The Regulation and Quality Improvement Authority

Inspection Report

12 and 13 February 2025

TFP Belfast Fertility

Type of Service: Independent Hospital (IH) – Fertility Services and Assisted Conception
Address: Edgewater House, Edgewater Business Park, Edgewater Road, Belfast BT3 9JQ
Tel No: 028 9078 1335

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/Registered Provider: GCRM Belfast Ltd **Responsible Individual:** Mr James Moohan	**Registered Manger:** 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: clinics 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.	

2.0 Inspection summary

A short notice announced inspection was undertaken to TFP Belfast Fertility, which commenced with an onsite care inspection on 12 February 2025 from 10.00 am to 5.00 pm and an onsite medicines management inspection on 13 February 2025 from 11.15 am to 2.15 pm.

The onsite component of the inspection was completed on 12 February 2025 by three care inspectors accompanied by a Human Fertilisation and Embryology Authority (HFEA) representative and on 13 February 2025 by two pharmacist inspectors. Feedback of the onsite inspection findings was delivered to the TFP Belfast Fertility senior management team on the days of the inspection.

The electronic submission of additional documentation in relation to the premises aspect of the inspection was reviewed remotely by an RQIA estates inspector and feedback was provided to the registered person following the inspection.

The purpose of this inspection was to assess progress with any areas for improvement identified during and since the last care inspection and to examine a number of aspects of the establishment from front-line care and practices, the management of medicines and the management and oversight of governance across the establishment.

A multidisciplinary inspection methodology was employed during this inspection and the inspection team met with various staff members; reviewed care practices; and reviewed relevant records and documentation used to support the governance and assurance systems. Medication management was reviewed during the inspection to determine if medicines were managed safely and effectively.

It was determined that staffing levels and morale in the clinic were good; with evidence of good multidisciplinary team working and open communication between staff. Staff feedback was positive and it was evident that there were good working relationships.

Examples of good practice were evidenced in respect of: staffing; staff training; recruitment and selection of staff; safeguarding; the provision of assisted conception services; management of the patients' care pathway; management of medical emergencies; infection prevention and control; medicines management; maintenance of the environment; engagement to enhance the patients' experience; and organisational and clinical governance.

No immediate concerns were identified in relation to patient safety and the inspection team noted areas of good practice in relation to the delivery of assisted fertility and conception services.

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

- notifiable events since the previous care inspection
- the registration status of the establishment
- written and verbal communication received since the previous care inspection
- the previous care inspection report

One week prior to the onsite inspection, TFP Belfast Fertility was provided with a list of specific documents requesting items to be reviewed remotely in respect of the maintenance of the premises and grounds. These items were to be sent electronically to RQIA's estates inspector on or before 21 February 2025 for review.

The onsite component of our inspection was completed on 12 and 13 of February 2025 and was facilitated by Mr Moohan, Mr Caulfield, the TFP Group Fertility legal manager and other members of the TFP Belfast Fertility management team. The inspection team met with various staff members, observed care practices and reviewed relevant records and documentation used to support the governance and assurance systems.

The onsite inspection teams examined a number of aspects of the clinic's services as outlined in section 2.0 of this report. The care team undertook a tour of the premises and met with various staff members and reviewed relevant records and documentation.

4.0 What people told us about the service.

The inspection team did not have the opportunity to speak with patients during the inspection.

Posters were issued to TFP Belfast Fertility by RQIA prior to the inspection inviting patients and members of staff to complete an electronic questionnaire. No completed patient or staff questionnaires were received prior to the inspection.

Mr Caulfield confirmed that monthly patient satisfaction surveys are completed and the findings are shared through their governance structures. A review of recent patient satisfaction reports demonstrated that TFP Belfast Fertility pro-actively seeks the views of patients and their partners about the quality of care, treatment and other services provided.

Patient feedback regarding the fertility service was found to be positive in respect to all aspects of care received and reflected that staff deliver a very high standard of care. It was noted that any suggestions made by patients on areas that could be improved were discussed at monthly quality management meetings.

An annual summary of the findings of the patient satisfaction reports are published in the service user guide for review by patients and interested parties.

All staff spoken with during the inspection spoke about TFP Belfast Fertility in positive terms. Staff spoke in a complimentary manner regarding the TFP Belfast Fertility management team and the communication and support they have provided. No areas of concern were raised by staff during the onsite inspection.

