The Regulation and Quality Improvement Authority

# Inspection Report

## 26 February 2024

# 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:**<br>GCRM Belfast Ltd<br><br>**Responsible Individual:**<br>Mr James Moohan | **Registered Manager:**<br>Mr Andrew Caulfield – acting manager<br><br>**Date registered:**<br>Application submitted - awaiting registration |
| **Person in charge at the time of inspection:**<br>Mr Andrew Caulfield | |
| **Categories of care:**<br>Independent hospital (IH)<br>Prescribed techniques or prescribed technology: establishments providing in vitro fertilisation techniques PT (IVF)<br>Private doctor (PD) | |
| **Brief description of how the service operates:**<br>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.<br><br>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

An announced inspection was undertaken to TFP Belfast Fertility which commenced with an onsite inspection on 26 February 2024 from 10.00 am to 5.00pm and included a request for the submission of information electronically.

The onsite component of the inspection was completed on 26 February 2024 by three care inspectors. Feedback of the onsite inspection findings was delivered to the TFP Belfast Fertility senior management team on the day of the inspection.

The electronic submission of additional documentation in relation to the premises aspect of the inspection was reviewed remotely by a RQIA estates inspector and feedback was provided to the clinic 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, to the management and oversight of governance across the establishment.

Through discussion with a number of staff who have differing roles and responsibilities it was determined that staffing levels and morale were good with evidence of good multidisciplinary team working and effective 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; safeguarding; the provision of assisted conception services; the management of medical emergencies; infection prevention and control; adherence to best practice guidance in relation to COVID-19: the management of the patients' care pathway; engagement to enhance the patients' experience; and the maintenance of the environment; clinical and organisational governance;

One area for improvement has been identified in relation to the storage of an item of emergency equipment.

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

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

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 our estates inspector on or before 11 March 2024 for review.

The onsite component of our inspection was completed on 26 February 2024 and was facilitated by the head of quality, TFP UK; Mr Caulfield, applicant registered manager and other members of the TFP Belfast Fertility management team. The inspection team undertook a tour of the premises and met with various staff members. They also observed care practices and reviewed relevant records and documentation used to support the governance and assurance systems.

## 4.0 What people told us about the service

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.

The inspection team were informed 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 last inspection?

| **Areas for improvement from the last inspection on 13 March 2023** | | |
|---|---|---|
| **Action required to ensure compliance with The Independent Health Care Regulations (Northern Ireland) 2005** | | **Validation of compliance** |
| **Area for Improvement 1**<br><br>**Ref:** Regulation 18 (2) (a)<br><br>**Stated:** First time | The responsible individual must ensure that the staff members not included in the training matrix undertake all areas of mandatory training as a priority. Confirmation in this area should be provided upon submission of this QIP. | |

| | | |
|---|---|---|
| | **Action taken as confirmed during the inspection**:<br>This area for improvement has been assessed as met. Further detail is provided in section 5.2.1 | **Met** |
| **Area for Improvement 2**<br><br>**Ref:** Regulation 18 (2) (a)<br><br>**Stated:** First time | The responsible individual must establish effective oversight of staff training and ensure that all persons who work in the establishment have completed training as outlined in the RQIA training guidance and that training is refreshed within the required timeline. | **Met** |
| | **Action taken as confirmed during the inspection**:<br>This area for improvement has been assessed as met. Further detail is provided in section 5.2.1 | |
| **Area for Improvement 3**<br><br>**Ref:** Regulation 19 (2) (d), (as amended)<br><br>**Stated:** Second time | The responsible individual must ensure that all information as listed in Regulation 19 (2) (d), Schedule 2 of the Independent Health Care Regulations (Northern Ireland) 2005 is sought and retained for any new staff commencing work in the future. | **Met** |
| | **Action taken as confirmed during the inspection**:<br>This area for improvement has been assessed as met. Further detail is provided in section 5.2.2 | |
| **Area for Improvement 4**<br><br>**Ref:** Regulation 25 (3) (c)<br><br>**Stated:** Second time | The responsible individual must ensure that all staff undertake fire safety awareness training as outlined in the RQIA training guidance. | **Met** |
| | **Action taken as confirmed during the inspection**:<br>This area for improvement has been assessed as met. Further detail is provided in section 5.2.1 | |
| **Area for Improvement 5**<br><br>**Ref:** Regulation 26<br><br>**Stated:** First time | The responsible individual shall ensure that an unannounced monitoring visit is undertaken on a six monthly basis as required under Regulation 26 of The Independent Health Care Regulations (Northern Ireland) 2005. | |

