The Regulation and Quality Improvement Authority

Inspection Report

6 December 2021

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	**Applicant Registered Manager:** Mr Mathew Laird **Date registered:** Mr Mathew Laird application received- "registration pending"
Person in charge at the time of inspection: Mr Mathew Laird	
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: Belfast Fertility is registered 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. 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 unannounced inspection was undertaken to Belfast Fertility which commenced with an onsite inspection on 6 December 2021 from 10.00 am to 5.00pm; followed by a request for the submission of information electronically.

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.

A multidisciplinary inspection methodology was employed during this inspection and the inspection team met with patients; various staff members; reviewed care practices; relevant records and documentation used to support the governance and assurance systems.

It was identified that since the previous inspection the name of the establishment has changed and also that there have been changes in key personnel within the establishment, these areas are discussed further in section 5.2.10 of this report.

It was determined that staffing levels and morale in the establishment were good; with evidence of good multidisciplinary team working and open communication between staff. Staff feedback was positive; they told us that they were happy, well supported and that there were good working relationships throughout the establishment.

Staff were observed treating patients with dignity and were respectful of patients' right to privacy and to make informed choices.

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.

The arrangements for governance and managerial oversight within the establishment were reviewed and this provided assurance concerning the overarching governance structure; including the arrangements for medical governance and management of incidents/events.

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 areas for improvement were identified against the regulations in relation to: staff training; recruitment and selection of staff; developing a staff register; the submission of a variation of registration application to change the name of the establishment; and for the responsible individual to establish robust arrangements that provides him with assurance that all areas for improvement identified are fully addressed in a timely manner.

Two areas for improvement identified against the standards at the previous inspection to update COVID-19 procedural guidance for staff and the implementation of robust infection control audits, had not been fully met and have been stated for a second time.

Nine areas for improvement have been identified against the standards in relation to: the completion and retention of induction records; undertaking annual staff appraisals; monitoring of the professional body registration status of all clinical staff and required professional indemnity; reviewing and updating identified policies (recruitment and selection; safeguarding and management of medical emergencies); reviewing the arrangements for checking the emergency equipment; re-establishing a robust audit programme of laboratory based activities and ensuring sharps containers are used in accordance with best practice guidelines.

3.0 How we inspect

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

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

In response to the COVID-19 pandemic we reviewed our inspection methodology during the 2020/21 inspection year and considered various options to undertake inspections. The purpose of this was to minimise risk to patients and staff, including our staff, whilst being assured that registered services are providing services in keeping with the minimum standards and relevant legislation. Having considered different inspection methodologies a decision was taken to undertake multidisciplinary blended themed inspections. The blended methodology includes an onsite inspection and electronic submission of additional documentation to be reviewed remotely by the inspector. As the COVID-19 pandemic is ongoing a decision was taken to continue with this inspection methodology during the 2021/22 inspection year. The onsite component of our inspection was completed on 6 December 2021 by three care inspectors supported by Dr Leanne Morgan, RQIA's clinical lead and a RQIA pharmacy inspector. The onsite inspection team examined a number of aspects of the Belfast Fertility services as outlined in section 2.0 of this report.

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

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

At the onset of this inspection 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 10 December 2021 for review remotely.

Formal feedback of the inspection findings was delivered to the Belfast Fertility senior management team on 13 January 2022 during a Zoom teleconference.

4.0 What people told us about the service

The inspection team had the opportunity to speak with patients during the inspection who stated that they had experienced a very high standard of care and treatment and were very pleased with all aspects of the services they received.

Staff provide satisfaction surveys to patients on a monthly basis and findings are shared through their governance structures. A review of recent patient satisfaction reports demonstrated that 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 very positive in respect to all aspects of care received and reflected staff deliver a very high standard of care.

Staff were invited to complete an electronic questionnaire. No completed staff questionnaires were submitted following the inspection.

All staff spoken with during the inspection spoke about 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 challenges faced as a result of the COVID-19 pandemic and how as a team they had overcome these 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?

