure

The inspectors reviewed the detailed audit plan in place. The results of the audits are discussed at the monthly quality management meeting and a quality report is produced which identifies action to be action to address any issues. The quality report is shared at weekly team meetings and fortnightly management team meetings. An annual quality report will be completed in January 2015 and shared

with the team.

The laboratory director informed the inspectors that the quality management system would be fully operational once they had established 12 months statistical data. This would enable meaningful statistical comparisons to be made on a monthly basis. The data would be reviewed and used to further enhance the services provided or identify any issues.

The responsible individual is involved in the day to day running of the establishment.

As there are no overnight beds within the establishment there are written procedures outlining the arrangements in place between the establishment and a HSC trust providers for accessing additional services, when patients require to be admitted overnight.

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

The inspectors reviewed incident management and found that incidents were well documented, fully investigated and had outcomes recorded.

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

The registered manager confirmed that no research is currently being undertaken within the establishment. Ms Tennant also confirmed before any research involving patients would be considered a research proposal would be prepared and approval obtained from the appropriate Research Ethics Committee (REC).

Evidenced by:

Review of policies and procedures
Review of training records/competency records
Discussion with registered manager
Review of monitoring reports
Review of audits
Review of incident management
Review of research arrangements

STANDARD 10	
Qualified Practitioners, Staff and Indemnity	**Staff are educated, trained and qualified for their role and responsibilities and maintain their training and qualifications.**

The inspectors reviewed the personnel files of four medical practitioners and confirmed that:

- There was evidence of confirmation of identity
- There was 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 in assisted conception services
- Evidence of enhanced Access NI disclosure check
- Completed orientation
- There was evidence of ongoing professional development and continuing medical education that meet the requirements of the Royal Colleges and GMC
- There was evidence of ongoing annual appraisal by a trained medical appraiser

The inspectors confirmed that each medical practitioner has an appointed responsible officer.

The inspectors reviewed the personnel files of two registered nurses and confirmed that:

- There was evidence of confirmation of identity
- There was evidence of current registration with the Nursing and Midwifery Council (NMC)
- Completed orientation and competency assessments
- Evidence of enhanced Access NI disclosure check
- There was evidence of ongoing professional development and continuing education that meet the requirements of the NMC
- There was evidence of annual appraisal

The inspectors reviewed the personnel file of one embryologist and confirmed that:

- There was evidence of confirmation of identity
- There was evidence of current registration with the Health and Care Professions Council (HCPC)
- Completed orientation and competency assessments
- Evidence of enhanced Access NI disclosure check
- There was evidence of ongoing professional development and continuing education that meet the requirements of the HCPC
- There was evidence of annual appraisal

The inspectors discussed the arrangements in place for dealing with professional alert letters, managing identified lack of competence and poor performance for all staff and reporting incompetence in line with guidelines issues by the DHSSPS and professional regulatory bodies.

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

A recommendation was made to 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.

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. Ms Tennant ensures that all health care professionals adhere to their published codes of professional conduct and professional guidelines.

Evidenced by:

Review of staff personnel files for verification of registration status with professional bodies
Review of professional indemnity insurance
Review of specialist qualifications
Review of arrangements for dealing with alert letter/competency
Review of training records

STANDARD 11	
Practising Privileges:	**Medical practitioners may only use facilities in the establishment for consultation with and treatment of patients if they have been granted practising privileges.**

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

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

Review of personnel files confirmed that there was a written agreement between each medical practitioner, who was not a director of the company 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.

The inspectors confirmed that written arrangements were in place for the sharing of information between the establishment and HSC trust employers to enable “whole practice appraisal” to take place.

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 16	
Management and Control of Operations	**Management systems and arrangements are in place that ensure 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 establishment also had a chain of responsibility policy and procedure in place.

A policy and procedure to ensure that RQIA is notified if the registered manager is absence for more than 28 days was forwarded to the inspectors following the inspection. The policy included the interim management arrangements for the establishment.

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

The inspectors reviewed the establishment's Patient Guide and Statement of Purpose and found them to contain all of the information required by legislation. As previously stated in Standard 7 a recommendation was made to amend the complaints procedure within these documents.

The inspectors confirmed that appropriate light refreshments are provided in line with the assessed needs of the patients.