5.0 The inspection

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

The last inspection to TFP Belfast Fertility was undertaken on 26 February 2024; One area for improvement was identified.

Areas for improvement from the last inspection on 26 February 2024		
Action required to ensure compliance with Minimum Care Standards for Independent Healthcare Establishments (July 2014)		**Validation of compliance**
Area for Improvement 1 **Ref:** Standard 20.5 **Stated:** First time	The responsible individual shall ensure laryngoscope blades which are available as part of the emergency equipment are stored in sterile packaging following reprocessing or disposable laryngoscope blades are used on a single use approach basis.	**Met**
	Action taken as confirmed during the inspection: It was confirmed laryngoscope blades are available as part of the emergency equipment; are stored in sterile packaging; and are treated as a single use only item.	

5.2 Inspection findings

5.2.1 How does the establishment ensure that safe staffing arrangements are in place to meet the needs of patients?

Staffing arrangements were reviewed and it was confirmed that there are appropriately skilled and qualified staff involved in the delivery of services. This includes a team of doctors, anaesthetists, embryologists and nurses who have completed specialist qualifications and can demonstrate competency in fertility treatments.

A review of records confirmed that comprehensive induction and competency programmes were in place appropriate to the roles and responsibilities within the establishment. A review of induction and competency records in respect of recently appointed staff evidenced robust completion of these programmes with ongoing learning needs identified and addressed.

A training matrix was in place to monitor the status of staff training requirements that included all staff who work in the establishment. The staff training matrix evidenced a high compliance rate with the establishment's mandatory training requirements. The matrix enables the effective oversight of staff training and ensure that all persons who work in the establishment complete training as outlined in the RQIA training guidance and that training is refreshed within the required timelines.

Rotas for on call, staffing and clinical cover were made available for review and included availability of the quality manager and general manager.

Review of documentation identified that arrangements were in place to check the registration status for all clinical staff on appointment for example: medical practitioners with the General Medical Council (GMC), nursing staff with the Nursing and Midwifery Council (NMC) and health and care professionals with the Health Care Professional Council (HCPC).

It was evidenced that the registration status and professional indemnity of medical practitioners continues to be monitored on an annual basis.

It was confirmed that a robust system was in place for ongoing monitoring of the professional body registration status of all other staff groups.

Discussion with staff confirmed there are good working relationships. They all spoke positively regarding the establishment, felt valued as members of the team and confirmed they were supported by management.

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

5.2.2 How does the establishment ensure that recruitment and selection procedures are safe?

The arrangements in respect of the recruitment and selection of staff were reviewed.

A review of the policy and procedure for the recruitment and selection of staff found that the policy was in accordance with legislation and best practice guidance.

A staff register was available to review which was up to date and included the names and details of all staff who are and have been employed.

It was confirmed that a number of staff had been recruited since the previous inspection. A review of a random sample of three personnel files of newly recruited staff could not confirm that all relevant information had been sought, reviewed and stored as required. This matter was discussed with Mr Caulfield who subsequently accessed the outstanding information. Mr Caulfield was advised to ensure that all required recruitment records are retained within corresponding personnel files and are readily accessible for review at inspection.

The oversight of recruitment and selection of staff was discussed. It was established that all recruitment records are centrally held electronically by TFP human resources (HR) department and that the TFP Belfast Fertility management have access to the electronic system enabling oversight of the recruitment and selection of staff. It was confirmed that new employee's details are reviewed monthly at the quality meetings.

Robust recruitment and selection procedures were in place to ensure compliance with the legislation and best practice guidance.

5.2.3 Are the arrangements in place for safeguarding in accordance with current regional guidance?

The arrangements in respect of the safeguarding of adults and children were reviewed. It was confirmed that treatments are not provided to persons under the age of 18 years.

Policies and procedures were in place for the safeguarding and protection of adults and children at risk of harm. The policies included the types and indicators of abuse and distinct referral pathways in the event of a safeguarding issue arising with an adult or child. The relevant contact details were included for onward referral to the local Health and Social Care Trust should a safeguarding issue arise.

Review of records demonstrated that all staff had received training in safeguarding adults as outlined in the Minimum Care Standards for Independent Healthcare Establishments July 2014.

