Unannounced Inspection Report
14 October 2020

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
Inspectors: Carmel McKeegan, Winifred Maguire, Paul Nixon, Gavin Doherty and Dr Leanne Morgan

It should be noted that this inspection report should not be regarded as a comprehensive review of all strengths and areas for improvement that exist in the service. The findings reported on are those which came to the attention of RQIA during the course of this inspection. The findings contained within this report do not exempt the service from their responsibility for maintaining compliance with legislation, standards and best practice.

1.0 What we look for

In respect of assisted conception services for the 2020/21 inspection year we are moving to a more focused, shorter inspection which will concentrate on the following key patient safety areas:

- review of areas for improvement identified during the previous care inspection;
- management of operations in response to COVID-19 pandemic;
- infection prevention and control (IPC);
- provision of assisted conception services;
- organisational and medical governance:
- medicine management;
- the environment; and
- patient and staff feedback.

Membership of the Inspection Team

Carmel McKeegan	Inspector, Independent Healthcare Team Regulation and Quality Improvement Authority
Winifred Maguire	Inspector, Independent Healthcare Team Regulation and Quality Improvement Authority
Paul Nixon	Inspector, Pharmacy Team Regulation and Quality Improvement Authority
Gavin Doherty	Inspector, Estates Team Regulation and Quality Improvement Authority
Dr Leanne Morgan	Medical Peer Reviewer

2.0 Profile of service

Belfast Fertility is a registered independent hospital that provides fertility services and assisted conception.

3.0 Service details

Organisation/Registered Provider: Belfast Fertility **Responsible Individual:** Mr James Moohan	**Registered Manager:** Mr Robbie Kerr – Acting Manager
Person in charge at the time of inspection: Mr Robbie Kerr	**Date manager registered:** Awaiting application
Categories of care: Independent hospital (IH) - Prescribed technologies (PTIVF) or prescribed technology: establishments providing in vitro fertilisation and Private Doctor (PD)	

4.0 Inspection summary

We undertook an unannounced inspection to Belfast Fertility over two days commencing on 14 October 2020 and concluding on 15 October 2020.

This inspection was underpinned by The Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003, The Independent Health Care Regulations (Northern Ireland) 2005, The Regulation and Improvement Authority (Independent Health Care) (Fees and Frequency of Inspections) (Amendment) Regulations (Northern Ireland)

2011 and the Department of Health (DoH) Minimum Care Standards for Independent Healthcare Establishments (July 2014).

We employed a multidisciplinary inspection methodology during this inspection. The purpose of this inspection was to focus on the themes for the 2020/21 inspection year.

Our multidisciplinary inspection team examined a number of aspects of the establishment from front-line care and practices, to management and oversight of governance across the organisation. We met with various staff members, reviewed care practice and reviewed relevant records and documentation used to support the governance and assurance systems.

We were satisfied with the overarching governance structure, medical governance arrangements and management of incidents/events within the establishment.

We determined that the premises were maintained to a high standard of maintenance and décor and confirmed that robust arrangements were in place with regards to the maintenance of the premises, equipment and the environment.

We identified good aspects in respect of the delivery of front line care within Belfast Fertility. However, we identified that immediate improvement was required in some areas of infection prevention and control in response to COVID-19. We discussed our areas of concern with management and Belfast Fertility agreed to submit an action plan to RQIA outlining how they intend to address the matters identified. RQIA received an action plan immediately following this inspection. We reviewed the action plan and we were assured that appropriate action was being taken to address the areas identified. These areas are also included within the quality improvement plan as outlined in section 7.0 of this report.

We identified one area for improvement made against the regulations at the previous inspection in relation to practising privileges was partially met and this area has been stated for a second time.