The registered manager confirmed that no agency staff are used within the establishment.

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 inspectors discussed the insurance arrangements within the establishment and confirmed current insurance policies were in place. The certificate of registration was 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
Review of arrangements for light refreshments
Review of insurance arrangements

STANDARD 44	
Facilities for Assisted Conception Services	**The facilities are appropriate for fertility treatment and in line with HFEA requirements**

The inspectors undertook a review of the premises which were found to be maintained to an excellent standard of maintenance and décor. The establishment was found to be clean, tidy and free from clutter.

The inspectors observed that clean sharps containers were stored close to sharps containers which had been closed and were awaiting collection by the waste management company; a recommendation was made to store them in separate locations.

The ground floor of the establishment has three private patient recovery rooms with en-suite facilities, a dedicated room for the production of semen specimens, fertility treatment suite, 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 first floor of the establishment consists of a reception area, toilet facilities, consultation rooms, scanning room, treatment room and offices. All areas of the establishment are designed to enable patient privacy. All treatment and consultation areas are secured by controlled access.

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

The inspectors reviewed the written protocols for the following:

- 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

Evidenced by:

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

STANDARD 45	
Information and Decision Making for Patients and Clients Undergoing Fertility Treatments	**Patients and clients are effectively involved in making decisions about treatment**

The establishment is required to be registered with RQIA and licenced by the Human Fertilisation Embryology Authority (HFEA) to provide assisted conception services. The inspectors reviewed the HFEA licence which due for renewal on 24 November 2015.

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, are evidence based and in line with other national best practice guidelines.

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. 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 information is written in plain English and when required can be made available in an alternative language or format.

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.

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 47	
Management of Patients and Clients Undergoing Fertility Treatment	**Patient and client care is managed, delivered and reviewed by professional staff who provide care safely and effectively in line with HFEA Guidance.**

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), are evidence based and in line with best practice guidelines. The registered manager confirmed that appropriate arrangements are in place to report to the Northern Ireland Maternal and Child Health (NIMACH).

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 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.

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

The inspectors 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:

- 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 consultation with 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 within their quality management system. The inspectors reviewed some of the audits relating to patient care records and an excellent compliance rate was noted.

Evidenced by:

Review of patient care records
Review of treatment protocols
Review of standard operating procedures
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 Donna Tennant and Dr Robbie Kerr 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

Quality Improvement Plan

Announced Inspection

GCRM Belfast

27 October 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 Donna Tennant and Dr Robbie Kerr either during or after 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.

RECOMMENDATIONS

These recommendations are based on the DHSPPS Minimum Care Standards for Independent Healthcare Establishments, 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	7.1	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. **Ref: Standard 7**	One	Complaints procedure documents updated to show RQIA and HFEA as clinic's regulators	Three months
2	10.3	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. **Ref: Standard 10**	One	Registerd manager has established an Excel spreadsheet to record regular visits to NIAIC website. The registered manager will check weekly for relevant alerts and action as appropriate.	Immediately and ongoing
3	44	The registered manager should ensure that clean and used sharps containers are stored in separate locations. **Ref: Standard 44**	One	Clean, unused sharps containers are now stored separately from used containers	Immediately and ongoing

Please complete the following table to demonstrate that this Quality Improvement Plan has been completed by the registered manager and approved by the responsible person / identified responsible person and return to independent.healthcare@rqia.org.uk

Name of Registered Manager Completing QIP	Mrs.Donna Tennant
Name of Responsible Person / Identified Responsible Person Approving QIP	Dr. A. I. Traub

QIP Position Based on Comments from Registered Persons	**Yes**	**Inspector**	**Date**
Response assessed by inspector as acceptable	Yes	Jo Browne	10/12/14
Further information requested from provider	No	Jo Browne	10/12/14

1 of D.

The Regulation and Quality Improvement Authority

Pre-Inspection Self-Assessment
Assisted Conception Services

Name of Establishment:	**GCRM Belfast**
Establishment ID No:	**12177**
Date of Inspection:	**10 September 2014**
Inspector's Name:	**Jo Browne & Winnie Maguire**
Inspection No:	**17383**

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		

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 WE USE 'SINGLE USE' INSTRUMENTS		

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		

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
DONNA TENNANT		CLINIC MANAGER	21/8/14