The Regulation and Quality Improvement Authority

Inspection Report

19 August 2025

TFP Belfast Fertility

Type of Service: Independent Hospital (IH) – Fertility Services and Assisted Conception \ Private Doctor
Address: Edgewater House, Edgewater Business Park, Edgewater Road, Belfast, BT3 9JQ
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Information on legislation and standards underpinning inspections can be found on our website https://www.rqia.org.uk/, The Independent Health Care Regulations (Northern Ireland) 2005 and the Minimum Care Standards for Independent Healthcare Establishments (July 2014)

1.0 Service information

Organisation/Provider: GCRM Belfast Ltd **Responsible Individual:** Mr James Moohan	**Registered Manager:** Mr Andrew Caulfield **Date registered:** 9 September 2024
Person in charge at the time of inspection: Mr Andrew Caulfield	
Categories of care: Independent hospital (IH) Prescribed techniques or prescribed technology: establishments providing in vitro fertilisation techniques PT (IVF) Private doctor (PD)	
Brief description of how the service operates: TFP Belfast Fertility is registered with the Regulation and Quality Improvement Authority (RQIA) as an independent hospital (IH) with Prescribed techniques or prescribed technology: establishments providing in vitro fertilisation techniques PT (IVF) and private doctor (PD) categories of care. The Fertility Partnership (TFP) is a group of international clinics specialising in assisted conception and is the parent company of GCRM Belfast Ltd which owns TFP Belfast Fertility. GCRM Belfast Ltd is the provider organisation registered with RQIA and Mr James Moohan is the responsible individual for GCRM Belfast Ltd. On 14 May 2025, RQIA received a variation to registration application on behalf of GCRM Belfast Ltd to add both AH (DS) - Acute hospitals (day surgery only) and PT(E) Prescribed techniques or prescribed technology – establishments using endoscopy categories of care. The establishment will provide diagnostic and operative hysteroscopy under general anaesthetic as an outpatient procedure. This application formed the basis of this inspection.	

2.0 Inspection summary

This was an announced variation to registration inspection undertaken by two care inspectors and an estates inspector on 19 August 2025 from 10.00 am to 12.30 pm.

The purpose of the inspection was to review the readiness of TFP Belfast Fertility to provide outpatient hysteroscopy procedures under general anaesthetic.

During the inspection, inspectors reviewed a number of policies and procedures relating to the hysteroscopy patient pathway. The inspectors also reviewed the clinical environment from which the hysteroscopy procedures proposed are to be performed.

An RQIA estates inspector reviewed the variation to registration application in regards to matters relating to the premises. Their findings are incorporated into this report under section 5.2.8.

There was evidence of good practice concerning staffing arrangements; the management of medical emergencies; infection prevention and control (IPC); the management of the patients' care pathway; and maintenance of the premises.

Additional areas of good practice identified included 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.

Scrutiny of this information means that this variation to registration application is approved from a care perspective. Mr Caulfield is aware that separate approval has yet to be confirmed by the RQIA estates inspector. Information in relation to this is included in Section 5.2.8 of this report and in the quality improvement plan in Section 6.

3.0 How we inspect

RQIA is required to inspect registered services in accordance with legislation. To do this, we gather and review the information we hold about the service, examine a variety of relevant records, meet and talk with staff and management and observe practices on the day of the inspection.

The information obtained is then considered before a determination is made on whether the clinic is operating in accordance with the relevant legislation and minimum standards. Examples of good practice are acknowledged and any areas for improvement are discussed with the person in charge and detailed in the quality improvement plan (QIP).

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

- the variation to registration application
- the proposed statement of purpose
- the proposed patient guide
- the floor plans of premises

During the inspection, the inspectors met with Mr Caulfield and a nurse manager.

Examples of good practice were acknowledged and any areas for improvement have been discussed with the person in charge and are detailed in the quality improvement plan (QIP).

4.0 What people told us about the service?

This inspection focused on assessing the variation to registration application and the views of patients were not sought. Patients views will be actively sought as part of future inspections.