Six areas for improvement were identified against the standards in relation to; ensuring that policies relating to the management of operations in response to the COVID-19 are kept under review and are updated in line with current best practice guidance; the appointment of a COVID-19 lead to co-ordinate the response within Belfast Fertility to the pandemic; ensuring patient appointment times are kept under review to ensure there is sufficient time to undertake the required cleaning of the area and equipment between appointments; ensure cleaning records are completed in a timely manner; ensure staff training is completed in respect of COVID-19 and general IPC training as discussed and also to implement a robust system of audit to assure that IPC training and best practice guidance has been embedded into practice.

We determined that the premises were maintained to a high standard of maintenance and décor. We confirmed suitable arrangements were in place with regards to the premises and the environment.

4.1 Inspection outcome

	Regulations	Standards
Total number of areas for improvement	1	6

We discussed the details of the Quality Improvement Plan (QIP) with Dr Robbie Kerr, Acting Manager, as part of the inspection process. The timescales for completion commence from the date of inspection.

Enforcement action did not result from the findings of this inspection.

4.2 Action/enforcement taken following the most recent unannounced inspection dated 17 September 2019

Other than those actions detailed in the QIP no further actions were required to be taken following the most recent inspection on 17 September 2019.

5.0 How we inspect

In response to the COVID-19 pandemic we reviewed our inspection methodology and considered various options to undertake inspections. The purpose of this was to minimise risk to service users and staff, including our staff, whilst being assured that registered services are providing services in keeping with the minimum standards and relevant legislation.

In order to meet with best practice guidance we reduced the number of inspectors and planned for inspectors to attend on separate days in smaller groups with three inspectors present on 14 October 2020 and two inspectors present on 15 October 2020. We also advised Belfast Fertility that any outstanding issues could be followed up by email or teleconference following the on-site inspection.

Prior to the inspection we reviewed a range of information relevant to the service. 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; and
- the returned QIP from the previous care inspection.

We were unable to meet with patients on the day of the inspection and assessed patient feedback by reviewing the most recent patient satisfaction survey completed by Fertility Clinic. We invited staff to complete an electronic questionnaire. No completed staff questionnaires were submitted to us. Staff and patient feedback is further discussed in section 6.10 of this report.

A poster informing patients that an inspection was being conducted was displayed during the inspection.

We undertook a tour of the premises and met with, Dr Kerr, Acting Manager; the Quality Manager; the General Manager; a Fertility Nurse Practitioner; two Registered Nurses and an Administration Officer; and reviewed relevant records and documents in relation to the day to day operation of the establishment. Following the on-site inspection we also spoke with a Consultant, and one of the Directors of Belfast Fertility, by telephone. The inspection was facilitated by the Quality Manager and the General Manager. Dr Kerr, Acting Manager, is the Laboratory Director and also one of the Directors of Belfast Fertility. Dr Kerr was available

for discussion and was provided with the findings of the inspection at the conclusion of the inspection.

6.0 The inspection

6.1 Review of areas for improvement from the most recent inspection dated 17 September 2019

The most recent inspection of the establishment was an unannounced inspection. The completed QIP was returned and approved by the care inspector.

6.2 Review of areas for improvement from the last care inspection dated 17 September 2020

Areas for improvement from the last care inspection		
Action required to ensure compliance with The Independent Health Care Regulations (Northern Ireland) 2005		**Validation of compliance**
Area for improvement 1 **Ref**: Regulation 19 **Stated:** First time	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.	
	Action taken as confirmed during the inspection: We reviewed the personnel files of four medical practitioners and confirmed that practising privileges agreements were in place and had been reviewed within the last two years. During this inspection we identified that two Fetal Medicine Consultants operate a clinic, which is unconnected to Belfast Fertility, offering The Harmony Test. We discussed this service with Dr Kerr who confirmed that both Consultants involved in this clinic did not have practising privileges. Dr Kerr stated they did not realise that practising privileges would apply in this situation and confirmed this area would be followed up at the earliest opportunity. This area for improvement has been assessed as partially met and has been stated for a second time.	**Partially met**