| | | |
|---|---|---|
| | A report of this visit should be made available for patients, their representatives, staff, RQIA and any other interested parties to read. | **Met** |
| | **Action taken as confirmed during the inspection**:<br>This area for improvement has been assessed as met. Further detail is provided in section 5.2.9 | |
| **Area for improvement 6**<br><br>**Ref:** Regulation 17 (1)<br><br>**Stated:** Second time | The responsible individual must ensure that they have oversight of addressing the areas for improvement within this quality improvement plan and that the identified issues are actioned in a timely manner. | |
| | **Action taken as confirmed during the inspection**:<br>This area for improvement has been assessed as met. Further detail is provided in section 5.2.9 | |
| **Area for improvement 7**<br><br>**Ref:** Regulation 17 (1)<br><br>**Stated:** First time | The responsible individual should review the effectiveness of the current governance and oversight arrangements. Detail of the outcome of this review should be provided to RQIA upon return of the QIP. | |
| | **Action taken as confirmed during the inspection**:<br>This area for improvement has been assessed as met. Further detail is provided in section 5.2.9 | |
| **Action required to ensure compliance with The Minimum Care Standards for Independent Healthcare Establishments (July 2014)** | | **Validation of compliance** |
| **Area for Improvement 1**<br><br>**Ref:** Standard 13.9<br><br>**Stated:** Second time | The responsible individual must ensure staff have an annual appraisal to review their performance against their job description and an agreed personal development plan. | |
| | **Action taken as confirmed during the inspection**:<br>This area for improvement has been assessed as met. Further detail is provided in section 5.2.1 | **Met** |

| | | |
|---|---|---|
| **Area for improvement 2**<br><br>**Ref:** Standard 14<br><br>**Stated:** Second time | The responsible individual must ensure that the recruitment policy and procedures are further developed to include detail of the recruitment documents to be sought and retained, as outlined in Standard 14. | **Met** |
| | **Action taken as confirmed during the inspection**:<br>This area for improvement has been assessed as met. Further detail is provided in section 5.2.2 | |
| **Area for improvement 3**<br><br>**Ref:** Standard 46<br><br>**Stated:** First time | The responsible individual must devise a counselling procedure to compliment the counselling policy in place. | **Met** |
| | **Action taken as confirmed during the inspection**:<br>This area for improvement has been assessed as met. Further detail is provided in section 5.2.4 | |
| **Area for improvement 4**<br><br>**Ref:** Standard 47.3<br><br>**Stated:** First time | The responsible individual must include details in the ovarian hyper stimulation syndrome (OHSS) protocols of the Northern Ireland Maternal and Child Health (NIMACH) in relation to notification of patient's deaths associated with OHSS. | **Met** |
| | **Action taken as confirmed during the inspection**:<br>This area for improvement has been assessed as met. Further detail is provided in section 5.2.4. | |

## 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.

Staff spoken with confirmed that induction programmes were in place appropriate to the roles and responsibilities within the establishment. A review of an induction record in respect of recently appointed staff evidenced that this had been completed and retained.

A training matrix was in place to monitor the status of staff training requirements that included all staff who work in the establishment. It was determined that area for improvement 1 made against the regulations as outlined in section 5.1, has been addressed.