5.0 The inspection

5.1 What has this service done to meet any areas for improvement identified at or since last inspection?

The last inspection to TFP Belfast Fertility was undertaken on 26 February 2024; no areas for improvement were identified.

5.2 Inspection outcome

5.2.1. Has the statement of purpose been developed in keeping with Regulation 7

Review of the statement of purpose identified that it fully reflected the key areas and themes specified in Regulation 7, Schedule 1 of The Independent Health Care Regulations (Northern Ireland) 2005. The statement of purpose had been updated to reflect any changes detailed in the variation to registration application. Mr Caulfield is aware that the statement of purpose should be reviewed and updated as and when necessary.

5.2.2. Has the patient guide been developed in keeping with Regulation 8, of the regulations?

Review of the patient guide identified that it fully reflected the key areas and themes specified in Regulation 8 of The Independent Health Care Regulations (Northern Ireland) 2005. The patient guide had been updated to reflect any changes detailed in the variation to registration application. Mr Caulfield is aware that the patient guide should be reviewed and updated as and when necessary.

5.2.3 How does this service ensure that staffing levels are safe to meet the needs of patients and staff are appropriately trained to fulfil the duties of their role?

Staffing arrangements for hysteroscopy procedures were reviewed and discussed with Mr Caulfield and the nurse manager.

A staff register was available to review and was found to be up to date and contained staff details in keeping with legislation. A review of the register and discussion with Mr Caulfield confirmed there were sufficient staff in various roles to fulfil the needs of the hysteroscopy service and patients. No recruitment has been undertaken specifically for the hysteroscopy service.

The hysteroscopy clinical team consists of two consultant gynaecologists, both of whom have specialist qualifications, skills and up to date experience in hysteroscopy. The gynaecologist and the patient will be supported during the procedure by two nurses/midwives/ health care assistants (HCAs). A consultant anaesthetist will have responsibility for anaesthesia management of the patient, as well as the recovery and discharge of the patient. The patient support team are responsible for scheduling appointments, and providing patient support and assistance when required.

Training for clinical staff, with no prior hysteroscopy experience, was discussed with the nurse manager. It was confirmed that staff will have the opportunity to gain experience in hysteroscopy procedures under the supervision of an experienced senior nurse. Staff will also receive manufacturer-led application training to use the hysteroscopy surgical equipment. Advice and guidance was provided to the nurse manager and Mr Caulfield to formally document this training process and retain evidence thereof.

It was determined that appropriate staffing levels were in place to meet the needs of patients and the staff were suitable trained to carry out their duties.

5.2.4 How does the service ensure that medical emergency procedures are safe?

The arrangements in respect of the management of medical emergencies were reviewed.

TFP Belfast Fertility has policies and procedures in place for dealing with medical emergencies.

The British National Formulary (BNF) and the Resuscitation Council (UK) specify the emergency medicines and medical emergency equipment that must be available to safely and effectively manage a medical emergency.

It was confirmed that an emergency trolley is located on the ground floor outside theatre, and in close proximity to the three recovery rooms. This will ensure that all staff have immediate access to appropriate drugs and equipment in the event of a medical emergency. Systems were in place to ensure that emergency medicines and equipment do not exceed their expiry date. The automated external defibrillator, oxygen cylinder and suction machine are checked daily.

A discussion took place regarding the life support training to be undertaken by all clinical team members involved in managing patients having sedation. Mr Caulfield confirmed that consultants, nurses and midwives in theatre and recovery areas have completed immediate life support (ILS) training. Consultant anaesthetists have completed advanced life support (ALS) training and will remain on duty whilst the patients are in recovery awaiting discharge.

The clinic has a policy in place for the management of medical emergencies which outlines procedures on how to manage recognised medical emergencies, location and details of emergency drugs and equipment held, staff responsibilities and training for staff.

An emergency transfer out procedure/major blood loss protocol was in place for patients requiring transfer to hospital by ambulance due to an increase in either their medical or nursing care need.

Sufficient emergency medicines and equipment were in place and the team is trained to manage a medical emergency as specified in the legislation, professional standards and guidelines.

