The Regulation and Quality Improvement Authority

Inspection Report

13 March 2023

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 Manager:** Mr Malik Hasson – acting manager **Date registered:** Awaiting application
Person in charge at the time of inspection: UK Operations Director	
Categories of care: Independent hospital (IH) Prescribed techniques or prescribed technology: establishments providing in vitro fertilisation techniques PT (IVF) Private doctor (PD)	
Brief description of how the service operates: TFP Belfast Fertility is registered with the Regulation and Quality Improvement Authority (RQIA) as an independent hospital (IH) with Prescribed techniques or prescribed technology: establishments providing in vitro fertilisation techniques PT (IVF) and private doctor (PD) categories of care. The Fertility Partnership (TFP) is a group of international clinics specialising in assisted conception and is the parent company of GCRM Belfast Ltd which owns TFP Belfast Fertility. GCRM Belfast Ltd is the provider organisation registered with RQIA and Mr James Moohan is the responsible individual for GCRM Belfast Ltd.	

2.0 Inspection summary

An announced inspection was undertaken to TFP Belfast Fertility which commenced with an onsite inspection on 13 March 2023 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 13 March 2023 by three care inspectors supported by RQIA's Adept Fellow. 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.

It was identified that since the previous inspection there have been changes in the general manager and quality manager personnel within the establishment and this area is discussed further in section 5.2.10 of this report.

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.

No concerns were identified in relation to patient safety and the inspection team noted areas of strength, particularly in relation to the delivery of front line care.

Examples of good practice were evidenced in patient safety in respect of the provision of assisted conception services; medicines management; the management of the patients' care pathway; communication; records management; and engagement to enhance the patients' experience.

Five of the sixteen areas for improvement identified as a result of the previous inspection have been assessed as not met and have been stated for a second time. These areas relate to the recruitment of staff, fire safety training, staff appraisal and the role of the responsible individual in addressing areas outlined in the QIP.

In addition, four new areas for improvement have been made against the regulations in relation to; the oversight of staff training; completion of mandatory training for identified staff; ensuring unannounced monitoring visits are undertaken on a six monthly basis as required under Regulation 26 of The Independent Health Care Regulations (Northern Ireland) 2005 and to review the effectiveness of the current governance and oversight arrangements.

Two new areas for improvement had also been identified against the standards in relation to devising a counselling procedure to compliment the counselling policy in place and to include details of the Northern Ireland Maternal and Child Health (NIMACH) in relation to notification of patient's deaths associated with ovarian hyper stimulation syndrome(OHSS) within the OHSS policy.

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 16 March 2023 for review.

The onsite component of our inspection was completed on 13 March 2023. A multi-disciplinary inspection methodology was employed during this inspection. The inspection team undertook a tour of the premises and met with various staff members and had the opportunity to speak with one patient. 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

As discussed the inspectors had the opportunity to speak with one patient during the inspection who stated that they had experienced a very high standard of care delivery and was very pleased with all aspects of the services they received.

Posters were issued to TFP Belfast Fertility by RQIA prior to the inspection inviting patients and staff to complete an electronic questionnaire. One completed patient questionnaire was submitted to RQIA following the inspection. The respondent indicated that they felt their care was safe and effective, that they were treated with compassion and that the service was well led. The patient indicated that they were very satisfied with each of these areas of their care. The patient also provided an additional comment stating they felt they could trust this clinic.

The inspection team were informed that monthly patient satisfaction surveys are completed and the that 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 staff deliver a very high standard of care. It was noted that where suggestions were made by patients on areas that could be improved that these suggestions were discussed at monthly quality management meetings.

No completed staff questionnaires were submitted following the inspection.