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 3 Stated: First time	The Responsible Individual shall ensure that the safeguarding and protection of adults and children at risk of harm policies and procedures are updated to include all designated safeguarding leads working in the establishment.	**Met**
	Action taken as confirmed during the inspection: We reviewed the safeguarding and protection of adults and children at risk of harm policies and found that safeguarding leads were included. We were informed that the new General Manager will also be included as a safeguarding lead upon completion of the appropriate safeguarding training and the policy will be updated in this regard. We noted the safeguarding and protection of adults and children at risk of harm policies lacked detail in relation to the different types of abuse and how these may be identified. We found the reader was provided with electronic links to the most recent regional safeguarding guidance documents. We were informed that all staff access policies and procedures electronically and that this process is incorporated into the training programme.	
Area for improvement 2 **Ref**: Standard 7 **Stated:** First time	The Responsible Individual shall ensure that the complaints procedure is further developed to include the contact details of RQIA and the role of RQIA in the oversight of complaints management.	**Met**
	Action taken as confirmed during the inspection: We reviewed the complaints procedure and confirmed that the contact details of RQIA and the role of RQIA were included in the complaints procedure.	

6.3 Inspection findings

6.4 Management of operations in response to the COVID-19 pandemic

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.

We reviewed the COVID-19 Policy which had a review date of June 2020, we found this policy was not in accordance with current best practice and had not been reviewed since June 2020. We found a risk assessment had been completed in May 2020 and not been updated or reviewed in the intervening time frame.

We reviewed The Operational Policy for Resuming Fertility Diagnosis and Treatment, dated June 2020, and found the content was generic in nature and did not provide information to staff specific to the jurisdiction of Northern Ireland.

We found the COVID-19 Cleaning and Disinfection Policy, dated March 2020, was not in accordance with current guidance and practice.

An area for improvement had been made against the standards to ensure that policies relating to the management of operations in response to the 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.

We found there was no COVID-19 lead or person identified to co-ordinate the response to the COVID-19 pandemic. An area for improvement had been made against the standards in this regard.

We also identified that COVID-19 training provided for staff on the resumption of services was largely based on reading policies, which we have identified were found not to be in accordance to current guidance. Staff training is further discussed in section 6.5 and area for improvement has been made against the standards in this regard.

During this inspection discussion with staff highlighted that the appointment system did not allow for enhanced cleaning of the treatment room and equipment between patient appointments, which in turn can put additional pressure on staff. An area for improvement has been made against the standards in this regard.

We discussed the management of operations in response to the COVID-19 with staff. We concluded that staff were knowledgeable and were doing the best they could; however, we determined there was a fragmented approach to managing COVID-19 within Belfast Fertility.

We identified further areas of concern in relation to infection prevention and control measures which are outlined in Section 6.5.

Areas of good practice: Management of operations in response to COVID-19 pandemic

We found that staff were knowledgeable on COVID-19 pandemic restrictions.

Areas for improvement: **Management of operations in response to COVID-19 pandemic**

Ensure that policies relating to the management of operations in response to the 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.

A COVID-19 lead should be appointed to co-ordinate the response within Belfast Fertility to the pandemic.

Ensure patient appointment times are kept under review to ensure there is sufficient time to undertake the required cleaning of the area and equipment between appointments.

	Regulations	Standards
Areas for improvement	0	3

6.5 Infection prevention control (IPC)

We reviewed arrangements for IPC procedures throughout the establishment to evidence that the risk of infection transmission to patients, visitors and staff was minimised. We confirmed that the clinic had an overarching IPC policy and procedures in place. As previously stated the policies regarding the management of operations in response to COVID-19 should be updated.

We undertook a tour of the premises and noted that the establishment was tidy and uncluttered. Overall we observed equipment was clean, free from damage and in good repair. However we identified one piece of equipment had not been cleaned following use; this was discussed with nursing staff who took immediate action. We identified that some cleaning records were not up to date, staff spoken with confirmed the cleaning tasks had been undertaken and that records had not been completed due to pressures of work. An area for improvement against the standards was made in this regard.

