Unannounced Inspection Report
17 September 2019

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: Jo Browne, Carmel McKeegan, Paul Nixon and Gavin Doherty

Membership of the Inspection Team

Jo Browne	Senior Inspector, Independent Healthcare Team Regulation and Quality Improvement Authority
Carmel McKeegan	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 Stuart Brown	Medical Adept Fellow
Dr Claire Dougan	Medical Peer Reviewer

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

2.0 Profile of service

Belfast Fertility is registered as an independent hospital (IH) with the following categories of care: Prescribed technologies (PT) In vitro fertilisation and Private Doctor (PD).

3.0 Service details

Organisation/Registered Provider: Belfast Fertility **Responsible Individual:** Mr James Moohan	**Registered Manager:** Ms Carly Hanna

Person in charge at the time of inspection: Ms Carly Hanna	**Date manager registered:** 2 December 2019
Categories of care: Independent hospital (IH) - Prescribed technologies (PTIVF) or prescribed technology: establishments providing in vitro fertilisation and Private Doctor (PD)	

Prior to this inspection Dr Traub, Responsible Individual, notified RQIA that he is retiring from the position of Responsible Individual. RQIA subsequently received a Responsible Individual application from Mr James Moohan. In addition the previous Registered Manager, Ms Donna Tennent, had also informed RQIA that she was stepping down as Registered Manager to commence a new position. A Registered Manager application was submitted to RQIA by Ms Carly Hanna. Each application was approved by RQIA on 3 December 2019.

During this inspection we were informed that the name of this service has changed from GCRM Belfast Limited to Belfast Fertility.

4.0 Inspection summary

We undertook an unannounced inspection to Belfast Fertility on Tuesday 17 September 2019 from 09:30am to 17:45pm

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. 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 found 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.

Patients attending the establishment were not involved in the inspection process due to the sensitive nature of their visit to Belfast Fertility. We observed staff treating patients and/or their representatives with dignity, staff 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 multiple areas of strength, particularly in relation to the delivery of front line care in the establishment.

We undertook a detailed review of the current arrangements for governance and managerial oversight within the establishment.

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

The inspection assessed progress with any areas for improvement identified during and since the last care inspection and to determine if the establishment was delivering safe, effective and compassionate care and if the service was well led.

Examples of good practice were evidenced in all four domains. These related to: patient safety in respect of staff training and development; recruitment; safeguarding; the provision of assisted conception services; resuscitation arrangements and the management of medical emergencies; medicines management; infection prevention control; and the environment. Other examples included: the management of the patients' care pathway; communication; records management; the management and governance arrangements and engagement to enhance the patients' experience.

Three areas requiring improvement were identified during this inspection. One area for improvement relating to practising privileges had been made against the standards at the previous inspection, as we found that this area has not been met it has been stated against the regulations. Two areas for improvement have been made against the standards, one in relation to further development of the safeguarding adults and children at risk of harm policy and one to further develop the complaints procedure.

The findings of this report will provide the establishment with the necessary information to assist them to fulfil their responsibilities, enhance practice and patients experience.

4.1 Inspection outcome

	Regulations	Standards
Total number of areas for improvement	1	2

Details of the Quality Improvement Plan (QIP) were discussed with, the Laboratory Director, Ms Carly Hanna, Registered Manager, and the Quality 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 care inspection dated 29 November 2018

Other than those actions detailed in the QIP no further actions were required to be taken following the most recent inspection on 29 November 2018.

5.0 How we inspect

Prior to the inspection a range of information relevant to the establishment was reviewed. 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;
- the application for Responsible Individual; and
- the application for Registered Manager.

We provided the establishment with questionnaires to distribute to patients on behalf of RQIA. Returned completed patient questionnaires were analysed following the inspection and are further discussed in Section 6.9 of this report.

Posters informing patients, staff and visitors of our inspection were displayed while our inspection was in progress.

During the inspection the inspectors met with, the Laboratory Director, the Registered Manager, the Quality Manager, a Fertility Nurse Practitioner, two Registered Nurses and an Administration Officer. A tour of some areas of the premises was also undertaken.