5.2.5 How does the service ensure that it adheres to infection prevention and control (IPC) and decontamination procedures?

The arrangements for IPC procedures were reviewed to evidence that the risk of infection transmission to patients, visitors and staff was minimised.

There were IPC policies and procedures in place that were in keeping with best practice guidance.

Outpatient hysteroscopy is to be undertaken in a ground floor multi-purpose theatre. There are three single bedded recovery rooms with ensuites and various consultation rooms nearby.

A tour of the ground floor theatre, recovery rooms and communal areas was undertaken and all areas were found to be clean, tidy, and uncluttered. The cleaning of communal areas was discussed and records were retained.

Arrangements for decontaminating the theatre environment and equipment between patients were discussed with the nurse manager and were found to be in keeping with best practice. The nurse manager confirmed that procedures are undertaken using ANTT techniques and staff have received IPC and ANTT training. There were dedicated hand washing facilities and hand sanitiser was observed throughout the clinic.

Personal protective equipment (PPE) was readily available in keeping with best practice guidance.

The nurse manager confirmed that only single-use medical devices are used during hysteroscopy procedures. Waste management arrangements were in place and clinical waste bins were pedal operated in keeping with best practice guidance.

The service had appropriate arrangements in place in relation to IPC and decontamination.

4.2.6 Are there safe practices in place for the hysteroscopy service?

We reviewed the arrangements for the provision of hysteroscopy services in the clinic outlined under their statement of purpose and categories of care.

The standard operating procedure (SOP) for the hysteroscopy service was reviewed. Review of policies and procedures evidenced that the service will operate in accordance with best practice and national standards to ensure care delivery is safe and effective.

The scheduling of patients is co-ordinated by the relevant TFP consultant gynaecologist and the patient support team. Scheduling takes into account individual patient requirements, consultant availability and staffing levels.

As mentioned previously the hysteroscopy team consists of a consultant, a lead nurse, one other assistant (nurse/midwife/HCA) and an anaesthetist.

Staff complete a surgical safety checklist based on World Health Organisation (WHO) guidance. This will be completed before general anaesthesia, the hysteroscopy procedure and before the patient leaves theatre.

It was confirmed that patients will be observed during and after the procedure by appropriately trained nursing staff.

The anaesthetist will be present in the operating theatre throughout the procedure and is to be present on site until the patient has recovered from the immediate effects of the anaesthetic. The anaesthetist discharges the patient in accordance to discharge criteria. This is recorded in the anaesthetic record.

One nurse is in charge of the three room recovery area. It was confirmed that if there are any concerns about the patient's condition, the consultant will be immediately informed for ongoing management. Patients are to be provided with clear, post procedure advice and information on follow up and who to contact in the event of a post treatment emergency.

The nurse manager advised that an electronic surgical register is maintained for all procedures undertaken at TFP Belfast Fertility and is kept in accordance with the regulations. Advice and guidance was provided to Mr Caulfield and the nurse manager regarding the integrity of electronic documents and the governance in place around this.

Care record pro-formas were reviewed and were found to provide a clear framework for recording the following: admission, medical history, IPC status, medication, observations on admission, pre-procedure checklist, surgical safety checklist and a detailed discharge record.

It was noted that the traceability form (sticker/label) for medical devices did not reflect the single use equipment used for hysteroscopy. Advice was provided to Mr Caulfield and the nurse manager to action this matter.

The anaesthetic record required further development to include reference to the volume of irrigation fluid used during the hysteroscopy procedure. This was brought to the attention of the nurse manager who agreed to address this matter.

There was a policy and procedure in place for the management of specimens. The nurse manager was able to outline the process for the collection, labelling, storage, preservation, transport and administration of specimens. There is a contract in place with an external pathology laboratory service. Pathology results are shared only with the TFP consultant and the patient. Results are available to the patient via the patient portal.

It was determined that there are safe practices in place for the hysteroscopy service.

5.2.7 How does the clinic ensure patients have a planned programme of care and have sufficient information to consent to treatment?