We reviewed staff training records and identified that IPC training was overdue from 2019 and as previously stated we found that COVID-19 training was lacking in areas. We were informed that a new training platform had been implemented to facilitate staff training. We reviewed the new training platform and found this difficult to access and the level of training unclear. We advised that IPC training should also include practical aspects and include competency based assessments to provide assurance that training has been effective. An area for improvement has been made in this regard.

We found clinical protocols and a risk assessment in relation to personal protective equipment (PPE) had not been fully reviewed. We identified that an IPC audit, completed in August 2020 did not reflect Covid 19 and an IPC programme of audit had not been implemented. This is of particular importance to ensure additional PPE measures are compliant with COVID-19 and IPC best practice guidance. An area for improvement has been made in this regard.

We found that clinical hand washing sinks located in each consulting room and other clinical areas were clean. Hand washing sinks were found to be used for hand hygiene practices only and a hand hygiene poster was displayed close to each sink. We observed staff carried out hand hygiene in accordance with best practice.

We observed that there were social distancing screens in place at the reception desk and that hand sanitisers were readily available for staff and patient use throughout the clinic. We

established that PPE was readily available in keeping with best practice guidance and confirmed that no reusable medical devices are used in the clinic

We confirmed waste management arrangements were in place and we observed clinical waste bins were pedal operated in keeping with best practice guidance.

We observed that a colour coded cleaning system was in place and staff were aware of best practice guidance in this regard.

We discussed the identified areas for improvement with Dr Kerr. We were pleased to learn that Belfast Fertility had already met with staff and recognised that additional staff were required in several areas within the clinic. We were informed that Belfast Fertility had recently recruited additional nursing staff who are due to commence work in the clinic within the next two weeks. Dr Kerr told us that management have adjusted the workload and have reduced new patient consultations to ensure staff are not placed under undue pressure. We were informed that appointment times had been re-arranged to facilitate enhanced cleaning procedures but with unplanned staff absences this resulted in a reduced nursing team which had an impact on staff availability to undertake the additional cleaning tasks. Dr Kerr recognised that urgent action was required to support staff to ensure the risk of infection transmission to patients, visitors and staff was minimised. We agreed that Belfast Fertility would provide a timed action plan to RQIA outlining how they would address the issues discussed.

Areas of good practice: IPC

We reviewed the current arrangements with respect to IPC practice and evidenced some areas of good practice in relation to

Areas for improvement: IPC

Ensure cleaning records are completed in a timely manner.

Ensure staff training is completed in respect of COVID-19 and general IPC training. IPC training should also include practical aspects and competency based assessments to provide assurance that training has been effective

Implement a robust system of audit to assure that IPC training and best practice guidance has been embedded into practice.

	Regulations	Standards
Areas for improvement	0	3

6.6 Management of patients undergoing fertility treatment

We found that a range of treatment protocols are 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 and are evidence based and in line with best practice.

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

We found that there is an elective single embryo transfer (e SET) protocol. The eSET protocol sets out the number of embryos that can be placed in a woman in any one cycle and it complies with the Human Fertilisation Embryology Authority (HFEA) Code of Practice. The protocols and procedures were discussed with the Laboratory Director and the Fertility Nurse Practitioner who demonstrated detailed knowledge on the matter.

Staff outlined the implementation in the establishment of the 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.

Staff informed us that there is a weekly clinical review meeting, attended by the consultants, registered nurses and members of the embryology team at which treatment plans for patients and the medicines being prescribed were agreed and patient outcomes discussed. There are also daily clinical meetings to discuss the management of patients and any recommended changes to treatment plans were discussed and agreed at these meetings.

We were informed and saw evidence that there is suitable counselling regarding treatment and outcomes and there was documentation to reflect this.