A sample of records was examined during the inspection in relation to the following areas:

- staffing;
- recruitment and selection;
- safeguarding;
- management of medical emergencies;
- infection prevention and control;
- medicines management;
- management of patients undergoing fertility treatment;
- clinical records;
- patient information and decision making;
- practising privileges arrangements;
- management and governance arrangements; and
- maintenance arrangements.

Areas for improvement identified at the last inspection were reviewed and assessment of compliance recorded as met, partially met, or not met.

The findings of the inspection were provided to the Ms Hanna, Registered Manager; the Laboratory Director and the Quality Manager at the conclusion of the inspection.

6.0 The inspection

6.1 Review of areas for improvement from the most recent inspection dated 29 November 2018

The most recent inspection of the establishment was an unannounced care 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 29 November 2018

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 23 (4) **Stated:** First time	The registered person shall within 28 days of receipt of a complaint ensure that the complainant is informed of the investigative process outcome and action (if any) that is to be taken.	**Met**
	Action taken as confirmed during the inspection: We were informed that all complaints received are documented on a complaints log. Our inspection team reviewed the complaints log and confirmed that a system was in place to ensure that within 28 days of receipt of a complaint, the complainant is informed of the investigative process outcome and action (if any) that is to be taken. We were informed that the complaints log is monitored by the Quality Manager who is responsible for auditing complaints management.	
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 11.5 **Stated:** First time	The registered person 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.	**Not Met**
	Action taken as confirmed during the inspection: We reviewed the personnel files for two Medical Practitioners who are not on the Board of Directors and therefore are required to have a practising privileges agreement in place. We identified that a practising privileges agreement was in place for only one of the Medical Practitioners. This was discussed during feedback with those present and this area for improvement is now stated against the regulations.	
Area for improvement 2 **Ref**: Standard 8.2	The registered person shall ensure that the management of records policies and procedures are updated to include the patient portal system.	**Met**

Stated: First time		
	Action taken as confirmed during the inspection: We confirmed that the management of records policies and procedures have been updated to include the procedures for the patient portal system.	
Area for improvement 3 **Ref**: Standard 7.1 **Stated:** First time	The registered person shall ensure that the complainant is provided with written acknowledgement of their complaint within the appropriate time frame in keeping with the establishment's complaints procedure.	
	Action taken as confirmed during the inspection: We reviewed records of complaints received by Belfast Fertility since the previous inspection and the complaints log. We found that the complainants had been provided with an acknowledgement of their complaint within the time frame stated in the Belfast Fertility complaints procedure.	**Met**

6.3 Current inspection findings

6.4 Is care safe?

Avoiding and preventing harm to patients and clients from the care, treatment and support that is intended to help them.

6.4.1 Staffing

We confirmed through discussion with staff and review of duty rosters 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 evidence of specialist qualifications and skills in fertility treatments.

We found that induction programmes are in place appropriate to the roles and responsibilities within the establishment. Review of a recently appointed member of staff personnel file confirmed that an induction record had been completed.

We discussed arrangements in place for ensuring that staff training and continuing professional development opportunities are available for all staff and were satisfied that staff had completed training in accordance with RQIAs mandatory training guidance. A training record matrix is maintained to monitor the status of staff training requirements for all staff.

We confirmed that there are rigorous systems in place for undertaking, recording and monitoring all aspects of staff supervision, appraisal and ongoing professional development in keeping with the RQIA training guidance.

We reviewed of a sample of records and confirmed that there are arrangements are in place for monitoring the professional body registration status of all clinical staff. We also found that arrangements are in place for monitoring the professional indemnity of all staff who require individual indemnity cover.

We found that arrangements were in place to monitor the competency and performance of all staff and report to the relevant professional regulatory bodies in accordance to guidance. There were also systems in place to check the registration status of the health care professionals with their appropriate professional bodies on an annual basis.

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.

6.4.2 Recruitment and selection

We reviewed the arrangements for recruitment and selection of staff to ensure compliance with relevant employment legislation and best practice guidance. We found that one new staff member had been recruited since the previous inspection. A review of the staff member's personnel file demonstrated that all the information required by legislation had been sought and retained.