All staff spoken with during the inspection spoke about TFP Belfast Fertility in positive terms. Staff spoke in a complimentary manner regarding the senior management team and the communication and support they have provided. Staff discussed the ongoing challenges as a result of the COVID-19 pandemic with high numbers of patients seeking assisted fertility treatment and how as a team they have managed the situation and continued to provide high quality care. 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 21 December 2021		
Action required to ensure compliance with The Independent Health Care Regulations (Northern Ireland) 2005		**Validation of compliance**
Area for Improvement 1 **Ref:** Regulation 19 (2) (d), (as amended) **Stated:** First 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.	**Not Met**
	Action taken as confirmed during the inspection: This area for improvement has been assessed as not being met and is stated for a second time. Further detail is provided in section 5.2.2.	
Area for Improvement 2 **Ref:** Regulation 25 (3) (c) **Stated:** First time	The responsible individual must ensure that all staff undertake fire safety awareness training as outlined in the RQIA training guidance.	**Not Met**
	Action taken as confirmed during the inspection: This area for improvement has been assessed as not being met and is stated for a second time. Further detail is provided in section 5.2.1.	
Area for Improvement 3 **Ref:** Regulation 21 (1) (3), Schedule 3 Part II (6) **Stated:** First time	The responsible individual must ensure that a staff register is developed and maintained to include the name, date of birth, position, dates of employment and details of professional qualification and professional registration where applicable.	**Met**
	Action taken as confirmed during the inspection: This area for improvement has been assessed as met, further detail is provided in section 5.2.2.	

Area for Improvement 4 **Ref:** Regulation 30 (e) (i) **Stated:** First time	The responsible individual must ensure that a variation to registration application is submitted to RQIA to change the name of the establishment.	**Met**
	Action taken as confirmed during the inspection: A variation to registration was submitted to RQIA on 31 May 2022 to change the name of the establishment to TFP Belfast Fertility. This area for improvement has been met.	
Area for Improvement 5 **Ref:** Regulation 17 (1) **Stated:** First time	The responsible individual must ensure that they have oversight over addressing the areas for improvement within this quality improvement plan and that the identified issues are actioned in a timely manner.	**Not met**
	Action taken as confirmed during the inspection: This area for improvement has been assessed as not being met and is stated for a second time. 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 **Ref:** Standard 10.2 **Stated:** Second time	The responsible individual shall ensure that policies relating to the management of operations in response to COVID-19 are kept under review and are updated in line with current best practice guidance. Where policies have been updated arrangements should be established to ensure staff are informed and provided with additional training as required.	**Met**
	Action taken as confirmed during the inspection: This area for improvement has been assessed as met. Further detail is provided in section 5.2.6.	
Area for improvement 2 **Ref:** Standard 20.7 **Stated:** Second time	The responsible individual shall Implement a robust system of audit to assure that IPC training and best practice guidance has been embedded into practice.	

	Action taken as confirmed during the inspection: This area for improvement has been assessed as met. Further detail is provided in section 5.2.7.	**Met**
Area for improvement 3 **Ref:** Standard 13.3 **Stated:** First time	The responsible individual must ensure that newly appointed staff complete a structured induction and orientation within three months of employment and retain records.	**Met**
	Action taken as confirmed during the inspection: This area for improvement has been assessed as met. Further detail is provided in section 5.2.1.	
Area for improvement 4 **Ref:** Standard 13.9 **Stated:** First 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.	**Not Met**
	Action taken as confirmed during the inspection: This area for improvement has been assessed as not met and is stated for a second time. Further detail is provided in section 5.2.1.	
Area for improvement 5 **Ref:** Standard 10.7 **Stated:** First time	The responsible individual must establish a robust system to review the registration status of all clinical staff registered with a professional body and that staff who require individual indemnity cover have a valid indemnity certificate in place.	**Met**
	Action taken as confirmed during the inspection: This area for improvement has been assessed as met. Further detail is provided in section 5.2.1.	
Area for improvement 6 **Ref:** Standard 14.2 **Stated:** First 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.	