<table>
<tr><th colspan="3">Areas for improvement from the last inspection on 14 and 15 October 2020</th></tr>
<tr><th colspan="2">Action required to ensure compliance with The Independent Health Care Regulations (Northern Ireland) 2005</th><th>Validation of compliance</th></tr>
<tr><td rowspan="2">Area for Improvement 1

Ref: Regulation 19

Stated: Second time</td><td>The responsible individual shall ensure all medical practitioners have a practising privileges agreement in place and that robust arrangements are established to ensure this is reviewed every two years.</td><td rowspan="2">Met</td></tr>
<tr><td>Action taken as confirmed during the inspection:
This area for improvement has been assessed as met, further detail is provided in section 5.2.10.</td></tr>
<tr><th colspan="2">Action required to ensure compliance with The Minimum Care Standards for Independent Healthcare Establishments (July 2014)</th><th>Validation of compliance</th></tr>
<tr><td rowspan="2">Area for Improvement 1

Ref: Standard 19.2

Stated: First time</td><td>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.</td><td rowspan="2">Not met</td></tr>
<tr><td>Action taken as confirmed during the inspection:
This area for improvement has been assessed as not met and has been stated for a second time. Further detail is provided in section 5.2.6.</td></tr>
</table>

Area for improvement 2 **Ref:** Standard 20.1 **Stated:** First time	The responsible individual shall appoint a COVID-19 lead to co-ordinate the response within Belfast Fertility to the pandemic.	**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 3 **Ref:** Standard 20.5 **Stated:** First time	The responsible individual shall keep patient appointment times under review to ensure there is sufficient time to undertake the required cleaning of the area and equipment between appointments.	**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.	
Area for improvement 4 **Ref:** Standard 20.5 **Stated:** First time	The responsible individual shall ensure cleaning records are completed in a timely manner.	**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.	
Area for improvement 5 **Ref:** Standard 20.3 **Stated:** First time	The responsible individual shall ensure staff training is completed in respect of COVID-19 and general IPC training. IPC training should also include practical aspects and include competency based assessments to provide assurance that training has been effective.	**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.	

Area for improvement 6 **Ref:** Standard 20.7 **Stated:** First 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.	**Partially met**
	Action taken as confirmed during the inspection: This area for improvement has been assessed as partially met and has been stated for a second time. 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, 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 however, induction records in respect of recently appointed staff had not been completed or retained. This was discussed and an area for improvement against the standards has been made.

A system was in place to monitor all aspects of ongoing professional development and a record was retained of all training and professional development activities. A training matrix was in place to monitor the status of staff training requirements. However it was noted some dates were when training was undertaken, some when training was due and not all training was included in the training matrix. It was advised that the training matrix should be kept up to date at all times. A review of records identified that not all staff had undertaken fire safety awareness training in keeping with RQIA training guidance and legislation. An area for improvement against the regulations has been made.

Procedures were in place for appraising staff performance and whilst some staff confirmed that appraisals had taken place, it was identified that several staff appraisals had not been carried out in the past year. This was discussed and assurances were given that annual appraisals would be undertaken to review staff performance. An area for improvement against the standards has been made.

It was noted that nursing staff did not regularly receive professional/clinical supervision. Supervision is an important part of professional development and it was advised that nursing staff should have supervision in line with their professional regulatory body; legislation and minimum standards. This was discussed during feedback and assurances were provided that this would be an area for further developmental support for all nursing staff moving forward.

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). However, it was identified that a system for ongoing monitoring of the professional body registration status of all clinical staff needs to be established and the arrangements for monitoring the professional indemnity of all staff who require individual indemnity cover also needs to be improved. An area for improvement against the standards has been made.

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 concerning staff to ensure safe staffing arrangements.