An area for improvement had been made during the previous inspection to ensure that all staff undertake fire safety awareness training in keeping with RQIA training guidance and legislation. A review of the staff training matrix evidenced that this area for improvement 4 made against the regulations as outlined in section 5.1, has been addressed.

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 timeline. It was determined that area for improvement 2 made against the regulations as outlined in section 5.1, has been addressed.

Discussion with staff confirmed that the procedures for appraising staff performance had been reviewed and further developed since the previous inspection. It was confirmed arrangements have been established to ensure that all staff have an appraisal in February/March each year, this arrangement ensures that all staff including new staff members are captured. It was determined that area for improvement 1 made against the standards as outlined in section 5.1, has been addressed.

Discussion with the nurse manager and the laboratory manager, and 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 during the renewal of their practising privileges agreement which occurs every two years, this is discussed further in section 5.2.10. In relation to nursing staff, a system was in place for ongoing monitoring of the professional body registration status. However, it was identified that there was no evidence of professional body registration status for one new member of staff recently recruited and there was also no evidence that two nurses had renewed their professional body registration. Following the inspection RQIA received evidence of the professional body registration status for the identified new member of staff and for both identified nurses.

The current system should be reviewed to ensure the registration status of staff is available for inspection. Although it is not compulsory for embryologists to register with the HCPC, it was confirmed that four embryologists are registered with the HCPC and other trainee embryologists are working towards registration. The laboratory manager confirmed that they monitor the registration status of the embryologists.

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.

During the previous inspection it was identified that the recruitment and selection policy did not include the recruitment records required to be sought and retained in respect of a new staff member as outlined in legislation and best practice guidance and an area for improvement had been made in this regard. On the day of this inspection a recruitment and selection policy and procedure was in place, which adhered to legislation and best practice guidance for the recruitment of staff. It was determined that area for improvement 2 made against the standards as outlined in section 5.1, has been addressed. Adhering to the policy and procedure will ensure that all required recruitment documentation has been sought and retained for inspection.

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 evidenced that relevant information had been sought, reviewed and stored as required, with the exception of; a criminal conviction declaration for one staff member and evidence of the professional body registration status for one staff member. Following the inspection evidence of the criminal conviction declaration and professional registration for the identified staff members was provided to RQIA. It was determined that area for improvement 3 made against the regulations as outlined in section 5.1, has been addressed.

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 giving oversight of the recruitment and selection of staff. It was confirmed that new employee's details are reviewed monthly at the quality meetings.

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 advised to include an additional column in the staff register to record the date staff leave employment at TFP Belfast Fertility. The staff register evidenced that a number of staff had been recruited since the previous inspection.

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.

Staff spoken with were aware of the types and indicators of abuse and the actions to be taken in the event of a safeguarding issue being identified.

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. The safeguarding lead are identified to all staff members on a daily basis during the daily safety brief.

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 determined that area of improvement 4 made against the standards as outlined in section 5.1, has been addressed.

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 senior embryologist, the nurse manager and fertility nurses 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. It was determined that area for improvement 3 made against the standards as outlined in section 5.1, has been addressed.

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 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 two 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 had been reviewed since the previous inspection and was found to be in keeping with best practice.

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. It was advised to ensure the expiry date for each emergency medication is recorded in the monitoring record. The resuscitation trolley checklist fully reflected the items retained in the trolley and emergency equipment had been stored within their expiry dates.

It was noted that an uncovered laryngoscope blade was available as part of the emergency equipment, it was advised this type of equipment requires to be stored in sterile packaging following reprocessing or disposable laryngoscope blades should be used as a single use approach. An area of improvement has been identified against the standards on this matter.

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 Are arrangements in place to minimise the risk of COVID-19 transmission?

The management of operations in response to the COVID-19 pandemic was discussed with the staff; and application of the current best practice guidance. The policy and procedure for the management of COVID-19 had been updated.

There is an identified COVID-19 lead and arrangements were in place to ensure the clinic is regularly reviewing COVID-19 advisory information, guidance and alerts. The nurse manager confirmed that staff had completed COVID-19 training in line with current guidance.