	Action taken as confirmed during the inspection: This area for improvement has been assessed as not met and is stated for a second time. Further detail is provided in section 5.2.2.	**Not Met**
Area for improvement 7 **Ref:** Standard 3.1 **Stated:** First time	The responsible individual must ensure that the policy and procedure for the safeguarding and protection of adults and children at risk of harm is updated to fully reflect the regional policies and guidance documents.	**Met**
	Action taken as confirmed during the inspection: This area for improvement has been assessed as met. Further detail is provided in section 5.2.3.	
Area for improvement 8 **Ref:** Standard 9.3 **Stated:** First time	The responsible individual must re-establish audits of laboratory activities and ensure ongoing monitoring in this area.	**Met**
	Action taken as confirmed during the inspection: This area for improvement has been assessed as met. Further detail is provided in section 5.2.4.	
Area for improvement 9 **Ref:** Standard 18.1 **Stated:** First time	The responsible individual must ensure the management of medical emergency policy is further developed in keeping with legislation and best practice guidance.	**Met**
	Action taken as confirmed during the inspection: This area for improvement has been assessed as met. Further detail is provided in section 5.2.5.	
Area for improvement 10 **Ref:** Standard 18.3 **Stated:** First time	The responsible individual must ensure that robust arrangements are in place to check that all required emergency equipment is available, in date and ready for immediate use.	

	Action taken as confirmed during the inspection: This area for improvement has been assessed as met. Further detail is provided in section 5.2.5.	**Met**
Area for improvement 11 **Ref:** Standard 20 **Stated:** First time	The responsible individual must ensure the sharps containers are used in accordance with best practice guidance.	**Met**
	Action taken as confirmed during the inspection: This area for improvement has been assessed as met. Further detail is provided in section 5.2.7.	

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. It was determined that area for improvement 3 made against the standards as outlined in section 5.1, has been addressed.

A training matrix was in place to monitor the status of staff training requirements however; it was noted that the training matrix did not include all staff who work in the establishment. Meaning that the service could not be assured that all staff had completed all areas of training as outlined in the RQIA training guidance. This was discussed and an area for improvement has been made against the regulations to ensure the staff members not included in the training matrix undertake all areas of mandatory training as a priority. A further area for improvement has been made against the regulations to establish 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.

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. Records were not available to evidence that all staff had completed fire safety awareness training. It was determined that this area for improvement 2 made against the regulations as outlined in section 5.1, has not been addressed and has been stated for a second time.

Discussion with staff confirmed that the procedures for appraising staff performance had been reviewed and further developed since the previous inspection. However, it was identified that several staff members had not had an appraisal carried out in the past year. This was discussed and assurances were given that annual appraisals would be undertaken to review staff performance. This issue had been identified during the previous inspection and an area for improvement against the standards had been made. It was determined that this area for improvement 4 made against the standards as outlined in section 5.1, has not been addressed and has been stated for a second time.

Discussion with the nurse 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) and nursing staff with the Nursing and Midwifery Council (NMC). It was evidenced that for medical practitioners, their registration status and professional indemnity continues to be monitored during the renewal of their practising privileges agreement which occurs every two years (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, therefore it was determined that area for improvement 5 made against the standards as outlined in section 5.1, has been addressed. The current system should be reviewed to ensure the registration status of staff is available for inspection.

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 evidenced that sufficient staff were in place to meet the needs of patients. Addressing the areas for improvement made will further strengthen the governance and oversight arrangements to ensure safe staffing arrangements are in place at all times.

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 the recruitment and selection policy could not be located. Following the inspection, RQIA received a copy of the recruitment policy. A review of this policy again identified that detail of the required recruitment documents to be sought and retained in respect of any new staff member, as outlined in legislation and best practice, were not included. It was determined that area for improvement 6 made against the standards as outlined in section 5.1, has not been addressed and has been stated for a second time.

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; evidence of employment history for another staff member; evidence of the professional body registration status for one staff member and evidence of qualifications in respect of all three staff members. Similar issues had been identified during the previous inspection in relation to the recruitment and selection of staff and an area for improvement had been made. It was determined that this area for improvement 1 made against the regulations as outlined in section 5.1, has not yet been fully addressed and has been stated for a second time.