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

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

A review of the policy and procedure for the recruitment and selection of staff found that the policy outlined the TFP recruitment and selection process. It was identified that this policy did not outline the recruitment records required to be sought and retained in respect of a new staff member as outlined in legislation and best practice guidance. This was discussed with Mr Laird who was provided with advice and guidance on how to further develop the policy in accordance with Regulation 19 (2) Schedule 2 of the Independent Healthcare Regulations (Northern Ireland) 2005. An area for improvement against the standards has been made.

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 all the relevant information had been sought, reviewed and stored as required, with the exception of a criminal conviction declaration, two written references and evidence of a health declaration, in respect of all three staff. This was discussed and advice was given to ensure that all information as listed in Regulation 19, Schedule 2 of the Independent Health Care Regulations (NI) 2005 would be sought and retained for any new staff commencing work in the future. An area for improvement against the regulations has been made.

A staff register was not available to review. This was discussed and it was advised that a staff register should be developed and maintained to include the name, date of birth, position, dates of employment and details of professional qualification and professional registration where applicable. An area for improvement against the regulations has been made.

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. However, some staff were not aware who the nominated safeguarding lead was. This was discussed and assurances were given that this issue would be addressed.

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.

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. However, the policy had not been updated to fully reflect the regional policies and guidance documents. This was discussed and an area for improvement against the standards was made.

It was advised that 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' should be made available for staff reference.

The further development of the safeguarding policy to include the regional best practice guidance will ensure that the establishment complies with best practice guidance.

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

Belfast Fertility is licensed with the Human Fertilisation and Embryology Authority (HFEA), the UK's independent regulator for the fertility sector. Belfast Fertility has held a Treatment and Storage license with the HFEA since November 2013 and provides a full range of fertility services.

A range of treatment protocols were in place for the management of patients receiving assisted conception services which have been developed and agreed by all professionals within the establishment.

The protocols for the prevention and management of ovarian hyper stimulation syndrome (OHSS) have been written by the lead clinicians, a review of these protocols demonstrated that they were evidence based and in line with best practice.

It was confirmed that written protocols are in place for the close monitoring of patients, in order to avoid unnecessary complications including multiple pregnancies.

An elective single embryo transfer (eSET) protocol was in place. It was confirmed that the eSET protocol sets out the number of embryos that can be placed in a woman in any one cycle

and this protocol complies with the HFEA Code of Practice. The protocols and procedures were discussed with the 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. We observed a number of limited interactions between staff and patients that confirmed this approach.

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 five patients' electronic clinical records found that all records were well completed and clearly outlined the patient pathway.

Management informed us that a new laboratory manager had been recruited and is to commence employment in January 2022. During the interim period this has presented challenges in the ongoing staffing and management of the laboratory services. It was established that a locum consultant embryologist has been supporting the laboratory services in the interim period. Prior to this inspection RQIA had identified a slight increase in incident notifications relating to laboratory based activities and whilst none of the incidents had a negative impact on patient care, this was an area identified for our review during this inspection. The inspection team noted that a range of laboratory audits had been conducted by the previous laboratory manager however, these had not been fully carried out since the previous laboratory manager left the establishment. An area of improvement against the standards has been made to ensure the re-establishment of robust laboratory audits and ongoing monitoring in this area.

Discussion with staff and review of relevant policies and procedures evidenced that 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 reviewed was not in keeping with best practice. The policy should be further developed to include the list of emergency medicines and equipment provided, the types of medical emergencies that could take place and the action to take in the event of a medical emergency occurring.

The policy should also include the roles and responsibilities of staff, the location of the emergency medicines and equipment, incident documentation and staff debriefing. An area for improvement against the standards has been made.

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. In the main, the resuscitation trolley was observed to be well organised and well stocked. Emergency medicines were checked daily and a system was in place to ensure that emergency medicines do not exceed their expiry date. However, the resuscitation trolley checklist did not fully reflect the items retained in the trolley and some items of emergency equipment had exceeded their expiry date. The importance of reviewing the current system for checking the emergency equipment stored in the resuscitation trolley was discussed. An area for improvement against the standards has been made.