6.4.3 Safeguarding

We reviewed arrangements for safeguarding of children and adults in accordance with the current regional guidelines. We confirmed that policies and procedures were in place in relation to safeguarding and protection of adults and children at risk of harm. We spoke to staff who demonstrated they were aware of types and indicators of potential abuse and the actions to be taken should a safeguarding issue be identified, including who the nominated safeguarding lead in the establishment was.

Review of the staff training record matrix demonstrated that all staff had received training in safeguarding children and adults as outlined in the Minimum Care Standards for Independent Healthcare Establishments July 2014. We confirmed that the designated safeguarding lead has completed formal training in safeguarding adults and children in keeping with the Northern Ireland Adult Safeguarding Partnership (NIASP) training strategy (revised 2016). We identified that the designated safeguarding lead is not present in the establishment on a full time basis. Ms Hanna confirmed that on completion of formal training in safeguarding adults and children, she will also be included as a designated safeguarding lead. We advised that the safeguarding policies and procedures in relation to safeguarding and protection of adults and children at risk of harm should be updated to reflect this arrangement so that staff are aware of who they can speak with should they have any concerns. An area for improvement against the standards was made in this regard.

We found that a whistleblowing/raising concerns policy was available which provides guidance to help staff make a protected disclosure should they need or wish to. Staff confirmed that they knew who to contact should they have concerns or needed to discuss a whistleblowing matter.

6.4.4 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.

Our inspection team spoke with medical and nursing staff who 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.

6.4.5 Medicines management

We were informed 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 independent 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 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 Consultants and the quantities of medicines prescribed were determined by the independent 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 Consultant 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 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.

Arrangements were in place to audit all aspects of the management of medicines. Evidence of this activity was maintained. 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.

6.4.6 Resuscitation and management of medical emergencies

We reviewed arrangements for management of medical emergencies and resuscitation of patients and visitors to the establishment. A wide range of policies and procedures were in place in this regard, which reflected best practice guidance.

We confirmed that the emergency medicines held were in line with the British National Formulary (BNF); and that emergency equipment was available as recommended by the Resuscitation Council (UK). A system was in place to check emergency medicines and to ensure that equipment did not exceed its expiry date. An individual with responsibility for checking emergency medicines and equipment was identified. We examined the emergency trollies located in the theatre/recovery area, which contained all the necessary medication and equipment.

6.4.7 Infection prevention control and decontamination procedures

We reviewed arrangements for infection prevention and control (IPC) and decontamination procedures in place throughout the establishment, to ensure the risk of infection for patients, visitors and staff are minimised.

There were clear lines of accountability in relation to IPC and the establishment had a designated IPC lead Nurse.

We found that patient treatment areas and the theatre environment were clean, tidy and well maintained. IPC information was displayed on notice boards in the clinical areas and we observed good practice in relation to hand hygiene and the use of personal protective equipment. There was a range of information available for patients and staff regarding hand-washing techniques.

We reviewed a sample of IPC audits, which included information relating to the environment; hand hygiene; and post treatment infection. We noted that the results of these audits are discussed during the two weekly management committee meetings. We found that the compliance rate was high in relation to the outcome of the various IPC audits and action plans were formulated to address issues identified within the audits, as appropriate.

We confirmed that no reusable medical devices requiring decontamination are used in the establishment; only single use equipment is used.

6.4.8 Environment

We found the premises to be maintained to a very high standard of maintenance and décor.

Suitable arrangements were in place for maintaining the environment. The following documentation was reviewed during the inspection and found to be up to date:

- the Fire Risk Assessment;
- service records for the premises 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' of the premises passenger lift;
- 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; and
- service records and validation checks for the premises ventilation systems.

We found that a current Legionella Risk Assessment was in place which had been recently reviewed on 7 August 2019. Suitable temperature monitoring of the premises hot and cold water systems is in place with records being maintained as recommended. Regular bacteriological sampling of the hot and cold water systems is also undertaken and the most recent results on file confirmed that legionella bacteria were not detected.

We confirmed that a Fire Risk Assessment had been undertaken by a suitably accredited fire risk assessor. The overall assessment was assessed as 'tolerable' and no significant findings were identified. Through discussion with staff and review of the records we confirmed suitable fire safety training was being delivered, and the most recent fire drill had been completed on the 25 July 2019. Staff demonstrated that they were aware of the action to be taken in the event of a fire.