It was confirmed are aware of the types and indicators of abuse and the actions to be taken in the event of a safeguarding issue being identified. The identified safeguarding lead had completed safeguarding training at the level required in keeping with the Northern Ireland Adult Safeguarding Partnership (NIASP) training strategy (revised 2016) and minimum standards.

It was confirmed that a copy of the regional guidance document entitled Adult Safeguarding Prevention and Protection in Partnership (July 2015) was available for reference.

It was demonstrated that appropriate arrangements were in place to manage a safeguarding issue should it arise.

5.2.4 Does the establishment adhere to best practice guidance concerning the management of patients undergoing fertility treatment?

TFP Belfast Fertility is licensed until November 2027 with the Human Fertilisation and Embryology Authority (HFEA), the UK's independent regulator for the fertility sector.

TFP Belfast Fertility has held a Treatment and Storage license with the HFEA since November 2013 and provides a full range of fertility services.

A range of treatment protocols were 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 clinicians, a review of these protocols demonstrated that they were evidence based and in line with best practice.

It was confirmed that written protocols are in place for the close monitoring of patients, in order to avoid unnecessary complications including multiple pregnancies. An elective single embryo transfer (eSET) protocol was in place.

It was confirmed that the eSET protocol sets out the number of embryos that can be placed in a woman in any one cycle and this protocol complies with the HFEA Code of Practice.

The protocols and procedures were discussed with the laboratory manager, embryologist and a fertility nurse who demonstrated detailed knowledge on the matter.

It was confirmed that the establishment have 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.

There was evidence that there is suitable counselling regarding treatment and outcomes and there was documentation to reflect this. Staff confirmed that patients and their partners are treated with respect, dignity and compassion. A small number of interactions between staff and patients were observed that confirmed this approach.

A counselling policy and procedure was in place providing patients and their partners with information on how to access counselling services.

A weekly multidisciplinary clinical review meeting (CRM) takes place and is attended by the consultants, registered nurses and members of the embryology team to decide and agree patient treatment plans and the agreed outcome is recorded in the patient's electronic record.

The agreed treatment schedule is then transcribed by a nurse and thereafter signed by a consultant with appropriate checks in place to ensure accuracy. There are also daily clinical meetings that take place to discuss the management of patients and any recommended changes to treatment plans would be discussed and agreed at these meetings.

A review of three patients' electronic clinical records found that all records were well completed and clearly outlined the patient pathway.

The inspection team noted that a range of laboratory audits were in place which demonstrated a high level of compliance with laboratory protocols. The outcome of these audits is shared with the team to continue to drive improvement.

Discussion with staff and review of relevant policies and procedures evidenced that TFP Belfast Fertility were adhering to HFEA best practice guidance.

5.2.5 Is this establishment fully equipped and are the staff trained to manage medical emergencies?

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

The policy for the management of medical emergencies was in place and review found it to be largely in keeping with best practice. Advice was provided to include a list of contents and the location of the emergency medicines and emergency equipment; the monitoring arrangements for the medical emergency equipment and medications; and arrangements for a debrief following a medical emergency. Following the inspection RQIA received evidence this matter had been actioned.

Emergency medicines are kept in the theatre and the emergency equipment is kept in the resuscitation trolley located in the corridor outside the theatre and recovery area. The resuscitation trolley was observed to be well organised and well stocked. An anaphylaxis kit was also available in the 'blood room'.

Emergency medicines were checked daily and staff confirmed that the system in place to ensure that emergency medicines do not exceed their expiry date is being further developed. The resuscitation trolley checklist fully reflected the items retained in the trolley and emergency equipment had been stored within their expiry dates. It was determined an area of improvement in relation to the storage of laryngoscope blades outlined in section 5.1 of this report had been addressed.

The management of a massive blood loss was discussed with staff who clearly outlined the arrangements. However, there was no formal massive blood loss protocol in place and a dedicated massive blood loss tray. Following the inspection RQIA received evidence that the management of a medical emergency procedure had been amended to include management of a massive blood loss emergency. Assurances were given that the establishment of a massive blood loss tray would be considered.

Staff spoken with have knowledge and understanding of managing resuscitation and other medical emergencies and confirmed they had completed training in this area. Sufficient emergency medicines and equipment were in place and staff demonstrated action to be taken in the event of a medical emergency.