We established a weekly multidisciplinary clinical review meeting (CRM) is held 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 Consultant. We recognised potential for error and discussed this process with staff. We determined that checks are built into the system to mitigate and against human error as far as possible. However ultimately it is the Consultant's professional responsibility to ensure each prescription is correct prior to signing.

We reviewed three patients' clinical records and identified that there was a lack of detailed individualised counselling of success rates or risks documented in the initial consultation by the consultant in two out of three clinical records. Nursing staff reported to us administrative burden of completing checklists which could be completed by the Consultants when counselling patients in this regard. We advised management should review this area during future clinical record auditing.

We identified the current safeguarding screen consists of sending an electronic form to the patient which is completed remotely. This does not give the individual undergoing treatment adequate opportunity, free from coercion, to disclose domestic abuse or for staff to adequately assess for adult or child safeguarding concerns. In addition, General Practitioner (GP), information is not routinely sought therefore there is the potential for safeguarding concerns to not be flagged. We advised that Belfast Fertility review the processes employed to assure Belfast Fertility that safeguarding of the patient and child are robustly assessed.

6.7 Medicines Management

We were satisfied that there were safe systems for the management of medicines.

We confirmed that patients were provided with information regarding their treatment and the medicines prescribed by the Consultants and Registered Nurses; this included detailed advice on the purpose of the medicines, how to administer them at home and any potential side

effects. This information was given verbally, in paper form and via the establishment's electronic portal. Any changes to treatment were communicated to patients both verbally and through the electronic portal. A twenty-four hour telephone service/help line was provided by the medical consultants.

We confirmed that systems were in place to manage the ordering of prescribed medicines to ensure adequate supplies were available. Medicines were prescribed by the Medical Consultants and the quantities of medicines prescribed were determined by the establishment's protocols. Medicines were normally obtained from a pharmacy supplier in England and then provided to the patients and advice and guidance on their use reinforced by a Registered Nurse. In certain agreed circumstances medicines were supplied by Registered Nurses directly from the establishment's stock against a Medical Consultant's signed prescription; for example, top-up prescriptions of fertility medicines or analgesia post procedure. Patient information leaflets were provided with the medicines. We established that on the uncommon occasion that a medicine was not in stock a private prescription, signed by a Medical Consultant, was issued to the patient.

The nursing staff spoken to demonstrated a detailed knowledge of the medicines management policy and procedures.

We found that medicine records reviewed were legible and well maintained to ensure that there was a clear audit trail. Staff confirmed that the electronic portal was used to record information pertaining to treatment.

We observed that medicines were stored safely and securely and in accordance with the manufacturer's instructions. Medicine storage areas were clean, tidy and well organised. Systems were in place to alert staff of the expiry dates of medicines with a limited shelf life, once opened.

Medicines required for resuscitation or other medical emergency were clearly defined and were regularly monitored. These medicines were readily accessible in suitable packaging and available for use at all times.

We established arrangements were in place to audit all aspects of the management of medicines and evidence of this activity was maintained. We noted this included a process audit of six randomly selected patient records each month and a six monthly controlled drugs audit. The organisation could demonstrate if necessary that mechanisms had been put in place to change practice.

We were satisfied that there were incident reporting systems in place for identifying, recording, reporting, analysing and learning from adverse incidents and near misses involving medicines and medicinal products. Incidents were discussed at the staff quality meetings and any learning from incidents was discussed at the monthly meetings of registered nurses.

6.8 Environment

We determined that the premises were maintained to a high standard of maintenance and décor.

We confirmed suitable arrangements were in place with regards to the premises and the environment. We reviewed the following documentation during the inspection which was found to be comprehensive and up to date:

- the Fire Risk Assessment;
- service records for the premises fire alarm and detection system;
- service records for the premises emergency lighting installation;
- service records for the premises portable fire-fighting equipment;
- records relating to the required weekly and monthly fire safety function checks;
- records relating to staff fire safety training;
- records of fire drills undertaken;
- LOLER 'Thorough Examination' reports of the premises stair lifts;
- condition report for the premises fixed wiring installation;
- condition report for the formal testing of the premises portable electrical appliances;
- the Legionella Risk Assessment;
- gas safe servicing and test records;
- records relating to the premises backup generator and uninterruptible power supply; and
- service records and validation checks for the premises specialist ventilation systems.