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 staff do not have access to the electronic system meaning TFP Belfast Fertility does not have oversight of the recruitment and selection of staff. These arrangements should be reviewed at the earliest opportunity to ensure that the recruitment and selection of staff is in keeping with legislation and best practice. On 31 March 2023, RQIA received confirmation by email that the new general manager will have remote access to all recruitment and HR files.

Establishments registered with RQIA are required to maintain a staff register, however, a staff register could not be located. Advice was provided in this regard and a staff register was developed during the inspection that included the name, date of birth, position, dates of employment and details of professional qualification and professional registration where applicable. It was advised that this staff register should be kept up to date at all times. It was determined that area for improvement 3 made against the regulations as outlined in section 5.1, has been addressed.

The recruitment and selection procedures require further development 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.

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.

Review of records demonstrated that the majority of staff had received training in safeguarding adults as outlined in the Minimum Care Standards for Independent Healthcare Establishments July 2014. As previously discussed the training matrix in place to monitor the status of staff training requirements did not include all staff who work in the establishment. Therefore, TFP Belfast Fertility were unable to confirm that all staff had undertaken safeguarding training. Two areas for improvement have been made to address this issue.

A policy and procedure was in place for the safeguarding and protection of adults and children at risk of harm. The policy included the action to take in the event of a safeguarding issue arising and the relevant contact details for onward referral to the local Health and Social Care Trust.

The policy had been updated since the previous inspection to fully reflect the regional policies and guidance documents therefore it was determined that area for improvement 7 made against the standards as outlined in section 5.1, has been addressed.

Copies of the regional guidance documents entitled 'Adult Safeguarding Prevention and Protection in Partnership' and 'Co-operating to Safeguard Children and Young People in Northern Ireland' were available for staff reference.

The service had appropriate arrangements 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 with the Human Fertilisation and Embryology Authority (HFEA), the UK's independent regulator for the fertility sector and a renewal of license site visit by HFEA is scheduled for May 2023. 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 largely in line with best practice. An area of improvement has been made against the standards to include in these protocols details of the Northern Ireland Maternal and Child Health (NIMACH) in relation to notification of patient's deaths associated with OHSS.

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 was in place however a counselling procedure, providing patients and their partners with information on how to access counselling services was not available. An area for improvement was made against the standards on this matter.

A weekly multidisciplinary clinical review meeting (CRM) attended by the consultants, registered nurses and members of the embryology team, takes place, 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 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.

It was good to note that a laboratory manager has been recruited since the previous RQIA inspection and the embryology team had stabilised with eight embryologists now in post including two trainee embryologists. 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. It was determined that the previous area of improvement 8, made against the standards, as outlined in section 5.1, has been addressed.

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 therefore it was determined that area for improvement 9 made against the standards as outlined in section 5.1, has been addressed.

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. 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 that area for improvement 10 made against the standards as outlined in section 5.1, has been addressed.

Staff spoken with have knowledge and understanding of managing resuscitation and other medical emergencies and confirmed they had completed training in this area. As discussed, the training matrix in place to monitor the status of staff training requirements did not include all staff who work in the establishment. Therefore, TFP Belfast Fertility were unable to evidence that all staff had undertaken managing resuscitation and other medical emergencies training. Two areas for improvement have been made to address this issue.

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?

COVID-19 has been declared as a public health emergency and we all need to assess and manage the risks of COVID-19, and in particular healthcare settings need to consider the risks to their patients and staff.

The management of operations in response to the COVID-19 pandemic was discussed with the nurse manager and staff; and application of the current best practice guidance. The COVID-19 policy had been reviewed since the previous inspection and the nurse manager was aware that new guidance had been issued in March 2023 by the Health and Social Care Public Health Agency. Assurances were given that the policy would be reviewed to reflect the current best practice guidance. It was determined that the previous area of improvement 1, made against the standards, as outlined in section 5.1, has been addressed.

There was an identified COVID-19 lead and arrangements are in place to ensure the clinic is regularly reviewing COVID-19 advisory information, guidance and alerts.