Staff spoken with have knowledge and understanding of managing resuscitation and other medical emergencies and confirmed they had completed training in this area.

Review of the arrangements to manage a medical emergency identified that staff were suitably trained and appropriate medicines and equipment were in place to manage a medical emergency. The further development of the policy and inclusion of the emergency medical in the check list will further enhance the current arrangements.

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 a review date of May 2021, however there was no record to show that this policy had been reviewed, and the policy was not reflective of 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 not been met and has been stated for a second time.

Records examined verified that a risk assessment had been updated on 26 August 2021 which was detailed and outlined the COVID-19 risks within the establishment. However, it was noted that it did not fully reflect the outcome of staff risk assessments. The management were able to verbally outline that currently there are no vulnerable staff working within the establishment however this was not documented. Staff were advised that this should be reflected in the COVID-19 risk assessment and the importance of reviewing this risk assessment each time new COVID-19 best practice guidance is issued was discussed. Advice was provided on the benefit of reviewing the risk assessments periodically to ensure they are reflective of current guidance and arrangements.

There is an identified COVID-19 lead and arrangements are in place to ensure the clinic is regularly reviewing COVID-19 advisory information, guidance and alerts. It was determined that the previous area for improvement 2, as outlined in section 5.1, had been met.

Review of staff training records demonstrated that staff had completed COVID-19 training. Management were advised that it would be beneficial to consider staff undertaking refresher training on COVID -19 in line with current guidance and arrangements.

Clear COVID-19 measures were observed throughout the patient pathway to minimise the risk of transmission. Social distancing screens were in place at the reception desk and hand sanitisers were readily available for staff and patient use throughout the establishment.

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. It was pleasing to note that improvement has been made in this area and review of the COVID-19 policy and risk assessments will further strengthen the arrangements to minimise the risk of transmission.

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. As previously stated the policies regarding the management of operations in response to COVID-19 should be updated.

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. Discussion with staff confirmed that additional time has been incorporated into appointments to allow the required cleaning of the area and equipment. It was determined that the previous areas for improvement 3 and 4, as outlined in section 5.1, had been met.

Review of staff training records evidence that staff IPC training had been completed by all staff and was up to date. It was determined that the previous area for improvement 5, as outlined in section 5.1, had been met.

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 new decontamination equipment had been procured for the decontamination of ultrasound probes and staff confirmed that arrangements were in place to have 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 number of sharps boxes closures were not operated in line with IPC best practice and an area of improvement has been made against the standards.

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 a limited high level IPC related audit is carried out by the quality manager on a monthly basis. Advice was provided on the further development of robust auditing on all aspects of IPC within the establishment to be undertaken by clinical staff members. Where deficits are identified a meaningful action plan should be developed to include a process of re-audit to track improvement and sustained compliance. It was determined that the previous area for improvement 6, as outlined in section 5.1, had been partially met and has been stated for a second time.

In the main the arrangements in place to adhere to IPC best practice guidelines were satisfactory. The further development of IPC specific audits will further strengthen the current arrangements.

5.2.8 Does the establishment adhere to best practice guidance concerning the management of controlled drugs?

The maintenance of the controlled drugs register and the arrangements for the destruction of controlled drugs were reviewed.

The controlled drugs register was seen to be maintained in a satisfactory manner. A controlled drugs audit had been undertaken on 7 November 2021 which identified several minor issues in relation to the maintenance of the controlled drugs register, including two occasions when either the time or the patient identification number was not recorded. Action was taken and specific non-compliances were discussed with the relevant anaesthetists and nurses in order to identify where change in practice were required. In response a workshop was arranged with the nursing team to discuss the issues identified and how improvement could be achieved. As a result a named nurse has been identified to be responsible for undertaking a daily check of the controlled drug register to ensure that a good standard of record keeping is maintained. It was evidenced that since the audit undertaken on 7 November 2021, a further audit was completed which evidenced that the previous identified issues had been addressed. It was also confirmed that further audits are planned to ensure continued compliance.