The current risk assessment with regards to the control of legionella bacteria in the premises hot and cold water supply was undertaken on 20 February 2020 and any required remedial works had been attended to. We observed that suitable temperature monitoring of the premises hot and cold water systems was in place with records being maintained as recommended. We evidenced that regular bacteriological sampling of the hot and cold water systems was also in place and the most recent results on file dated 13 February 2020, confirmed that legionella and pseudomonas bacteria were not detected.

We confirmed that the current Fire Risk Assessment had been undertaken by a suitably accredited fire risk assessor on 8 October 2020. The overall assessment was assessed as 'tolerable' and no significant findings were identified. Staff demonstrated that they were aware of the action to be taken in the event of a fire.

We noted 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.

We found that all areas of the establishment were fully equipped to meet the needs of patients.

6.9 Organisational and Medical governance

6.9.1 Organisational governance

Belfast Fertility is part of The Fertility Partnership (TFP), which is a group of international clinics specialising in assisted conception. We examined various aspects of the organisational and medical governance systems in place and found there was clear organisational structure within the clinic. We confirmed that Dr Kerr is currently in day to day charge of the establishment.

During April 2020 the previous registered manager, Mrs Carly Morrow (nee Hanna), informed RQIA that she was leaving the organization. On 28 April RQIA were notified of the Registered Manager absence and that Dr Kerr was appointed as Acting Manager in the interim.

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 must be undertaken and

documented every six months; as required by Regulation 26 of The Independent Health Care Regulations (Northern Ireland) 2005. During this inspection we established that Dr Moohan, Responsible Individual, was not in day to day charge of the service, therefore unannounced quality monitoring visits by the Registered Provider would apply. Further discussion with Dr Kerr identified that he would be in a position to undertake the Responsible Individual role as he is present in Belfast Fertility most days every week. It was agreed that Dr Kerr would discuss this proposal with the Belfast Fertility Board of Directors and inform RQIA of the outcome at the earliest opportunity.

We were also informed that a new General Manager had been appointed in June 2020, it is intended that upon successful completion of their induction and six month probationary period they will submit a Registered Manager application to RQIA.

We reviewed a sample of records, minutes of meetings and discussed the establishment's governance arrangements and managerial oversight with a number of staff. We were able to evidence that there remains a clear organisational structure within the establishment and staff were able to describe their roles and responsibilities and were aware of who to speak with if they had a concern.

We established that the Board members along with representatives for the TFP meet quarterly and confirmed that this group undertakes the Medical Advisory Committee (MAC) function for the establishment. The MAC reviews the latest key performance indicators and audit findings within the establishment. We confirmed through discussion with staff and review of records that a Management Committee Meeting (MCM) takes place every two weeks and is also attended by the clinical directors of the board.

We noted there was the potential for a lack of continuity of care as Consultants work on different days and more remotely than before due to the impact of COVID-19. However we were assured that the electronic patient portal mitigates against this as information is stored on secure platform accessible to all consultants at all times.

We were informed by staff working in different roles within the establishment that there were good working relationships and that management were responsive to any suggestions or concerns raised.

6.7.2 Clinical governance

We confirmed that 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 NHS in Northern Ireland and are not on the GP's performer list in Northern Ireland. Review of the three Private Doctors' details confirmed there was evidence of the following:

- confirmation of identity;
- current General Medical Council (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); and
- 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. Discussion with Dr Kerr confirmed that all Private Doctors are aware of their responsibilities under GMC Good Medical Practice.

All medical practitioners working within the hospital must have a designated RO. In accordance with the General Medical Council (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.