5.2.6 Does the establishment adhere to infection prevention and control (IPC) best practice guidance?

The arrangements for IPC procedures throughout the establishment were reviewed to ensure measures were in place to minimise the risk of infection transmission to patients, visitors and staff. It was confirmed that an overarching IPC policy and procedures were in place. During a tour of the premises it was noted that the establishment was clean, tidy and uncluttered.

Equipment was also found to be clean, free from damage and in good repair. Review of relevant records confirmed that cleaning records were completed and up to date. Review of staff training records evidence that staff IPC training had been completed. Discussion on aseptic non touch technique (ANTT) training noted that there was not a formalised approach to this. Following the inspection RQIA received a written detailed standard operating procedure (SOP) for ANTT which included clear arrangements to ensure the SOP is adhered to and relevant staff receive ANTT training.

It was noted that clinical hand washing basins located in each consulting room and other clinical areas were clean and clutter free. Hand washing basins were found to be used for hand hygiene practices only and a hand hygiene poster was displayed close to each basin.

Staff were observed to undertake hand hygiene in accordance with best practice. Personal protective equipment (PPE) was readily available in keeping with best practice guidance. It was observed that a list of PPE required for each procedure was displayed on the main procedure room door. Staff told us that contracts are in place for the laundering of uniforms/scrubs and bedlinen.

It was confirmed that there was decontamination equipment in place for the decontamination of ultrasound probes and staff confirmed that they had received training on the use of this equipment. Staff informed us that no reusable medical devices are used in the clinic.

Waste management arrangements were in place and clinical waste bins were pedal operated in keeping with best practice guidance. The management of sharps was discussed with staff outlined arrangements in line with IPC best practice.

We observed that a colour coded cleaning system was in place and staff were aware of best practice guidance in this regard. It was evidenced that robust IPC related audits are being carried out by staff and where deficits are identified a meaningful action plan has been developed. An IPC summary report of the findings of the wide range of IPC audits was in place to allow for increased accessibility to this valuable information by management and staff.

It was determined that the establishment had appropriate arrangements in place in relation to IPC and decontamination.

5.2.7 Does the establishment adhere to best practice guidance concerning the management of medicines, including controlled drugs?

Written policies and Standard Operating Procedures (SOP)s for the management of medicines, including controlled drugs, were in place. There was evidence these were routinely reviewed and updated. Revised SOPs were currently in development. A system was in place to ensure all staff involved in the management of medicines had read and understood the policies and procedures.

Medicines for use in theatre, recovery and for take-home (following a procedure) were prescribed by an anaesthetist. Medicines for use at home were prescribed by a consultant; the patient was either provided with a private prescription or the medicines were supplied directly to the patient's home from a specialist pharmacy supplier. If top-up prescriptions of fertility medicines were required, a private prescription signed by a consultant was issued and the medicines were supplied directly to the patient.

There was suitable counselling regarding treatment and outcomes and documentation to reflect this. Patients were provided with information regarding their treatment and the medicines prescribed; this included detailed advice on the purpose of the medicines, how to administer them at home and any potential side effects. This information was given verbally, in paper form and electronically. Any changes to treatment were communicated to patients both verbally and electronically and records were maintained.

There were safe arrangements in place for the stock control and storage of medicines. Stock medicines were ordered on requisition forms from a local wholesaler; controlled drug requisition forms (CDRF1s) were used for controlled drugs.

Medicines were stored safely and securely and in accordance with the manufacturer's instructions, in locked cupboards in theatre and in a separate treatment room. Temperatures of the medicine storage areas were monitored to ensure medicines were stored according to the manufacturers' instructions. Satisfactory arrangements were in place for monitoring the temperature of the medicine refrigerators and for the disposal of medicines.

The Accountable Officer (AO) is responsible for the management of controlled drugs and related governance issues in their organisation. The management of controlled drugs was in compliance with legislative requirements, professional standards and guidelines.

A controlled drug licence, issued by the Medicines Regulatory Group at the Department of Health, was in place. Satisfactory arrangements were in place for the destruction of controlled drugs, with denaturing kits available for this purpose.

Systems were in place to ensure training on medicines management was provided for relevant staff. Refresher training and competency assessment was completed annually. Competencies were reassessed following any medication related incidents or if a need was identified through the audit process.

Systems were in place for the management of drug and medical device alerts issued by the Medicines and Healthcare Regulatory Agency (MHRA). Mr Caulfield maintains a database of all alerts received and the action taken.