It was determined the management of COVID-19 was in line with best practice guidance and appropriate actions had been taken in this regard.

### 5.2.7 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.

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 identified that decontamination equipment had been procured 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. However, as outlined in section 5.2.5 the use of reusable laryngoscope blade requires to be reviewed.

Waste management arrangements were in place and clinical waste bins were pedal operated in keeping with best practice guidance. A review of the management of sharps had been undertaken since the previous inspection and a number of sharps boxes observed evidenced that the closures were being operated 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.

Discussion with staff and review of IPC audits demonstrated that the system for auditing had been reviewed since the previous inspection. It was evidenced that more 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.

### 5.2.8 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 4 April 2023 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 7 February 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 a group of international clinics specialising in assisted conception. Various aspects of the organisational and medical governance systems were reviewed and evidenced a clear organisational structure within TFP Belfast Fertility and also within the TFP Group.

The Belfast Fertility Board of Directors includes four clinical directors from TFP Belfast Fertility, the TFP's chief executive officer, the chief operating officer, and the medical director. The Board of Directors meet quarterly and this meeting is also attended by the TFP UK operations director and the TFP Belfast Fertility general manager. Minutes of meetings were reviewed and confirmed that the Board of Directors undertakes the Medical Advisory Committee (MAC) function for the establishment. The MAC reviews the latest key performance indicators 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 who work in Belfast Fertility. This meeting is also attended by the general manager; the quality manager and the nurse manager. A quality management meeting takes place every month and is attended by two of the Board's clinical directors; the general manager; the quality manager and the nurse manager.

Weekly operations meetings take place and are attended by the general manager; the nurse manager and the TFP UK operations director.

A sample of minutes from each meeting type was reviewed. These evidenced that the governance structures were functioning well to provide a level of assurance to the Board of Directors and the clinical governance team.

Review of documents and discussion with staff evidenced that the Board has the opportunity to interrogate the data provided to them and provide appropriate challenge to the senior management team. Through discussions with staff we were able to see a live governance system working from front line service delivery through to the Board of Directors.

Since the last RQIA inspection on 13 March 2023, Mr Andrew Caulfield, has been appointed as the new general manager and is being supported remotely by the head of quality TFP UK. Mr Caulfield has submitted a registered manager application to RQIA. It was also confirmed that a new quality manager is to commence work within the next few weeks.

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 since the previous RQIA inspection that the head of quality TFP UK had undertaken unannounced monitoring visits during September 2023 and February 2024. The report of the unannounced monitoring visits along with any identified actions were available for inspection. It was determined that area for improvement 5 made against the regulations as outlined in section 5.1, has been addressed.

As result of the previous RQIA inspection an area for improvement had been made to ensure that Mr Moohan as the responsible individual had oversight in addressing the areas for improvement outlined in the previous QIP and to ensure that the identified issues were actioned in a timely manner. Following the previous inspection RQIA received confirmation that corrective actions had been completed and that oversight of these would be achieved through regular quality improvement meetings with Mr Moohan and the then acting manager. It was determined that area for improvement 6 made against the regulations as outlined in section 5.1, has been addressed.

Due to the number of areas for improvement identified during the previous RQIA inspection, an area for improvement had been made against the regulations to review the effectiveness of the current governance and oversight arrangements. It was noted that the February 2024 unannounced monitoring visit identified that not all of the corrective actions taken to meet some of the previous areas for improvement had been sustained and deficits identified. However, RQIA were assured by the timely corrective actions taken following the February 20204 unannounced monitoring visit to address the identified deficit areas.

The inspection team were informed that during the transition period with the appointment of the new general manager and the departure of the previous general manager/quality manager meant that there had been a temporary lapse in the oversight arrangements. Following this inspection, the head of quality TFP UK informed RQIA that the structures in place had previously been working well and will continue with the new general manager and new quality manager in place. Overall an improvement has been noted in relation to the oversight and governance arrangements with only one area for improvement identified as a result of this inspection. RQIA were informed that there are ongoing management discussions and that governance and oversight arrangements will continue to be monitored. It was determined that area for improvement 7 made against the regulations as outlined in section 5.1, has been addressed.