We discussed current arrangements supporting medical appraisal and revalidation with a RO for all consultants working in the establishment. Apart from the three Private Doctors, the remainder work in both private and hold a substantive post in HSC/NHS practice and are not connected with Belfast Fertility for the purposes of revalidation, rather they complete their annual appraisal and medical revalidation through their employing organisations which are either local HSC Trusts or other HSC/NHS organisations.

We confirmed that The Fertility Partnership (TFP) is a designated body and has an identified Responsible Officer (RO) with whom consultants working in wholly private practice are connected for the purpose of appraisal and revalidation.

6.7.3 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 hospital. 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.

We discussed the arrangements relating to practising privileges agreements and reviewed four Consultant's personnel files. We found that there was a written agreement between each Consultant and the establishment setting out the terms and conditions of practising privileges which has been signed by both parties.

As previously discussed we identified that two Consultants operate a clinic, which is unconnected to Belfast Fertility, offering The Harmony Test. We discussed this service with Dr Kerr who confirmed that the two consultants involved in this clinic did not have practising privileges as Belfast Fertility. Dr Kerr has confirmed this area would be followed up at the earliest opportunity.

Following the inspection we spoke with a Consultant who is also one of the Directors of Belfast Fertility and holds the responsibility for overseeing practising privileges agreements. We were informed that Consultant Anaesthetists also work on a sessional basis in Belfast Fertility. The Consultant confirmed that practising privileges agreements were in place for each Consultant Anaesthetist and these agreements are reviewed every two years. We further discussed the arrangements for reviewing supporting documents required to be submitted by medical practitioners in respect of their practising privileges. We suggested that Belfast Fertility requests the full appraisal for each medical practitioner, as this can provide invaluable insight

into the medical practitioner's practice rather than reviewing the appraisal sign off sheet alone. We discussed internal arrangements to discuss any concerns or complaints regarding a doctor's practice should this occur and we were assured that Belfast Fertility is well linked in to the regional RO network.

We confirmed Belfast Fertility has a policy and procedure in place which outlines the arrangements for application, granting, maintenance, suspension and withdrawal of practising privileges. We accept that Belfast Fertility were unaware that practising privileges should have been in place for the two consultants providing the Harmony blood test clinics. We were assured that all practising privileges agreements are reviewed every two years.

An area for improvement had been made at the previous inspection to ensure all Consultants have a practising privileges agreement in place and that robust arrangements are established to ensure this is reviewed every two years. This area for improvement has been assessed as partially met and has been stated for a second time.

The Quality Manager confirmed that a system was in place to check registration status of the health care professionals on an annual basis and that all health care professionals adhere to their published codes of professional conduct and professional guidelines.

The establishment has arrangements in place to monitor the competency and performance of all staff and reports to the relevant professional regulatory bodies in accordance to guidance.

6.7.4 Quality assurance

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

We confirmed that 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.

We found that 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.

We confirmed that 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 we confirmed that current insurance policies were in place.

6.7.5 Notifiable Events/Incidents

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

We reviewed notifications submitted to us since the previous inspection, and confirmed 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 senior managers' weekly 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.

6.7.6 Complaints Management

A copy of the complaints procedure was available in the establishment. We found this to be in line with the relevant legislation and DoH guidance on complaints handling.

A copy of the complaints procedure is made available for patients/and or their representatives. Staff demonstrated good awareness of complaints management.

We found 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.

Areas of good practice: Is the service well led?

We found examples of good practice in relation to governance arrangements, management of incidents, quality improvement and maintaining good working relationships.

Areas for improvement: Is the service well led?

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.

6.9 Equality data

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

6.10 Patient and staff views

We were unable to meet with patients on the day of the inspection and assessed patient feedback by reviewing the most recent patient satisfaction survey completed by Fertility Clinic.

We found Belfast Fertility undertakes patient satisfaction surveys on an annual basis. The most recent patient satisfaction report demonstrated that the practice pro-actively seeks the views of

patients about the quality of treatment and other services provided. Patient feedback whether constructive or critical, was seen to be included in the summary report. We advised that an action plan could be developed by Belfast Fertility to capture were comments or issues have been highlighted by patients to improve, as appropriate.