An effective incident reporting system was in place to identify, record, report and share learning from any medicine related incidents. Medicine related incidents are reported to RQIA and any which involve controlled drugs are also reported to the Local Intelligence Network.

Arrangements were in place to audit the management of medicines. Evidence of this activity was maintained. In addition to the six-monthly controlled drugs audit and annual medicine management audit, there was regular review of patient records and daily review of the controlled drug record book. The was weekly stock level and date checking for the medicines held on-site.

It was demonstrated that establishment adheres to best practice guidance concerning the management of medicines, including controlled drugs.

5.2.8 How does the service ensure the environment is safe?

The management of the environment component of this inspection was completed remotely. The management team of the establishment were provided with a checklist of estates related items to submit to the estates inspector for review. This included certification relating to the maintenance and upkeep of the building and engineering services as well as relevant risk assessments.

All requested documentation was submitted and was found to be in order. It was confirmed that the maintenance of the building and engineering services were in line with relevant codes of practice and standards and are carried out by a range of specialist contractors.

These included:

- Fire alarm & detection system including weekly user checks
- Emergency lighting installation including monthly user checks
- Portable fire-fighting equipment including monthly user checks
- Passenger lift service contract
- LOLER Thorough Examination of lifting equipment
- Legionella risk assessment
- Fixed electrical installation
- Portable appliance testing
- 'Gas Safe' certification
- Boiler and space heating service contract
- Mechanical ventilation systems service contract and validation reports

The fire risk assessment was undertaken on 2 April 2024 by a risk assessor who is listed on an accredited register of fire risk assessors. The fire risk assessor assessed the risk in the premises as 'tolerable'.

All staff have undertaken fire safety training within the last 12 months. The legionella risk assessment was carried out by a specialist legionella control company on 19 December 2024, and it was determined that the recommendations made in the risk assessment report have been addressed and suitable control measures are being maintained.

The current arrangements, with respect to estates management, were noted to be of a high standard with suitable arrangements in place for the provision of necessary specialist services. It was noted that the premises specialised ventilation systems are serviced in accordance with current best practice guidance and suitable validation is undertaken in accordance with the current HFEA guidance. Records and validation reports were available and inspected at the time of the inspection.

It was determined that procedures are in place for maintaining the premises, engineering services and equipment in line with legislation, current standards of best practice and manufacturers' and suppliers' guidance and that these are regularly reviewed and updated.

5.2.9 Are robust arrangements in place regarding clinical and organisational governance?

Organisational governance

TFP Belfast Fertility is one of the HFEA licensed centres belonging to The Fertility Partnership (TFP), which is an international network of fertility treatment clinics with eight treatment clinics and 16 satellite clinics operating across the UK.

Various aspects of the organisational and medical governance systems were reviewed and evidenced a clear organisational structure within TFP Belfast Fertility with support from management at the TFP Group.

Discussion with Mr Moohan and the TFP group legal manager confirmed that the senior management team in TFP Belfast are supported by the TFP group's chief clinical officer (CCO) and chief operating officer (COO).

The clinical team at TFP Belfast is led by the medical director, and he is supported by a group of clinicians, who are also clinic level minority shareholders within the TFP Group. One clinician, Mr James Moohan, is the clinic's nominated responsible individual for RQIA.

A Medical Advisory Committee (MAC) is formalised within the governance structures of the clinic. A review of the terms of reference identified that membership of the MAC consists of the clinical team along with the general manager, the quality manager and the three departmental managers for laboratory, nursing and patient support respectively. Discussion with Mr Moohan and review of minutes confirmed that the MAC meets every two months. The MAC reviews the latest key performance indicators, clinical incidents and audit findings within the establishment.

Discussion with staff and a review of records evidenced that a clinicians meeting takes place every two months and is attended by all clinicians and managers who work in Belfast Fertility. The meeting acts as a forum in which the medical director can provide feedback from the TFP group's lead clinician and the (UK) medical directors meeting.

A clinical review meeting takes place every Thursday. There are staff meetings monthly and managers hold separate departmental meetings which allow important information from management forums to be disseminated to and discussed with staff.

A formal quality management review meeting takes place annually to which all staff are invited. The most recent presentations from this meeting were available for review.

It was evidenced that governance structures were functioning well to provide a level of assurance to the TFP group senior management and governance teams.