## Clinical governance

A team of consultants and embryologists who have specialist qualifications and skills in fertility treatments work in Belfast Fertility. We identified that three 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 five 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 completed 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 discussed. TFP is a designated body and has an identified RO with whom the 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 four medical practitioner's practising privileges records confirmed that all required documents were in place. It was confirmed that one of the Board of Directors is responsible for ensuring practising privileges 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**

A systematic programme of clinical and internal audit was in place at the inspection with arrangements in place to monitor, audit and review the effectiveness and quality of care and treatment delivered to patients at appropriate intervals. The results of audits are analysed and actions identified for improvement are embedded into practice. If required, an action plan is developed and embedded into practice to address any shortfalls identified during the audit process.

There were clear effective processes for managing risks, issues and performance. The service conducted monthly and annual risk assessments and made regular updates to the risk register.

The risk register recorded a brief description, the severity and likelihood rating, mitigation measures, responsible person and a target review date. Staff also told us that they are actively encouraged to contribute to the review of the risk register.

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 learning from root cause analysis and subsequent learning from incidents and events was examined. It was evidenced that learning is discussed and recorded in the minutes of the weekly operations meetings and a multidisciplinary approach is applied to ensure the dissemination of learning to all staff.

The inspection team spoke with several staff members and 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. An audit is maintained, reviewed and the findings are presented to the clinical directors during the MAC meetings.

It was determined that the service managed patient safety incidents well. Staff recognised and reported incidents and near misses 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.

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 staff evidenced that complaints were investigated and responded to appropriately. Records were kept of all complaints and included details of all communications with complainants; the result of any investigation; the outcome and any action taken. The head of quality TFP UK and Mr Caulfield demonstrated a good awareness of complaints management and told us that staff are aware of their responsibilities should a complaint be raised with them directly.

Complaints received are reviewed and discussed on a monthly basis at the general management meeting. Review of the meeting minutes demonstrated that corrective action is agreed and the outcome monitored. Complaints are also reviewed on a quarterly basis to identify trends and take appropriate action. However, it was noted that on occasions the nature of a complaint had been incorrectly categorised meaning the result of complaint data analysis may not be accurate. This was discussed with management who provided assurance that this area would be reviewed.

The head of quality TFP UK informed us that the information gathered from complaints was used to improve the quality of services provided.

It was demonstrated that the governance structures within the establishment provide the required level of assurance to the senior management team and Board of Directors that the service is well managed.

## 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

Areas for improvement have been identified where action is required to ensure compliance with The Independent Health Care Regulations (Northern Ireland) 2005 and the Minimum Care Standards for Independent Healthcare Establishments (July 2014)

| | Regulations | Standards |
|---|---|---|
| **Total number of Areas for Improvement** | 0 | 1 |

An area for improvement and detail of the QIP were discussed with the head of quality TFP UK; Mr Caulfield and other members of the TFP Belfast Fertility management team. The timescale for completion commence 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**<br><br>**Ref:** Standard 20.5<br><br>**Stated:** First time<br><br>**To be completed by:**<br>26 April 2024 | 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.<br><br>**Ref: 5.2.5** |
| | **Response by registered person detailing the actions taken**:<br>Single use laryngoscope blades are in use and remain covered in sterile packaging. |

***Please ensure this document is completed in full and returned via the Web Portal***
***


The Regulation and Quality Improvement Authority

RQIA, 1st Floor
James House
Gasworks
2 – 4 Cromac Avenue
Belfast
BT7 2JA

**Tel** 028 9536 1111
**Email** info@rqia.org.uk
**Web** www.rqia.org.uk
@RQIANews


Assurance, Challenge and Improvement in Health and Social Care