We determined that the premises specialised ventilation systems are serviced in accordance with current best practice guidance and suitable validation is undertaken in accordance with current HFEA guidance. Records were available and inspected at the time of the inspection.

The establishment has a recovery area, a dedicated room for the production of semen specimens, a fertility treatment room and embryology and andrology laboratories, which were reviewed and found to be suitable for their purposes.

We confirmed that there were secure designated areas for the atmospheric and temperature controlled storage of gamete and embryos only accessible by authorised personnel.

In keeping with best practice we confirmed that the room used for egg collection for in vitro fertilisation is close to the laboratory where fertilisation is to take place.

Areas of good practice: Is care safe?

We found examples of good practice in relation to staff recruitment, induction, training, the management of patients undergoing fertility treatment, the management of medical emergencies, medicines management, infection prevention control and decontamination procedures, and the environment.

Areas for improvement: Is care safe?

The safeguarding and protection of adults and children at risk of harm policies and procedures should be updated to include all designated safeguarding leads working in the establishment.

	Regulations	Standards
Areas for improvement	0	One

6.5 Is care effective?

The right care, at the right time in the right place with the best outcome.

6.5.1 Clinical records

As previously discussed patient care records are held electronically on the patient portal system. A staff member demonstrated the patient portal system and three patient's records were reviewed. The patient care records were well documented, contemporaneous and clearly outlined the patient journey.

The care records reviewed contained the following:

- patient registration form
- patient health questionnaire

- pre-operative and post -operative checklists
- intraoperative records
- screening results
- patient treatment plan including medication regime
- copy of the treatment plan schedule which HFEA was provided to the patient
- a range of signed consent forms for each procedure
- signed patient contract
- HFEA consent
- record of consultation with the medical practitioner
- embryology records and
- follow up letters to patient's GP or referring medical practitioners.

We confirmed that systems are in place to audit the patient care records as outlined in the establishment's quality assurance programme. A number of audits relating to patient care records were reviewed and an excellent compliance rate was noted. It was also confirmed that where the need for improvement was identified that an action plan was implemented and re-auditing would take place.

We confirmed that information was available for patients on how to access their health records in accordance with the General Data Protection Regulations that came into effect during May 2018 and where appropriate Information Commissioner's Office (ICO) regulations and Freedom of Information legislation. The establishment is registered with the ICO.

We found that the establishment has a range of policies and procedures in place for the management of records which includes the arrangements for the creation, use, retention, storage, transfer, disposal of and access to records. Discussion with staff confirmed they had a good knowledge of effective records management.

Our inspection team noted that a policy and procedure in place for clinical record keeping in relation to patient treatment and care which complies with the General Medical Council (GMC) guidance and Good Medical Practice was in place.

We confirmed that templates for referral forms and letters to healthcare practitioners have been developed in association with HFEA guidelines to ensure all required information is provided.

6.5.2 Patient information and decision making

Our inspection team confirmed that written information was available for prospective patients regarding the services provided how to access these and costs of treatment. We found that this information is written in plain English and we were informed that when required the information can be provided in an alternative language or format. We reviewed the Belfast Fertility website which provides detailed information for prospective patients on the services provided in the establishment, the website also includes a frequently asked question section relating to wide variety of topics in relation to assisted fertility treatments, including the patient pathway and the potential additional costs of medications.

A Patient Guide is also available on the website and in the patient waiting area, assurances were given this document would be updated to reflect the changes in the responsible individual and registered manager.

A range of information leaflets on each procedure outlining risks, complications and expected outcomes are available and staff confirmed these are given to patients on consultation.

We found that patients are provided with information on who to contact if they want advice or have any issues/concerns and are provided with contact numbers for office hours and out of office hours. Staff confirmed that there is a Nurse and a Consultant on call during office hours and a Consultant is on call out of hours, at all times.

Areas of good practice: Is care effective?

We found examples of good practice in relation to the management of clinical records, the range and quality of audits and ensuring effective communication between patients and staff.

Areas for improvement: Is care effective?