During discussion with staff members regarding the management of operations in response to the COVID-19 pandemic, staff demonstrated good knowledge and awareness of current best practice guidance.

The management of COVID-19 was in line with best practice guidance and it was determined that 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. As previously discussed, the staff training matrix did not include all staff who work in the establishment. Therefore, TFP Belfast Fertility were unable to evidence that all staff had undertaken IPC training. Two areas for improvement have been made to address this issue.

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.

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 evidence that the closures were being operated in line with IPC best practice. It was determined that the previous area of improvement 11, made against the standards, as outlined in section 5.1, has been addressed.

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 now being carried out by staff and where deficits are identified a meaningful action plan has been developed. It was determined that the previous area for improvement 2, as outlined in section 5.1, had been met. It was advised to devise an IPC summary report of the findings of the wide range of IPC audits 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 overdue for review at the time of the inspection. However, this was subsequently undertaken on the 4 April 2023 by a risk assessor who is listed on a recognised register of fire risk assessors. The fire risk assessor assessed the risk in the premises as 'tolerable'.

The legionella risk assessment was carried out by a specialist legionella control company and it was determined that the recommendations made in the risk assessment report have been addressed and suitable control measures are being maintained. Legionella bacteria were not detected in the most recent legionella sampling results 2 March 2023.

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.

All areas of the establishment were found to meet the needs of patients.

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

Organisational governance

TFP Belfast Fertility is one 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 to through to the Board of Directors.

Since the last RQIA inspection on 2 December 2021 the previous general manager and the previous quality manager have resigned. It was confirmed that a new quality manager has been successfully recruited and commenced work in TFP Belfast Fertility in November 2022. We were informed that the recruitment process for the new general manager was in the final stages and that an applicant had been offered the general manager position. In the interim, the new quality manager, Malik Hasson, is the acting manager and is being supported remotely by the UK operations director and the patient support manager who works in TFP Belfast Fertility.

We were informed that upon successful completion of induction and a six-month probationary period that the new general manager would submit a registered manager application to RQIA.

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, 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 TFP UK regional quality lead had undertaken an unannounced monitoring visit on 13 July 2021. The report of the unannounced monitoring visit along with any identified actions was available for inspection. However, there has not been any further unannounced monitoring visits undertaken since 13 July 2021. This was discussed and an area for improvement has been made against the regulations in this regard.

As result of the previous RQIA inspection an area for improvement had been made to ensure that the responsible individual had oversight in addressing the 16 areas for improvement outlined in the previous QIP and to ensure that the identified issues were actioned in a timely manner. A review of these areas for improvement concluded that of the five areas made against the regulations; two areas were assessed as met and three assessed as not met and have been stated for a second time. In relation to the previous 11 areas for improvement made the standards; nine areas have been assessed as met and two assessed as not met and have been stated for a second time. Therefore, it was determined that area for improvement 5 made against the regulations as outlined in section 5.1, has not been addressed and has been stated for a second time.

This inspection has identified that a total of 5 areas for improvement have been stated for a second time and it is of concern that these areas relate to the recruitment of staff, fire safety training, staff appraisal and the role of the responsible individual in addressing areas outlined in the QIP.

There is a lack of general oversight in such areas as staff recruitment, fire safety training, staff appraisals and assurance that the areas outlined in the previous QIP had been fully addressed. In light of these findings an area for improvement has been made against the regulations to 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.

Clinical governance

A team of consultants and embryologists who have specialist qualifications and skills in fertility treatments work in Belfast Fertility. We identified that five 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 the training matrix in place to monitor the status of staff training requirements did not include all staff who work in the establishment. Therefore, TFP Belfast Fertility were unable to confirm that all private doctors had undertaken all aspects of training in accordance with the RQIA training guidance. As previously stated an area for improvement in relation to the oversight of training has been made.

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're 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 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.

Staff told us that a copy of the complaints procedure is made available for patients/and or their representatives on request and staff demonstrated a good awareness of complaints management.

Through review of records it was 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.

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.