Satisfactory arrangements were in place for the destruction of controlled drugs, with denaturing kits being used for this purpose.

5.2.9 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.

The fire risk assessment was undertaken 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.

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.

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

Organisational governance

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 Belfast Fertility and also within the TFP Group.

The Belfast Fertility Board of Directors includes four clinical directors from 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 regional general manager for the United Kingdom (UK) region north and Matthew Laird. 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 Management Committee Meeting takes place every two weeks which 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 regional general manager UK region north.

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.

During the previous inspection on 14 and 15 October 2020 it was established that Mr Mathew Laird, had been appointed as the new general manager in June 2020. RQIA were informed that upon successful completion of Mr Laird's induction and six month probationary period that a registered manager application would be submitted to RQIA. On 3 September 2021 RQIA received correspondence from Mr Laird and subsequently a registered manager application was received by RQIA which is being progressed.

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 in October 2020 it was established that Dr Moohan, Responsible Individual, was not in day to day charge of the service, therefore unannounced quality monitoring visits would need to take place.

During this inspection it was established 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.

Staff working in different roles within the establishment confirmed that there were good working relationships and that management were responsive to any suggestions or concerns raised.

It was identified that since our previous inspection the makeup of the Board of Directors has changed, as one of the previous directors has resigned and is no longer named as an officer in Companies House. RQIA should have been formally notified at the time the change occurred. In addition it has been identified that Belfast Fertility has been rebranded as TFP Belfast Fertility, this change of name requires a variation of registration to be submitted to RQIA. An area for improvement has been made against the regulations in this regard.

As this inspection has identified a total of 16 areas for improvement including two areas that have been stated for a second time, and given that Mr Moohan is not in day to day charge of Belfast Fertility, an area for improvement has been identified against the regulations to 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.

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 three 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

Personnel files for the three private doctors also evidenced that they had each completed training in accordance with RQIAs training guidance for private doctors. It was confirmed by management that all private doctors are aware of their responsibilities under GMC Good Medical Practice.

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 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.

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. It was determined that the previous area of improvement 1, made against the regulations, as outlined in section 5.1, has been met.

Quality assurance

It was evidenced that arrangements were in place to review risk assessments, a risk management register is maintained and reviewed with the clinical directors on a regular basis. Staff also told us that they are actively encouraged to contribute to the review of the risk register.

Arrangements were 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.

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 quality manager outlined the process for analysing incidents and events to detect potential or actual trends or weakness in a particular area in order that a prompt and effective response can be 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.

As previously discussed, an area for improvement has been identified to re-establishment robust laboratory audits and ongoing monitoring in this area and to further developed the IPC audit programme.

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.

Information gathered from complaints was used to improve the quality of services provided.

Overall, the governance structures within the establishment provided the required level of assurance to the senior management team and Board of Directors.

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	5	11*

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

Areas for improvement and details of the Quality Improvement Plan were discussed with Mr James Moohan, Responsible Individual, Mr Mathew Laird, Registered Manager applicant, the medical director, the quality manager and the deputy nurse manager during a Zoom teleconference on 13 January 2022. 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 19 (2) (d), (as amended) **Stated:** First time **To be completed by:** 6 December 2021	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: The clinic have reviewed the required information as listed in Regulation 19 (2) (d), Schedule 2 of the Independent Health Care Regulations (Northern Ireland) 2005. We have instructed our central HR department that this information is required for all new staff commencing work in the clinic in the future. The General Manager (Registered Manager applicant) has forwarded the relevant workflows to the central HR department and communicated the requirements. In addition a check list to ensure compliance with this area for improvement has been created of which the General Manager (Registered Manager applicant) is in control of. The TFP UK HR Lead has confirmed compliance of the Central TFP HR team in this Area for Improvement.
Area for improvement 2 **Ref:** Regulation 25 (3) (c) **Stated:** First time **To be completed by:** 6 March 2022	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: All staff complete fire safety awareness training as outlined in the RQIA training guidance. There is now a process in place that all new staff complete this on their first/induction day to the clinic and this is then renewed annually by means of online training. In addition the General Manager (Registered Manager applicant) and Quality Manager are supported by a clinic appointed auditor to ensure compliance in this area.
Area for improvement 3 **Ref:** Regulation 21 (1) (3), Schedule 3 Part II (6)|	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.