No areas for improvement were identified during the inspection.

	Regulations	Standards
Areas for improvement	0	0

6.6 Is care compassionate?

Patients and clients are treated with dignity and respect and should be fully involved in decisions affecting their treatment, care and support.

6.6.1 Person centred care

We looked at care records, observed care practice and met with various grades of staff to understand how the establishment ensures that patients receive person centred care; we found good systems in place across the establishment.

We observed positive interactions between staff and patients during our inspection and witnessed patients being treated with compassion, dignity and respect. We heard staff introducing themselves and explaining processes to patients in a kind and caring manner whilst maintaining their privacy and respecting confidentiality for the patient and their companion.

Staff wore badges with their name and profession/designation clearly visible and legible.

6.6.2 Breaking bad news

Through discussion with staff we confirmed there is procedure on breaking bad news to patients and staff demonstrated a very good understanding of it. Staff spoken with stated that they had been provided with training in this area which they considered to be very beneficial.

Staff informed us that when that bad news is delivered to patients and/or their representatives this is done by experienced professionals and in accordance with the Belfast Fertility's policy and procedure.

Staff told us that when bad news is shared, future treatment options were discussed and fully documented in the patient's care records. With the patient's consent information is shared with their General Practitioner (GP), their representatives and/or other healthcare professionals involved in their ongoing treatment and care.

6.6.3 Patient Engagement

We examined the methods used by the establishment to obtain the views of patients and/or their representatives through speaking with patients, staff and reviewing relevant documentation. We found this to be an integral part of the service delivered in the establishment. Patients and their partners are offered an opportunity to provide feedback on their care through completion of a questionnaire.

We found that information received from these questionnaires was available to patients and other interested parties within an annual report. This report is made available to patients and other interested parties to read in the waiting area of the establishment. It was confirmed through discussion that comments received from patients are reviewed by the Registered Manager and discussed at committee management meetings. Action is implemented to address any issues identified.

We reviewed meeting notes and found that the Quality Manager uses the annual report to inform service delivery and improvement to improve services.

Areas of good practice: Is care compassionate?

We found examples of good practice found in relation to maintaining patient confidentiality ensuring the core values of privacy and dignity were upheld and providing the relevant information to allow patients to make informed choices.

Areas for improvement: Is care compassionate?

No areas for improvement were identified during the inspection.

	Regulations	Standards
Areas for improvement	0	0

6.7 Is the service well led?

Effective leadership, management and governance which creates a culture focused on the needs and experience of service users in order to deliver safe, effective and compassionate care.

6.7.1 Organisational governance

Belfast Fertility is part of The Fertility Partnership (TFP), which is a group of international clinics specialising in assisted conception. As previously discussed RQIA received a Responsible Individual application submitted by Mr James Moohan and a Registered Manager application submitted by Ms Carly Hanna. Each application was approved on 3 December 2019.

We were informed that Mr Moohan, Responsible Individual, is involved in the day to day running of the establishment and participates in meetings within each department on a weekly basis.

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 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.

Where the entity operating the establishment is a corporate body or partnership or an individual owner who is not in day to day management of the practice, Regulation 26 unannounced quality monitoring visits must be undertaken and documented every six months. Mr Moohan is in day to day charge of the establishment, therefore Regulation 26 unannounced quality monitoring visits do not apply and are not undertaken.

6.7.2 Clinical governance

As previously discussed 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 two Consultants are considered to be Private Doctors as they no longer hold a substantive post in the NHS in Northern Ireland and are not on the General Practitioners (GPs) list in Northern Ireland. Review of the two 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 two Private Doctors also evidenced that they had completed training in accordance with RQIAs training guidance for Private Doctors. Discussion with Ms Hanna confirmed that the Private Doctors are aware of their responsibilities under GMC Good Medical Practice.

We discussed current arrangements supporting medical appraisal and revalidation with a RO for all consultants working in the establishment.

Apart from the two Private Doctors, the remainder work in both private and 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 purely private practice are connected for the purpose of appraisal and revalidation.

6.7.3 Practising Privileges

We discussed the arrangements relating to practising privileges agreements and reviewed three Consultant's personnel files. We found that there was a written agreement between two Consultants and the establishment setting out the terms and conditions of practising privileges which has been signed by both parties. A practising privileges agreement was not in place for one the Consultants. 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 now been made against the regulations.