We invited staff to complete an electronic questionnaire. No completed staff questionnaires were submitted to us.

Total number of areas for improvement

	Regulations	Standards
Total number of areas for improvement	**1**	**6**

7.0 Quality improvement plan

Areas for improvement identified during this inspection are detailed in the QIP. Details of the QIP were discussed with Dr Kerr, Acting Manager, as part of the inspection process. The timescales commence from the date of inspection.

The registered provider/manager should note that if the action outlined in the QIP is not taken to comply with regulations and standards this may lead to further enforcement action including possible prosecution for offences. It is the responsibility of the registered provider to ensure that all areas for improvement identified within the QIP are addressed within the specified timescales.

Matters to be addressed as a result of this inspection are set in the context of the current registration of the establishment. The registration is not transferable so that in the event of any future application to alter, extend or to sell the premises RQIA would apply standards current at the time of that application.

7.1 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, The Regulation and Improvement Authority (Independent Health Care) (Fees and Frequency of Inspections) (Amendment) Regulations (Northern Ireland) 2011 and the Department of Health (DOH) Minimum Care Standards for Independent Healthcare Establishments (July 2014).

7.2 Actions to be taken by the service

The QIP should be completed and detail the actions taken to address the areas for improvement identified. The registered provider should confirm that these actions have been completed and return the completed QIP via Web Portal for assessment by the inspector.

Quality Improvement Plan

Action required to ensure compliance with The Independent Health Care Regulations (Northern Ireland) 2005	
Area for improvement 1 **Ref**: Regulation 19 **Stated:** Second time **To be completed by:** 15 January 2021	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. Ref; 6.2
	Response by registered person detailing the actions taken: Outstanding practising privileges being addressed and will be completed by the 15th of January 2021. Quality Manager will monitor compliance of this process to ensure two yearly update.
Action required to ensure compliance with The Minimum Care Standards for Independent Healthcare Establishments (July 2014)	
Area for improvement 1 **Ref**: Standard 19.2 **Stated:** First time **To be completed by:** 15 November 2020	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: 6.4
	Response by registered person detailing the actions taken: Policies updated to reflect current best practice and distributed to staff via our Quality Management system Q-Pulse..
Area for improvement 2 **Ref**: Standard 20.1 **Stated:** First time **To be completed by:** 15 November 2020	The Responsible Individual shall appoint a COVID-19 lead to co-ordinate the response within Belfast Fertility to the pandemic. Ref: 6.4
	Response by registered person detailing the actions taken: Deputy Nurse Manager appointed as a COVID-19 and IPC Lead.
Area for improvement 3 **Ref**: Standard 20.5 **Stated:** First time **To be completed by:** 15 November 2020	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. Ref: 6.4
	Response by registered person detailing the actions taken: Calender amended to allow adequate time for cleaning and drying between patients.

Area for improvement 4 **Ref**: Standard 20.5 **Stated:** First time **To be completed by:** 15 October 2020	The Responsible Individual shall ensure cleaning records are completed in a timely manner. Ref: 6.5
	Response by registered person detailing the actions taken: Audit completed during November/December 2020. Evidence forwarded to inspector 14.12.2020.
Area for improvement 5 **Ref**: Standard 20.3 **Stated:** First time **To be completed by:** 15 November 2020	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 Ref: 6.5
	Response by registered person detailing the actions taken: All staff have completed the above training and audit of practice completed.
Area for improvement 6 **Ref**: Standard 20.7 **Stated:** First time **To be completed by:** 15 November 2020	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: 6.5
	Response by registered person detailing the actions taken: IPC practice has been added to clinical audit checklist.

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

The Regulation and Quality Improvement Authority
9th Floor
Riverside Tower
5 Lanyon Place
BELFAST
BT1 3BT

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