Stated: First time **To be completed by:** 6 February 2022	**Ref: 5.2.2** **Response by registered person detailing the actions taken**: The staff register has been developed in line with 'Area for Improvement 1' 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. This is the checklist that is referred to in 'Area for Improvement 1 Ref: 5.2.2' and is under the control of the General Manager (Registered Manager Applicant'. In addtition to new staff being added to this register, existing staff are also included. The TFP UK HR Lead has confirmed compliance of the Central TFP HR team in this Area for Improvement.

Area for improvement 4 **Ref:** Regulation 30 (e) (i) **Stated:** First time **To be completed by:** 6 March 2022	The responsible individual must ensure that a variation to registration application is submitted to RQIA to change the name of the establishment. **Ref: 5.2.10**
	Response by registered person detailing the actions taken: The clinic have requested an invoice for the payment of the fee with respects of the variation to registration application. The Statement of Purpose and Patient Guide have been updated and following receipt of the invoice from the RQIA this can also be uploaded to the RQIA portal and then this 'Area for Improvement' can be closed.
Area for improvement 5 **Ref:** Regulation 17 (1) **Stated:** First time **To be completed by:** 6 March 2022	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. **Ref: 5.2.10**
	Response by registered person detailing the actions taken: The actions from this Quality Improvement plan were discussed with Dr Jim Moohan, Responsible Individual, immediately following the informal feedback on the day of inspection as well as communicated prior to the 'virtual' feedback meeting on Thursday 13th January 2022. Dr Moohan was then presented with the action plan for the Quality Improvement Plan and all updates regularly communicated to him so that he had complete oversight of the progress of the actions.
Action required to ensure compliance with Minimum Care Standards for Independent Healthcare Establishments (July 2014)	
Area for improvement 1 **Ref:** Standard 10.2 **Stated:** Second time **To be completed by:** 6 March 2022	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. **Ref: 5.1 and 5.2.6**
	A local policy has been created by the IPC/Covid Lead, uploaded on Q-pulse and distributed to all staff for acknowledgement. This policy will be reviewed when guidance on local Govermnet restrictions or HFEA regulatory amendments are made. The review will be conducted by the Lead Clinician and IPC/Covid Nursing Lead.

Area for improvement 2 **Ref:** Standard 20.7 **Stated:** Second time **To be completed by:** 6 February 2022	The responsible individual shall Implement a robust system of audit to assure that IPC training and best practice guidance has been embedded into practice. **Ref: 5.1 and 5.2.7**
	Response by registered person detailing the actions taken: IPC audit is included in the TFP Belfast Fertility Audit Schedule and will be performed every two months by the IPC/Covid Lead, who has completed the IPC Level 3 training and is fully competent. These audits will be conducted throught out all departments of the multidisciplinary team.