Staff informed us that the information gathered from complaints was used to improve the quality of services provided.

Addressing the areas for improvement will strengthen the governance structures within the establishment to 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	7*	4*

***The total number of areas for improvement includes three that have been stated for a second time against the regulations and two that have been stated for a second time against the standards.

Areas for improvement and details of the QIP were discussed with Mr James Moohan, Responsible Individual, the UK operations director and other members of the TFP Belfast Fertility management. The timescales for completion commence from the date of inspection.

Quality Improvement Plan	
Action required to ensure compliance with The Independent Health Care Regulations (Northern Ireland) 2005	
Area for improvement 1 **Ref:** Regulation 18 (2) (a) **Stated:** First time **To be completed by:** 13 May 2023	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. **Ref: 5.2.1**
	Response by registered person detailing the actions taken: All staff in the clinic have been added to the training matrix, in order to track their manditory. Mandatory training certificates have been requested and obtained from the staff that were not included on the training matrix. These certificates are held digitally in the clinic for each staff member. They will be reviewed as part of the update to the monthly Quality Meeting with Dr. Moohan.

Area for improvement 2 **Ref:** Regulation 18 (2) (a) **Stated:** First time **To be completed by:** 13 May 2023	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. **Ref: 5.2.1**
	Response by registered person detailing the actions taken: Training has now been introduced as a section in the Monthly Quality meeting between the Clinic Quality Manager and the Responsible Person. A monthly reminder email will also be issued to all staff in the clinic, to ensure that they keep up to date with any outstanding comulsory training requirements. GB01-POL-QMS-0017 Management ToR has been updated to reflect this change.
Area for improvement 3 **Ref:** Regulation 19 (2) (d), (as amended) **Stated:** Second time **To be completed by:** 13 March 2023	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. **Ref: 5.2.2**
	Response by registered person detailing the actions taken: Regulation 19 (2) (d),Schedule 2 of the Independent Healthcare regulations (Northern Ireland) 2005 has been reviewed by the clinic. GB01-POL-HR-0003 Recruitement policy has been updated to reflect these specific requirments in line with area for improvement 2 (standard 14). A list of new starts at the clinic will be reviewed monthly at the Quality meeting to ensure compliance with these requirements.
Area for improvement 4 **Ref:** Regulation 25 (3) (c) **Stated:** Second time **To be completed by:** 13 May 2023	The responsible individual must ensure that all staff undertake fire safety awareness training as outlined in the RQIA training guidance. **Ref: 5.2.1**
	Response by registered person detailing the actions taken: Fire safety awarness training has now been completed by all staff at the clinic. RQIA manditory training for: Moving and Handling (yearly) Fire Safety (yearly) Basic Life Support (yearly)

	Control and Prevention of Infection (yearly) POVA and Safeguarding Children (Every 3 years) Have been included as part of GB01-POL-QMS-0017 "Management ToR" and will be reviewed monthly by the Quality Manager to ensure all staff have up to date training.
Area for improvement 5 **Ref:** Regulation 26 **Stated:** First time **To be completed by:** 13 May 2023	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. **Ref: 5.2.9**
	Response by registered person detailing the actions taken: This has been raised with TFP UK Head of Quality Assurance. Monitoring inspections will be undertaken by the UK Head of Quality Assurance in an unannounced fashion on a six monthly basis. A report of the visit will be made available to the clinic Quality Manager, and will be distributed to staff. Patients, their representitives, RQIA and any other interested parties will also have access to the report via the Patient Guide - when available.
Area for improvement 6 **Ref:** Regulation 17 (1) **Stated:** Second time **To be completed by:** 13 May 2023	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. **Ref: 5.2.9**
	Response by registered person detailing the actions taken: The actions in the Quailty improvement plan have been discussed and agreed with Dr. Moohan. The issues outlined and the corrective actions have also been discussed with Dr. Moohan and he will have ovesight of them via regular Quality Improvement Meetings with the clinic Quality Manager.
Area for improvement 7 **Ref:** Regulation 17 (1) **Stated:** First time **To be completed by:**	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. **Ref: 5.2.9**