We reviewed patient consent and procedure information leaflets and discussed the patient care pathway with the nurse manager.

Prior to the procedure, patients will be sent information about the specific procedure, the risks, complications, expected outcomes, and any advance preparation. The patient support team contact the patient via telephone two days prior to the procedure to confirm fasting instructions, escort arrangements and to answer any queries.

The consent process is completed on the day of the hysteroscopy by the consultant carrying out the procedure. An anaesthetist undertakes consent for the general anaesthetic as part of the admission process.

There are clear discharge arrangements in place. Patients are provided with clear post-operative instructions along with contact details if they experience any complications, this includes emergency out of hours care.

The consultant will speak to the patient directly after the procedure and follow up can be arranged via telephone or face to face appointment. A written summary of the procedure is made available to the patient.

It was determined that appropriate arrangements were in place to ensure patients have a planned programme of care and have sufficient information to consent to treatment.

5.2.8 Is the premises fit for the purpose of providing safe and effective care?

As discussed in section 2.0 above, an RQIA estates inspector conducted an on-site inspection of the ground floor of the premises.

Documentation presented prior to and during the inspection indicated that the premises engineering services and equipment are currently maintained in line with relevant legislation, Approved codes of practice and current best practice guidance.

A current Legionella Risk Assessment was in place and suitable control measures for the premises hot and cold water systems were being undertaken with appropriate records being maintained. Regular bacteriological sampling of the hot and cold water systems is also undertaken and appropriate action is taken when necessary.

The Fire Risk Assessment continues to be suitably reviewed. The overall assessment of the risk assessment was assessed as ‘tolerable’ and the significant findings had been suitably addressed.

Commissioning tests such as the most recent airborne particulate and microbiological survey had been carried out on 24 July 2024 and the findings were in accordance with best practice and current standards.

An external IPC audit had been undertaken during July 2024. An action plan had been developed and all actions completed and re-audited to ensure compliance with IPC standards.

The premises specialised ventilation systems and medical gas pipeline services, continue to be serviced and maintained in accordance with current best practice guidance.

The Clinic's Authorising Engineer, Ventilation (AE)V is currently evaluating issues with the premises existing critical ventilation system, which will enable suitable validation with HTM 03:01 'Specialised Ventilation for Healthcare Premises Part A'.

On completion of this validation process and upon submission of the required validation documentation the estates component of the variation to registration application will be approved.

An area for improvement in relation to the validation of the critical ventilation system was identified as a result of this inspection.

5.3 Variation to registration application

The variation to registration application to add an Acute Hospital - Day Surgery, AH (DS) and PT(E) Endoscopy categories of care has been approved from a care perspective. As discussed in section 2.0, Mr Caulfield is aware that separate approval has yet to be confirmed by the RQIA estates inspector. They will inform Mr Caulfield of the outcome in due course.

These additional categories of care relate to the hysteroscopy service. Mr Caulfield was advised to inform RQIA should TFP Fertility Belfast plan to introduce any future additional surgical procedures.

6.0 Quality Improvement Plan/Areas for Improvement

One new area for improvement has been identified where action is required to ensure compliance with The Minimum Care Standards for Independent Healthcare Establishments (July 2014).

	Regulations	Standards
Total number of Areas for Improvement	0	1

The area for improvement and details of the QIP were discussed with Mr Caulfield as part of the inspection process. The timescale for completion commences from the date of inspection.

Quality Improvement Plan

Action required to ensure compliance with The Minimum Care Standards for Independent Healthcare Establishments (July 2014)

Area for improvement 1 **Ref:** Standard 22 **Stated:** First time **To be completed by:** 19 August 2025	The responsible individual shall ensure that the Authorising Engineer, Ventilation (AE)V provides validation of the premises existing critical ventilation system, indicating suitable compliance with HTM 03:01 'Specialised Ventilation for Healthcare Premises Part A'. Ref: 5.2.8
	Response by registered person detailing the actions taken: as discussed with Mr Doherty I have not had any response from the suggested 3rd party and am exploring other routes regarding HTM03

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