Since the last RQIA inspection, a new quality manager has commenced work. The quality manager is supported by TFP group Head of Quality and the Group Director of Quality, Compliance and Risk. We noted through discussions with staff, that the new quality manager has had a positive impact on the team and quality management system which we found to be well developed and maintained.

Where the business entity operating an assisted fertility service is a corporate body or partnership or an individual owner who is not in day to day management of the service, unannounced quality monitoring visits by the registered provider, or person acting on their behalf, must be undertaken and documented every six months; as required by Regulation 26 of The Independent Health Care Regulations (Northern Ireland) 2005.

During the previous RQIA inspection, it was established that Mr Moohan, Responsible Individual, is not in day to day charge of the service and therefore unannounced quality monitoring visits would need to take place.

It was evidenced that the Group Director of Quality, Compliance and Risk had undertaken two unannounced monitoring visits to TFP Belfast during August 2024 and January 2025. The reports of the unannounced monitoring visits along with any identified actions were available for inspection.

Mr Moohan confirmed that, as the responsible individual, he had oversight of these reports and confirmed that any identified deficits would be addressed at the regular management meetings, at which Mr Moohan is in attendance.

Clinical governance

A team of consultants and embryologists who have specialist qualifications and skills in fertility treatments work in TFP Belfast Fertility.

We identified that four consultants are considered to be wholly private doctors as they no longer hold a substantive post in the Health and Social Care (HSC) sector in Northern Ireland (NI) and are not on the General Practitioner's (GP's) performer list in NI.

Review of the four private doctors' details confirmed there was evidence of the following:

- confirmation of identity
- current GMC registration
- professional indemnity insurance
- qualifications in line with service provided
- ongoing professional development and continued medical education that meets the requirements of the Royal Colleges and GMC
- ongoing annual appraisal by a trained Medical Appraiser
- each doctor/surgeon has an appointed Responsible Officer (RO)
- arrangements for revalidation

Private doctors are required to complete training in accordance with RQIA's training guidance. As previously discussed a training matrix was in place to monitor the status of staff training requirements that included all staff who work in the establishment.

All medical practitioners working within the establishment must have a designated RO. In accordance with the GMC all doctors must revalidate every five years. The revalidation process requires doctors to collect examples of their work to understand what they are doing well and how they can improve. Experienced senior doctors (called Responsible Officers) work with the GMC to make sure doctors are reviewing their work. As part of the revalidation process RO's make a revalidation recommendation to the GMC. Where concerns are raised regarding a doctor's practice information must be shared with their RO who then has a responsibility to share this information with all relevant stakeholders in all areas of the doctor's work.

The current arrangements supporting medical appraisal and revalidation with a RO for all consultants working in the establishment was reviewed. TFP is a designated body and the group has an identified RO with whom these private doctors are connected for the purpose of appraisal and revalidation. It was confirmed that the other consultants who work in TFP Belfast Fertility hold a substantive post in HSC and complete their annual appraisal and medical revalidation through their employing organisations which are either by local HSC Trusts or other HSC organisations.

It was confirmed by management that all private doctors are aware of their responsibilities under GMC Good Medical Practice.

Practising Privileges

The only mechanism for a clinician to work in a registered independent hospital is either under a practising privileges agreement or through direct employment by the establishment.

Practising privileges can only be granted or renewed when full and satisfactory information has been sought and retained in respect of each of the records specified in Regulation 19 of The Independent Health Care Regulations (Northern Ireland) 2005, as amended.

A policy and procedural guidance for the granting, review and withdrawal of practicing privileges agreements was in place.

An electronic list of all medical practitioners with a practising privileges agreement in place was provided for review. The list included the date practising privileges were established and the renewal date for each individual.

A review of a sample of three medical practitioner's files confirmed that all documentation was in place with regards to practising privileges.

It was confirmed that the medical director is responsible for ensuring practising privileges agreements for clinicians are updated every two years.

During this inspection a review of the oversight arrangements of the granting of practicing privileges agreements has provided assurance of robust medical governance arrangements within the organisation.

Quality assurance

The procedures in place for clinical and internal audit were reviewed with the quality manager. It was confirmed that an annual, organisational audit programme has been devised with the assistance of the medical director, which aims to ensure that patients receive the best quality of care. The schedule reviewed included audit topics for clinical and laboratory areas. Process audits are undertaken to measure compliance with policies and procedures. The quality manager confirmed that ad-hoc audits can be conducted in response to incident trends, events and near misses.