Belfast Fertility has a policy and procedure in place which outlines the arrangements for application, granting, maintenance, suspension and withdrawal of practising privileges. We were assured that robust arrangements will be established to ensure that all practising privileges agreements are reviewed every two years.

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

As previously stated the registration status of the health care professionals with their appropriate professional bodies was confirmed during inspection. Ms Hanna 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.

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 Laboratory Director stated that the results of audits are analysed and actions identified for improvement are embedded into practice. We were told that the fertility rate has increased in Belfast Fertility through applying the findings for audits undertaken in the laboratory and standardisation of treatment and practice.

If required, an action plan is developed and embedded into practice to address any shortfalls identified during the audit process. The following audits had been undertaken;

- infection prevention and control (IPC) audit
- consent to disclosure audit
- oocyte retrieval audit

- chart file audit
- chart location audit
- patient treatment pathway audit
- supporting process audit and
- compliance audit.

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.

We felt that the management of medication incidents was strong and that this should continue in future.

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. We recommended 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. An area for improvement against the standards was made in this regard.

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.

The complaints procedure should be further developed to include the contact of RQIA and the role of RQIA in the oversight of complaints management

	Regulations	Standards
Areas for improvement	0	2

6.8 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 with staff and management.

6.9 Patient and staff views

Eight patient questionnaire responses were submitted to RQIA following the inspection. All eight indicated that they felt their care was safe and effective, that they were treated with compassion and that the service was well led. All patients also indicated that they were very satisfied with each of these areas of their care. The following comments were provided in the submitted questionnaires:

- 'Excellent care and treatment and staff kept us informed at all times.'
- 'Lovely staff.'
- 'Very timely and efficient treatment, satisfied with everything.'
- 'The staff are helpful however if nursing staff are unavailable I have had to call again to speak to someone rather than returning my call.'

The comments were discussed with the applicant registered manager following the inspection,

We spoke with a range of staff during the inspection who informed that there is good communication within Belfast Fertility and that they all felt supported and valued. Staff also stated that patients were treated with dignity and respect and were provided with a good standard of care and treatment. There were no concerns raised by any staff members during this inspection.

Total number of areas for improvement

	Regulations	Standards
Total number of areas for improvement	One	Two

7.0 Quality improvement plan

Areas for improvement identified during this inspection are detailed in the QIP. Details of the QIP were discussed with Ms Hanna, Registered Manager, the Laboratory Director, and the Quality 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:** First time **To be completed by:** 17 December 2019	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 and 6.7.3
	Response by registered person detailing the actions taken: A local matrix is now in place to ensure more robust governance in relation to the practising privileges and proof of GMC registration. All relevant medical practitioners now have been forwarded practising privileges agreements signed by a Director. This supports the centralised Fertility Partnership HR function which has now assumed responsibility for the oversight of monitoring & reviewing of all medical practitioners appraisals, registration, revalidation, indemnities & practising privileges
Action required to ensure compliance with The Minimum Care Standards for Independent Healthcare Establishments (July 2014)	
Area for improvement 1 **Ref**: Standard 3 **Stated:** First time **To be completed by:** 17 December 2019	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. Ref: 6.4.3
	Response by registered person detailing the actions taken: Local safeguarding policy has been updated to name Ms Hanna as the local safeguarding lead in the establishment. Online training has been sourced to refresh all staff in safeguarding throughour the coming year.
Area for improvement 2 **Ref**: Standard 7 **Stated:** First/ time **To be completed by:** 17 December 2019	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. Ref: 6.7.6
	Response by registered person detailing the actions taken: A request has been lodged through our Quality Management system with our Group Head of Quality to make the appropriate amendments to the Group Complaints procedure ('A Patients Guide; Making Comments and Complaints') in relation to the address/contact details for the RQIA & the specific role of the RQIA in relation to complaints management. Confirmation of completion of this has not yet been received & sits with The Fertility Partnership Head of Quality. We continue to develop our local complaints SOP as a result of learning

	from complaints & incidents.

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

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