Area for improvement 3 **Ref:** Standard 13.3 **Stated:** First time **To be completed by:** 6 December 2021	The responsible individual must ensure that newly appointed staff complete a structured induction and orientation within three months of employment and retain records. **Ref: 5.2.1**
	Response by registered person detailing the actions taken: The Responsible Individual is being supported by the General Manager (Registered Manager Applicant) with respects of the structured induction and orientation of newly appointed staff. This action has been formalised in clinic and completion of the Induction form added to the Staff Register checklist in 'Area for Improvement 1 Ref: 5.2.2'.
Area for improvement 4 **Ref:** Standard 13.9 **Stated:** First time **To be completed by:** 6 March 2022	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**
	Response by registered person detailing the actions taken: The Responsible Individual is being supported by the General Manager (Registered Manager Applicant) this has been added to the Staff Register checklist in 'Area for Improvement 1 Ref: 5.2.2'. The General Manager (Registered Manager Applicant) is able to view these and update the relevant Staff Register following Appraisal periods having been granted Access to the centrally held HR files. This has been communicated to the relevant Heads of Department with Annual timeframes communicated to the Line Managers for completion.
Area for improvement 5 **Ref:** Standard 10.7 **Stated:** First time **To be completed by:** 6 March 2022	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. **Ref: 5.2.1**
	Response by registered person detailing the actions taken: The Responsible Individual is being supported by the General Manager (Registered Manager Applicant), Nurse Manager and Lab Manager for this 'Area of Improvement'. This area has been added to the Staff Register checklist in 'Area for Improvement 1 Ref: 5.2.2'. The General Manager (Registered Manager Applicant) is responsible for the completion and continual update of this area for improvement. All staff that work at the clinic are covered by the clinic and TFP Group indemnities.
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. **Ref: 5.2.2**

To be completed by: 6 March 2022	**Response by registered person detailing the actions taken**: The clinic have reviewed the required information as listed in Regulation 19 (2) (d), Schedule 2 of the Independent Health Care Regulations (Northern Ireland) 2005. We have instructed our central HR department that this information is required for all new staff commencing work in the clinic in the future as outlined in Standard 14. The General Manager (Registered Manager applicant) has forwarded the relevant workflows to the central HR department and communicated the requirements as well as forwarding an updated Recruitment Policy. In addition a check list to ensure compliance with this area for improvement has been created of which the General Manager (Registered Manager applicant) is in control of. The TFP UK HR Lead has confirmed compliance of the Central TFP HR team in this Area for Improvement.
Area for improvement 7 **Ref:** Standard 3.1 **Stated:** First time **To be completed by:** 6 March 2022	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. **Ref: 5.2.3** **Response by registered person detailing the actions taken**: The Safeguarding Policy has been updated to reflect the current guidance and the revision in line with Government guidance of moving away from the concept of 'vulnerability' but to that of a concept of 'risk of harm'.

Area for improvement 8 **Ref:** Standard 9.3 **Stated:** First time **To be completed by:** 6 March 2022	The responsible individual must re-establish audits of laboratory activities and ensure ongoing monitoring in this area. **Ref: 5.2.4**
	Response by registered person detailing the actions taken: The audits of the laboratory activities are now part of a robust audit schedule which is coordinated by the Clinic Quality Manager in conjuction with the newly appointed Lab Manager.
Area for improvement 9 **Ref:** Standard 18.1 **Stated:** First time **To be completed by:** 6 March 2022	The responsible individual must ensure the management of medical emergency policy is further developed in keeping with legislation and best practice guidance. **Ref: 5.2.5**
	Response by registered person detailing the actions taken: The Management of medical emergency policy has been updated in line with the current Resuscitation Council guidelines. The policy has been distributed to all staff for acknowledgement.
Area for improvement 10 **Ref:** Standard 18.3 **Stated:** First time **To be completed by:** 6 January 2022	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. **Ref: 5.2.5**
	Response by registered person detailing the actions taken: The resuscitation check list has been updated to include number of items to be held in trolley to ensure optimum stock level held. In additon, a new guidance document has been created to advice regarding reordering of stock.
Area for improvement 11 **Ref:** Standard 20 **Stated:** First time **To be completed by:** 6 January 2022	The responsible individual must ensure the sharps containers are used in accordance with best practice guidance. **Ref: 5.2.7**
	Response by registered person detailing the actions taken: Reminder to all staff given at the nurse meeting about the importance of closing sharps containers. In addition, training has been organised with the clinical waste supplier to raise awareness of best practice and proper waste segregation. The compliance of closing sharps containers is included in the IPC audit.

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

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