The quality manager explained the arrangements are in place for departmental managers to monitor and review the results of relevant audits at appropriate intervals. Staff receive audit training and inter-departmental audits are standard practice.

The results of audits and actions identified for improvement are shared with staff. The quality manager demonstrated how action plans are developed and embedded into practice to address any non-compliances identified during the audit process.

There were clear effective processes for managing risks, issues and performance. Review of the risk register confirmed that risk is understood and subjected to regular and ongoing review and management. The risk register recorded a brief description, the severity and likelihood rating, mitigation measures, responsible person and a target review date.

The quality manager confirmed TFP group level objectives and quality indicators were established. Key performance indicators (KPIs) were discussed. KPIs are used to measure performance and are collated by the quality manager and then reported quarterly at group level.

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 Statement of Purpose and Patient's Guide were kept under review, revised and updated when necessary and available on request.

The RQIA certificate of registration was up to date and displayed appropriately and current insurance policies were in place.

Notifiable Events/Incidents

A robust system was in place to ensure that notifiable events were investigated and reported to RQIA or other relevant bodies as appropriate.

A review of notifications submitted to us since the previous inspection demonstrated that a system was in place to ensure that notifiable events were investigated and reported to RQIA, HFEA or other relevant bodies as appropriate within a timely manner.

The quality manager demonstrated that incidents, events and near misses are reported and managed on the clinic's quality management system (QMS).

Discussion with the quality manager and review of the QMS found that a robust process is in place for analysing incidents and events to detect potential or actual trends or weakness in a particular area.

It was established that a prompt and effective response is considered by the senior management team with regards to any identified trends.

It was found that a robust process for analysing incidents and events to detect potential or actual trends or weakness in a particular area was in place. It was established that a prompt and effective response is considered by the senior management team at the earliest opportunity.

It was evidenced that learning from incidents is shared with staff. Learning is discussed and recorded in the minutes of the staff and departmental meetings and an annual analysis is presented to all staff at the annual quality management review group.

It was demonstrated that governance structures and systems were in place to ensure that patient safety incidents and near misses were being monitored and managed, when required, in a prompt and effective manner.

Complaints Management

A copy of the complaints procedure was available in the establishment and was found to be in line with the relevant legislation and Department of Health (DoH) guidance on complaints handling. It was noted that an amendment was required to be made to the complaints policy.

This matter was discussed with Mr Caulfield and assurances where provided to RQIA that this matter would be addressed following the inspection.

A copy of the complaints procedure is made available for patients/and or their representatives on request and that patients can make a complaint verbally, in writing, electronically or via the Patient Support Centre.

Discussion with Mr Caulfield and the quality manager evidenced that complaints were investigated and responded to appropriately.

Records of all complaints were managed on the clinic's quality management system (QMS). A review of these records confirmed that they included details of all communications with complainants; the result of any investigation; the outcome and any action taken. The QMS allows the quality manager to track the progress of complaints and ensure they are resolved in a timely manner.

Complaints received are reviewed and discussed on a monthly basis by management. Review of the meeting minutes demonstrated that corrective action is agreed and the outcome monitored.

Mr Caulfield, in his role as complaints manager for TFP Belfast, demonstrated a good awareness of complaints management and told us that staff have customer support training and are aware of their responsibilities should a complaint be raised with them directly.

Complaints are also reviewed on a quarterly basis to identify trends and take appropriate action. The quality manager provided examples to RQIA of how the information gathered from complaints has been used to improve the quality of services provided.

It was demonstrated that governance structures and systems were in place to ensure that complaints were being managed effectively in accordance with legislation and best practice guidance.

5.3 Does the service have suitable arrangements in place to record equality data?

The arrangements in place in relation to the equality of opportunity for patients and the importance of staff being aware of equality legislation and recognising and responding to the diverse needs of patients was discussed with several members of the team.

Discussion and review of information evidenced that the equality data collected was managed in line with best practice.

6.0 Quality Improvement Plan/Areas for Improvement

This inspection resulted in no areas for improvement being identified. Findings of the inspection were discussed with Mr Caulfield, Registered Manager, the TFP Group Fertility legal manager and other members of the TFP Belfast Fertility management team, as part of the inspection process and can be found in the main body of the report.

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