13 May 2023	**Response by registered person detailing the actions taken**: The current Governance and oversight arranagements in the clinic have been reviewed by the management team and Dr. Moohan. There are four layers to governance and oversight arranagements in place 1. Semi-annual Management review committee - this is designed to ensure that the objectives of the Belfast Fertility are met through reviewing the completed audits. This process is used: • To specify and review Indicators to achieve effective monitoring of Belfast Fertility operations and outcomes. • To develop and operate an effective risk management programme. • To ensure an effective Quality Management Programme for Belfast Fertility 2. Management Meeting - • The 'Management Meeting is designed to ensure that the objectives of the Belfast Fertility are met through ongoing evaluation of quality, clinical indicators and business objectives. More specifically: • To organize and coordinate the routine operations of the Belfast Fertility • To coordinate communication of current issues related to Belfast Fertility activities, both internally and externally. • To discuss, implement and evaluate as required, strategic goals for Belfast Fertility at the request of the Belfast Fertility Directors and or the Business Committee. The Management meeting is atteneded by the management committee - Management Committee Membership • General Manager (chair) • Nurse Manager • HFEA Person Responsible • Lead Clinician • Laboratory Director • Office Manager (Minutes) • Quality Manager 3. Full staff meetings - Meeting of all staff working at Belfast Fertility is organized monthly, and additionally on an ad hoc basis whenever there is significant need, as determined by the Management Committee 4. Department meetings -

	Individual departments (e.g. administration, medical, laboratory and nursing) will hold meetings of their staff. Patient Support Team: A. Once a month B. Chaired by Patient Support Manager C. Minutes by rotation of admin staff Nursing: A. Once a month B. Chaired by the Nurse Manager / Deputy Nurse Manager C. Minutes by rotation of nursing staff Laboratory & KPI Quality Assurance A. Once a month B. Chaired by the Laboratory Director / Deputy Laboratory Manager C. Minutes by rotation of laboratory staff Additionally, a monthly Quality Meeting is conducted with Dr. Moohan to allow oversight of Quality matters within the clinic.
Action required to ensure compliance with The Minimum Care Standards for Independent Healthcare Establishments (July 2014)	
Area for improvement 1 **Ref:** Standard 13.9 **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. **Ref: 5.2.1**
To be completed by: 13 May 2023	**Response by registered person detailing the actions taken**: The annual appraisal process has been actioned as of May 2023. Dr. Moohan will have oversight of this process via the monthly Quality Meeting, where any upcoming appraisals as well as appraisal outcomes, will be highlited. The current appraisals are to take place between May 2023 to June 2023. Apraisal objectives have been set within the management team. By the end of June 2023, these objectives will have been discussed and assigned for individual team members in each department based on the requirements of each department manager and the skillset within their department. The method of appraisal delivery is via 1:1 appraisal meetings.
Area for improvement 2 **Ref:** Standard 14	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.

Stated: Second time **To be completed by:** 13 May 2023	**Ref: 5.2.2**
	Response by registered person detailing the actions taken: The recruitment policy has been updated (GB01-POL-HR-0003) to include detail of the recruitement documents to be sought and retained as outlined in standard 14.
Area for improvement 3 **Ref:** Standard 46 **Stated:** First time **To be completed by:** 13 May 2023	The responsible individual must devise a counselling procedure to compliment the counselling policy in place. **Ref:5.2.4**
	Response by registered person detailing the actions taken: The counselling Standard Operating Procedure (GB01-SOP-NUR-0007) has been created in reference to FCSNI to complement the counselling policy in place.
Area for improvement 4 **Ref:** Standard 47.3 **Stated:** First time **To be completed by:** 13 May 2023	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. **Ref: 5.2.4**
	Response by registered person detailing the actions taken: The Prevention and Management of OHSS standard Operating procedure (GB01-SOP-CLIN-0001), has been updated to include details of Notification of NIMACH regarding patient's deaths associated with OHSS.

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